

APPLICANTS ASSISTANCE

FOR PERMITTING HAZARDOUS WASTE MANAGEMENT FACILITIES:

Applicant's Training Course

- This course is a one-day session for permit applicants. It explains how the permit should be structured and what kind of information the permit writer needs on the application before a permit can be written.
- All applicants whose Part B's are called in will be invited to attend the training course.
- The course has been given in several states for storage facility permit applicants. It has not yet been developed for incineration or land disposal permit applicants.

Applicant's Guide

- This publication gives a brief description of the kind of information needed to satisfy each section of the RCRA regs. The Guide also includes information on the application review and decision process.
- The draft Applicant's Guide for Storage Facilities is included in today's handouts. The Guides for incineration facilities and for land disposal facilities have not yet been prepared. They will include the information that has already been developed for satisfying the storage requirements.

Model Application

- This publication is a companion to the Applicant's Guide. It covers all of Part A and Part B of the permit application and translates the information from the Guide into a permit application.
- The permit application is divided into functional areas. These are the same divisions that are used in the Training Course and the Applicant's Guide (e.g. Facility Description, Waste Characteristics, Process Information, etc.).
- The Applicant's Guide and the Model Application will be given to applicants who attend the Applicant's Training Course.

Copied for distribution to the

- The draft Model Application for Storage Facilities is included in your handouts. The Model Applications for incineration and land disposal have not yet been prepared, but will include the information on storage.

Permit Writer's Guide and Training Course

- The guide aids permit writers in evaluating an application and preparing a permit.
- It gives key words or phrases for each permit requirement followed by a list of technical references for that requirement. The technical references are intended to help the permit writer in determining if the application is reasonable and in writing the permit conditions.
- The training course is conducted for permit writers to give them experience in writing a permit. A permit is written based on a mock application that has both obvious and subtle errors and upon the information in the Permit Writers Guide.
- A Guide has been written for storage facility permits but has not been cleared for distribution. The Guides for incineration and storage facilities have not yet been written.

Model Permit

- This shows what form a permit should take. The Model Permit consists of boilerplate and general and specific permit conditions.
- The philosophy behind the Model Permit is that the permit itself may not need to be highly technical. The permittee in his application has demonstrated whether or not he can operate his facility in accordance with RCRA. The permit can reference the application as necessary. It can also be highly specific where necessary. This is a decision for the permit writer based on his judgement and the complexity of the facility.
- A draft Model Permit has been prepared for storage facilities; model permits for incineration and land disposal facilities have not yet been prepared. The draft Model Permit for storage facilities is among today's handouts. Model permits for incineration and land disposal would include the same language for their storage operations.

WHAT DO WE WANT FROM YOU?

- Comments on the Applicant's Training Course, the Applicants Guide and the Model Application for storage facilities. Comments should include estimates of the time necessary to prepare a permit application and the costs of preparing the application. We are also interested in determining who should be presenting the Applicants Training Course - EPA, the states, industry groups?

- Similarly, as the permitting documents for incineration facilities and land disposal facilities are being written, we will ask for your inputs on the drafts of those documents.

RCRA PERMIT STRATEGY

RCRA Permit Process

- Existing facilities (ie., facilities with interim status) submitted Part A of permit application by November 1980, must submit Part B of permit application within six months of EPA request.
- New facilities submit both Part A and Part B of permit application at least 180 days before construction is expected to begin. (New facilities can not be constructed or operated without a permit.)
- EPA conducts a completeness review within 30 days of receipt of application from new facilities (60 days for existing facilities).
- EPA prepares draft permit and fact sheet for public comment.
- RCRA requires EPA to notify public in local vicinity of facility and hold a local hearing if requested.
- EPA issues final permit with maximum duration of 10 years.

Status of Permit Standards

- Storage and Treatment Facilities: Permits can be issued to all facilities except for certain underground tanks.
- Incineration Facilities: Permits can be issued to all facilities.
- Land Disposal Facilities: Permits can be issued to new facilities. EPA will be able to request Part B permit applications and issue permits to existing facilities as of January 1983 (except for underground injection wells).

ROLE of the STATES

Phase I Interim Authorization

- State programs must be substantially equivalent to federal program
- Covers:
 - Identification and listing of hazardous wastes
 - Regulation of generators and transporters
 - Enforcement of interim status standards
 - 32 States have been authorized

Phase II Interim Authorization

- Permitting of hazardous waste facilities
- Four States have been authorized

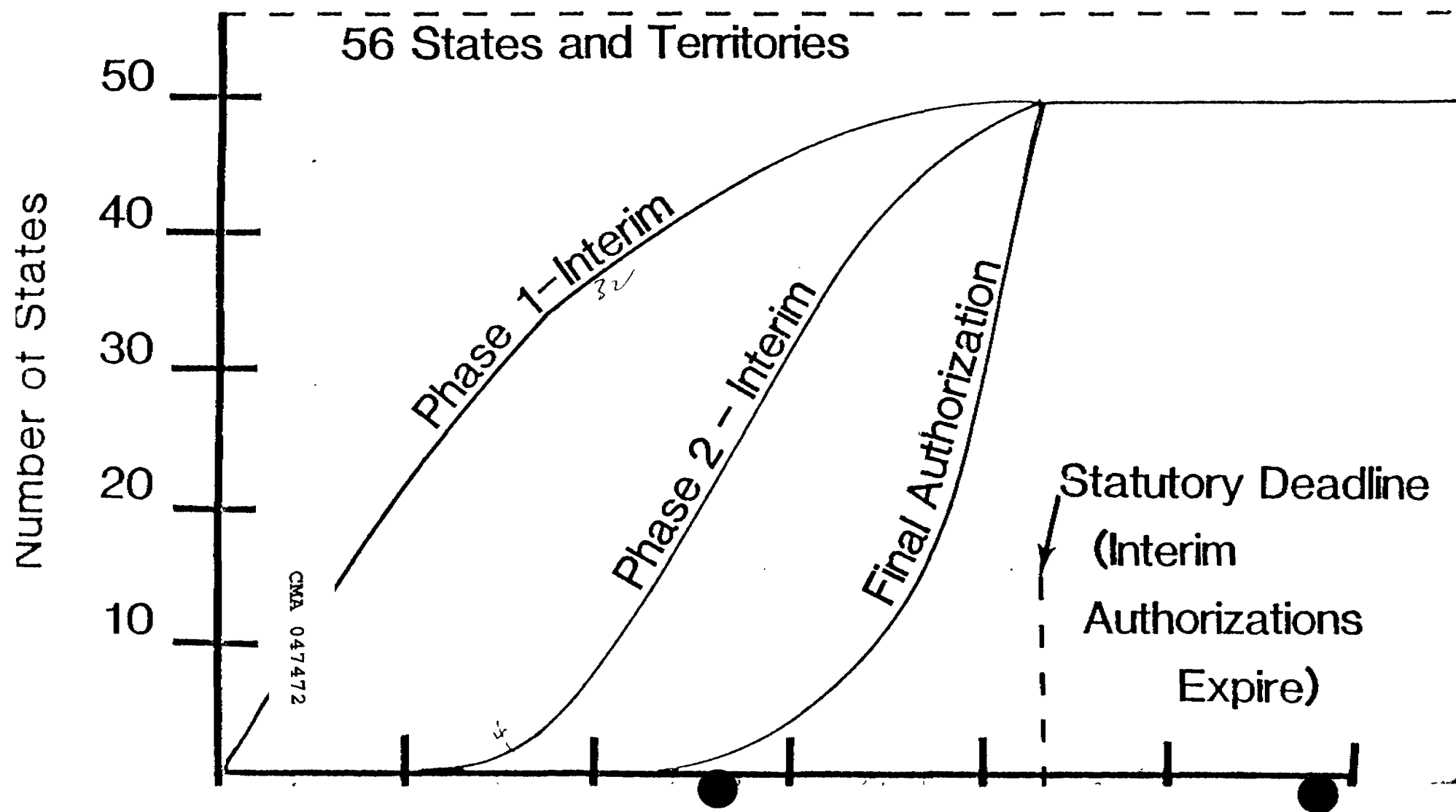
Final Authorization

- State programs must be equivalent and consistent with federal program
- States may now begin to apply for final authorization
- Interim authorizations expire in January 1985

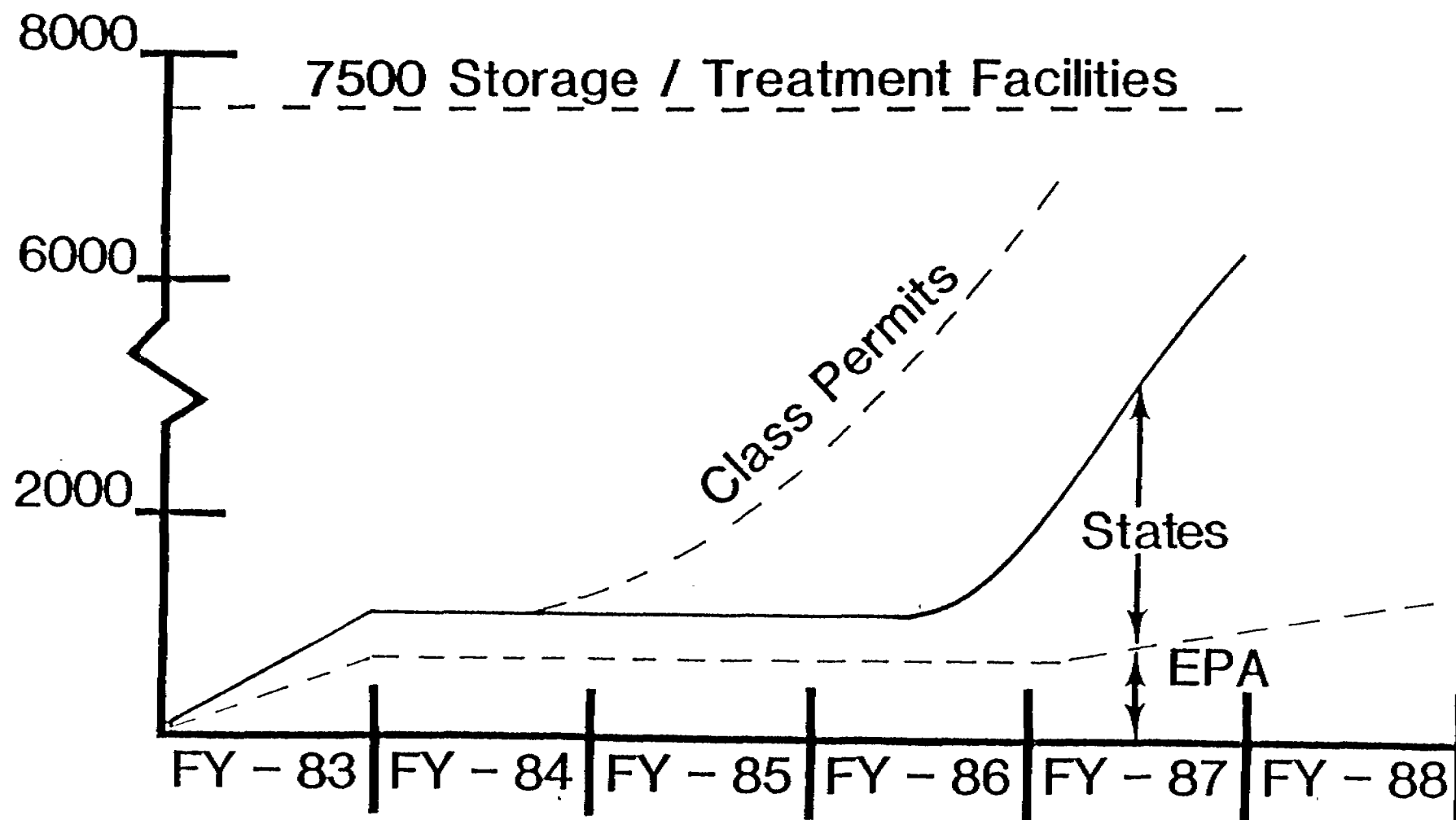
Relationship of State and EPA Hazardous Waste Programs

- Authorized State programs operate in lieu of federal program
- Both EPA and State programs apply in a State without authorization. In order to avoid confusing duplication with State programs, EPA is:
 - Involving States in development of permitting priorities and permit conditions
 - Encouraging joint public hearing and permit issuance procedures
 - Establishing mechanisms to transfer pending RCRA permit applications to States at time of authorization and to allow State to assume full responsibility for administering previously issued Federal permits

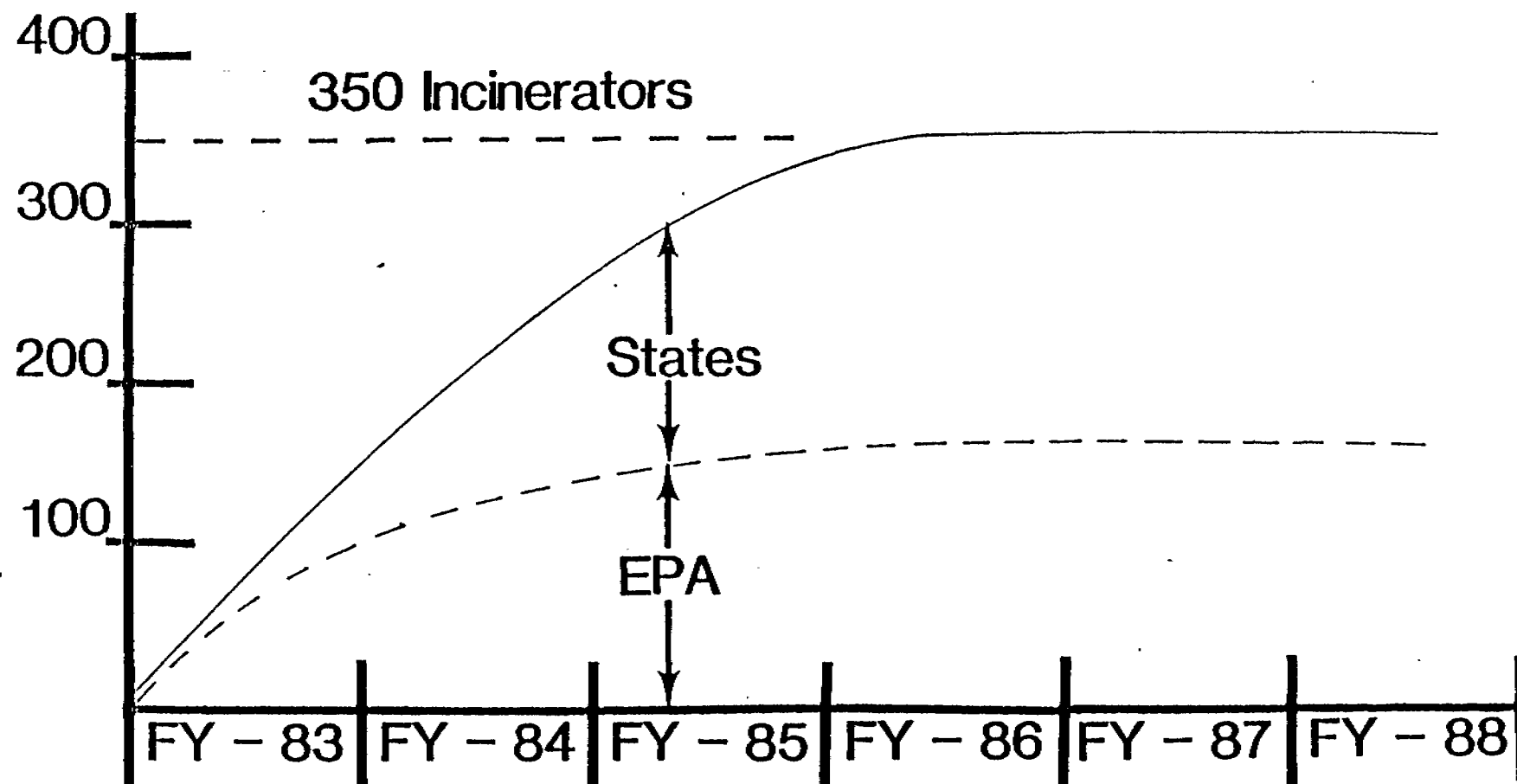
PROJECTIONS FOR RCRA STATE AUTHORIZATION



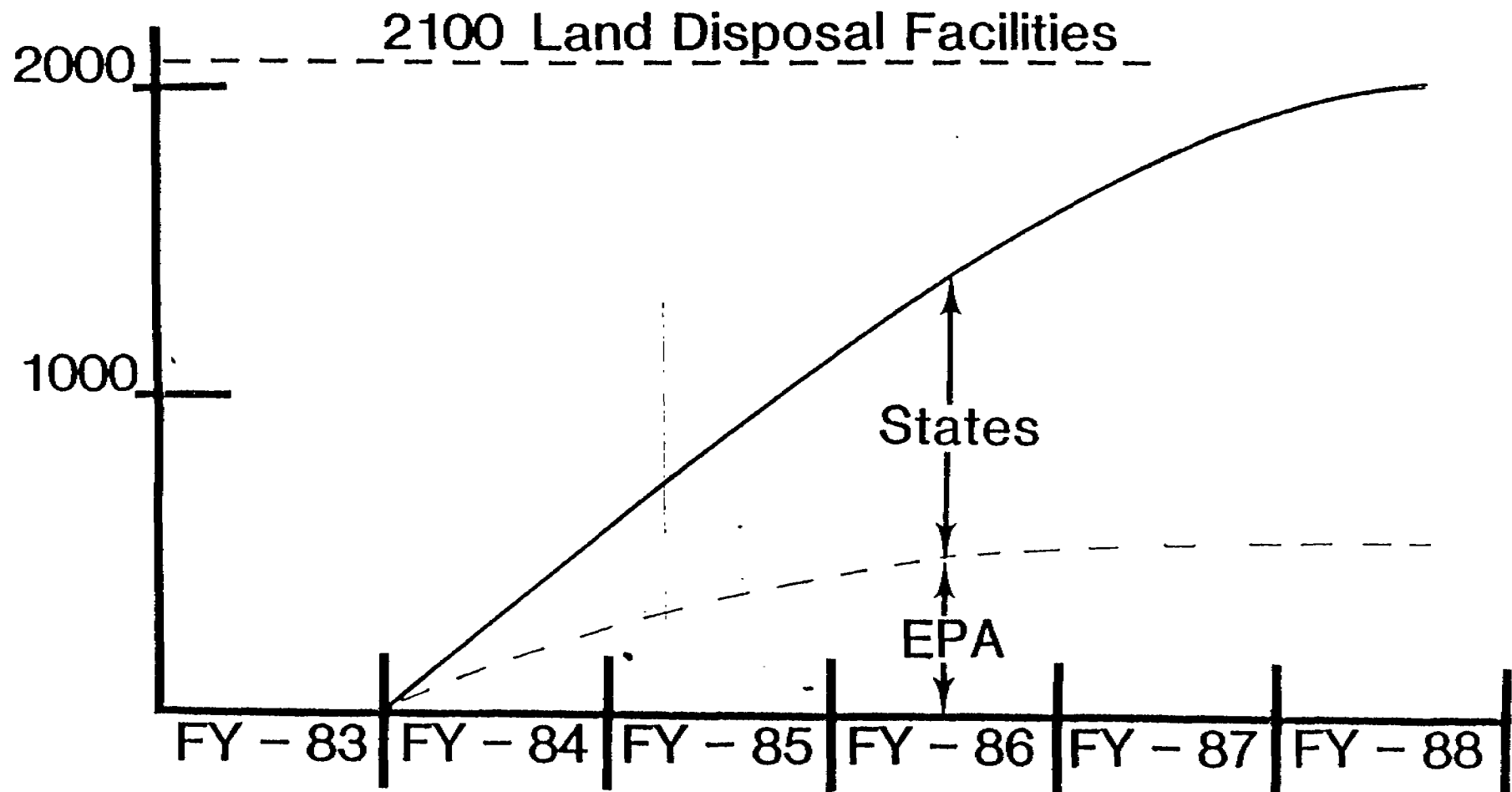
RCRA PERMIT ISSUANCE



RCRA PERMIT ISSUANCE



RCRA PERMIT ISSUANCE



Permit Assistance Activities

Applicant Assistance

- Model application
- Detailed applicant guidance
- Pre-application meetings

Permit Writers Assistance

- Model permit
- Permit writers guidance
- Training
- Permit assistance teams
 - contractor support
 - Agency technical expertise

New Concepts in Permitting

- Class permits
- Mobile permits

Permitting Task Force

- Goal
 - Identify ways to improve permitting process

PUBLIC MEETING ON THE EPA
HAZARDOUS WASTE PERMIT PROGRAM

July 22, 1982
Room S353 Waterside Mall

Meeting Agenda

PRESENTATION

Introductory Remarks

SPEAKER

Rita M. Lavelle, Assistant
Administrator for Solid
Waste and Emergency Response
(202) 382-4610

RCRA Permitting Strategy

- o Status
- o EPA program priorities

John H. Skinner, Acting
Director, Office of Solid
Waste
(202) 755-9107

Hazardous Waste Ad Hoc Advisory Committee

- o Charter
- o Proposed Task Forces
- o Membership

David B. Sussman, Program
Manager
(202) 382-4692

Assistance for Permit Applicants

- o Scope and status of
- o Guides for preparing permit applications
- o Model permits
- o Applicant training

Chaz Miller, Environmental ---
Protection Specialist
(202) 382-5435

Class Permits

- o Background, concept, applicability

David B. Sussman

Mobile Treatment Units

- o Background, concept, applicability

Jeffrey E. Detlefsen
Environmental Protection
Specialist
(202) 382-4500

COMMENT PERIOD

CMA 047478

CONCEPT OUTLINE CLASS PERMITS

The current regulations treat every hazardous waste management facility as being unique and highly complex. However, some classes of hazardous waste management facilities, particularly those that store or treat hazardous waste in tanks, piles, and containers, are neither unique nor complex. Such facilities employ relatively simple and well - proven technology which varies little with the locality. Thus, a permit issued to one such facility, in most respects, would be quite similar or even identical to permits issued to many other such facilities.

EPA believes it will be able to develop "class permits" reflecting the standard accepted practices for the storage and treatment of hazardous waste in tanks, piles, and containers. The conditions of such class permits could be established at the national level through rulemaking procedures which provide for public notice and opportunity for comment.

Under the current provisions of RCRA class permits could be developed using the following steps:

Step 1

- EPA proposes a class definition, national permit conditions, and abbreviated application procedures.
- The public comments on the definition, conditions and application procedures.
- EPA promulgates final definition, national permit conditions and abbreviated application procedures.

Step 2

- Applicants submit abbreviated applications.
- EPA issues a public notice in each community where a class permit applicant's facility is located.
- EPA accepts public comment and holds an informal local public hearing if one is requested.
- As the general technical issues would have been resolved in the development of the national permit conditions, the public comment and local hearing could focus on the following three issues:
 - Is the facility really in the class specified?

- Can the applicant comply with the class permit conditions?
- Are there any additional site-specific factors which must be considered?

Step 3

- EPA issues a permit.

The advantages of a class permit process are:

- It reduces the burden on permit applicants through a much streamlined application and review process.
- It reduces paperwork through standardized permit conditions.
- It establishes the general technology permit conditions in advance and therefore reduces the number of issues likely to be raised at the local hearing.

RCRA Amendment

- EPA is developing a statutory amendment to RCRA authorizing the development of Class Permits and streamlining the public review process.
 - ° Avoids the repetitive review of identical general technical permit conditions for each permit.
 - ° Allows the Regional Administrator to hold public hearings focusing on those issues not addressed in the general technical permit conditions.

The major questions that need to be resolved are:

- Can we define classes that include a significant number of facilities?
- Is it worthwhile to setup a special process for just a few hundred facilities or can classes be more generally defined?

EPA RECCOMENDED ADMENDMENT
ON CLASS PERMITS

"Sec. 3005 (g) CLASS PERMITS. -- (1) After notice and opportunity for hearing, the Administrator may promulgate permit conditions applicable to owners and operators of a class of facilities if he determines that the facilities in the class should be subject to similar design, operating and management requirements. Such classes shall not include hazardous waste incinerators or facilities which dispose of hazardous waste on the land.

"(2) If, after notice and opportunity for an informal hearing, the Administrator determines that a facility in any class designated under paragraph (1) meets the requirements and conditions promulgated under that paragraph, he may issue a class permit for such facility containing such permit conditions. These notice and hearing procedures may be used in lieu of the procedures in section 7004 (b) (2).

"(3) Notwithstanding the foregoing, the Administrator may, in establishing requirements and conditions under paragraph (1), provide that certain permit conditions shall be established for each facility on a site-specific basis.

Class Permits

Suggested Points to be Made in Legislative History

Under the current hazardous waste regulations, each applicant must submit information adequate to demonstrate, in detail, how his facility will achieve compliance with the regulations. Each bit of information, each plan, and each management strategy is then reviewed by the permit writer. The public must be notified of the permit by notices in local newspaper and radio stations and the public must be provided an opportunity for comment and a local public hearing, according to Section 7004.

The class permit concept recognizes that certain classes of facilities share common features and practices. Further, the permit conditions necessary to assure adequate protection of public health and the environment are not affected by the location of the facility or other site-specific features. As a result, permits issued to these facilities under the existing regulations would be essentially identical.

An amendment is desirable that would provide the authority for EPA to identify classes of facilities and to establish through informal rulemaking a specific set of standards and permit conditions for those facilities. Upon promulgation of those standards, facilities within the class would not be required to complete detailed permit applications. Rather, each applicant would only need to submit a minimum amount of information about the facility and certify that he will comply with the class permit conditions.

EPA does not intend to use the class permit process for issuing permits to land disposal facilities, incinerators or other facilities where site specific concerns are of paramount importance. Rather, it is the intent of EPA that the class permit process be applied to those facilities having lower environmental and public health concerns such as facilities which treat or store hazardous waste in tanks or containers. Thus paragraph (1) excludes hazardous waste incinerators and land disposal facilities from these class permit provisions.

Paragraph (2) of the amendment requires that the Administrator provide notice and opportunity for an informal hearing on his decision to grant or deny a class permit. It is EPA's intent that, for class permits, these notice and hearing procedures be used in lieu of the more detailed procedures in Section 7004(b) of the Act.

Because most terms and conditions of class permits will have been established by regulation, the matters at issue in individual permit proceedings, including factors to be considered when deciding whether to grant requests for public hearings, shall be limited to (1) whether the facility is a member of the class, (2) whether the facility meets (or will meet) the requirements and conditions promulgated by the Administrator and (3) the appropriateness of any terms and conditions established by the Administrator on a case-by-case basis. The narrow focus of these proceedings should expedite the issuance of class permits, thus allowing the Agency to concentrate its resources on more environmentally sensitive and complicated individual permits.

EPA recognizes that a few terms and conditions of a class permit (e.g., closure cost estimates) may need to be crafted on a site-specific basis. Thus, paragraph (3) of the amendment provides that in promulgating class permit conditions, the Administrator may designate certain conditions to be determined on a case-by-case basis.

It is EPA's intent that States which have class permit regulations which are equivalent or substantially equivalent to those issued by the Administrator be considered eligible for final authorization and interim authorization, respectively, under Section 3006. However, class permit regulations are not necessary for full authorization.

CMA 047484

Model Storage Permit

The model storage permit has been developed to provide a standard permit format for facilities that store hazardous wastes in tanks, containers and piles. The model is divided into five modules.

- ° Module I - Standard Conditions - Covers the conditions required of all permits found in 40 CFR Part 122.
- ° Module II - General Facility Conditions - Covers the conditions required of all permits found in 40 CFR Part 264, Subparts B, C, D, E, G and H.
- ° Module III - Container Storage - Covers the conditions required in 40 CFR Part 264, Subpart I for facilities that store hazardous wastes in containers.
- ° Module IV - Tank Storage - Covers the conditions required by 40 CFR 264, Subpart J for facilities that store hazardous wastes in tanks.
- ° Module V - Waste Pile Storage - Covers the conditions required by 40 CFR Part 264, Subpart L for facilities that store hazardous wastes in piles. The conditions in this module reflect the existing requirements for waste piles. Waste piles permitted after the effective date of the land disposal regulations must meet the revised requirements for waste piles found in those regulations.

In developing this model, we used our best judgement in deciding which regulatory provisions should be written out versus those which may be referenced. Some provisions must be written out because the standards offers options or the permit conditions must be more explicit than the regulation to be enforceable. In other cases, regulatory provisions are spelled out because of their importance to the permittee or the public.

The model identifies conditions that are exclusive to existing, as opposed to new, facilities; where optional methods of meeting the regulatory requirements are allowed; and which conditions may be waived in accordance with the regulations.

The model also identifies where parts of the application may be incorporated into the permit by reference. For example, the condition 40 CFR 264.61(b) - Implementation of contingency plan may read:

"The permittee shall immediately carry out the provisions of the contingency plan (Attachment) whenever there is a fire, explosion, or release of hazardous waste or constituents which threatens or could threaten human health or the environment."

In cases where the permit writer does not wish to attach parts of the application, then the permit must spell out what the permittee must do to meet the regulatory requirement.

The model permit uses notes (in brackets) following certain permit conditions to explain how they are to be applied. As this information is for the permit writer's use, it should not appear in the permit.

Two conditions required by 40 CFR Part 122 have not been incorporated into the model. §122.10 deals with compliance schedules and should be used on a case-by-case basis. Such schedules should be specified in the parts of the permit where they are needed. §122.11 concerns recording and reporting of monitoring results. Conditions addressing this requirement should also be inserted in the parts of the permit where they are needed.

A permit document of course is the end result of the permit process. Once a permit application is submitted, the permit writer reviews the application and any subsequent revisions to ensure that the facility will meet all the requirements in the regulations. If it does not and the permit can not be conditioned to bring the facility into compliance, then the permit must be denied. EPA is preparing guidance documents to aid applicants in submitting acceptable applications and to assist permit writers in making decisions about whether the application is sufficient to meet design and performance standards required by the regulations.

The language provided in the model permit assumes that the application has demonstrated that the facility will meet all the requirements in the regulations to the appropriate level of detail. The model permit does not explain how technical adequacy decisions will be made by the permit writer. Users of this model should understand that many of the performance standards cited herein must be amplified by conditions specific to the facility in question. This model is designed to provide a format for standard permit conditions and to aid permit writers in ensuring that all the applicable requirements of the regulations are addressed by the permit.

It is important to note that all permit conditions must have a regulatory basis and that all applicable regulatory requirements must be addressed in the permit. The statement of basis or fact sheet (see 40 CFR 124.7 and 124.3) should describe the rationale for the conditions in the

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permit and any waivers that are granted. When a permit condition reflects an unambiguous regulatory requirement, the fact sheet/statement of basis need merely reference that requirement. When a permit condition fulfills a performance standard, the fact sheet/statement of basis should explain why or how that condition satisfies the regulation. Where the regulatory basis for a permit condition is not obvious, the fact sheet/statement of basis should clearly support including that condition.

In most cases, the fact sheet/statement of basis for a storage permit will be quite brief. The attached check list may be used as a guide to or an index for the fact sheet/statement of basis. If lengthy explanations are needed for permit conditions, the permit writer may prefer to summarize those explanations in the fact sheet/statement of basis and reference the administrative record for the complete documentation.



Permit

02757

Permittee _____

I.D. Number _____

Permit Number _____

Pursuant to the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, as amended (42 USC Section 6901 et. seq., commonly known as RCRA) and attendant regulations promulgated thereunder by the U.S. Environmental Protection Agency (EPA) and codified in Title 40 of the Code of Federal Regulations, a permit is issued to the _____, hazardous waste storage facility located in _____, on _____ Road, at latitude _____ and longitude _____.

The Permittee must comply with all terms and conditions of the permit. This permit consists of the conditions discussed in Parts I and II and the applicable regulations contained in 40 CFR Parts 260 through 264 and 122 and 124 as specified in the permit. Applicable regulations are those which are in effect on the date of issuance of this permit (40 CFR §122.3(b)(2)).

This permit is based on the assumption that the information submitted in the permit application attached to Permittee's letter dated _____ as modified by subsequent amendments dated _____ and _____ (hereafter referred to as the application) is accurate and that the facility will be constructed and operated as specified in the application. Any inaccuracies found in this information could lead to the termination or modification of this permit and potential enforcement action (40 CFR §122.15, §122.16 and §122.17). The Permittee shall inform EPA of any deviation from or changes in the information in the application which would affect the Permittee's ability to comply with the applicable regulations or permit conditions.

This permit is effective as of _____, and shall remain in effect until _____, unless revoked and reissued, or terminated (40 CFR §122.9) or continued in accordance with §122.5(a).

PART I

MODULE I - STANDARD CONDITIONS

A. EFFECT OF PERMIT

The permittee is allowed to store hazardous waste in accordance with the conditions of this permit. Any storage of hazardous waste not authorized in this permit is prohibited. Compliance with this permit constitutes compliance, for purposes of enforcement, with Subtitle C of RCRA. Issuance of this permit does not convey property rights of any sort or any exclusive privilege; nor does it authorize any injury to persons or property, any invasion of other private rights, or any infringement of State or local law or regulations. Compliance with the terms of this permit does not constitute a defense to any action brought under Section 7003 of RCRA, Section 106(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9601 et seq., commonly known as CERCLA), or any other law governing protection of public health or the environment for any imminent and substantial endangerment to human health, or the environment.

B. PERMIT ACTIONS

This permit may be modified, revoked and reissued, or terminated for cause as specified in 40 CFR 122.15, 122.16, and 122.17. The filing of a request for a permit modification, revocation and reissuance, or termination or the notification of planned changes or anticipated noncompliance on the part of the permittee does not stay the applicability or enforceability of any permit condition.

C. SEVERABILITY

The provisions of this permit are severable, and if any provision of this permit or the application of any provision of this permit to any circumstance, is held invalid, the application of such provision to other circumstances, and the remainder of this permit shall not be affected thereby.

D. DUTIES AND REQUIREMENTS

1. Duty to Comply. The permittee shall comply with all conditions of this permit, except to the extent and for the duration such noncompliance is authorized by an emergency permit. Any permit noncompliance constitutes a violation of RCRA and is grounds for enforcement action, permit termination, revocation and reissuance, modification, or for denial of a permit renewal application.

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1. Duty to Reapply. If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the permittee must submit a complete application for a new permit at least 180 days before this permit expires.
2. Permit Expiration. This permit and all conditions therein will remain in effect beyond the permit's expiration date if the permittee has submitted a timely, complete application (see 40 CFR 122.25 and 122.4) and through no fault of the permittee, the Regional Administrator has not issued a new permit as set forth in 40 CFR 124.15.
4. Need To Halt Or Reduce Activity Not A Defense. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.
5. Duty to Mitigate. The permittee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from noncompliance with this permit.
6. Proper Operation and Maintenance. The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance includes effective performance, adequate funding, adequate operator staffing and training, and adequate laboratory and process controls, including appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facility or similar systems only when necessary to achieve compliance with the conditions of the permit.
7. Duty to Provide Information. The permittee shall furnish to the Regional Administrator, within a reasonable time, any relevant information which the Regional Administrator may request to determine whether cause exists for modifying, revoking and re-issuing, or terminating this permit, or to determine compliance with this permit. The permittee shall also furnish to the Regional Administrator, upon request, copies of records required to be kept by this permit.
8. Inspection and Entry. The permittee shall allow the Regional Administrator, or an authorized representative, upon the presentation of credentials and other documents as may be required by law to:
 - (a) Enter at reasonable times upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

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- (b) Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;
- (c) Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and
- (d) Sample or monitor, at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by RCRA, any substances or parameters at any location.

9. Monitoring and Records.

- (a) Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity. The method used to obtain a representative sample of the waste to be analyzed must be the appropriate method from Appendix I of 40 CFR Part 261. Laboratory methods must be those specified in Test Methods for Evaluating Solid Waste: Physical/ Chemical Methods SW-846 [insert date of publication], Standard Methods of Wastewater Analysis [insert reference number and date of publication]; or an equivalent method as specified in the attached Waste Analysis Plan.
- (b) The permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports and records required by this permit, and records of all data used to complete the application for this permit for a period of at least 3 years from the date of the sample, measurement, report or record. These periods may be extended by request of the Regional Administrator at any time and are automatically extended during the course of any unresolved enforcement action regarding this facility.
- (c) Records of monitoring information shall include:
 - (i) The date, exact place, and time of sampling or measurements;
 - (ii) The individual(s) who performed the sampling or measurements;
 - (iii) The date(s) analyses were performed;
 - (iv) The individual(s) who performed the analyses;
 - (v) The analytical techniques or methods used; and

(vi) The results of such analyses.

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10. Reporting Planned Changes. The permittee shall give notice to the Regional Administrator as soon as possible of any planned physical alterations or additions to the permitted facility.
11. Certification of Construction or Modification. The permittee may not commence storage of hazardous waste at a newly permitted facility nor in a modified portion of an existing facility until:
 - (a) The permittee has submitted to the Regional Administrator by certified mail or hand delivery a letter signed by the permittee and a registered professional engineer stating that the facility has been constructed or modified in compliance with the permit; and
 - (b) (i) The Regional Administrator has inspected the modified or newly constructed facility and finds it is in compliance with the conditions of the permit; or
(ii) The Regional Administrator has either waived the inspection or has not within 15 days notified the permittee of his or her intent to inspect.
12. Anticipated Noncompliance. The permittee shall give advance notice to the Regional Administrator of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.
13. Transfer of Permits. This permit may be transferred to a new owner or operator only if it is modified or revoked and reissued pursuant to 40 CFR 122.15(b)(2) or 122.17(d). Before transferring ownership or operation of the facility during its operating life, the permittee shall notify the new owner or operator in writing of the requirements of 40 CFR 264 and 40 CFR 122.
14. Compliance Schedules. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 14 days following each schedule date.
15. Twenty-four Hour Reporting. The permittee shall report to the Regional Administrator any noncompliance which may endanger health or the environment. Any information shall

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be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. The following shall be included as information which must be reported orally within 24 hours:

- (a) Information concerning release of any hazardous waste that may cause an endangerment to public drinking water supplies.
- (b) Any information of a release or discharge of hazardous waste, or of a fire or explosion from the facility, which could threaten the environment or human health outside the facility. The description of the occurrence and its cause shall include:
 - (i) Name, address, and telephone number of the owner or operator;
 - (ii) Name, address, and telephone number of the facility;
 - (iii) Date, time, and type of incident;
 - (iv) Name and quantity of material(s) involved;
 - (v) The extent of injuries, if any;
 - (vi) An assessment of actual or potential hazard to the environment and human health outside the facility, where this is applicable; and
 - (vii) Estimated quantity and disposition of recovered material that resulted from the incident.

A written submission shall also be provided within 5 days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the periods of noncompliance (including exact dates and times), and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent recurrence of the noncompliance. The permittee need not comply with the five day written notice requirement if the Regional Administrator waives that requirement and the permittee submits a written report within fifteen days of the time the permittee becomes aware of the circumstances.

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16. Other Noncompliance. The permittee shall report all other instances of noncompliance not otherwise required to be reported at the time monitoring reports are submitted. The reports shall contain the information listed in Condition D.15.
17. Other Information. Where the permittee becomes aware that he failed to submit any relevant facts in the permit application, or submitted incorrect information in a permit application or in any report to the Regional Administrator, the permittee shall promptly submit such facts or information.
- E. Signatory Requirement. All reports or other information requested by the Regional Administrator shall be signed and certified according to 40 CFR 122.6.
- F. Documents To Be Submitted Prior to Operation. [Note: Include here the requirement to submit any documents not complete or ready at time of permit issuance with the schedule for such submission (e.g., an updated contingency plan or the financial assurance instruments).]
- G. Documents To Be Maintained at Facility Site. The permittee shall maintain at the facility, until closure is completed and certified by an independent registered professional engineer, the following documents and amendments, revisions and modifications to these documents:
- (1) Waste analysis plan submitted in accordance with 40 CFR 264.13.
 - (2) Personnel training documents and records submitted in accordance with 40 CFR 264.16(d).
 - (3) Contingency plan submitted in accordance with 40 CFR 264.53(a).
 - (4) Closure plan submitted in accordance with 40 CFR 264.112(a).
 - (5) Cost estimate for facility closure submitted in accordance with 40 CFR 264.114(a).
 - (6) Operating record required by 40 CFR 264.73.
 - (7) Inspection schedules developed in accordance with 40 CFR 264.15(o).

All amendments, revisions and modifications to any plan or cost estimates required by this permit shall be submitted to the Regional Administrator for approval and permit modification.

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PART II

MODULE II - GENERAL FACILITY CONDITIONS

- A. Authorized Waste. The permittee is authorized to store, the following hazardous waste(s) or categories of hazardous waste in accordance with the conditions specified in this permit:

Waste #	Waste Description	[Module]

[Note: The permit may alternately list the authorized wastes in each module of the permit.]

- B. Design and Operation of Facility. The permittee shall maintain and operate the facility to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

C. Required Notice.

- (1) The permittee shall notify the Regional Administrator in writing at least four weeks in advance of the date the permittee expects to receive hazardous waste from a foreign source. Notice of subsequent shipments of the same waste from the same foreign source is not required.
- (2) When the permittee receives hazardous waste from an off-site source (except where the permittee is also the generator), he must inform the generator in writing that he has the appropriate permit(s) for, and will accept, the waste the generator is shipping. The permittee shall keep a copy of this written notice as part of the operating record.

[Note: This condition is only applicable if the facility receives waste from off-site.]

- D. General Waste Analysis. The permittee shall follow the procedures described in the waste analysis plan, Attachment _____.

The permittee shall verify its waste analysis as part of the quality assurance program. The quality assurance program will be in accordance with current EPA practices (Test Methods for Evaluating Solid Waste: Physical/Chemical Methods SW-846 [insert date of publication], or equivalent methods approved by the Regional Administrator; and at a minimum insure that the permittee maintains proper functional instruments, uses approved sampling and analytical methods, assures the validity of sampling and analytical procedures, and performs correct calculations.

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- E. Security. The permittee shall comply with the security provisions of 40 CFR 264.14(b) [select either (1) or (2) based upon the applicant's submittal] and (c).

[Note: If permittee has successfully demonstrated in accordance with 40 CFR 264.14(a) that the security requirements §264.14(b) and (c) are not necessary, no security permit condition is needed. This demonstration must be documented in the administrative record. If any specific security provisions are needed to meet the performance standard in §264.14(a), they should be so noted. For example, specify language of signs required by §264.14(c) if necessary.]

- F. General Inspection Requirements. The permittee shall follow the inspection schedule (Attachment _____) and shall comply with 40 CFR 264.15 (c) and (d).
- G. Personnel Training. The permittee shall conduct personnel training in accordance with 40 CFR 264.16. This training program shall follow the attached outline (Attachment _____).
- H. General Requirements for Ignitable, Reactive, or Incompatible Waste. The permittee shall comply with the requirements of 40 CFR 264.17(a) and the documentation requirements of 264.17(c).

[Note: This condition applies only if the permittee handles ignitable, reactive or incompatible wastes. Conditions specific to different types of storage (i.e., tanks, containers, or piles) are specified later.]

- I. Location Standards.

[Note: Seismic Considerations - If the proposed facility is located in an area listed in Appendix VI of 40 CFR Part 264, the applicant must have demonstrated compliance with 40 CFR 264.18(a). This must be documented in the administrative record.]

[Note: Floodplains - If the proposed (new) facility is not located in the floodplain, there is no permit condition needed. This must be documented in the administrative record. For facilities located in the 100-year floodplain, provision by which the permittee must meet the requirements of 40 CFR 264.18(b) must be specified. Existing facilities not in compliance with 40 CFR 264.18(b) must be placed on a compliance schedule (see 40 CFR 122.25(a)(ii)(v)).]

- 1
- J. Required Equipment. At a minimum, the permittee shall equip the facility with the equipment set forth in the contingency plan (Attachment _____).

[Note: If the permittee has successfully demonstrated in accordance with 40 CFR 264.32 that any of the equipment is not required the decision should be documented in the administrative record.]

- K. Testing and Maintenance of Equipment. The permittee shall test and maintain the equipment specified in the previous permit condition as necessary to assure its proper operation in time of emergency.

[Note: If any specific testing and maintenance of the equipment is needed, the permit should so specify.]

- L. Access to Communications or Alarm System. The permittee shall maintain access to the communications or alarm system as required by 40 CFR 264.34.

[Note: If the permittee has successfully demonstrated that such a device is not required under 40 CFR 264.32, the decision should be documented in the administrative record.]

- M. Required Aisle Space. At a minimum, the permittee shall maintain aisle space as required by 40 CFR 264.35.

[Note: If the permittee has successfully demonstrated that aisle space is not needed for any of the purposes specified in the regulations, the decision should be documented in the administrative record. Any plans or specifications which demonstrate how the permittee will meet this regulatory standard should be referenced and attached to the permit.]

- N. Arrangements with Local Authorities. If State or local officials refuse to enter into preparedness and prevention arrangements with the permittee, the permittee must document this refusal in the operating record.

[Note: The permittee is required to describe arrangements with local authorities in the contingency plan (See 40 CFR 264.52(c)). If the permittee cannot submit these arrangements with his contingency plan, the permit must be conditioned to require such arrangements prior to operation. See Standard Condition F.]

- O. Contingency Plan.

1. Implementation of Plan. The permittee shall immediately carry out the provisions of the contingency plan (Attachment _____) whenever there is a fire, explosion, or release of hazardous waste or constituents

which threatens or could threaten human health or the environment.

2. Copies of Plan. The permittee shall comply with the requirements of 40 CFR 264.53.
3. Amendments to Plan. The permittee shall review and immediately amend, if necessary, the contingency plan, in accordance with 40 CFR 264.54.
4. Emergency Coordinator. The permittee shall comply with the requirements of 40 CFR 264.55, concerning the emergency coordinator.

[Note: For new facilities, the names, addresses, and phone numbers of all persons qualified to act as emergency coordinators shall be supplied to the Regional Administrator at the time of certification (See 40 CFR 264.52(d).)]

- P. Manifest System. The permittee shall comply with the manifest requirements of 40 CFR 264.71, 264.72, and 264.76.

[Note: This condition applies only to facilities accepting off-site waste.]

. Recordkeeping and Reporting.

1. Operating Record. The permittee shall maintain a written operating record at the facility in accordance with 40 CFR 264.73(a), (b)(1), (3), (4), (5), (7) (off-site only), and (8).
2. Annual Report. The permittee shall comply with the annual report requirements of 40 CFR 264.75. If 40 CFR 264.75 is amended, compliance with the amended regulation will be deemed compliance with this permit condition.

R. Closure.

1. Performance Standard. The permittee shall close the facility in accordance with the closure plan, Attachment ____.
2. Amendment to Closure Plan. The permittee shall amend the closure plan in accordance with 40 CFR 264.112(b).
3. Notification of Closure. The permittee shall notify the Regional Administrator at least 180 days prior to the date he expects to begin closure.
4. Time Allowed For Closure. After receiving the

final volume of hazardous waste, the permittee shall treat or remove from site all hazardous waste in accordance with the schedule specified in the closure plan (Attachment _____). After receiving the final volume of hazardous waste, the permittee shall complete closure activities in accordance with the schedule specified in the closure plan (Attachment _____).

5. Disposal or Decontamination of Equipment. The permittee shall comply with the requirements of 40 CFR 264.114.
6. Certification of Closure. The permittee shall certify that the facility has been closed in accordance with the specifications in the closure plan as required by 40 CFR 264.115.
- S. Cost Estimate for Facility Closure. The permittee shall comply with the requirements of 40 CFR 264.142, including the requirements to adjust and revise the cost estimates, when necessary.
- T. Financial Assurance for Facility Closure. The permittee shall demonstrate continuous compliance with 40 CFR 264.143 and .145, or where applicable with 40 CFR 264.146, .149, .150 and .151 by providing documentation of financial assurance in at least the amount of the cost estimates required by permit condition II.S.
- U. Liability Requirements. The permittee shall comply with the requirements of 40 CFR 264.147, including the requirements to have and maintain liability coverage for sudden and accidental occurrences in the amount of at least \$1 million per occurrence with an annual aggregate of at least \$2 million, exclusive of legal defense costs, and must have and maintain liability coverage for non-sudden accidental occurrences in the amount of at least \$3 million per occurrence with an annual aggregate of at least \$6 million exclusive of legal defense costs. Demonstration of coverage of non-sudden and accidental occurrences shall be made by [date].
- V. Incapacity of Owners or Operators, Guarantors, or Financial Institutions.

The permittee shall comply with 40 CFR 264.148.

MODULE III - STORAGE IN CONTAINERS

[Note: The permit should specify the location and volume of containers.]

- A. Condition of Containers. If a container holding hazardous waste is not in good condition (e.g., severe rusting, apparent structural defects) or if it begins to leak, the permittee shall transfer the hazardous waste from such container to a container that is in good condition or manage the waste in some other way that complies with the requirements of the conditions of this permit.

- B. Compatibility of Waste with Containers. The permittee shall comply with 40 CFR 264.172 and assure that the ability of the container to contain the waste is not impaired.

[Note: If any specific procedures or equipment are required to assure compliance with this standard, the permit should so specify (e.g., liner specifications, testing procedures, etc.).]

- C. Management of Containers. The permittee shall manage containers in accordance with 40 CFR 264.173.

- D. Inspections. The permittee shall inspect container storage areas in accordance with 40 CFR 264.174.

- E. Containment.

1. The permittee shall comply with the requirements of a containment system found in 40 CFR 264.175(b)(1)-(3), including having a base which is free of cracks and gaps and able to contain leaks, spills and accumulated rainfall until such time that the material is detected and removed, be designed for efficient drainage and having sufficient capacity to contain 10% of the volume of containers. The permittee shall construct and maintain the containment system in accordance with the attached plans and specifications (attachment ____).
2. The permittee shall comply with the requirements of 40 CFR 264.175(b)(3) and (5).

[Note: If a waiver under 40 CFR 264.175(b)(4) is granted, it should be so documented in the administrative record.]

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3. The permittee and maintain shall construct the container storage area in accordance with the attached plans and specifications, Attachment _____, to assure compliance with 40 CFR 264.175(c).

[Note: Conditions E.1 and .2 apply only to those container storage areas that store wastes containing free liquids. For container storage areas storing wastes that do not contain free liquids, condition E.3 applies.]

- F. Special Requirements for Ignitable or Reactive Waste.
The permittee shall not locate containers holding ignitable or reactive waste within 15 meters (50 feet) of the facility's property line.

- G. Special Requirements for Incompatible Waste.

- (1) The permittee shall not place incompatible wastes in the same container.
- (2) The permittee shall not place hazardous waste in an unwashed container that previously held an incompatible waste or material.
- (3) The permittee shall not store a container of hazardous waste that is incompatible with any waste or material stored nearby in other containers, piles, open tanks or surface impoundments unless the container is separated from the other materials by a dike, beam, wall, or other device.

[Note: If specific procedures or designs are specified by the permittee in the application to meet these standards, they should be incorporated into the permit. Also, if the permittee has successfully demonstrated that he has complied with 40 CFR 264.17(b), that decision should be documented in the administrative record.]

- H. Closure. The permittee shall comply with the closure plan (attachment _____).

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MODULE IV - STORAGE IN TANKS

[Note: The permit writer should specify the number, type and size of the tanks and the waste the permittee may store.]

- A. Design of Tanks. The permittee shall construct all tanks in accordance with the attached plans and specifications (attachment ____). The permittee shall maintain the minimum shell thickness specified in these plans and specifications at all times to ensure sufficient shell strength.

[Note: The minimum shell thickness must be specified in the permit.]

- B. General Operating Requirements.

1. The permittee shall comply with 40 CFR 264.192(a) [select either (1) or (2) based upon the applicant's submittal].
2. The permittee shall comply with 40 CFR 264.192(b) [select (1) and/or (2) based upon the applicant's submittal].

[Note: If any plans or specifications indicate how these standards will be met, they should be incorporated into the permit. 40 CFR 264.192(b)(2) applies only to uncovered tanks.]

- C. Inspections. The permittee shall comply with the inspection requirements set forth in attachment ____.

[Note: 40 CFR 264.194(a)(3) only applies to uncovered tanks. If tank inspection is addressed in the inspection schedule, it need not be addressed here. 40 CFR 264.194(b) must be addressed in the inspection schedule. 40 CFR 264.194(c) must be addressed in the Contingency Plan.]

- D. Closure. The permittee shall comply with the closure plan (attachment ____).

- E. Special Requirements for Ignitable or Reactive Wastes.

1. The permittee shall not place ignitable or reactive waste in a tank.

[Note: If the permittee demonstrates compliance in the application with 40 CFR 264.193(a)(1), (2) or (3), the permit should set forth the conditions under which ignitable or reactive waste may be placed in a tank.]

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2. The permittee shall comply with the requirements of 40 CFR 264.198(b).

[Note: This condition applies only to facilities that store hazardous wastes in covered tanks.]

F. Special Requirements for Incompatible Wastes

1. The permittee shall not place incompatible wastes in the same tank.
2. The permittee shall not place hazardous waste in an unwashed tank which previously held an incompatible waste or material.

[Note: If the permittee has successfully demonstrated compliance with 40 CFR 264.17(b), the permit condition should set forth the appropriate conditions.]

MODULE V - STORAGE IN WASTE PILES

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[Note: Condition V.A. applies only to non-free liquid waste piles. Conditions V.B, .C, .D and .E apply to waste piles that store wastes that contain free liquids. Conditions F, G and H apply to both types of waste piles.]

A. Non-Free Liquid Piles.

1. The permittee shall not place liquids or materials containing free liquids in piles.
2. The waste pile shall be constructed and operated in accordance with the attached plans and specifications (attachment __) which provide for (a) that run-off or leachate is not generated; (b) that the waste pile is protected from surface run-on; (c) that wind dispersal is controlled by other means than wetting and (d) that leachate will not be generated by decomposition.

B. General Design Requirements. The permittee shall construct and operate the waste piles in accordance with the attached plans and specifications (attachment __).

[Note: The attached plans and specifications must address the design requirements of 40 CFR 264.251 and the requirements of 40 CFR 264.253.]

C. General Operating Requirements.

1. The permittee shall control wind dispersal of hazardous waste from the piles.

[Note: The permit shall specify control practices where necessary to meet this condition 40 CFR 264.252(a)).]

2. The permittee shall divert run-on away from the waste pile.
3. The permittee shall collect and control leachate and run-off from the waste pile.

[Note: Plans and specifications addressing the latter two conditions should be referenced or attached.]

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- D. Inspections and Testing. During construction or installation of the waste pile base, the permittee shall inspect and test the liner systems and materials in accordance with the inspection schedule (attachment _____).

[Note: The Inspection Schedule required by 40 CFR 264.15(b) must address 40 CFR 264.254.]

- E. Containment System Repairs; Contingency Plans.

1. The permittee shall activate the containment system evaluation and repair plan (Contingency Plan, attachment _____), whenever there is any indication of a possible failure of the containment system, as specified in 40 CFR 264.255(a).
2. The permittee shall comply with 40 CFR 264.255(b) and (c) regarding removing a waste pile from service, with 40 CFR 264.255(e) regarding restoring a waste pile to service and with 40 CFR 264.255(f) regarding closing a waste pile.

- F. Special Requirements for Ignitable or Reactive Wastes.
The permittee shall not place ignitable or reactive waste in a waste pile.

[Note: If the permittee has demonstrated compliance with 40 CFR 264.255(a)(1) or (2) the administrative record must so document and the permit must specify the circumstances under which this condition is waived.]

- G. Special Requirements for Incompatible Wastes.

1. The permittee shall not place incompatible wastes in the same pile.
2. The permittee shall not store a pile of hazardous waste that is incompatible with any waste or other material stored nearby in other containers, piles, open tanks, or surface impoundments unless the waste pile is separated from the other materials by a dike, berm or wall.

3. The permittee shall not pile or place hazardous waste on the same base where incompatible wastes or materials were previously piled or stored.

[Note: If the permittee has successfully demonstrated in the permit application that he need not meet the requirements of 40 CFR 264.256 and 40 CFR 264.257, the administrative record must so document and the permit must specify the circumstances under which these conditions are waived.]

- H. Closure. The permittee shall comply with the closure plan, (attachment ____).

SIGNATURE PAGE

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Signature: _____

Regional Administrator

Date: _____

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Checklist For RCRA Permit Conditions

A. Standard Conditions

§122.5	Continuation of Expiring Permits 122.5(a)	<u>COVER, D-3</u>
§122.6	Signatures to Permit Application and Reports 122.6	<u>I. D. 19</u>
§122.7	Conditions Applicable to all Permits	
	122.7(a)	<u>I. D. 1</u>
	122.7(b)	<u>I. D. 2</u>
	122.7(c)	<u>I. D. 4</u>
	122.7(d)	<u>I. D. 5</u>
	122.7(e)	<u>I. D. 6</u>
	122.7(h)	<u>I. D. 7</u>
	122.7(i)	<u>I. D. 8</u>
	122.7(j)	<u>I. D. 9</u>
	122.7(l)	<u>I. D. 10</u>
	122.7(l)(2)	<u>I. D. 12</u>
	122.7(l)(5)	<u>I. D. 14</u>
	122.7(l)(6)	<u>I. D. 15</u>
	122.7(l)(7)	<u>I. D. 16</u>
	122.7(l)(8)	<u>I. D. 17</u>
§122.9	Duration of Permits 122.9	<u>COVER</u>
§122.10	Schedule of Compliance 122.10	<u> </u>
§122.11	Requirements for Recording and Reporting of Monitoring Results 122.11	<u> </u>
§122.13	Effect of a Permit 122.13	<u>I. A.</u>
§122.14	Transfer of Permits 122.14	<u>I. D. 13</u>

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2.15 Modification or Revocation and Reissuance of Permits 122.15	<u>I. B.</u>
§122.16 Termination of Permits 122.16	<u>I. B.</u>
§122.17 Minor Modifications of Permits 122.17	<u>I. B.</u>
§122.22 Applications for a Permit 122.22(d)	<u>I. D. 2</u>
§122.28 Additional Conditions Applicable to all RCRA Permits	
122.28(a)	<u>I. D. I</u>
122.28(c)	<u>I. D. 11</u>
122.28(d)	<u>I. D. 15</u>

Severability c [Note: The severability clause has no foundation in the 40 CFR Part 122. However, it has become standard practice to provide this clause in other permits (i.e., NPDES).]

B. Specific Facility Conditions

§264.12 Required Notices	
264.12(a)	<u>II.C. 1</u>
264.12(b)	<u>II.C. 2</u>
264.12(c)	<u>I. D. 13</u>
§264.13 General Waste Analysis	
264.13(a)	<u>II.D.</u>
264.13(b)	<u>II.D.</u>
264.13(c)	<u>II.D.</u>
§264.14 Security	
264.14(a)	<u>II.E.</u>
264.14(b)	<u>II.E.</u>
264.14(c)	<u>II.E.</u>
§264.15 General Inspection Requirements	
264.15(a)	<u>II.F.</u>
264.15(b)	<u>II.F.</u>
264.15(c)	<u>II.F.</u>
264.15(d)	<u>II.F.</u>
§264.16 Personnel Training	
40 CFR 122.25(a)(12) requires the preparation of introductory and continuing training programs to demonstrate compliance with 40 CFR 264.16, specifically 264.16(a)(3).	
264.16(e)	<u>II.G.</u>

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264.17 General Requirements for Ignitable, Reactive or Incompatible Wastes	
264.17(a)	<u>II.H.</u>
264.17(b)(1)-(5)	III.E.,F.;IV.E.,F.;V.F.,G.
264.17(c)	<u>II.H.</u>
§264.18 Location Standards	
264.18(a) Seismic	<u>II.I.</u>
264.18(b) Floodplains	<u>II.I.</u>
§264.31 Design and Operation of Facility	
264.31	<u>B</u>
§264.32 Required Equipment	
264.32(a)	<u>II.J.</u>
264.32(b)	<u>II.J.</u>
264.32(c)	<u>II.J.</u>
264.32(d)	<u>II.J.</u>
[Note: 40 CFR 122.25(a)(6) provides for a waiver of these requirements if a documented demonstration has been provided.]	
§264.33 Testing and Maintenance of Equipment	
264.33	<u>II.K.</u>
§264.34 Access to Communications or Alarm System	
264.34(a)	<u>II.L.</u>
264.34(b)	<u>II.L.</u>
[Note: See explanation under §264.32.]	
§264.35 Required Aisle Space	
264.35	<u>II.M.</u>
§264.36 Special Handling for Ignitable or Reactive Waste	
264.36 (see 264.17(a))	<u>II.H.</u>
§264.37 Arrangements with Local Authorities	
264.37(a)	<u>II.O.</u>
264.37(b)	<u>II.N.</u>
§264.51 Purpose and Implementation of Contingency Plan	
264.51(a)	<u>N/A</u>
264.51(b)	<u>II.O.I</u>
§264.52 Content of Contingency Plan	
[Note: The contingency plan developed pursuant to 40 CFR 264.51(a) must address the requirements of 264.52.]	

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4.53 Copies of Contingency Plan 264.53	<u>II. 0.2</u>
264.54 Amendment of Contingency Plan 264.54	<u>II. 0.3</u>
§264.55 Emergency Coordinator [Note: The responsibilities of the emergency coordinator should be more fully spelled out pursuant to 40 CFR 264.56 and the contingency plan (40 CFR 264.51(a).]	<u>II. 0.4</u>
§264.56 Emergency Procedures [Note: The contingency plan developed pursuant to 40 CFR 264.5(a) must address the requirements of 264.56.]	<u>II. 0.1</u>
§264.71 Use of Manifest System 264.71(a) 264.71(b) 264.71(c)	<u>II.P.</u> <u>II.P.</u> <u>II.P.</u>
[Note: These requirements applies only to facilities receiving wastes from off-site.]	
§264.72 Manifest Discrepancies 264.72(b)	<u>II.P.</u>
[Note: This requirement applies only to facilities receiving wastes from off site.]	
§264.73 Operating Record 264.73(a) 264.73(b)(1) 264.73(b)(3) 264.73(b)(4) 264.73(b)(5) 264.73(b)(7) 264.73(b)(8)	<u>II.Q.</u> <u>II.Q.</u> <u>II.Q.</u> <u>II.Q.</u> <u>II.Q.</u> <u>II.Q.</u> <u>II.Q.</u>
[Note: 264.73(b)(7) applies only to off-site facilities.]	
§264.74 Availability, Retention, and Disposition of Records 264.74(a) 264.74(b)	<u>I.D.7, D.8</u> <u>I. D. 9</u>
§264.75 Annual Report 264.75	<u>II.Q.</u>
§264.76 Unmanifested Waste Report 264.76	<u>II.P.</u>

[Note: This requirement applies only to facilities receiving wastes from off-site.]

§264.111 Closure Performance Standard 264.111	<u>II.R. 1</u>
§264.112 Closure Plan; Amendment of Plan 264.112(a) 264.112(b) 264.112(c)	<u>II.R. 1</u> <u>II.R. 2</u> <u>II.R. 3</u>
§264.113 Closure Time; Time Allowed for Closure 264.113(a) 264.113(b)	<u>II.R. 4</u> <u>II.R. 5</u>
§264.114 Disposal or Decontamination of Equipment 264.114	<u>II.R. 6</u>
§264.115 Certificate of Closure 264.115	<u>II.R. 7</u>
§264.142 Cost Estimate for Facility Closure 264.142(a) 264.142(b) 264.142(c)	<u>II.S.</u> <u>II.S.</u> <u>II.S.</u>
§264.143 Financial Assurance for Facility Closure 264.143	<u>II.T.</u>
[Note: In addition to meeting this requirement, the permittee shall demonstrate continuous compliance with 40 CFR 264.146, (Use of mechanism for financial assurance of both closure and part-closure care, .149 (State financial mechanism), .150 (State assumption of responsibility) and .151 (Working of instruments, where applicable.)]	
§264.147 Liability Requirements 264.147	<u>II.U.</u>
§264.148 Incapacity of Owner or Operators, Guarantors, or Financial Institution 264.148	<u>II.V.</u>
<u>C. Use and Management of Containers</u>	
§264.171 Condition of Containers 264.171	<u>III.A.</u>
§264.172 Compatibility of Waste with Containers 264.172	<u>III.B.</u>

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64.173 Management of Containers
264.173

III.C.

§264.174 Inspection
264.174

III.D.

§264.175 Containment
264.175(b)
264.175(c)

III.E.1., 2.
III.E.3

[Note: 264.175(b) applies only to container storage areas that store containers with wastes that contain free liquids, whereas 264.175(c) applies to storage areas that store containers holding only wastes that don't contain free liquids.]

§264.176 Special Requirements for Ignitable or Reactive Waste
264.176

III.F.

§264.177 Special Requirements for Incompatible Waste
264.177(a)
264.177(b)
264.177(c)

III.G.1
III.G.2
III.G.3

[Note: Compliance with 40 CFR 264.177(a) may be waived, if the permittee has provided a successful demonstration under 40 CFR 264.17(b).]

§264.178 Closure
264.178

III.H.

D. Tanks

§264.191 Design of Tanks
264.191

IV.A.

§264.192 General Operating Requirements
264.192(a)(1) or,
264.192(a)(2)
264.192(b)(1)
264.192(b)(2)

IV.B. 1
IV.B. 1
IV.B. 2
IV.B. 2

[Note: 264.192(b)(2) applies only to uncovered tanks.]

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§264.191 Inspections

264.191(a)
264.191(b)
264.191(c)

IV.C.

IV.C.

IV.C.

[Note: 264.191(c) must be addressed pursuant to the contingency plan (40 CFR 264.61(a).]

§264.197 Closure

264.197

IV.D.

§264.193 Special Requirements for Ignitable or Reactive Wastes

264.193(a)(1) or,
264.193(a)(2) or,
264.193(a)(3)
264.193(b)

IV.E. 1

IV.E. 1

IV.E. 1

IV.E. 2

[Note: Compliance with 40 CFR 264.193(a)(1) may be waived, if the permittee have provided a successful demonstration under §261.21 or 261.23 and §264.17(b).]

§264.199 Special Requirements for Incompatible Wastes

264.199

IV.F.

E. Waste Piles

§264.250 Applicability

264.250(b)

V. A.

[Note: Waste piles used to treat or store hazardous waste that do not contain free liquids are not subject to the requirements under §§264.251, 264.252, 264.253, 264.254 and 264.255.]

§264.251 General Design Requirements

264.251(a)
264.251(b)

V. B.

V. B.

§264.252 General Operating Requirements

264.252(a)
264.252(b)
264.252(c)

V. C. 1

V. C. 2

V. C. 3

§264.253 Containment Systems

264.253(a)(1), and either
264.253(a)(2); or
264.253(a)(3)
264.253(b)(1)
264.253(b)(2)
264.253(c)
264.253(d)

V.B.&C.

V.B.&C.

V.B.&C.

V.B.&C.

V.B.&C.

V.B.&C.

V.B.&C.

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§264.254 Inspections and Testing

264.254(a)(1)
264.254(a)(2)

V.D., II.0.
V. B.

§264.255 Containment System Repairs Contingency Plans

264.255(a)
264.255(b)
264.255(c)(1)-(4)
264.255(d)(1)
264.255(d)(2)
264.255(e)
264.255(f)

V. E. 1
V. E. 2
V. E. 2
II. 0
II. 0
V. E. 2
V. E. 2

[Note: 264.255(d)(1) and (2) must be addressed pursuant to the contingency plan (40 CFR 264.51(a)).]

§264.256 Special Requirements for Ignitable or Reactive Waste

264.256(a)
264.256(a)(1) or,
264.256(a)(2)

[Note: Compliance with 40 CFR 264.256(a) may be waived, if the permittee has provided a successful demonstration under 264.17(b) or 264.256(a)(2) has been complied with.]

§264.257 Special Requirements for Incompatible Waste

264.257(a)
264.257(b)
264.257(c)

V. F.
V. F.
V. F.

[Note: Compliance with 40 CFR 264.257(a) and (c) may be waived, if the permittee has provided a successful demonstration under 264.17(b).]

§264.258 Closure

264.258

V. H.

CMA 047516

CONCEPT OUTLINE MOBILE TREATMENT UNITS

A Mobile Treatment Unit (MTU) is a transportable device which can physically, biologically, chemically or thermally treat hazardous waste. This treatment generally results in waste reduction or waste detoxification. An MTU can treat wastes at several sites in a year and may return to a site on a regularly scheduled basis. Under the current regulations, MTUs require a RCRA permit for each site where waste is to be treated, even though the MTU has operated in the same manner at another site at which it has a permit.

Under existing procedures, MTUs must obtain a RCRA permit at each site. Since the technical operations of the MTU will not vary substantially from site to site, a large part of each site's permit may be identical. In order to assure that repetitive development of non site-specific permit conditions does not occur, EPA will encourage MTU applicants to submit copies of their original permit application and the resulting permit conditions, in any subsequent application. Only site specific permit conditions would need to be developed for each site. An MTU's first permit will serve as a model for all subsequent permits.

EPA is considering the use of the Class Permit concept for permitting MTUs that treat hazardous wastes in tanks. Such permitting procedures should reduce repetition and expedite the permitting of mobile treatment units.

DRAFT

**A GUIDE FOR PREPARING
RCRA STORAGE PERMIT APPLICATIONS**

Note: This preliminary guidance document is intended to assist owner or operators of hazardous waste storage facilities in developing RCRA Part B Permit Applications. It is being distributed to prospective permit applicants and others for their review, comment and use. EPA is interested in receiving comments on the usefulness of the guide and suggestions as to how it may be improved. It was developed by a contractor in concert with EPA permit writers in Region I and Headquarters but has not yet been reviewed by applicants or other persons outside of the Agency.

This guide was prepared by

A. T. Kearney, Inc.
P.O. Box 1405
699 Prince Street
Alexandria, Virginia 22313

and by

PEDCo Environmental, Inc.
11499 Chester Road
Cincinnati, Ohio 45246

U.S. ENVIRONMENTAL PROTECTION AGENCY

1982

CMA 047518

DISCLAIMER

This Industry Guidance Document has been developed to assist hazardous waste storage facilities in preparing Part B of the RCRA Permit Application. It is intended that permit applicants will use the document as a guide to prepare their own applications in a format and level of detail acceptable to the U.S. Environmental Protection Agency. The model permit application contained in the document was developed for a typical representative storage facility. Therefore, some sections of the model may not be applicable to all facilities. The U.S. EPA urges applicants to contact their EPA Regional Office to discuss the applicability of this guide to their facility and other facility-specific requirements.

PREFACE

The purpose of this guide is to assist hazardous waste management facilities in the preparation of their RCRA Permit Applications. Its intent is to provide sufficient information and detail to enable a facility to submit an application; however, in some situations certain regulations may not apply to every facility. When this is the case, the applicable regional office of the U.S. Environmental Protection Agency should be contacted to arrange a preapplication meeting to discuss RCRA permit application needs that are not covered or understood.

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PART 1 GUIDANCE MATERIAL

SECTION I

INTRODUCTION

Under Subtitle C of the Resource Conservation and Recovery Act of 1976 (RCRA), the U.S. Environmental Protection Agency (EPA) established regulations to insure the protection of human health and the environment through the proper management of hazardous wastes. These regulations require certain facilities that treat, store, or dispose of hazardous wastes to submit RCRA permit applications to EPA. These applications should contain sufficient information to assure that the management practices at those facilities will provide adequate levels of protection.

This Guide has been written specifically for owners and operators of storage and treatment facilities that have hazardous wastes in tanks, containers, or piles. It provides detailed technical instructions covering the required content of the RCRA permit applications and explains the administrative procedures that the EPA will use in the RCRA permitting program.

The intent of this Guide is to minimize the effort and time required of industry to apply for and obtain RCRA permits. The detailed explanations provided in this Guide will help to prevent applicants from developing and presenting more information than needed to evaluate the applications. The suggested application format is presented as a guide for organizing submissions.

The information presented concerning EPA's administrative and confidentiality procedures in the RCRA permitting program is intended to assist applicants in an understanding of Agency requirements. Ultimately, this Guide should serve to improve communications and cooperation between industry and the EPA in the RCRA permitting program and increase the effectiveness and timeliness with which EPA carries out its regulatory responsibilities.

The second section of this Guide describes the administrative procedures that will be followed in the RCRA permitting program. It includes discussions of how applications will be requested, the two-stage process that EPA will use for reviewing applications, public participation procedures, permit issuance procedures, and the timing of these events. This section also describes the procedures that should be followed in requesting protection from public disclosure of confidential business information. It provides details of the types of information that will receive confidential treatment by EPA and how the legitimacy of confidentiality claims will be determined.

The third section of the Guide presents an accepted format for structuring a RCRA permit application and provides detailed explanations of the information that must be included in the application.

Part 2 of this document presents an example of a complete RCRA permit application for a hypothetical storage facility. This example provides a model on which actual applications can

be based. It is structured to assist RCRA permit applicants in determining the appropriate level of detail and the proper presentation of that material. Applicants should be aware, however, that the level of detail will also be related to the size and complexity of the facility.

SECTION II

ADMINISTRATIVE PROCEDURES IN THE PERMITTING PROCESS

This section outlines the activities entailed in applying for and obtaining a RCRA permit for a hazardous waste management (HWM) facility (Figure 1). An understanding of these procedures will allow applicants to deal effectively with EPA in the permitting program.

Most facilities that treat, store, or dispose of hazardous waste must obtain a RCRA permit. The application for this permit consists of two parts, Part A and Part B. Certain facilities (i.e., those in existence before November 19, 1980) have been required to submit Part A. These facilities have been granted an "interim status" that allows them to continue to operate until final administrative action is taken on their permit. To obtain a RCRA permit, however, these facilities must submit Part B applications. The EPA Regional Administrators have the authority to request owners and operators of existing HWM storage and treatment facilities to submit Part B of their RCRA permit application, but any facility may submit the Part B application voluntarily.

Coordination With States

An applicant for a RCRA permit should be aware that the EPA and the states share responsibilities for the administration of

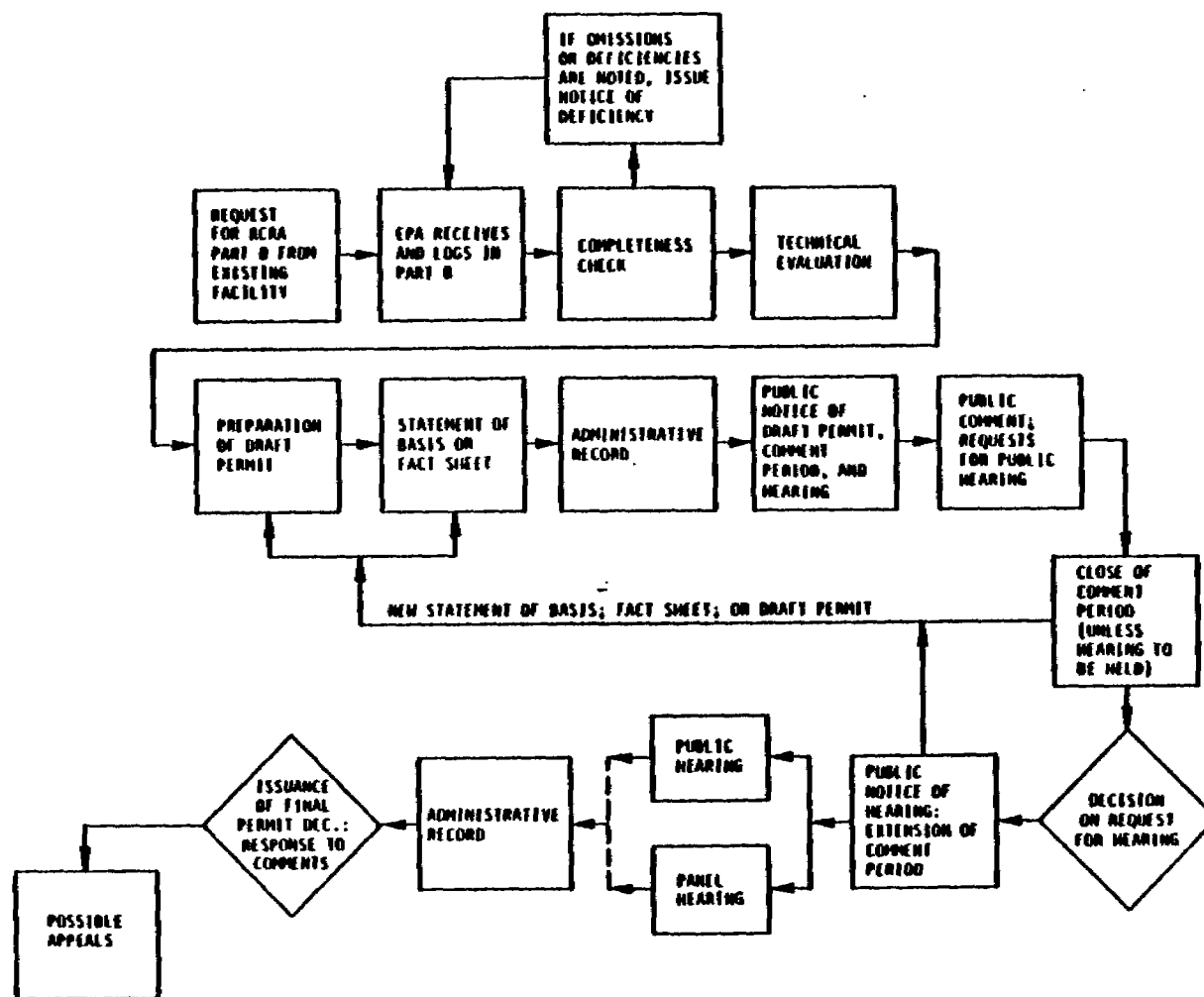


Figure 1. Flow diagram of the RCRA permitting process.

the RCRA permit program. Each state's role in the permitting process varies according to the status of its authorization to administer the hazardous waste permit program. Applicants should familiarize themselves with the state's permitting process and be aware that EPA permit writers will be communicating with the states at appropriate stages in the permit process.

Submitting RCRA Part B Permit Applications

The EPA Regional Office may request submission of Part B of the RCRA permit application from an existing facility, or a facility may voluntarily submit Part B. The letter of request will generally include a list of the items in Part B that are applicable to the permit applicant's facility type, a copy of the Part 264 and Part 122.25 regulations, notice of the applicant's right to claim confidentiality, notice of the right to question the EPA Regional staff about application requirements and the names and phone numbers of the appropriate contacts, information on the number of copies required and where the applicant is to submit them, and a recommendation that the applicant contact the appropriate state authority.

An existing facility that has been requested to submit Part B of the RCRA permit application is allowed at least 6 months to gather, organize, and send the required data to EPA. During this time, the facility can contact the EPA Regional Office for clarification or assistance. Depending on the depth and complexity of the issues, the EPA or the applicant may find it

useful to schedule a conference. Such a meeting can facilitate the permitting process by identifying problems early and enabling the applicant to resolve them.

Claims of Confidentiality

At the time of submittal, applicants for a RCRA permit may assert a claim of business confidentiality for proprietary information included in their application. General EPA regulations governing claims of confidentiality are found in Title 40 of the Code of Federal Regulations (40 CFR), Part 2. Specific provisions for claims of confidentiality submitted with permit applications are found in 40 CFR 122.19.

In these regulations, "business information" means "...any information which pertains to the interest of any business, which was developed or acquired by that business, and which is possessed by EPA in recorded form." "Commercial information" refers to processes, operations, style of work, or apparatus. "Financial information" refers to the identity, confidential statistical data, amount of source of any income, profits, losses, or expenditures of the applicant.

An applicant may claim that business information is entitled to confidential treatment for "reasons of business confidentiality." This includes trade secrets and commercial or financial information, that, if released, would be likely to cause substantial harm to the competitive position of the applicant.

Claims of confidentiality must be asserted when the permit application is submitted. If no claim is asserted at that time, the EPA may make the information available to the public without further notice to the applicant.

To assert a claim, the applicant must attach a cover sheet to the information, or stamp or type a notice on each page of the information, or otherwise identify the confidential portions of the application. Words such as "trade secret", "confidential business information", "proprietary", or "company confidential" should be used. The notice should also state whether the applicant desires confidential treatment only until a certain date or a certain event.

Prior to releasing any information for which a claim of confidentiality has been made, the Agency will give the applicant an opportunity to substantiate its claim and will then determine whether the information warrants confidential treatment.

Applicants should limit their requests for confidential treatment to such material that if released, is likely to cause substantial harm to the competitive position of their respective companies. Claims of confidentiality should not be asserted for information that is reasonably obtainable without the applicant's consent (for example, standard engineering designs). It is important not to claim confidentiality for the entire permit application, as such claims will significantly delay the permitting process.

Whenever possible, the applicant should separate the information contained in the application into confidential and nonconfidential units and submit them under separate cover letters. Claiming confidentiality for a large portion of the information in the permit application and failing to separate the application into

confidential and nonconfidential units may result in significant delays in processing the permit application because the EPA lacks the in-house resources for expeditiously separating out the information entitled to confidential treatment.

EPA's Review of
Part B Applications

When the EPA Regional Office receives a RCRA permit application, it reviews the application for administrative and technical completeness. The administrative review involves a check of the timeliness of the submittal, general data items, correct signatures, and certification of relevant technical data by registered professional engineers.

If the application is incomplete, the EPA requests the missing information through a "Notice of Deficiency" (NOD) letter. This letter details the information needed to complete the application and specifies the date for submission of these data. When the EPA has received all the necessary information, they will notify the applicant in writing that the application is complete.

The EPA then performs a technical review of the application to determine whether the facility under review has satisfied the requirements of the standards promulgated under Title 40 of the Code of Federal Regulations (40 CFR), Part 264, and should be granted a RCRA permit. A site inspection may be conducted during the RCRA permit application review process to verify the information contained in the application.

The Agency may choose to use state officials or a contractor to provide technical expertise and assist in the technical review of a permit application or to conduct onsite visits to verify information pertinent to the issuance or denial of a RCRA permit.

Draft RCRA Permits and Permit Denials

Upon completion of the technical review, the EPA Regional Administrator tentatively decides whether to issue or deny a RCRA permit. If the tentative decision is to issue the permit, the EPA regional staff prepares a draft permit for public review. The draft RCRA permit specifies all the limitations, requirements, and conditions to be placed on the facility. The Regional Office also prepares a "fact sheet" or "statement of basis," which explains in simple language the reason for each condition included in the draft permit.

When writing a RCRA permit, the EPA may specify a schedule for compliance rather than requiring the facility to be in full compliance at the time of permit issuance. A compliance schedule allows the facility to operate while it is upgrading its operations to meet all the regulatory requirements. Such a compliance schedule is used only when it is clear that temporary noncompliance will have no unacceptable effects on human health or the environment. In its decision regarding a schedule for compliance, the Agency also considers such factors as availability of any materials required to upgrade the facility, construction time, and the time required to contract for such services.

A permit may be denied if it is determined that an applicant cannot meet the requirements of the standards set forth in 40 CFR 264, that activities at the facility will endanger human health or the environment, or that an applicant either has not fully disclosed all relevant facts in the application or during the RCRA permit issuance process or has misrepresented any relevant facts at any time.

If the Regional Administrator tentatively decides to deny a RCRA permit, a notice of intent to deny a permit is prepared. This notice is considered a type of draft permit and follows the same procedures as any draft permit. These procedures include preparation of a statement of basis or fact sheet containing reasons supporting the tentative decision to deny the permit, public notice of the denial, acceptance of comments, a possible hearing, preparation of a final decision, and possible receipt of a request for appeal.

Public Notice, Comments, Informal
Public Hearings, Panel Hearings

All draft RCRA permits are subject to public notice, public comments, and public hearing (if the Regional Administrator finds a significant degree of public interest). Public notice provides interested persons a minimum of 45 days to comment on the draft permit.

If written opposition to the Agency's intent to issue a permit and a request for a hearing are received during the comment period, a public hearing will be held. Notification of the hearing is issued at least 30 days prior to the scheduled

date, and the public comment period is extended until the close of the public hearing.

The EPA Regional Office also has the option of conducting more formal "panel hearings" when the issuance of a draft RCRA permit is complicated enough to justify such a proceeding. Also, any person may request a panel hearing. The panel hearing enables the EPA to obtain facts on objectionable aspects of the draft permit and to receive evidence to support suggested alternative permit conditions and to aid in the preparation of a final decision on a permit.

Final Permits

After the close of the public comment period (which includes the public hearing period or any panel hearing), the Regional Office either prepares and issues a final RCRA permit or denies the permit application. In either case, the applicant and interested parties will receive public notice, which includes information regarding appeal procedures. Unless a later date is specified, uncontested terms and conditions of the draft RCRA permit become effective 30 days after the date of the public notice. At the time the final RCRA permit is issued, the Regional Office also issues a response to any significant public comments received and indicates any provisions of the draft permit that have been changed and the reasons for the changes. The response to comments becomes part of the administrative record.

Appeal to the Regional Administrator

Persons who submitted comments on the draft RCRA permit or participated in any public hearing are allowed 30 days after the

1

final permit decision to file a notice of appeal and a petition for review with the Regional Administrator. The Regional Administrator then grants or denies the petition within a reasonable time. If the Administrator decides to conduct a review, the parties are given the opportunity to file briefs in support of their positions. Within the 30-day period, the Administrator also may decide to review the decision to grant or deny a hearing on his/her own motion. The Administrator then notifies the parties and sets up a briefing schedule. On review, the Administrator has several options regarding the final decision. It may be summarily affirmed without opinion, modified, set aside, or remanded for further proceedings. This petition for review by the Administrator is a prerequisite for judicial review of the Administrator's final decision.

SECTION III
INSTRUCTIONS FOR PREPARATION OF A
RCRA PERMIT APPLICATION

This section attempts to simplify preparation of a RCRA permit application by describing in detail the information required. It also includes a suggested permit application format. The information presented is based on RCRA regulations dealing with Part B permit requirements (40 CFR 122.25) and the technical standards in 40 CFR 264. Using the suggested format and meeting the detailed requirements should enable the applicant to complete the RCRA permit application in a timely and cost-effective manner. When submitting an application, the applicant should be sure that the document is presented in a manner that will allow for major and minor revisions during the subsequent review by EPA (e.g., a three-ring binder).

RCRA Permit Application Format

The suggested permit application format presented in the following pages includes all information required for a permit application. Most sections of the application must be completed by all facilities, but a few sections do not apply to certain facilities. For example, existing facilities need not address the seismic standards in Section B - Facility Description. The applicability of such sections is indicated in the narrative that follows the outline.

The format and explanations presented in this section are supplemented by a model RCRA permit application for a hypothetical plant, which appears as Part 2 to this document. This model carefully follows the outline and provides a practical illustration of how to approach the RCRA permit application process.

Suggested Permit Application Format

A. Part A Application

B. Facility Description

- B-1 General description [40 CFR Section 122.25(a)(1)]
- B-2 Topographic map [40 CFR Section 122.25(a)(19)]
- B-3 Location information [40 CFR Sections 122.25(a)(11), and 264.18]
 - B-3a Seismic standard (reserved)
 - B-3b Floodplain standard
 - B-3b(1) Demonstration of compliance
 - B-3b(1)(a) Flood proofing and flood protection measures
 - B-3b(1)(b) Flood plain
 - B-3b(2) Plan for future compliance
- B-4 Traffic patterns [40 CFR Sections 122.25(a)(10)]

C. Waste Characteristics

- C-1 Chemical and physical analyses [40 CFR Sections 122.25(a)(2) and 264.13(a)]
- C-2 Waste analysis plan [40 CFR Sections 122.25(a)(13) and 264.13(b) and (c)]
 - C-2a Parameters and rationale
 - C-2b Test methods
 - C-2c Sampling methods
 - C-2d Frequency of analyses
 - C-2e Additional requirements for waste generated offsite

D. Process Information

- D-1 Containers [40 CFR Sections 122.25(b)(1), 264.171, 264.172, 264.173, 264.175 and 264.176]
 - D-1a Containers with free liquids
 - D-1a(1) Description of containers
 - D-1a(2) Container management practices

Suggested Permit Application Format (continued)

- D-1a(3) Secondary containment system design and operation
 - D-1a(3)(a) Requirement for base to contain liquids
 - D-1a(3)(b) Containment system drainage
 - D-1a(3)(c) Containment system capacity
 - D-1a(3)(d) Control of run-on
 - D-1a(4) Removal of liquids from containment system
- D-1b Containers without free liquids
 - D-1b(1) Test for free liquids
 - D-1b(2) Description of containers
 - D-1b(3) Container management practices
 - D-1b(4) Container storage area drainage
- D-2 Tanks [40 CFR Sections 122.25(b)(2), 264.191, 264.192]
 - D-2a Description of tanks
 - D-2b Tank corrosion and erosion
 - D-2c Tank management practices
- D-3 Waste piles [40 CFR Sections 122.25(b)(4), 264.250, 264.251, 264.252, 264.253]
 - D-3a Waste piles with free liquids
 - D-3a(1) Control of wind dispersal
 - D-3a(2) Control of run-on
 - D-3a(3) Collection of leachate and runoff
 - D-3a(4) Foundation
 - D-3a(5) Waste pile base
 - D-3a(5)(a) Containment system design
 - D-3a(5)(b) Leachate detection, collection, and removal system
 - D-3a(6) Vegetation and rodent control
 - D-3a(7) Equipment and procedures for waste pile movement
 - D-3b Waste piles without free liquids
 - D-3b(1) Test for free liquids
 - D-3b(2) Control of wind dispersal
 - D-3b(3) Protection from precipitation and run-on
 - D-3b(4) Demonstration that no free liquids are placed on pile
- D-4 Surface impoundments
- D-5 Incinerators
- E. Ground Water Monitoring Systems (Reserved)
- F. Procedures to Prevent Hazards
 - F-1 Security [40 CFR Sections 122.25(a)(4) and 264.14]
 - F-1a Security procedures and equipment
 - F-1a(1) 24-hour surveillance system
 - F-1a(2) Barrier and means to control entry
 - F-1a(2)(a) Barrier
 - F-1a(2)(b) Means to control entry

Suggested Permit Application Format (continued)

- F-1a(3) Warning signs
- F-1b Waiver
 - F-1b(1) Injury to intruder
 - F-1b(2) Violation by intruder
- F-2 Inspection schedule [40 CFR Sections 122.(a)(5), 264.15, 264.33, 264.174, 264.194, 264.254, 264.255]
 - F-2a General inspection requirements
 - F-2a(1) Types of problems
 - F-2a(2) Frequency of inspection
 - F-2b Specific process inspection requirements
 - F-2b(1) Container inspection
 - F-2b(2) Tank inspection
 - F-2b(2)(a) Construction materials
 - F-2b(2)(b) Surrounding area
 - F-2b(2)(c) Overfilling control equipment
 - F-2b(2)(d) Monitoring data
 - F-2b(2)(e) Level of waste
 - F-2b(2)(f) Tank condition assessment
 - F-2b(2)(g) Tank interior inspection
 - F-2b(3) Waste pile inspection
 - F-2b(3)(a) Liner systems
 - F-2b(3)(b) Manufactured liner materials
 - F-2b(3)(c) Containment system
 - F-2c Remedial action
 - F-2d Inspection log
- F-3 Waiver of preparedness and prevention requirements [40 CFR Sections 122.25(a)(6), 264.32, and 264.35]
 - F-3a Equipment requirements
 - F-3a(1) Internal communications
 - F-3a(2) External communications
 - F-3a(3) Emergency equipment
 - F-3a(4) Water for fire control
 - F-3b Aisle space requirement
- F-4 Preventive procedures, structures, and equipment [40 CFR Section 122.25(a)(8)]
 - F-4a Loading/unloading operations
 - F-4b Runoff
 - F-4c Water supplies
 - F-4d Equipment and power failure
 - F-4e Personnel protection equipment
- F-5 Prevention of reaction of ignitable, reactive, or incompatible wastes [40 CFR Sections 122.25(a)(9), 122.25(b)(1)(iii), 122.25(b)(2)(vi), 122.25(b)(4)(i)(c)(4), 122.25(b)(4)(ii)(b)(1), 264.17, 264.21, 264.23, 264.176, 264.177, 264.198, 264.199, 264.256, 264.257]
 - F-5a Precautions to prevent ignition or reaction of ignitable or reactive wastes
 - F-5b General precautions for handling ignitable or reactive wastes or accidentally mixing incompatible wastes

Suggested Permit Application Format (continued)

- F-5c Management of ignitable or reactive wastes in containers
- F-5d Management of incompatible wastes in containers
- F-5e Management of ignitable or reactive wastes in tanks
- F-5f Management of incompatible wastes in tanks
- F-5g Management of ignitable or reactive wastes in waste piles
- F-5h Management of incompatible wastes in waste piles

G. Contingency Plan

- G-1 General information [40 CFR Section 122.25(a)(7)]
- G-2 Emergency coordinators [40 CFR Sections 122.25(a)(7), 264.52(d), and 264.55]
- G-3 Implementation of the contingency plan [40 CFR Sections 122.25(a)(7), 264.51(b)]
- G-4 Emergency response procedures [40 CFR Sections 122.25(a)(7), 264.52(a), 264.56, 264.171, 264.194(c), 264.255, and 264.258]
 - G-4a Notification
 - G-4b Identification of hazardous materials
 - G-4c Assessment
 - G-4d Control procedures
 - G-4e Prevention of recurrence or spread of fires, explosions, or releases
 - G-4f Storage and treatment of released material
 - G-4g Incompatible wastes
 - G-4h Post-emergency equipment maintenance
 - G-4i Container spills and leakage
 - G-4j Tank spills and leakage
 - G-4k Waste piles
 - G-4k(1) Indication of waste pile containment system failure
 - G-4k(2) Elements of a containment system evaluation and repair plan
 - G-4k(3) Criteria and procedures for removal of waste pile from service in the case of positive failure of the containment system
 - G-4k(4) Restoration of a waste pile to service
 - G-4k(5) Course of action after waste pile is removed from service
- G-5 Emergency equipment [40 CFR Sections 122.25(a)(7) and 264.52(e)]
- G-6 Coordination agreements [40 CFR Sections 122.25(a)(7), 264.52(c) and 264.37]
- G-7 Evacuation plan [40 CFR Sections 122.25(a)(7), 264.52(f)]
- G-8 Required reports [40 CFR Sections 122.25(a)(7), 264.56(d), 264.56(i), and 264.73(b)(4)]

Suggested Permit Application Format (continued)

H. Personnel Training

- H-1 Outline of training program [40 CFR Sections 122.25(a)(12) and 264.16]
 - H-1a Job titles and duties
 - H-1b Training content, frequency, and techniques
 - H-1c Training director
 - H-1d Relevance of training to job position
 - H-1e Training for emergency response
 - H-1e(1) Procedures for using, inspecting, repairing, and replacing facility's emergency and monitoring equipment
 - H-1e(2) Key parameters for automatic waste feed cutoff systems
 - H-1e(3) Communications on alarm systems
 - H-1e(4) Response to fires
 - H-1e(5) Response to groundwater contamination incidents
 - H-1e(6) Shutdown of operations
- H-2 Implementation of training program [40 CFR Sections 122.25(a)(12) and 264.16]

I. Closure Plans, Post-Closure Plans and Financial Requirements

- I-1 Closure plans [40 CFR Sections 122.25(a)(13), 264.111, 264.112, 264.113, 264.178, 264.197, and 264.258]
 - I-1a Closure performance standard
 - I-1b Partial closure
 - I-1c Maximum waste inventory
 - I-1d Disposal or decontamination of equipment
 - I-1d(1) Closure of containers
 - I-1d(2) Closure of tanks
 - I-1d(3) Closure of waste piles
 - I-1e Schedule for closure
 - I-1f Extensions for closure time
- I-2 Post-closure plans*
- I-3 Notice in deed and notice to local land authority*
- I-4 Closure cost estimate [40 CFR Sections 122.25(a)(15) and 264.142]
- I-5 Financial assurance mechanism for closure [40 CFR Sections 122.25(a)(1), 264.143, and 264.151]
 - I-5a Closure trust fund
 - I-5b Surety bond
 - I-5c Closure letter of credit
 - I-5d Closure insurance
 - I-5e Financial test
 - I-5f Combinations

* These items apply only to disposal facilities.

Suggested Permit Application Format (continued)

- I-5f(1) Multiple financial mechanisms
- I-5f(2) Use of financial mechanism for multiple facilities
- I-5g Proof of financial coverage by an equivalent state financial mechanism
- I-6 Post-closure cost estimate*
- I-7 Financial assurance mechanism for post-closure*
- I-8 Liability requirements [40 CFR Sections 122.25(a)(17), 264.147, and 264.151]
 - I-8a Sudden insurance
 - I-8b Non-sudden insurance**
 - I-8c Financial test for liability insurance
 - I-8d Variance procedures
 - I-8e Adjustment procedures
- I-9 State mechanisms
 - I-9a Use of state-required mechanisms [40 CFR Sections 122.25(a)(18), 264.149, and 264.150]
 - I-9b State assumption of responsibility
- J. Other Federal Laws [40 CFR Sections 122.12 and 122.25(a)(20)]
- X. Certification [40 CFR Sections 122.6(a) and (d)]

* These items apply only to disposal facilities.

** Required for surface impoundments, landfills, or land treatment facilities.

Detailed Instructions and Content Requirements

The detailed instructions provided herein encompass the content requirements of each permit section identified in the suggested RCRA Permit Application format and cites the Federal regulation from which they were developed.

Sources of information applicants may use to prepare portions of the permit application are identified by reference numbers in parentheses at the end of each section.

Certain technical data submitted in the permit application must be certified by a registered professional engineer; these include design drawings and specifications and engineering studies.

A. PART A APPLICATION [CFR Sections 122.4(d) and 122.24]

Submit a revised Part A application if corrections to your original submission are necessary because of changes at your facility, inaccuracies in your submission, or changes in the RCRA regulations. Unless a revised Part A application is received, your original submittal will be used for review purposes.

B. FACILITY DESCRIPTION

B-1 General Description [40 CFR Section 122.25(a)(1)]

Provide a general description of the hazardous waste management facility in sufficient detail to familiarize the reviewer with its overall operation. Include the facility name, contact, mailing address, and location. Briefly

describe the nature of the business (e.g., products or services offered). Provide a company brochure if one is available. Offsite facilities should identify the types of industries serviced. Onsite facilities should briefly describe the process(es) involved in the generation of hazardous waste (Reference 1).

B-2 Topographic Map [40 CFR Section 122.25(a)(19)]

Submit a topographic map with a scale in which 1 inch equals no more than 200 feet and with contour intervals that are sufficient to clearly show the pattern of surface water flow in the vicinity of the hazardous waste units. The map must cover an area extending 1000 feet beyond the facility property line. The map(s) must show the scale, date, 100-year floodplain area, surface waters (including intermittent streams) and direction of their flow, surrounding land uses, a wind rose, wind speed and direction, map orientation, legal property line boundaries of the facility, access control, injection and withdrawal wells, buildings, structures, the location of each intake and discharge structure, sewers, loading and unloading areas, fire control, flood control or drainage barriers, and location of hazardous waste operations units. More than one map may be used to indicate the items listed above. On a case-by-case basis the Agency may accept maps with contour intervals or scales other than those specified in the regulations. Consult your EPA or state agency for further guidance.

The Part B topographic map will differ from the map submitted with the Part A of the application in area of coverage and level of detail (References 2, 3, 4, 5, 6, 7, 8).

B-3 Location Information

B-3a Seismic Standard [40 CFR Section 264.18(a) and 122.25(a)(11)(i) and (ii)]

Existing facilities are not required to comply with the seismic standards.

B-3b Floodplain Standard [40 CFR Sections 122.25(a) (11)(iii) and 264.18(b)]

Provide documentation identifying whether the facility is located within a 100-year floodplain. The Federal Insurance Administration, through the National Flood Insurance Program,* is the prime supplier of floodplain maps. Other Federal agencies (e.g., the U.S. Army Corps of Engineers, the Soil Conservation Services, and the U.S. Geological Survey) supply maps or information that will help you determine the boundaries of the 100-year floodplain. If FIA maps are not available, equivalent mapping techniques must be used. Facilities located within the 100-year floodplain must identify the 100-year flood level and any other special flooding factors (e.g., wave action) that must be considered to prevent washout (References 9, 10, 3, 4, 5, 7, 8, 11).

* National Flood Insurance Program, P.O. Box 34294, Bethesda, Maryland 20034.

B-3b(1) Demonstration of Compliance [40 CFR Section 122.25(a)(11)(iv)]

If your facility is located within the 100-year floodplain, describe how the facility is designed, constructed, operated, and maintained to prevent washout of any hazardous waste in the event of a flood by either of the following methods.

B-3b(1)(a) Flood Proofing and Flood Protection Measures [40 CFR Section 122.25(a)(11) iv (A) and (B)]

Provide structural or other engineering studies showing the design of the tanks, containers, or waste piles and the flood-proofing and protection devices (i.e., freeboard, fencing, diversion structures) at the facility and how they will prevent washout. The study should include an analysis of the structural integrity of the waste units and/or the flood protection devices to withstand the various hydrodynamic and hydrostatic forces expected as a result of a 100-year flood (References 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25).

B-3b(1)(b) Flood Plan [40 CFR Section 122.25(a)(11)(iv)(C)]

Describe the procedures for removing hazardous waste to safety before the facility becomes flooded. Include the timing of such movement related to flood levels (including estimated time to move the waste) to show that it can be completed before floodwaters reach the facility; a description of the location(s) to which the waste will be moved and proof of the eligibility of these locations to

receive hazardous wastes (i.e., RCRA Interim Status Facilities or RCRA Permitted Facilities); the planned procedures, equipment, and personnel to be used and the means of ensuring that these resources will be available when needed; and the potential for accidental discharges of the wastes during movement.

B-3b(2) Plan for Future Compliance (40 CFR Section 122.25(a)(11)(v))

If your facility is not in compliance with the floodplain regulation, provide a plan showing how and when it will be brought into compliance. (Existing facilities located in the 100-year floodplain that do not have a flood plan or are not designed to withstand a washout are not in compliance with the floodplain regulations.)

B-4 Traffic Patterns [40 CFR Section 122.25(a)(10)]

Describe the means of transporting hazardous waste material on your facility's property; include traffic pattern, traffic control, and estimated volume. List the weight of trucks transporting hazardous waste (state the maximum weight of fully loaded trucks), the load bearing capacity of the roads, and the road surfacing.

For facilities receiving hazardous waste from offsite, also describe the movement of the waste material to the facility from the point where it leaves the nearest major highway. Provide a diagram indicating traffic route, traffic controls, and land use (commercial or residential streets) (Reference 26).

C. WASTE CHARACTERISTICS

C-1 Chemical and Physical Analyses [40 CFR Sections 122.25(a)(2) and 264.13(a)]

Provide the following information on each hazardous waste stored or treated at the facility: (1) general description; (2) hazardous characteristics (corrosive, toxic, ignitable, reactive); (3) basis for hazardous designation. (For a listed waste, identify the EPA hazardous waste number; for an ignitable waste, specify the flash point; for a reactive waste identify under what conditions the waste reacts; for a corrosive waste, identify pH; for an EP toxic waste, identify the EP toxic constituents and their concentrations.)

Include a copy of the laboratory report(s) detailing chemical and physical analyses of representative samples of the hazardous waste, and give the date these analyses were performed. The analyses may include existing published or documented data on the hazardous waste or on hazardous wastes generated from a similar process. Offsite facilities may submit information supplied by the generator (References 27, 28, 29, 30).

C-2 Waste Analysis Plan (40 CFR Sections 122.25(a)(3) and 264.13(b) and (c))

Provide a copy of the waste analysis plan indicating how the facility will ensure that analysis of hazardous waste is accurate and up to date (i.e., that includes any changes

in the process that generated the hazardous waste) (References 1, 3, 28, 45). The plan should include a description of how the waste analyses will be performed; a list of the parameters chosen for analysis and an explanation of the rationale for their selection; a description of the test methods used to test for the chosen parameters;* a list of the sampling methods used to obtain a representative sample of each waste;* a description of the frequency at which the analyses will be repeated; and for facilities handling waste generated offsite, a description of the procedures used to inspect and/or analyze wastes generated offsite (including procedures to determine their identity and the sampling methods used).

D. PROCESS INFORMATION

D-1 Containers

D-1a Containers with Free Liquids

D-1a(1) Description of Containers [40 CFR Sections 264.171 and 264.172]

Describe the facility's primary containment devices for hazardous waste storage. The description should include types, dimensions (including usable volume), and liner specifications, and whether the containers are new, reused,

* Refer to methods in EPA S.W. 846, Test Methods for Evaluating Solid Wastes, Physical/Chemical Methods or 40 CFR Part 261, Appendix I, II, and III where applicable.

recycled, or reconditioned. Include container manufacturer's specifications, if available. Types of containers can include, but are not restricted to, metal drums, fiber drums, barrels, kegs, bags, multiwall paper, polyethylene (PE) film, small bags, pouches, folding boxes, corrugated cartons, bulk boxes, carboys, plastic drums, bottles, cans, pails, and wrap materials. Indicate container markings (in the form of labels, placards, tags, or stencils). Document the compatibility of the waste(s) with the storage container(s) in use at the facility. This documentation can consist of references to published scientific or industrial engineering literature, data from trial tests (e.g., bench-scale or pilot-scale tests), waste analyses, or the results of the storage or treatment of similar wastes under comparable operating conditions. When information on experience with similar wastes and materials (structural materials and linings) is not available, corrosion tests are highly recommended. Only wastes that significantly accelerate corrosion or deterioration (as opposed to normal expected container corrosion) are considered incompatible with the containment material.

D-1a(2) Container Management Practices [40 CFR Section 264.173]

Describe what container management practices are used to ensure that containers holding hazardous waste are always closed during storage (except when adding or removing waste). Provide assurance that containers are not opened, handled, or stored in a manner that may rupture the container

or cause it to leak. Include a detailed exhibit (facility drawing) and discussion of the container storage area. The facility drawing must show the layout of the container arrangement for both outdoor and indoor locations. Specify the maximum number of containers in the storage area, the type and volume of containers to be stored, separation and aisle spacing distances, and the location of various waste types. Clearly show the storage locations of incompatible, reactive, and ignitable wastes. Also indicate possible ignition sources of the facility (e.g., open flames). If containers are stacked, indicate the maximum number of containers and the height of the containers. Also, distinguish between the location of container storage areas and container staging areas by clearly defining the design, function, and operation of the staging areas. On the facility drawing of outdoor storage areas, indicate locations that typically receive full sunlight. Describe the machinery, equipment, and procedures used to move containers containing hazardous waste to and within storage locations.

Indicate the frequency with which storage containers containing hazardous waste are opened to add or remove waste during the container's useful storage life at the facility.

If a system of tracking the age of drums and other containers is included in the container storage management practices, state whether the dates are actually marked on the drums and other containers or placed on the schematic of the container storage area.

D-1a(3) Secondary Containment System Design and Operation [40 CFR Sections 122.25(b)(1) and 264.175(b)]

Describe the design and operation of the secondary containment system in the container storage area. The description should clearly demonstrate the system's adequacy to hold spills, leaks, and precipitation until detection and removal. Include a drawing of the secondary containment system design; show the dimensions of the containment system, location of the storage area containers on the base/liner, leachate collection system, slope characteristics, base grading, height of auxiliary structures (curbs, dikes, berms, ditches, trenches), and the location of the sump or collection area.

D-1a(3)(a) Requirement for Base or Liner to Contain Liquids [40 CFR Section 264.175(b)(1)]

Demonstrate that the containers of free liquids are located on a base free of cracks or gaps and sufficiently impervious to contain leaks, spills, and accumulated precipitation until the collected material is detected and removed. Include the base or liner characteristics and specifications for all concrete, asphaltic, and membrane linings. Indicate the construction material used for the base or liner, provide liner/base manufacturer's specifications and information, and include engineering data used as the basis for construction of the base. This information should be sufficient to verify that the base material and thickness are adequate to support the weight of the containers. Document that the types of waste stored are compatible with the liner or base to be used.

D-1a(3)(b) Containment System Drainage [40 CFR Sections 122.25(b)(1)(i)(B) and 264.175(b)(2)]

If the containers are stored in direct contact with the base, state how the base is sloped or how the containment system is otherwise designed and operated to drain and remove liquids resulting from leaks, spills, or precipitation. Included in the various designs that comply with this requirement are drains that lead into a sump under the base, a sloped base that directs liquids into a sump, or a system by which accumulated liquids are pumped out of the containment area shortly after being detected. If the containers are elevated or otherwise protected from contact with accumulated liquids (i.e., a roof over the drain area), you only need to describe the storage practice used to accomplish this protection (i.e., how containers are stacked on pallets, plywood sheets, and/or racks).

D-1a(3)(c) Containment System Capacity [40 CFR Sections 122.25(b)(1)(i)(C) and 264.175(b)(3)]

Document that the containment system has sufficient capacity to contain 10 percent of the volume of all the containers or the volume of the largest container, whichever is greater. Describe how the containment system has fared during extreme precipitation events.

D-1a(3)(d) Control of Run-On [40 CFR Sections 122.25(b)(1)(i)(D) and 264.175(b)(4)]

Describe how run-on into the containment system is prevented, unless the collection system has sufficient capacity in excess of that required in the previous "Containment

System Capacity" discussion [D-1a(3)(c)] to contain any run-on that might enter the system. Describe the role of containment system auxiliary structures and other engineering land-grading designs in preventing run-on into the containment system, and in promoting drainage away from the containment area (e.g., drain tiles installed at the outside perimeter of the containment curb to drain any collected water to the sewer system).

D-1a(4) Removal of Liquids from Containment System [40 CFR Sections 122.25(b)(1)(i)(E) and 264.175(b)(5)]

Describe how spilled or leaked waste and accumulated precipitation will be removed from the collection area or sump in as timely a manner as is necessary to prevent overflow of the collection system. Include sump pump design and operating capabilities, piping specifications, and diagrams. Describe the management procedures for accumulated liquids and the ultimate fate of such liquids removed from the containment system.

D-1b Containers Without Free Liquids

D-1b(1) Test for Free Liquids [40 CFR Section 122.25(b)(1)(ii)(A)]

Describe the test procedures and results or provide other documentation or information to show that the containerized wastes do not contain free liquids.

A proposed test protocol for free liquids is provided on page 8311 of the February 25, 1982, Federal Register. The protocol calls for a representative sample of the waste

from a container to be filtered and the filtrate to be collected in a beaker or cylinder. If free liquid passes through the filter, then the waste is considered to hold free liquids.

D-1b(2) Description of Containers [40 CFR Sections
264.171 and 264.172]

Provide a description similar to the one used for free liquid containers, D-1a(1).

D-1b(3) Container Management Practices [40 CFR Section 264.173]

Provide a description of container management practices similar to the one used for free liquid containers, D-1a(2).

D-1b(4) Container Storage Area Drainage [40 CFR Sections
122.25(b)(1)(ii)(B) and 264.175(c)]

Provide a description of the container storage area drainage similar to the one used for free liquid containers,

-- D-1a(3)(b).

D-2 Tanks

D-2a Description of Tanks [40 CFR Sections 122.25(b)(2)
and 264.191]

Describe all facility storage, overflow, and processing tanks used for hazardous waste management. The description should include the number and types of tanks, the type of waste they contain, and whether the tanks are covered. Include manufacturer's literature or other engineering information, if available. Tank design specifications should include specific data on dimensions (height, diameter,

measured uniform shell thickness), capacity, and the material and method of construction. Include design operating temperature and pressure information. State that the tanks are designed in accordance with the design standard codes of the American Petroleum Institute (API), the American Society of Mechanical Engineers (ASME), Underwriters' Laboratories, the American Concrete Institute Standard, or some other standard design code. Provide the applicable standard code section and year. Indicate the specific gravity of the liquid in the tanks and the maximum height of the liquid level in the tank(s) during storage.

Provide detailed engineering drawings for each tank containing a hazardous waste. Give specifications for the foundation, structural support, seams, and pressure controls to demonstrate that the tanks will not collapse or rupture.

D-2b Tank Corrosion and Erosion [40 CFR Sections 122.25(b)(2)(ii) and 264.192(a)]

Describe the lining and coating materials (if any) used to protect tank construction materials from corrosion or erosion. Demonstrate the compatibility of the hazardous waste with the tank construction and the lining and coating materials. This documentation can consist of references to published scientific or industrial engineering literature, data from trial tests (e.g., bench-scale or pilot-scale tests), waste analyses, or the results of the storage or treatment of similar wastes under comparable operating conditions. When information on experience with similar

wastes and materials (structural materials and linings) is not available, corrosion tests are highly recommended. Provide information on the type of gaskets in use and their material of construction. Describe how the shell thickness will be maintained when the tank is built or converted to store hazardous waste. Provide information on the rate of tank corrosion or erosion actually detected by measurement. Include information about any treatment reagents used in all of the facility tanks.

D-2c Tank Management Practices [40 CFR Sections 122.25(b)(2)(iv), 122.25(b)(2)(v) and 264.192(b)]

Describe tank operating practices and control devices to prevent overfilling and overtopping. For covered tanks, submit engineering process flow diagrams indicating the location, numbers, and types of pressure and overfilling controls and feed systems. For uncovered tanks, submit engineering process flow diagrams indicating the location and operational practices of the safety cutoffs or bypass systems and the amount of freeboard. Describe what monitoring will be done to ensure that each tank is operated according to design. Describe the procedures used to measure the following process variables: temperature of waste, pressure, flow level, and specific gravity; indicate how frequently these measurements are taken. The process flow diagram should show the flow direction of liquid or vapor within the facility and (if available) flow rates. The flow diagram must indicate any waste streams in the

flow process that vent directly to the atmosphere or discharge directly to the municipal wastewater treatment system.

Provide a piping and instrumentation diagram (P&ID) that shows instruments such as valves, level and pressure controls, and temperature and pressure indicators that are used to control and monitor the operation of the tanks. Provide a plot plan of the facility with each piece of equipment (drawn to scale), and locate each piece of equipment in relation to the entire facility. Include the location of tank diking and drainage systems for tanks, space requirements between equipment, and receiving areas for wastes.

D-3 Waste Piles

D-3a Waste Piles with Free Liquids [40 CFR Section 122.25(b)(4)(i)]

D-3a(1) Control of Wind Dispersal [40 CFR Sections 122.25(b)(4)(i)(A), 264.251(a) and 264.252(a)]

For each waste pile, describe the technique(s) for controlling wind dispersal. Include such considerations as waste pile siting; pile slope design and compaction; the use of water sprays, dust suppressants other than water, and stabilizers; windbreaks; and enclosures (if they are used as waste pile management techniques for control of wind dispersal). If the waste pile is situated in a totally enclosed building, describe the dust evacuation method.

D-3a(2) Control of Run-on [40 CFR Sections 122.25(b)(4)(B)(1) and 264.252(b)]

Describe measures for preventing water from flowing into the pile. Discuss the diversion of run-on by describing the location and construction of such structures as berms, dikes, walls, curbs, trenches, or other manmade or natural barriers in the waste pile area.

D-3a(3) Collection of Leachate and Runoff [40 CFR Sections 122.25(b)(4)(B)(2), 122.25(b)(4)(i)(C)(2), 264.251(b), 264.252(b) and 264.253(a)(1)]

Describe the waste pile leachate and runoff collection and control system. Show how accumulated leachate and precipitation will be removed from the collection area or sump as necessary to prevent overflow of the leachate collection system. Include sump pump design and operating capabilities, piping specifications, and diagrams. Indicate the leachate management procedures and the ultimate fate of accumulated liquids removed from the containment system.

D-3a(4) Foundation [40 CFR Sections 122.25(b)(4)(B)(3) and 264.253(b)(2)]

Provide engineering data to demonstrate that the foundation is capable of holding the weight of the base or liner, the pile, and any equipment to be used. Also describe the foundation construction material (i.e., soil, concrete, or asphalt). (Refer to the Model Permit Application, Section D on Waste Piles - Foundation, for a specific example.)

D-3a(5) Waste File Base

D-3a(5)(a) Containment System Design [40 CFR Sections 122.25(b)(4)(B)(4), 264.253(a), 264.253(b), and 264.253(d)]

Present containment system engineering plan drawings depicting all control systems and structures associated with the waste pile. Provide information to demonstrate that the waste pile will be located on a base that is free of cracks or gaps and sufficiently impervious to contain leachate and accumulated precipitation until the collected material is detected and removed. Include the base or liner characteristics and manufacturers' specifications for all concrete, asphaltic, and membrane liners. Document that the types of waste to be stored in the pile will be compatible with the liner or base. Discuss which wastes will be contained and how these will be combined. State the estimated life of the hazardous waste pile and show that the containment system will have a containment life equal to or greater than the life of the pile.

D-3a(5)(b) Leachate Detection, Collection and Removal System [40 CFR Sections 122.25(b)(4)(i)(B)(6) and 264.253(a)]

If the base liners are not of sufficient strength and thickness to prevent failure due to physical damage from equipment used to clean and expose the liner surface for inspection, describe the leachate detection, collection, and removal system situated beneath the base to detect, contain, collect, and remove any discharge. Demonstrate that the system under the base is above the water table, or describe any necessary efforts to control the water table.

D-3a(6) Vegetation and Rodent Control [40 CFR Sections 122.25(b)(4)(i)(C)(1) and 264.253(c)]

Describe precautions taken to protect the waste pile base or liner and its components from plant growth that might puncture it and cause a failure. Indicate any precautions provided to prevent puncture by rodents or other ground-burrowing animals.

D-3a(7) Equipment and Procedures for Waste Pile Movement [40 CFR Sections 122.25(b)(4)(i)(C)(3)]

Describe all the facility equipment and operational procedures used to add waste to the pile or to remove waste from the pile, or to expose the liner surface for cleaning.

D-3b Waste Piles Without Free Liquids [40 CFR Section 122.25(b)(4)(ii)]

D-3b(1) Test for Free Liquids [40 CFR Section 122.25(b)(4)(ii)(A)]

Provide test procedures and results or other documentation or information to show that the piled wastes do not contain free liquids. Also show that the wastes will not generate leachate by decomposition or other reactions during the time they are managed in the waste pile.

D-3b(2) Control of Wind Dispersal [40 CFR Sections 122.25(b)(4)(ii)(C) and 264.250(b)(4)]

Provide descriptions similar to those for controlling wind dispersal for waste piles having free liquids, D-3a(1).

D-3b(3) Protection from Precipitation and Run-on [40 CFR Sections 122.25(b)(4)(ii)(B), 264.250(b)(2)], and 264.250(b)(3)]

Describe how the pile is protected from precipitation and run-on by a structure or cover so that neither runoff nor

leachate is generated. Include a detailed description of the structure. Also describe how the pile is protected from surface water run-on.

D-3b(4) Demonstration That No Free Liquids Are Placed on Pile
[40 CFR Sections 122.25(b)(4)(ii)(D)(2) and 264.250(b)(1)]

Describe procedures to insure that liquids or materials containing free liquids are not placed on the pile; i.e., by performing a waste analysis test for free liquids [see D-1b(1)] or testing the waste upon receipt at the facility and handling it appropriately before placement on the pile (Reference 31).

D-4 Surface Impoundments [40 CFR Sections 122.25(b)(3) and 264.220-264.223]

This section has been reserved until this document is expanded to address existing facilities that treat or store hazardous wastes in surface impoundments.

D-5 Incinerators [40 CFR Sections 122.25(b)(5) and 264.340-264.351]

This section has been reserved until this document is expanded to include requirements for existing incinerators.

E. GROUNDWATER MONITORING [40 CFR Section 265.90-265.94]

This section has been reserved until this document is expanded to include information on land disposal facilities.

F. PROCEDURES TO PREVENT HAZARDS

F-1 Security

Describe the security procedures and equipment identified below, or provide a request and substantiation for a waiver of any of these requirements.

F-1a Security Procedures and Equipment [40 CFR Sections 122.25 (a)(4) and 264.14]

The permit applicant has the option of fulfilling the requirements of either F-1a(1) or F-1a(2).

F-1a(1) 24-hour Surveillance System [40 CFR Section 264.14(b)(1)]

Describe the system used to monitor and control entry to the active portion of the facility. If possible, all related structures and equipment should be indicated on a plot plan. If a 24-hour surveillance system is used, describe all facets of the system, including personnel, procedures, structures, and equipment used (Reference 32).

F-1a(2) Barrier and Means to Control Entry [40 CFR Section 264.14 (b)(2)(i) and (ii)]

If a fence or wall is used to control entry, indicate height, type of material, and locking devices of the barrier. Describe how entry is controlled at all times (Reference 32).

F-1a(3) Warning Signs [40 CFR Section 264.14(c)]

Indicate the location of required warning signs. If the facility is in an area where any language other than English is commonly used, indicate the language and include the legend of posted signs. Indicate that warning signs are legible from at least 25 feet.

F-1b Waiver [40 CFR Section 264.14(a)]

If you believe a waiver of any of the requirements of 264.14 is appropriate, you must demonstrate that unknowing or unauthorized persons or livestock would not injure themselves or cause a RCRA violation upon entering the active portion of a facility. Both these points may be demonstrated by showing that the nature and duration of the hazard potential from the hazardous waste onsite does not warrant the required security procedure or equipment. In addition, if you can show that your facility provides certain features, such as cover materials or containers, that would prevent contact with the waste or potentially hazardous contact with equipment or structures, certain security procedures and equipment might not be needed. Finally, a waiver justification could show that safety or operating practices related to equipment and structures would eliminate the potential for an intruder to cause a spill, mix incompatible wastes, ignite ignitable or reactive waste, damage containment or monitoring systems, etc. The circumstances under which a waiver will be granted are limited (Reference 28).

F-2 Inspection Schedule [40 CFR Sections 122.25(a)(5), 264.15]

Provide a copy of the general inspection schedule (see Table 8 of the Model Permit Application in Part 2 of this document). The inspection schedule should be broken down into general inspection requirements and specific process

inspection requirements, as shown. For both general and specific inspection requirements, reference in the schedule any inspection procedures or frequencies the manufacturer has recommended for any equipment or structures. In addition, state that the inspection schedule will be kept at the facility.

F-2a General Inspection Requirements [40 CFR Sections 264.15(a) and (b) and 264.33]

The inspection schedule should indicate the safety, emergency, and security devices and monitoring, operating, and structural equipment to be inspected. Examples of the this equipment are flow and liquid level monitors, leachate monitors, hazardous gas detectors, respirators, alarm and communication systems, emergency power and lighting, fire protection and control equipment, smoke detectors, first aid equipment, decontamination equipment, surveillance systems, barriers surrounding the facility, locking devices, fire and explosion barriers, ventilation equipment, and spill detection, control, and collection equipment. The inspection plan must include areas inside and outside buildings where hazardous waste is handled (References 33, 34, 35, 32, 36).

F-2a(1) Types of Problems [40 CFR Section 264.15(b)(3)]

The schedule must identify the types of problems that are to be looked for during the inspection (e.g., malfunctions, deteriorations, inoperative sump pumps, leaking fittings, and eroding dikes).

F-2a(2) Frequency of Inspection [40 CFR Section 264.15(b)(4)]

The schedule must identify the frequency of inspection for the items on the schedule. The frequency may vary; it should be based on the rate of possible deterioration of the equipment and the probability of an environmental or human health incident if the deterioration, malfunction, or any operator error should go undetected between inspections. Areas subject to spills (e.g., loading and unloading areas) must be inspected daily when in use.

F-2b Specific Process Inspection Requirements

F-2(b)(1) Container Inspection [40 CFR Section 264.174]

Describe in detail how at least weekly inspections are performed in areas where containers are stored. Describe procedures and elaborate on methods used to detect leaking containers. Indicate how the inspection includes careful status checks for the deterioration of containers and the containment system as a result of corrosion or other factors.

F-2(b)(2) Tank Inspection [40 CFR Sections 264.194(a) and (b)]

Describe in detail how each of the tanks and its related facility components are inspected on a scheduled weekly or daily basis, as required. Provide a list of equipment and parts to be inspected. Describe how the tank construction materials of the above-ground external portions of the tank are inspected weekly (while the tank remains in service) to detect corrosion or erosion and leaking of fixtures and seams. Discuss how the area immediately surrounding the

tank is inspected weekly to detect obvious signs of leakage. Specify how tank overflow control equipment, such as waste feed cutoff systems and bypass systems, are inspected daily to ensure good working order. Describe the daily inspection procedures undertaken to ensure that the tank is being operated according to its design (by types of data gathered from tank monitoring equipment). For uncovered tanks, describe how the level of waste is measured daily to ensure maintenance of sufficient freeboard to prevent overtopping by wave or wind action or by precipitation.

Elaborate on the schedule, and document the methods used for comprehensive inspection of the tank interior to detect cracks, leaks, corrosion, or erosion that may lead to wall thinning to less than sufficient shell strength. Discuss established procedures for emptying the tank to allow entry and inspection of the interior. The frequency of these inspection assessments must be based on the tank's material of construction, the type of corrosion or erosion protection used, the rate of corrosion or erosion observed during previous inspections, and the characteristics of the waste being treated or stored (References 37, 38, 39, 40, 41).

F-2(b)(3) Waste Pile Inspection, [40 CFR Sections 264.254(a) and 264.255]

Describe how liner systems were inspected for uniformity, damage, and imperfections during the construction or installation of the waste pile base, and how manufactured liner materials are inspected to ensure tight seams and joints

and the absence of tears and blisters. Describe how the containment system is inspected whenever there is any indication of possible failure (Reference 42).

F-2c Remedial Action [40 CFR Sections 264.15(c) 264.194(c) and 264.255]

Describe procedures for ensuring that any deterioration or malfunction of equipment or structures revealed by the inspection will be remedied on a schedule that prevents an environmental or human health hazard. Procedures identified in the contingency plan that describe remedial actions to be taken in the event of potential hazard can be referenced in this section.

F-2d Inspection Log [40 CFR Section 264.15(d)]

Provide a copy of the inspection log. (Example is provided in Supplement 1-B of the Model Permit Application in Part 2 of this document.) At a minimum, these records must include the date and time of the inspection, the name of the inspector, a notation of the observations made, and the date and nature of any repairs or other remedial actions.

F-3 Waiver of Preparedness and Prevention Requirements [40 CFR Sections 122.25(a)(6), 264.32, and 264.35]

If you wish to request a waiver for preparedness and prevention requirements, you must provide the following:

F-3a Equipment Requirements [40 CFR Section 264.32]

Justification showing that none of the hazards posed by waste handled at the facility could require the following specified equipment: internal and external communications

equipment, spill- and fire-control equipment, decontamination equipment, and water at adequate volume and pressure for fire control (References 28, 33, 35, 36, 43).

F-3b Aisle Space Requirement [40 CFR Section 264.35]

Justification showing that aisle space is not needed for unobstructed movement of emergency personnel and equipment.

F-4 Preventive Procedures, Structures, and Equipment [40 CFR Section 122.25(a)(8)]

Applicable procedures, structures, and equipment addressed in other sections may be repeated or referenced to demonstrate compliance with any of the following requirements:

F-4a Unloading Operations [40 CFR Section 122.25(a)(8)(i)]

Describe the procedures, structures, and equipment that will be used to prevent hazards in unloading hazardous waste (Reference 28).

F-4b Runoff [40 CFR Section 122.25(a)(8)(ii)]

Describe the procedures, structures, and equipment that will be used to prevent runoff from hazardous waste handling areas to other areas of the facility or to prevent flooding (References 44, 45).

F-4c Water Supplies [40 CFR Section 122.25(a)(8)(iii)]

Describe the procedures, structures, and equipment that will be used to prevent contamination of water supplies.

F-4d Equipment and Power Failure [40 CFR Section 122.25(a)(8)(iv)]

Describe procedures and equipment for mitigating the effects of equipment failure and power outages, such as waste feed shutoff systems or emergency lighting.

F-4e Personnel Protection Equipment [40 CFR Section 122.25(a)(8)(v)]

Describe procedures, structures, and equipment for preventing undue exposure of personnel to hazardous waste, such as ventilation equipment or protective clothing. If the facility must meet any applicable OSHA requirements, state them (References 34, 46).

F-5 Prevention of Ignition or Reaction of Ignitable, Reactive, or Incompatible Wastes

F-5a Precautions to Prevent Ignition or Reaction of Ignitable or Reactive Waste [40 CFR Sections 122.25(a)(9) and 264.17(a)]

List each of the ignitable and reactive wastes to be stored at the facility. Describe the precautions for preventing sparking of ignitable or reactive wastes handled on site. Describe how the wastes are separated and protected from sources of ignition or reaction, such as open flames, smoking, cutting and welding, hot surfaces, frictional heat, sparks (static, electrical, or mechanical), and spontaneous ignition (e.g., from heat-producing chemical reactions and radiant heat). Describe how smoking and open flames are confined to specifically designated locations when ignitable or reactive wastes are being handled, and how "No Smoking" signs are conspicuously placed wherever there is a hazard from such wastes (References 7, 25).

F-5b General Precautions for Handling Ignitable or Reactive Waste or to Prevent Accidentally Mixing Incompatible Waste [40 CFR Sections 122.25(a)(9), 264.17(b)]

Describe onsite precautions taken for handling ignitable or reactive wastes and measures taken to prevent the mixing of

incompatible wastes or the mixing of other materials and wastes that are incompatible. Reactions that must be prevented are those that (1) generate extreme heat, pressure, fire, explosions, or violent reactions; (2) produce uncontrolled flammable fumes, dusts, or gases in sufficient quantities to threaten human health or the environment; (3) produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the device or facility; (5) through other like means may threaten human health or the environment (References 47, 48).

F-5c Management of Ignitable or Reactive Wastes in Containers [40 CFR Sections 122.25(b)(1)(iii) and 264.176]

Use sketches, drawings, or data to demonstrate how containers of ignitable or reactive waste are located at least 15 meters (50 feet) from the site property line (Reference 33).

F-5d Incompatible Wastes in Containers [40 CFR Sections 122.25(b)(1)(iii), and 264.177]

Describe the specific controls and/or practices utilized to ensure that incompatible wastes or wastes and other materials that are incompatible are not placed in the same container unless precautions are taken to prevent the reactions described in section F-5b - General Precautions for Handling Ignitable or Reactive Waste or to Prevent Accidentally Mixing Incompatible Waste. Include any documentation of compliance based on references to published scientific or engineering literature, data from trial tests, waste analyses, or the

results of the treatment of similar wastes by a comparable treatment process and under similar operating conditions.

Discuss how storage containers holding a hazardous waste incompatible with any other waste or materials that are stored nearby in other containers, piles, open tanks, or surface impoundments are separated or protected from the other materials by means of a dike, berm, wall, or other structure. Include a drawing to show separation of incompatible wastes (Reference 49).

F-3e Management of Ignitable or Reactive Wastes in Tanks [40 CFR Sections 122.25(b)(2)(vi) and 264.193]

Provide specific information of how ignitable or reactive wastes destined for tank storage are treated, rendered, or mixed before or immediately after placement in the tank. Indicate the general precautions that are taken for handling either ignitable or reactive waste when such wastes are destined for tank storage or how these wastes are stored or treated to protect them against any materials or conditions that may cause their reaction or ignition. State if the tank is reserved solely for use in emergencies. Demonstrate compliance with the National Fire Protection Association's buffer zone requirements contained in Tables 2-1 and 2-6 of the "Flammable and Combustible Code - 1977" for covered tanks used for the treating or storing of reactive or ignitable wastes (Reference 33).

F-5f Management of Incompatible Wastes in Tanks [40 CFR Sections 122.25(b)(2)(vi) and 264.199(b)]

Describe operating procedures to insure that a hazardous waste will not be placed in an unwashed tank that previously held an incompatible waste or material unless precautions are taken to prevent the reactions described in Section F-5b - General Precautions for Handling Ignitable or Reactive Waste or to Prevent Accidentally Mixing Incompatible Wastes (Reference 33).

F-5g Management of Ignitable or Reactive Wastes in Waste Piles [40 CFR Sections 122.25(b)(4)(ii)(D)(1), 261.21, 261.23, 264.17(b), 264.256]

Describe operating procedures to insure that an ignitable or reactive waste is placed in a pile only if the addition of that waste to an existing pile results in the waste or mixture no longer meeting the definition of ignitable or reactive waste. The waste pile must be shown to comply with Section F-5b - General Precautions for Handling Ignitable or Reactive Waste or to Prevent Accidentally Mixing Incompatible Wastes. Alternatively, describe the preventive measures that are taken to protect the waste from conditions that might cause it to ignite or react.

F-5h Management of Incompatible Wastes in Waste Piles [40 CFR Sections 122.25(b)(4)(i)(C)(4), 122.25(b)(4)(ii)(D)(1), 264.17(b) and 264.257]

Describe operating procedures ensuring that incompatible wastes are placed in the same pile only when in compliance

with section F-5b - General Precautions for Handling Ignitable or Reactive Waste or to Prevent Accidentally Mixing Incompatible Waste. Describe precautions for adequate buffer or protection of incompatible waste piles from other wastes or material stored at the facility. If the bases are to be reused for hazardous waste, describe how any bases on which incompatible wastes or materials previously had been piled are sufficiently decontaminated to ensure compliance with section F-5b - General Precautions for Handling Ignitable or Reactive Waste to Prevent Accidentally Mixing Incompatible Wastes.

G. CONTINGENCY PLAN [40 CFR Sections 122.25(a)(7) and 264.50-264.56]

The contingency plan should describe the actions to be taken by facility personnel in response to fires, explosions, or the release of hazardous waste. The following sections outline the requirements for describing these actions and other regulatory requirements. If a Spill Prevention, Control, and Countermeasures (SPCC) Plan (in accordance with 40 CFR Part 122 or Part 151) or some other contingency plan has already been prepared, the plan need only be amended to incorporate hazardous waste management provisions that are sufficient to comply with the requirements of this part. Demonstrate that the contingency plan will be reviewed and amended under any of the following conditions: whenever the facility permit is revised, if the plan should fail in an emergency, if the facility's

operations should change in a way that would alter the contingency plan, or if the list of emergency coordinators or emergency equipment should change.

G-1 General Information

Give the name and location of the facility and the operator's name. Include a site plan and description of facility operations.

G-2 Emergency Coordinators [40 CFR Sections 264.52(d) and 264.55]

Give name, address, office and home phone numbers of primary and alternate emergency coordinators, and a statement of authorization for them to commit necessary resources to implement the contingency plan. If more than one person is listed as Emergency Coordinator, one must be named as primary Emergency Coordinator and others listed in the order in which they will assume responsibility.

G-3 Implementation of the Contingency Plan [40 CFR Section 264.51(b)]

State criteria for implementation of the contingency plan for any potential emergency.

G-4 Emergency Response Procedures

G-4a Notification [40 CFR Section 264.56(a)]

State methodology for immediate notification of facility personnel and required state and local agencies in the event of an emergency (Reference 50).

G-4b Identification of Hazardous Wastes [40 CFR Section 264.56 (b)]

Describe procedures for identification of hazardous materials involved in the emergency (Reference 30).

G-4c Assessment [40 CFR Sections 264.56(c) and (d)]

State the policy for assessment of possible hazards to the environment and human health and the need for evacuation of residents and notification of authorities. Authority notification should include the appropriate local authorities and the government on-scene coordinator for that area or the National Response Center (use their 24-hour toll free number 800/424-8802) (References 28, 50, 51, 52, 53).

G-4d Control Procedures [40 CFR Section 264.52(a)]

Describe the specific control procedures to be taken in the event of a fire, explosion, or hazardous waste release. The contingency plan should examine potential emergency situations and outline planned responses (Reference 31, 50, 53).

G-4e Prevention of Recurrence or Spread of Fires, Explosions, or Releases [40 CFR Section 264.56(e)]

Describe the necessary steps to be taken to ensure that fires, explosions, or hazardous waste releases do not occur, recur, or spread to other hazardous wastes at the facility. This should include stopping processes and operations, isolating the materials involved in the emergency, and containing and collecting any wastes that have

been released. In addition, if the facility stops operations in response to an emergency, the emergency coordinator must monitor for leaks, pressure buildup, gas generation, or ruptures in valves, pipes, or other equipment, wherever appropriate (References 50, 53).

G-4f Storage and Treatment of Released Material [40 CFR Section 264.56(g)]

Discuss provisions for treatment, storage, or disposal of any material that results from a release, fire, or explosion at the facility.

G-4g Incompatible Wastes [40 CFR Section 264.56(h)(1)]

Discuss provisions for preventing incompatible wastes from being treated, stored, or disposed of in the affected areas before cleanup procedures have been completed.

G-4h Post-Emergency Equipment Maintenance [40 CFR Section 264.56(h)(2)]

Describe procedures for ensuring that all emergency equipment listed in the contingency plan is clean and fit for its intended use before operations are resumed.

G-4i Container Spills and Leakage [40 CFR Section 264.171]

Describe the procedures for response to container spills or leakage, including remedial procedures and timing for expeditious removal of spilled waste and repair or replacement of the container(s). Describe the availability of machinery, equipment, and personnel to be used as cleanup resources and how they will be utilized. Discuss the procedures for repair or disposal of the damaged containers, the management of spilled or leaked waste, and the decontamination process during incident mitigation.

G-4j Tank Spills and Leakage [40 CFR Section 264.194(c)]

Describe the procedures for response to tank spills or leakage, including remedial procedures and timing for expeditious removal of leaked or spilled waste and repair or removal of the tank. At a minimum, address the following kinds of incidents:

- ° Overfilling of tanks
- ° Rupture of tanks
- ° Leaks in tanks, pipes, valves and fittings
- ° Leaks in containment dikes

- Water flow from diked area through open dike valve
- ° Leaks from pump seals and maintenance
- ° Level instrument failure that allows tank overfilling
- ° Piping damage from collision with mobile equipment
- ° Spills from tank bottom cleanout and sludge disposal
- ° Spills from pipe and tank changes

Describe the availability of machinery, equipment, and personnel to be used as cleanup resources and how they will be utilized. Discuss the management of spilled or leaked waste and the decontamination process during incident mitigation (References 33, 53).

G-4k Waste Piles

G-4k(1) Indication of Waste Pile Containment System Failures
[40 CFR Section 264.255(a)]

Describe the mechanism by which indications of possible failure of the waste pile containment system will result in inspection of that system in accordance with the provisions of a containment system evaluation and repair plan. Indications of possible failure of the containment system;

include appearance of liquid in the leachate detection system, erosion of the base, evidence of leakage or potential of leakage in the base, and the apparent or potential deterioration of liner(s) (based on observation or test samples of liner materials).

G-4k(2) Elements of a Containment System Evaluation and Repair Plan [40 CFR Section 264.255(d)(2)]

Provide a containment system evaluation and repair plan that describes testing and monitoring techniques and procedures to be followed to evaluate the integrity of the containment system in the event of a possible failure. Include a schedule of actions to be taken in the event of a possible failure and a description of the repair techniques to be used in the event of leakage due to containment system failure or deterioration that does not require the removal of the waste pile from service.

G-4k(3) Criteria and Procedures for Removal of Waste Pile from Service in Case of Positive Failure of the Containment System [40 CFR Sections 264.255(b) and (c) and 264.255(d)(1)]

Show that provision is made for the waste pile to be removed from service whenever there is a positive indication of a failure of the containment system. Describe a procedure for removal of the waste pile from service, and give details of the cleanup resources to be implemented and how they will be utilized.

G-4k(4) Restoration of a Waste Pile to Service [40 CFR Section 264.255(e)]

Describe the conditions under which a waste pile that has been removed from service will be restored to service.

Show that a qualified engineer will certify that the containment system meets the design specifications approved in the RCRA permit.

G-4k(5) Course of Action After Waste Pile is Removed From Service [40 CFR Sections 264.255(f) and 264.258]

Describe what happens to a waste pile containment system that is no longer in use and will not be used in the future. Show that you either are meeting or will meet closure requirements for this system (Reference 54).

G-5 Emergency Equipment [40 CFR Section 264.52(e)]

Give the location, description, and capabilities of all emergency equipment available. If possible, indicate the location of emergency equipment on a site plan or plant layout. Such equipment includes, but is not be limited to, fire extinguishing equipment, spill-control equipment, alarm systems, communication systems, decontamination equipment, and personal protection equipment (References 28, 34, 35, 36, 50).

G-6 Coordination Agreements [40 CFR Sections 264.52(c) and 264.37]

Describe any coordination agreements with local agencies, contractors, or hospitals involved in emergency response that have been made or refused pursuant to Section 264.37. The contingency plan must list these organizations, detail what information (facility layout, waste properties, etc.) has been made available to them, describe potential situations that could necessitate such assistance, and outline

the lines of authority that will be followed in each situation.

G-7 Evacuation Plan [40 CFR Section 264.52(f)]

Provide a detailed description of the evacuation plan, including planned and alternate evacuation routes (if necessary) and the signals for beginning an evacuation.

G-8 Required Reports [40 CFR Section 264.56(d), 264.56(i) and 264.73(b)(4)]

Discuss provisions for submission of written reports of emergency incidents within 15 days of occurrence and the maintenance of records identifying the time, date, and details of any emergency incident.

H. PERSONNEL TRAINING

H-1 Outline of Training Program [40 CFR Sections 122.25(a)(12) and 264.16]

Provide an outline of both the introductory and continuing training programs used to prepare persons to operate or maintain the facility in a safe manner. Describe briefly how training will be designed to meet actual job tasks. Supervised on-the-job training may be used to comply with requirements in this section (Reference 55).

H-1a Job Titles and Duties [40 CFR Sections 264.16(d)(1) and (2)]

Indicate the name, job title, duties, and job description of each employee filling a position related to hazardous waste management at the facility.

H-1b Training Content, Schedules, and Techniques [40 CFR Sections 264.16(c) and 264.16(d)(3)]

Describe the content, frequency, and techniques used in both introductory and continuing training, including an annual review of the initial training for each employee. You must present and discuss the following points: personnel safety training; release prevention and response; decontamination procedures for personnel, equipment, and tools; facility operation and maintenance; high-hazard operations; maintenance of required facility documentation; hazards associated with each waste; and applicable RCRA and state hazardous waste regulations (Reference 55).

H-1c Training Director [40 CFR Section 264.16(a)(2)]

Show that the program is directed by a person trained in hazardous waste management. Specify the training director's experience and qualifications.

H-1d Relevance of Training to Job Position [40 CFR Section 264.16(a)(1)]

Show that the program includes instruction on hazardous waste management procedures (including contingency plan implementation) relevant to the positions held by personnel.

H-1e Training for Emergency Response [40 CFR Section 264.16(a)(3)]

Show that the program is designed to ensure that facility personnel are able to respond effectively to emergencies by familiarizing them with the following: contingency plan and emergency procedures, including inspecting, repairing,

and replacing facility emergency and monitoring equipment; key parameters for automatic waste feed cutoff systems; communication and alarm systems; response to fires, explosions, or releases; responses to groundwater contamination incidents; shutdown of operations and evacuation (References 34, 55).

H-2 Implementation of Training Program [40 CFR Sections 264.16(d)(4) and 264.16(b)]

For existing facilities, indicate that training has been given to and successfully completed by facility personnel within 6 months after the date of their employment or assignment to a facility, or to a new position at a facility, whichever is later. Employees hired after the effective date of these regulations must not work in unsupervised positions until they have completed the training requirements. Explain the methodology used by the facility to verify that employees have successfully completed training. Records documenting that facility personnel have completed the required training must be maintained. Indicate that training records on current personnel must be kept until closure of the facility, and records for former employees must be kept for 3 years after they leave.

I. CLOSURE PLANS, POST-CLOSURE PLANS AND FINANCIAL REQUIREMENTS
[40 CFR Sections 122.25(a)(13) and 264.110-120]

I-1 Closure Plans [40 CFR Sections 264.112 and 122.23(a)(13)]

A written closure plan must be submitted with the permit application. The closure plan must identify the steps necessary for complete or partial closure of the facility at any point during its intended operating life and for complete closure of the facility at the end of its intended operating life. If changes in the operating plans or facility design affect the closure plan or if there is a change in the expected year of closure, the closure plan must be amended. For example, changes in any of the following should result in a modification of the closure plan: facility size/capacity; types and quantities of wastes on site at maximum closure inventory; schedule for partial and final closure; and schedules for periodic maintenance and inspection activities. Changes in technical considerations also can result in closure plan modification; for example, the application of new technology or changes in monitoring requirements, operating contingencies, land-use patterns around the facility, and the response of Regional Administrators to petitions by owners/operators.

A copy of the approved plan and all revisions to the plan must be kept on site until the certification of closure completeness has been submitted and accepted by the EPA. The owner or operator must notify the Regional Administrator at least 180 days prior to the date closure is expected to begin. Upon completion of the closure, it is necessary to

submit to the Regional Administrator a certification by either the owner or operator and an independent registered professional engineer that the facility has been closed in accordance with the specifications in the approved closure plan.

A permit modification may be required for a closure plan amendment. The elements in the sections that follow should be included in the closure plan (References 54, 56).

I-1a Closure Performance Standard [40 CFR Section 264.111]

Describe how the facility will be closed in a manner that minimizes the need for further maintenance and controls; minimizes or eliminates threats to human health and the environment; and avoids post-closure escape of hazardous waste, hazardous waste constituents, leachate, contaminated rainfall, or waste decomposition products to ground or surface waters or to the atmosphere.

I-1b Partial and Final Closure Activities [40 CFR Section 264.122(a)(1)]

Describe any plans for partial closure and the circumstances under which the facility will undergo partial closure. Partial closure applies when a portion of the hazardous waste facility is to be closed at any time during the operating life of the facility (e.g., removal of a tank or waste pile from service or capping of portions of a landfill as they are filled). The procedures you will follow for partial or complete closure of the facility at any point

during its intended operating life, and for complete closure of the facility at the end of its intended operating life. Identify the date of final closure. Identify the maximum extent of the hazardous waste facility that will remain open during the life of the facility (References 54, 56).

I-1c Maximum Waste Inventory [40 CFR Section 264.112(a)(2)]

Describe the maximum inventory of wastes in storage and treatment at any time during the life of the facility. Actual amounts of waste should be indicated in the appropriate units for each type of facility (References 54, 56).

I-1d Inventory Removal, Disposal, or Decontamination of Equipment
[40 CFR Section 264.112(a)(3)]

Describe the steps needed to decontaminate facility equipment during final closure, the labor force you intend to use to perform decontamination (in-house or outside contractor), and your criteria for determining contamination. Name each piece of equipment and/or structures (e.g., waste feed systems, bypass systems, drainage systems, conveyors, transport containers, piping, pumps, valves, heat exchangers, compressors, discharge confinement structures such as dikes) and procedures for cleaning (e.g., steam-cleaning, hydroblasting). Describe the amounts of contaminated soil to be disposed of on and off the site, and describe the criteria used to determine the amount of contaminated soil. Describe the method for processing, treating, or disposing of residues from decontamination (including decontaminant

solutions, wastewater, and liquid wastes). Describe the testing program to be used to determine if decontamination has been effective for each piece of equipment and/or structure and surrounding soils (e.g., laboratory procedures, kits, mechanical, electrical, or visual methods). Describe the method of transport to the disposal site (e.g., truck, rail, water); the distance of transport to the disposal site, and the final disposal method (e.g., facility type such as a secure landfill) (Reference 57).

I-1d(1) Closure of Containers [40 CFR Section 264.178]

Describe in detail how, at closure, all hazardous wastes and hazardous waste residues will be removed from the container storage area, and how containers and the containment system will be removed or decontaminated. Describe safety precautions and procedures to protect the labor force during the operation. Show how the effectiveness of decontamination will be determined. Also describe the fate of all removed hazardous waste and waste residues and how containers, containment linings, contaminated solids, and decontamination washes will be handled and disposed of.

Provide an estimate of the maximum inventory of waste stored in containers at any time during the life of the facility.

I-1d(2) Closure of Tanks [40 CFR Section 264.197]

Describe in detail how, at closure, all hazardous wastes, hazardous waste residues, and flammable or toxic vapors

will be removed from tanks, associated piping, discharge control equipment, and the discharge confinement structure. Describe how all components will be decontaminated. Describe preparation steps before testing and cleaning (after the waste has been removed from the tanks) such as ventilation and gas testing, assurances for safe entry and exit, and safety protection for the cleaning crews. Also describe the fate of all hazardous wastes and hazardous waste residues removed from the tanks and associated structures and how decontamination washes and contaminated soil will be handled and disposed of. Describe any waste processing or treatment methods, if required, prior to transport or disposal (e.g., neutralization, stabilization, solidification). Describe the volume of waste that will be processed or treated and the volume of waste that will result from such processing/treatment (Reference 53).

Provide an estimate of the maximum inventory of wastes in storage tanks and in tank treatment at any time during the life of the facility.

I-1(d)(3) Closure of Waste Piles [40 CFR Section 264.258]

Describe in detail how, at waste pile closure, all hazardous waste and hazardous waste residues will be removed and how any component of the containment system containing or contaminated with hazardous wastes or hazardous waste residues will be removed or decontaminated. Also describe

the fate of all hazardous wastes and waste residues removed from the pile and associated structural containment components, and how linings, contaminated soils, and decontamination washes will be handled and disposed of.

Provide an estimate of the maximum inventory of wastes stored in piles at any time during the life of the facility.

I-1e Schedule for Closure [40 CFR Section 264.112(a)(4)]

Provide an estimate of the expected year of closure. The closure schedule must include the total time required to close the facility and a milestone schedule depicting the time required for intervening closure activities. This will allow tracking of the progress of closure. Include provisions in the plan for scheduling several periodic inspections during the closure period.

The milestone schedule should show that all hazardous wastes will be treated, removed from the site, or disposed of on the site within 90 days of receipt of the final volume of waste and that all closure activities will be completed within 180 days from receipt of the final volume of waste.

I-1f Extensions for Closure Time [40 CFR Sections 264.113(b) (264.113(a))]

In the event a longer period of closure time is needed than that specified in 40 CFR 264.113(a) and (b), you must

demonstrate one of the following: the activities will necessarily take longer than 180 days to complete; the facility has the capacity to receive additional wastes; a person other than the owner or operator will recommence operation of the site; or closure of the facility would be incompatible with continued operation of the site. You must also demonstrate that all steps have been and will continue to be taken to prevent threats to human health and the environment from the unclosed but inactive facility.

I-2 Post-Closure Plans

These requirements apply only to disposal facilities that are not addressed in this manual.

I-3 Notice in Deed and Notice to Local Land Authority

These requirements apply only to disposal facilities that are not addressed in this manual.

I-4 Closure Cost Estimate (40 CFR Sections 122.25(a)(15) - 264.142)

Provide a written, dated estimate, in current dollars, of the cost of closing the facility in accordance with the closure plan. The closure cost estimate must equal the cost of closure at the point in the facility's operating life when the extent and manner of its operation would make closure the most expensive, as indicated by its closure

plan. Adjust the closure cost estimate for inflation within 30 days after each anniversary of the date on which the first closure cost estimate was prepared.

Revise closure cost estimates annually to adjust for inflation by using a factor derived from the annual Implicit Price Deflator for Gross National Product, as published by the Department of Commerce in the Survey of Current Business. An illustration of the calculation is shown in the following hypothetical example, which uses the price deflators given in Table 1 adopted from the Survey of Current Business. (See next page).

Previous year cost estimate = \$50,000

Previous year deflator = \$177.36

Current year deflator = \$193.71

After rounding off to the nearest whole number, the inflation factor is computed as $194/177 = 1.096$. The current year cost is then:

$$1.096 \times \$50,000 = \$54,800$$

The closure cost estimate must also be revised whenever a change in the closure plan increases the cost of closure and the revised estimate must be adjusted for inflation in the previously described manner.

The owner or operator is required to keep the following items at the facility throughout the operating life of the

TABLE 1. IMPLICIT PRICE DEFLATORS
1972 WEIGHTS, FOR GROSS NATIONAL PRODUCT^a

	Implicit price deflators, 1972 = 100							
	Seasonally adjusted							
	1980	1981	1980	1981	1981	1981	1981	1982
			IV	I	II	III	IV	V
Gross national product	177.36	193.71	183.81	188.14	191.06	195.61	200.10	201.88
Personal consumption expenditures	178.9	193.7	184.9	188.5	191.5	195.7	199.3	201.8
Durable goods	156.0	166.4	160.5	162.3	165.4	168.3	170.1	171.9
Nondurable goods	188.6	202.4	195.2	199.2	200.4	203.7	206.2	207.2
Services	178.1	195.2	184.3	188.4	192.2	197.6	202.3	206.3
Gross private domestic investment								
Fixed investment	194.2	209.2	199.9	203.1	208.4	210.9	214.7	215.5
Nonresidential	186.8	202.5	192.4	195.0	201.4	204.5	208.8	209.3
Structures	224.7	246.3	233.3	236.2	244.1	249.2	255.3	258.4
Producers' durable equipment	170.2	182.4	174.5	176.8	182.0	184.0	186.7	186.2
Residential	218.6	233.3	223.3	228.7	231.8	235.4	238.8	242.0
Nonfarm structures	221.7	236.8	226.3	231.8	235.0	239.1	242.9	246.1
Farm structures	219.9	235.5	224.2	229.6	233.4	237.6	241.2	245.3
Producers' durable equipment	149.4	159.4	152.4	155.2	158.0	161.5	163.1	166.1
Change in business inventories								
Net exports of goods and services								
Exports	211.0	229.0	219.9	226.1	228.0	229.8	232.2	233.6
Imports	290.1	295.5	296.4	303.1	301.2	289.8	288.5	289.3

TABLE 1 (continued)

	Implicit price deflators, 1972 = 100 Seasonally adjusted							
	1980	1981	1980	1981				1982
			IV	I	II	III	IV	V
Government purchases of goods and services	184.4	202.7	192.8	196.4	199.5	204.2	210.6	212.3
Federal	183.9	206.4	197.4	199.4	201.9	206.6	217.2	216.2
National defense	185.6	208.8	196.8	201.2	204.2	208.3	220.8	223.1
Nondefense	180.6	201.7	198.7	195.9	197.3	203.1	210.3	203.3
State and local	184.7	200.3	190.0	194.5	198.0	202.8	206.1	209.8

^aSource: Adapted from Department of Commerce Survey of Current Business, Gross Product by Industry, 1981, Table 7.1-7.2.

facility: the latest closure cost estimate (as previously defined) and, when this estimate has been adjusted for inflation, the latest adjusted closure cost estimate.

I-5 Financial Assurance Mechanism for Closure [40 CFR Sections 122.25(a)(1) and 264.143]

State which of the following mechanisms is used.

1. Closure trust fund
2. Surety bond guaranteeing payment into a closure trust fund
3. Surety bond guaranteeing performance of closure
4. Closure letter of credit
5. Closure insurance
6. Financial test and corporate guarantee for closure

A fully executed financial assurance mechanism(s) must be made available at the time of permit issuance. In states that have only Phase I authorization, provide a completed but unexecuted copy of financial assurance mechanism(s) for closure in the Part B application.

Originally signed copies of each of the chosen instruments must be delivered to the Regional Administrator. When a mechanism is used for multiple facilities, submit criteria of financial assurance to the Regional Administrator in each region where the mechanism is applied; include a list showing the EPA identification number, name, address, and the amount of funds for closure assumed by the mechanism for each covered facility.

In states that do not have Phase I authorization, existing facilities were required to submit a copy of financial assurance mechanism(s) by July 6, 1982. In states that have Phase I or Phase II authorization, facilities must comply with the applicable state laws and regulations. (Note: An owner or operator of a new facility must have the chosen instrument delivered to the Regional Administrator by certified mail at least 60 days before the date on which hazardous waste is first received, and the instrument must become effective no later than the date of first receipt.) Instruments must be revised as appropriate, and evidence must be submitted to the Regional Administrator within 60 days of the revision to the current cost estimate for closure of a facility (Reference 59).

I-5a Closure Trust Fund [40 CFR Sections 264.143(a) and 264.151(a)(1)]

A trust fund is a mechanism whereby the site owner or operator sets aside funds in the form of cash or marketable securities to pay for the proper closure of the site. The trustee, a financial institution, controls the fund and invests the money in low-risk assets. All income earned by such investments is retained in the fund and reinvested along with fund principal.

Upon closure of the facility, monies in the fund are available to reimburse authorized expenditures for closure when itemized bills are submitted to the Regional Administrator.

Funds remaining after all closure requirements have been fulfilled are returned to the facility's owner or operator.

During interim status, payments into the trust are made annually over 20 years or over the remaining life of the facility, whichever is less. (This is referred to as the "pay-in" period.) After a permit has been issued, the pay-in period is reduced to the life of the initial permit. A Federal permit may be written for a maximum of 10 years.

The trustee will furnish annual valuations at least 30 days before the anniversary date of establishment of the fund to both the grantor (i.e., facility owner or operator) and the Regional Administrator of the closure trust fund at each facility. Valuations are based on market values no more than 60 days prior to the anniversary date of establishment of the fund.

During the pay-in period, the minimum annual payment is equal to the unfunded liability of the facility (the estimated closure divided by the number of years remaining in the pay-in period):

$$\text{Minimum annual payment} = \frac{CE - CV}{Y}$$

where CE = the current cost estimate for closure.

CV = is the current value of the trust fund.

Y = is the number of years remaining in the pay-in period.

The first payment should be made at the time the trust fund is established and subsequent payments, no later than 30 days after each yearly anniversary date of the trust fund. After the pay-in period is completed, the funding level of the trust fund must be revised within 60 days of any change in the cost estimates.

After the pay-in period is completed, the owner or operator must maintain the value of the trust fund at a level equal to or greater than the CE value. Release of amounts from the fund requires written instructions from the Regional Administrator to the trustee.

The trustee must be a bank or other financial institution that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or state agency. The trustee may accept written directions from the grantor concerning investment guidelines and objectives; however, the trustee must abide by the "prudent man" doctrine for investments and may not include securities or other obligations of the grantor in the trust fund portfolio. All expenses of the trust, including taxes, brokerage commissions, legal services, and trustee compensation--to the extent not paid directly by the grantor--are paid by the fund. The trustee must notify the Regional Administrator within 10 days following the expiration of the 30-day period of the failure of the grantor to make the required annual payments during the pay-in period.

Prospective grantors should review all tax aspects of trust fund operations with their accountants or tax advisors. Under present statutes, payments into a trust fund are not considered expenses (and are therefore not deductible) on Federal income tax returns. (The EPA is awaiting an IRS ruling on this.) Payments by the trust fund for closure or post-closure care expenses, however, are deductible in the year of closure or post-closure care when such expenses are incurred. Income earned by the trust fund is taxable, even though it is not distributed to the grantor in the year earned. The grantor's Federal income tax liability will be credited (reduced), however, to the extent of any Federal income taxes paid by the trust fund on a fiduciary return.

The trust fund is terminated and remaining monies are returned to the grantor when one of two conditions have been met:

- 1) The requirements for closure have been satisfied.
- 2) An alternative financial assurance instrument has been provided to substitute for all or part of the trust fund.

Only the Regional Administrator can release the trustee from this obligations under the trust agreement.

The wording of the trust agreement must be identical to the wording specified in 40 CFR Section 264.161(a)(1), and the trust agreement must be accompanied by a formal certification of acknowledgment.

I-5b Surety Bond [40 CFR Sections 264.143(b), 264.143(c),
264.151(b), and 164.151(c)]

A surety bond is a contract whereby a surety company guarantees to pay the amount of closure or post-closure care costs should the owner or operator fail to meet his obligation. A standby trust fund must be established in conjunction with the surety bond. Payments from a surety company would be made directly into the standby trust. The owner or operator need not make any payments into the standby trust fund.

After obtaining the surety bond from, at a minimum, a federally acceptable surety company (per Treasury Circular 570), the owner or operator delivers the bond and standby trust fund documents to the Regional Administrator. The penal sum of the bond is adjusted yearly to correspond to adjustments in the closure cost estimate. Adjustments to the penal sum must be made within 60 days after any changes in the cost estimate. The bond remains effective until cancelled with the consent of the Regional Administrator.

The cost to the owner or operator of providing financial assurance by means of a surety bond includes the cost of the bond itself plus the incremental opportunity cost of any capital required to be set aside as collateral. The direct cost of the surety bond is generally between 1.0 and 2.0 percent of the face value of the bond per year and is deductible for tax purposes. The EPA expects the use of

surety bonds for financial assurance to be limited (based on discussions with the Surety Association of America). Wording for the surety bond is specified in 40 CFR Section 264.151(c).

I-5c Closure Letter of Credit [40 CFR Sections 264.143d) and 264.151(d)]

A letter of credit is an instrument issued by a financial institution on behalf of the owner or operator of the hazardous waste facility that gives EPA the right to draw from the issuing institution to cover the costs of closure in the event the firm fails to meet its obligation. In a sense, the financial institution substitutes its credit for that of the facility.

The owner or operator establishes a standby trust fund in conjunction with a letter of credit in an amount equal to or greater than the current closure cost estimate. Both instruments are delivered to the Regional Administrator and are updated annually, as appropriate. Adjustments to the value of the letter of credit must be made within 60 days of any changes in the closure cost estimate.

The institution issuing the letter of credit must be a bank or other financial institution that has authority to issue letters of credit and whose operations for this purpose are regulated and examined by a Federal or state agency. The letter of credit is irrevocable; it is issued for a period of at least one year, with automatic extensions for at

least one additional year unless 90-day notification is given to the Regional Administrator.

Upon determination, under Section 3008 of RCRA, that the owner or operator has failed to meet his closure obligations, the Regional Administrator may draw on the letter of credit. Drafts under the letter of credit are deposited into a standby trust fund, from which payments are made for approved closure expenses.

The cost to the owner or operator of providing financial assurance by means of a letter of credit includes the cost of the letter of credit itself plus the incremental opportunity cost of any capital required to be set aside as collateral. The annual direct cost of the letter of credit is generally between 0.25 and 2.0 percent of the value of the letter of credit, depending on the credit-worthiness of the firm. Such costs are deductible for income tax purposes. Collateral required for letters of credit typically averages 20 percent of the value of the letters of credit. Wording for the letter of credit is specified in 40 CFR Section 264.151(d).

I-5d Closure Insurance [40 CFR Section 264.143(e) and 264.151(e)]

A firm may purchase an insurance policy for the amount of the estimated closure cost. The insurance company will pay the cost of closure up to the full amount of the policy whenever closure occurs.

The face value of the policy is at least the amount of current closure cost. Premiums paid during the active life of the site serve to fund the full amount of the policy, although it may not have a cash value. At the end of site life, the insurer will pay out funds, up to the face amount of the policy, to reimburse authorized expenditures for closure. The face amount of the insurance must be adjusted accordingly within 60 days of any change in the cost estimates. The policy cannot be cancelled except for failure to pay the premium, and then only 120 days after providing notification of such failure to both the Regional Administrator and the owner or operator.

The owner or operator submits a certificate of insurance [worded as specified in 40 CFR Section 264.151(e)] signed by the insurer and indicating the face amount of the policy. The insurer must be licensed to transact insurance business or eligible to provide insurance as an excess or surplus line insurer in one or more states. Either the face amount of the insurance must be adjusted to equal or exceed the covered cost of closure, or other forms of financial assurance must be provided to make up the difference.

The key issue regarding the insurance mechanism is the deductibility of premium payments for tax purposes. If the premiums are deductible, the insurance policy would be similar to the trust fund without the adverse tax treatment

of fund payments. Until the tax issue is resolved, however, it is doubtful whether any significant interest in this option will develop. Currently, no insurance firms are offering to issue this kind of policy.

I-5e Financial Test and Corporate Guarantee [40 CFR Sections 264.143(f), 264.151(f), and 264.151(h)]

The owner or operator can establish financial assurance for closure of one or more facilities by passing a financial test. The test [wording at 40 CFR Section 264.143(f)(1)] is based on the facility's most recent audited financial statements, and it must be recertified on an annual basis. The test takes into account the current adjusted cost of closure and post-closure care of all facilities that are not covered by an alternative financial mechanism. If a facility passes the financial test, it need not provide any additional assurance that it can meet its closure cost obligations. A parent company that passes the financial test can provide a guarantee of its subsidiary's obligations.

To certify satisfactory financial conditions under the financial test, the owner or operator supplies to the regional administrator: (1) a letter from the facility's chief financial officer [wording in 40 CFR Section 264.151(f)]; (2) an auditor's report confirming the results of the test; (3) the auditor's opinion; (4) a letter from a guarantor corporation, if applicable [wording in 40 CFR Section 264.151(g)]; (5) any other information requested by

the Regional Administrator. The auditor must be an independent certified public accountant. If a facility fails to provide certification of satisfactory financial condition at any time prior to termination of its closure obligations, an alternative financial assurance mechanism must be supplied within 30 days.

I-5f Combinations

I-5f(1) Use of Multiple Financial Mechanisms [40 CFR Section 264.143(g)]

A facility's use of multiple financial mechanisms requires a copy of a combination of trust fund agreements, surety bonds guaranteeing payment into a trust fund, letters of credit, insurance, and state guarantees. Neither the financial test nor surety bonds guaranteeing performance of closure can be used to provide partial financial assurance for closure of a single facility. The combined financial assurance provided for a facility must equal or exceed the facility's current (adjusted) closure cost estimate.

I-5f(2) Use of Financial Mechanisms for Multiple Facilities [40 CFR Section 264.143(h)]

A single financial mechanism may be used to provide financial assurance for closure of more than one facility. Total funding of the mechanism must equal or exceed the sum required for each facility considered separately. Evidence of financial assurance must be supplied to the Regional Administrator in each region where covered facilities are located; it should include a list showing the EPA identification number, name, address, and amount of funds for closure assured by the mechanism for each facility.

I-6 Post-Closure Cost Estimate [40 CFR Sections 122.15(a)(16) and 264.144]

These regulations only apply to disposal facilities.

I-7 Financial Assurance Mechanism for Post-closure [40 CFR Sections 122.15(a)(16) and 264.145]

These regulations only apply to disposal facilities.

I-8 Liability Requirements [40 CFR Section 122.15(a)(17) and 264.147]

In states that have only Phase I authorization, provide evidence that the liability coverage will be effective at the time of permit issuance. This may be done by stating which mechanism will be used and providing a copy of the proposed mechanism. In states that do not have Phase I authorization of liability coverage, existing facilities must submit evidence by July 17, 1982, for sudden and nonsudden (for surface impoundments, landfills, or land treatment facilities only) accidental occurrences that cause injury to persons or property. Evidence may be provided by submitting a certificate of insurance, by passing a financial test (self-insurance), or any combination of the two. Coverage amounts apply to all facilities owned or operated by the insured. Only states and the Federal government are not required to provide liability coverage. In states that have both Phase I and II authorization, facilities must comply with state laws and regulations that are or will be in effect at the time of application submitted. Coverage must be maintained until certification of closure of all facilities.

I-8a Sudden Insurance [40 CFR Sections 264.147(a), 164.151(i), and 264.151(j)]

All facility owners and operators must have coverage for sudden occurrences (accidents that are not continuous or repetitive in nature) in the amount of at least \$1 million per occurrence, with an annual aggregate of \$2 million, exclusive of legal defense costs.

If insurance is used to cover all or part of this liability, you must submit proof with your permit application to each the EPA Regional Administrator in each Region in which covered facilities are located. Such proof may be in the form of a signed duplicate original of either (1) the policy's Hazardous Waste Facility Liability Endorsement [wording in 40 CFR Section 264.151(g)], or (2) the Certificate of Liability Insurance [wording in 40 CFR 264.151(j)].

Alternatively, a facility may use a financial test or any combination of insurance and a financial test as evidence of liability.

Existing facilities must submit the required documents by July 15, 1982, in states that do not have Phase I authorization, and according to state law and regulations, in states that have Phase I or Phase II authorization.

I-8b Nonsudden Insurance [40 CFR Sections 264.147(b), 264.151(i), and 264.151(j)]

These requirements apply only to surface impoundments.

landfills, or land treatment disposal facilities that are not addressed in this manual.

I-8c Financial Test [40 CFR Sections 264.174(f), 264.151(J)]

Owners or operators may provide assurance for all or part of their financial liability requirements by passing a financial test. The test [wording in 40 CFR Section 264.147(f)] is based on the facility's most recent audited financial statements and must be recertified on an annual basis. To certify satisfactory financial condition under the financial test, you must supply the Regional Administrator with (1) a letter from your Chief Financial Officer [wording at 40 CFR Section 264.151(g)]; (2) an auditor's report confirming the results of the test; (3) the auditor's opinions; (4) any other information requested by the Regional Administrator.

The auditor must be an independent certified public accountant. If a facility fails to provide certification of satisfactory financial conditions for any portion of the required liability coverage, such coverage must be provided within 30 days through an insurance policy.

I-8d Variance Procedures [40 CFR Section 264.147(c)]

An owner or operator may obtain approval from the Regional Administrator for a reduction in the required liability amounts under this section. Such approval depends on an evaluation of the degree and duration of risks associated with the ownership or operation of each facility or group

of facilities and on other technical and engineering information as determined necessary by the Regional Administrator.

I-8e Adjustment Procedures [40 CFR Section 264.147(d)]

The Regional Administrator may elect to increase the amounts of liability coverage required for any facility or group of facilities, and may elect to impose nonsudden liability coverage requirements on treatment of storage facilities. Such a determination is based on an evaluation of the degree and duration of risks and what is deemed necessary to protect human health and the environment. Any adjustment of the level of required coverage for a facility that has a permit is treated as a permit modification under 40 CFR Sections 122.15(a)(7)(iii) and 124.5.

I-9 State Mechanisms

I-9a Use of State-Required Mechanisms [40 CFR Section 122.15 (2)(18), 264.149]

If a state has hazardous waste regulations equivalent to or greater than Federal liability requirements or financial assurance for closure, submit a copy of the state-required financial mechanisms and a letter requesting that the state mechanism be acceptable. Include the facility's EPA identification number, name, and address and the amounts of coverage. If the state coverage is less than Federal requirements, the owner or operator must provide proof of additional financial assurance mechanisms to equal Federal requirements.

To obtain approval for state-assumed coverage, the owner or operator must submit a letter written by the state to the Regional Administrator describing the nature of the state's assumption of responsibility, together with a request that such assumption be considered acceptable. The letter must include the facility's EPA identification number, name, and address and the amount of funds for closure or liability coverage that are guaranteed by the state.

I-9b State Assumption of Responsibility [40 CFR Section 264.150]

A state may assume either the owner's or operator's legal responsibility for closure and liability or the financial responsibility to cover those requirements in accordance with the Federal standards. If state guarantees for financial responsibility are less than the amounts estimated for closure, the owner or operator of the facility must supply additional financial assurance mechanisms to cover the shortfall.

J. OTHER FEDERAL LAWS [40 CFR Sections 122.25(a)20 and 122.12]

The EPA must ensure that RCRA permits are consistent with the requirements of applicable Federal laws, such as the Wild and Scenic Rivers Act, National Historic Preservation Act of 1966, Endangered Species Act, Coastal Zone Management Act, and the Fish and Wildlife Coordination Act. Therefore, it is necessary to consider the potential impact of the facility on these special environmental areas, and information related to the facility's compliance with other Federal laws in the RCRA permit application.

K. CERTIFICATION [40 CFR Sections 122.6(a) and (d)]

Applications must be accompanied by a certification letter reading as follows:

"I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all attachments and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

The required signatures are as follows: (1) for a corporation, a principal executive officer (at least at the level of vice-president); (2) for a partnership or sole proprietorship, a general partner or the proprietor, respectively; (3) for a municipal, state, Federal, or other public agency, either a principal executive officer or ranking elected official.

PART 2
MODEL RCRA PERMIT
APPLICATION

PART 2
MODEL RCRA PERMIT APPLICATION

Part 2 presents a model of a Part A application, a Part B application, and certification for a fictitious hazardous waste management facility.

Appendix A contains general information and hazardous characteristics of waste; Appendix B contains inspection log sheets; and Appendix C contains a Trust Agreement.

Date: 2/26/82*
Revision No.: 1
A

SECTION A
PART A APPLICATION .

The Part A application includes the completed forms that follow, a facility map (Figure 2), and a facility photograph (Figure 3).

* This is a suggested notation to facilitate revisions to the Part B Permit Application.

Form Approved OMB No. 1545-0047

GENERAL INFORMATION

1. **NAME OF FACILITY**
CANKOPILE FINISHING COMPANY INC

2. **NAME OF CONTACT**
JOHN Q SMITH ENVIRONMENTAL ENGINEER

3. **PHONE NO. (AREA CODE)**
555 6789

4. **STREET OR P.O. BOX**
PO BOX 1982

5. **CITY OR TOWN**
ANYTOWN

6. **STATE**
ANYTOWN

7. **ZIP CODE**
12345

8. **STREET, ROUTE NO. OR OTHER SPECIFIC IDENTIFIER**
1100 WEST ELEVENTH ST

9. **CITY OR TOWN**
WASHINGTON

10. **STATE**
WASHINGTON

11. **ZIP CODE**
98001

12. **DATE OF REPORT**
12/15/82

13. **DATE OF FACILITY OPERATION**
12/15/82

14. **DATE OF FACILITY CLOSURE**
12/15/82

15. **DATE OF FACILITY RE-ENTRY**
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12/15/82

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MARY P JONES		P 401 555 6789	
PO BOX 1982		RI 02881	
ANTTOWN		RI 02881	
Attach to this application a topographic map of the area extending to at least one mile beyond property boundaries. The map must show the location of the facility, the location of each of its existing and proposed waste and discharge structures, each of its hazardous waste treatment, storage, or disposal facilities, and each well where it injects fluids underground. Include all springs, rivers and other surface water bodies in the map area. See instructions for precise requirements.			
Primarily engaged in the manufacture of metal stampings such as automotive body parts and household appliance housings and parts.			
I, the undersigned, being duly sworn, depose and say that the information submitted in this application and all attachments and that I am the duly authorized representative of the person or persons immediately responsible for obtaining the information contained in this application, and that the information is true, accurate and complete. I further depose that there are no significant omissions for submitting this information.			
a. Name & official title (type or print)		b. Signature	
Mary P. Jones, President		Mary P. Jones	
		c. Date signed	
		08/01/80	

EPA Form 2010-1 (8-80) REVERSE

Date: 6/20/04
Revision No.: 0
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Date: 2/26/82
Revision No.: 0
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III. PROCESSES (continued)

C. SPACE FOR ADDITIONAL PROCESS CODES OR FOR DESCRIBING OTHER PROCESSES FROM THE : FOR EACH PROCESS ENTERED HERE INCLUDE DESIGN CAPACITY

IV. DESCRIPTION OF HAZARDOUS WASTES

A. EPA HAZARDOUS WASTE NUMBER - Enter the four-digit number from 40 CFR, Subpart C for each listed hazardous waste you are handling. If you handle hazardous wastes which are not listed in 40 CFR, Subpart C, enter the four-digit number from 40 CFR, Subpart C that describes the characteristics and/or the toxic constituents of these hazardous wastes.

B. ESTIMATED ANNUAL QUANTITY - For each listed waste entered in column A, estimate the quantity of that waste that will be handled in an annual year. For each characteristic or toxic constituent entered in column A, estimate the total annual quantity of all the non-listed wastes that will be handled which possess that characteristic or constituent.

C. UNIT OF MEASURE - For each quantity entered in column B, enter the unit of measure used. Units of measure which must be used and the appropriate codes are:

ENGLISH UNIT OF MEASURE	CODE	METRIC UNIT OF MEASURE	CODE
POUNDS	P	KILOGRAMS	K
TONS	T	METRIC TONS	M

If facility records use one other unit of measure for quantity, the units of measure must be converted into one of the required units of measure leaving units without the appropriate density or density gravity of the waste.

D. PROCESSES

1. PROCESS CODES

For listed hazardous waste: For each listed hazardous waste entered in column A, enter the code(s) from the list of process codes contained in item (1) to indicate how the waste will be stored, treated, and/or disposed of at the facility.

For non-listed hazardous waste: For each characteristic or toxic constituent entered in column A, enter the code(s) from the list of process codes contained in item (1) to indicate all the processes that will be used to store, treat, and/or dispose of all the non-listed hazardous wastes that possess that characteristic or toxic constituent.

Note: Four codes are provided for entering process codes if more are needed: (1) Enter the first three as described above; (2) Enter "000" in the extreme right box of item IV-D(1); and (3) Enter in the space provided on page 4, the line number and the additional codes.

2. PROCESS DESCRIPTION

If a code is not listed for a process that will be used, describe the process in the space provided on the form.

NOTE: HAZARDOUS WASTES DESCRIBED BY MORE THAN ONE EPA HAZARDOUS WASTE NUMBER - Hazardous wastes that can be described by more than one EPA Hazardous Waste Number shall be described on the form as follows:

- Select one of the EPA Hazardous Waste Numbers and enter it in column A. On the same line complete columns B, C, and D by estimating the total annual quantity of the waste and describing all the processes to be used to store, treat, and/or dispose of the waste.
- In column A of the next line enter the other EPA Hazardous Waste Number that can be used to describe the waste. In column B(2) on that line enter "included with above" and make no other entries on that line.
- Repeat step 2 for each other EPA Hazardous Waste Number that can be used to describe the hazardous waste.

EXAMPLE FOR COMPLETING ITEM IV (shown in line numbers X-1, X-2, X-3, and X-4 above) - A facility will treat and dispose of an estimated 900 pounds per year of drums sludging from leather tanning and finishing operations. In addition, the facility will treat and dispose of three non-listed wastes. Two wastes are corrosive only and there will be an estimated 200 pounds per year of each waste. The third waste is extremely flammable and there will be an estimated 100 pounds per year of this waste. Treatment will be in an incinerator and disposal will be in a landfill.

LINE NO.	A. EPA HAZ. WASTE NO. (from code)	B. ESTIMATED ANNUAL QUANTITY OF WASTE	C. UNIT OF MEAS. (from code)	D. PROCESSES	
				1. PROCESS CODES (from 1)	2. PROCESS DESCRIPTION (if a code is not received in D(1))
X-1	K054	900	P	T03D80	
X-2	D002	400	P	T03D80	
X-3	D001	100	P	T03D80	
X-4	D002				included with above

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CONTINUE ON PAGE 3

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Copy from page 1
NOTE: This form is to be completed if you have more than 25 units to list. Form Approved OMB No. 1545-0004

EPA ID NUMBER (from page 1)		FOR OFFICIAL USE ONLY	
W 3 1 0 0 0 9 9 9 9 9 9 9 9		DUP	
IV. DESCRIPTION OF HAZARDOUS WASTES CONTAINED			
A. EPA HAZARD WASTE NO.	B. ESTIMATED ANNUAL QUANTITY OF WASTE	C. UNIT OF MEASURE (TONS, YARDS, CUBIC YARDS, ETC.)	D. PROCESSES
1 0 0 0 7	15	T	S 0 1
2 0 0 0 8			Included with above
3 0 0 0 1	5	T	S 0 1
4 0 0 0 1	5	T	S 0 1
5 0 0 0 2	20	T	S 0 1
6 0 0 0 7			Included with above
7 0 0 0 8			Included with above
8 X 0 6 2	150	T	S 0 2
9 F 0 0 1	30	T	S 0 2
10 0 0 0 7	100	T	S 0 3
11 0 0 0 8			Included with above
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			

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Continued from the front

IV. DESCRIPTION OF HAZARDOUS WASTES (continued)
E. USE THIS SPACE TO LIST ADDITIONAL PROCESS CODES FROM ITEM 5(1), ON PAGE 1

EPA ID NO. (from page 1)
PRID0099999999

V. FACILITY DRAWING
All existing facilities must include in the space provided on page 5 a scale drawing of the facility (see instructions for more detail)

VI. PHOTOGRAPHS
All existing facilities must include photographs (aerial or ground-level) that clearly delineate all existing structures, existing storage, treatment and disposal areas, and sites of future storage, treatment or disposal areas (see instructions for more detail)

VII. FACILITY GEOGRAPHIC LOCATION
LATITUDE (degrees, minutes & seconds)
41 46 00 N
LONGITUDE (degrees, minutes & seconds)
071 33 00 W

VIII. FACILITY OWNER
3A. If the facility owner is also the facility operator as listed in Section VIII on Form 1 "General Information", please an "X" in the box to the left and skip to Section IX below.
B. If the facility owner is not the facility operator as listed in Section VIII on Form 1, complete the following items:
1. NAME OF FACILITY'S LEGAL OWNER
2. PHONE NO. (area code & no.)
3. STREET OR P.O. BOX
4. CITY OR TOWN
5. ST
6. ZIP CODE

IX. OWNER CERTIFICATION
I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

A. NAME (print or type)
Mary P. Jones
B. SIGNATURE
Mary P. Jones
C. DATE SIGNED
08/01/80

X. OPERATOR CERTIFICATION
I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

A. NAME (print or type)
Mary P. Jones
B. SIGNATURE
Mary P. Jones
C. DATE SIGNED
08/01/80

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CONTINUE ON PAGE 5

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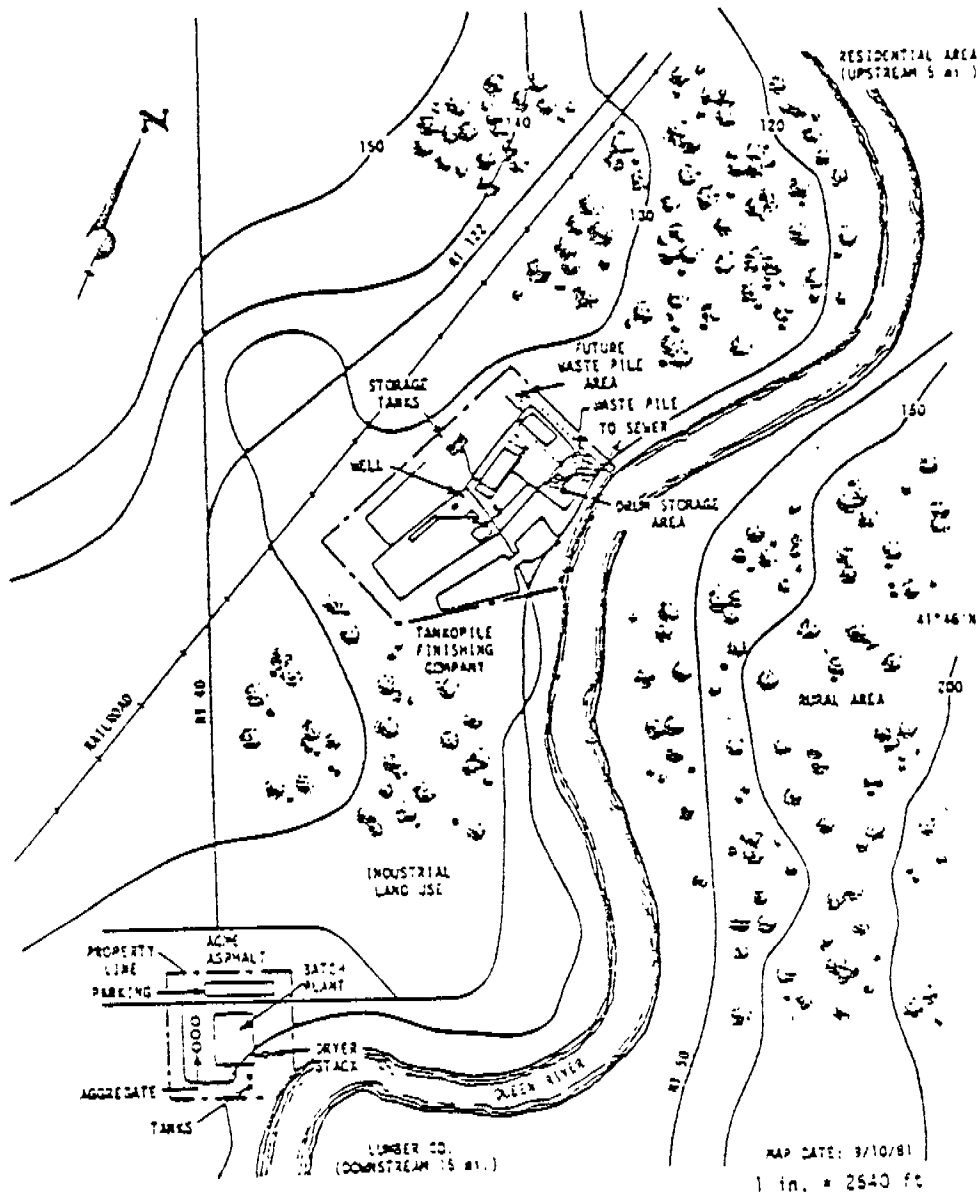


Figure 2. A topographical map of Tankopile Finishing Company and surrounding area.

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(An actual photograph would include existing structures
and future hazardous waste storage areas.)

Figure 3. Facility photograph, June 2, 1980.

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SECTION B
FACILITY DESCRIPTION

This section provides a general description of the hazardous waste management facility as required by 40 CFR §122.25(a). This description is intended to acquaint the permit application reviewer/permit writer with an overview of the facility. More complete details can be found in other parts of this permit application.

B-1 General Description [40 CFR 122.25(a)(1)]

Tankopile Finishing Company, Inc., is located 3 miles east of the city limits of Anytown, Rhode Island. The street address is:

Tankopile Finishing Company, Inc.
3100 West 11th Street
Washington County
Anytown, Rhode Island 02881

The mailing address is:

Tankopile Finishing Company, Inc.
P.O. Box 1982
Anytown, Rhode Island 02881

This facility is primarily a manufacturer of metal automotive parts (i.e., body parts, hubs, and trim) and household appliance housings and parts. Hazardous wastes are generated by metal fabrication, cleaning, finishing and

coating operations. Fabrication and machining of metal parts generates metal grindings. Cleaning of metal parts in hydrochloric acid generates pickle liquor sludge and spent pickle liquor. Vinyl acetate and vinyl chloride sludges are generated by the metal coating operations. The waste trichloroethane results from vapor degreasing of metal parts. The metal hydroxide sludge is generated as a byproduct from recycling wastes from chromium and lead plating operations.

The contact and party responsible for the hazardous waste management activities at Tankopile is:

John Q. Smith
Environmental Engineer
(401) 555-6789

B-2 Topographic Map [40 CFR 122.25(a)(19)]

Figure 4 is a topographic map showing the facility boundaries, buildings, waste storage areas, and other details. Figures 5 and 6 are topographic maps showing 5-ft contour intervals of elevation and the 100-year floodplain area, respectively. These maps also show surface waters. The scale on these maps is 1 in. equals 880 ft. whereas the regulations request a scale of 1 in. equal to not more than 200 ft. This was discussed with the permit application reviewer at EPA and this submission was considered acceptable (see letter to J. Q. Smith dated 12/1/81 from C. Siegel submitted separately).

11

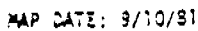


Figure 4. Facility map of Tenkocile Finishing Company.

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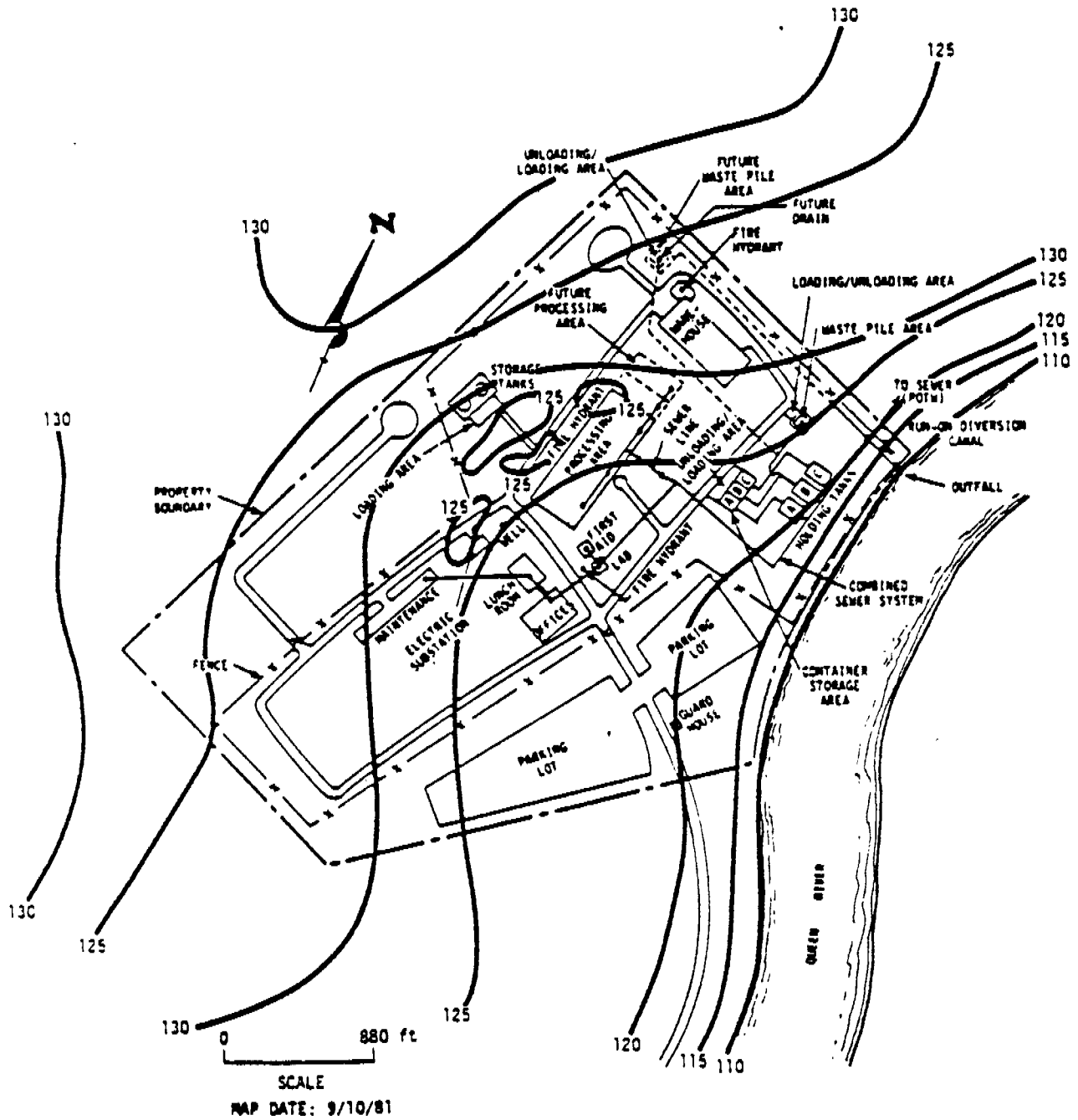


Figure 5. Facility map with 5-foot contour intervals of elevation (feet MSL).

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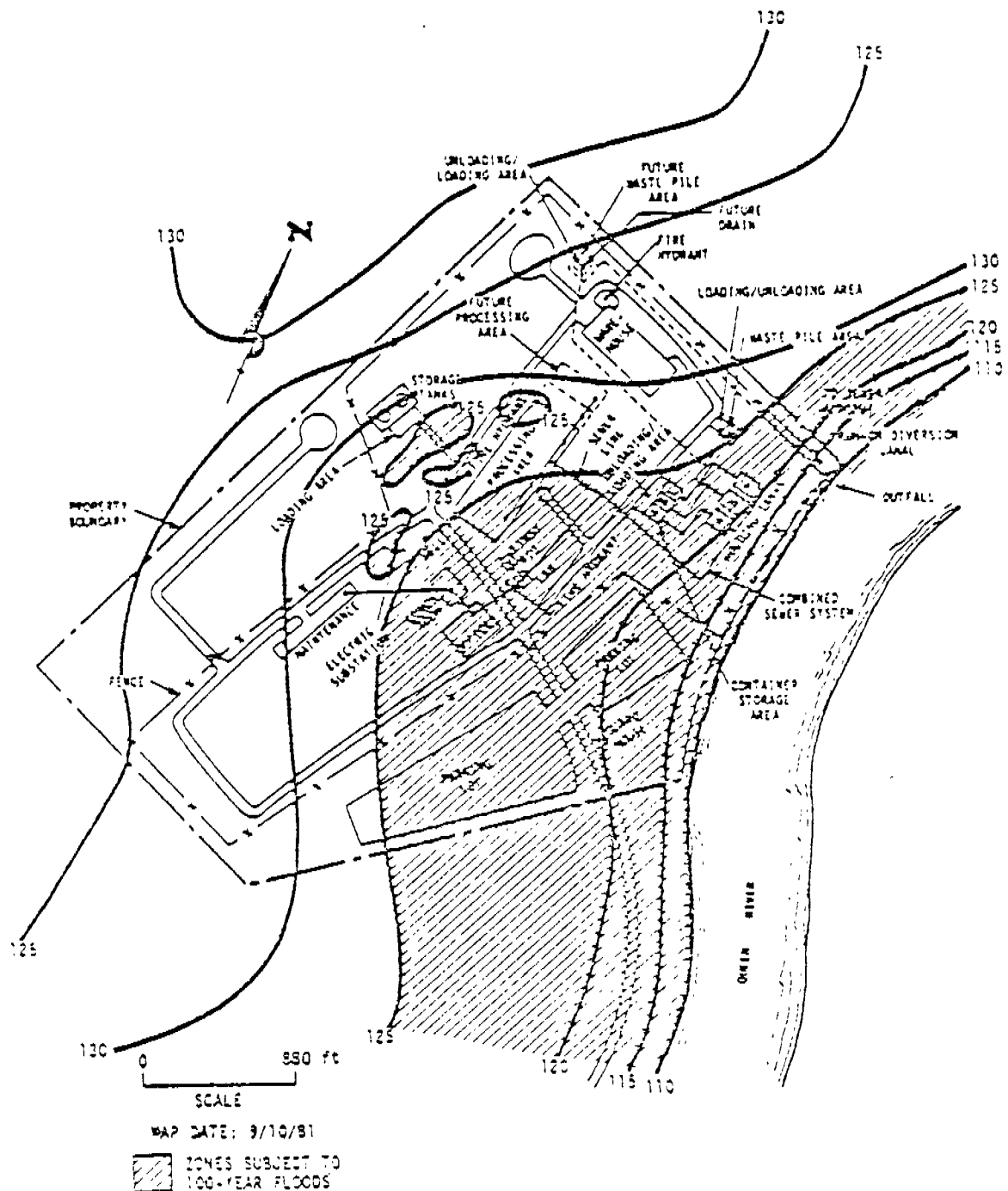


Figure 6. Facility map showing 100-year floodplain.

Land Uses: Figure 7 shows surrounding land-use areas. Other industry lies south of the facility; the rest of the surrounding area is undeveloped. Zoning maps of the area may be obtained from the City of Anytown Planning Commission.

Hazardous Waste Management Facility Boundary: The hazardous waste management facilities consist of the drum storage area (100 55-gallon drums), two 7500-gallon storage tanks, and one 50-yd³ waste pile (Figure 4). The figure also shows the location of the future waste pile area which is outside the 100-year floodplain. The existing waste pile area is within the 100-year floodplain (Figure 6).

Wind Rose: Figure 8 shows an annual wind rose of meteorological data collected from 1965 through 1974 at the nearest weather station, approximately 5 miles west of the Tankopile facility in Anytown, Rhode Island.

Access Control: The facility is surrounded by a fence, and a guard house is situated at the only entrance to the plant. Employees must show identification to obtain access; visitors must sign in and out and wear a visitor's badge. Access control is discussed in further detail in Section F-1a.

Injection and Withdrawal Wells: The site has no injection wells. One withdrawal well is located north of the electric substation (see Figure 4) and is used to supply cooling water for vapor degreasers at the facility. No other wells are located on-site or off-site within 1000 feet of the facility.

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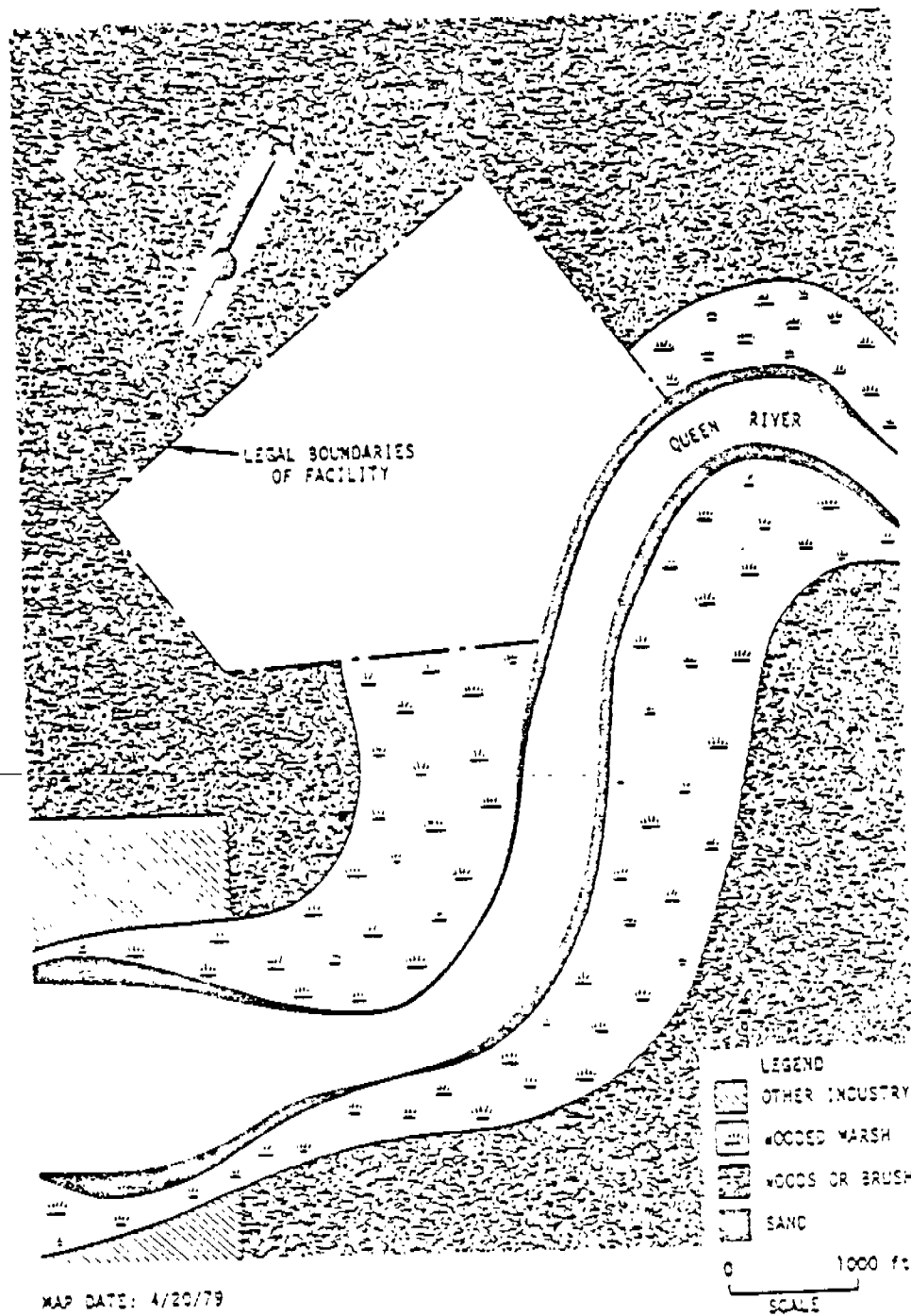
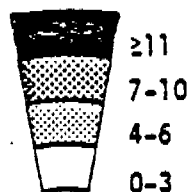
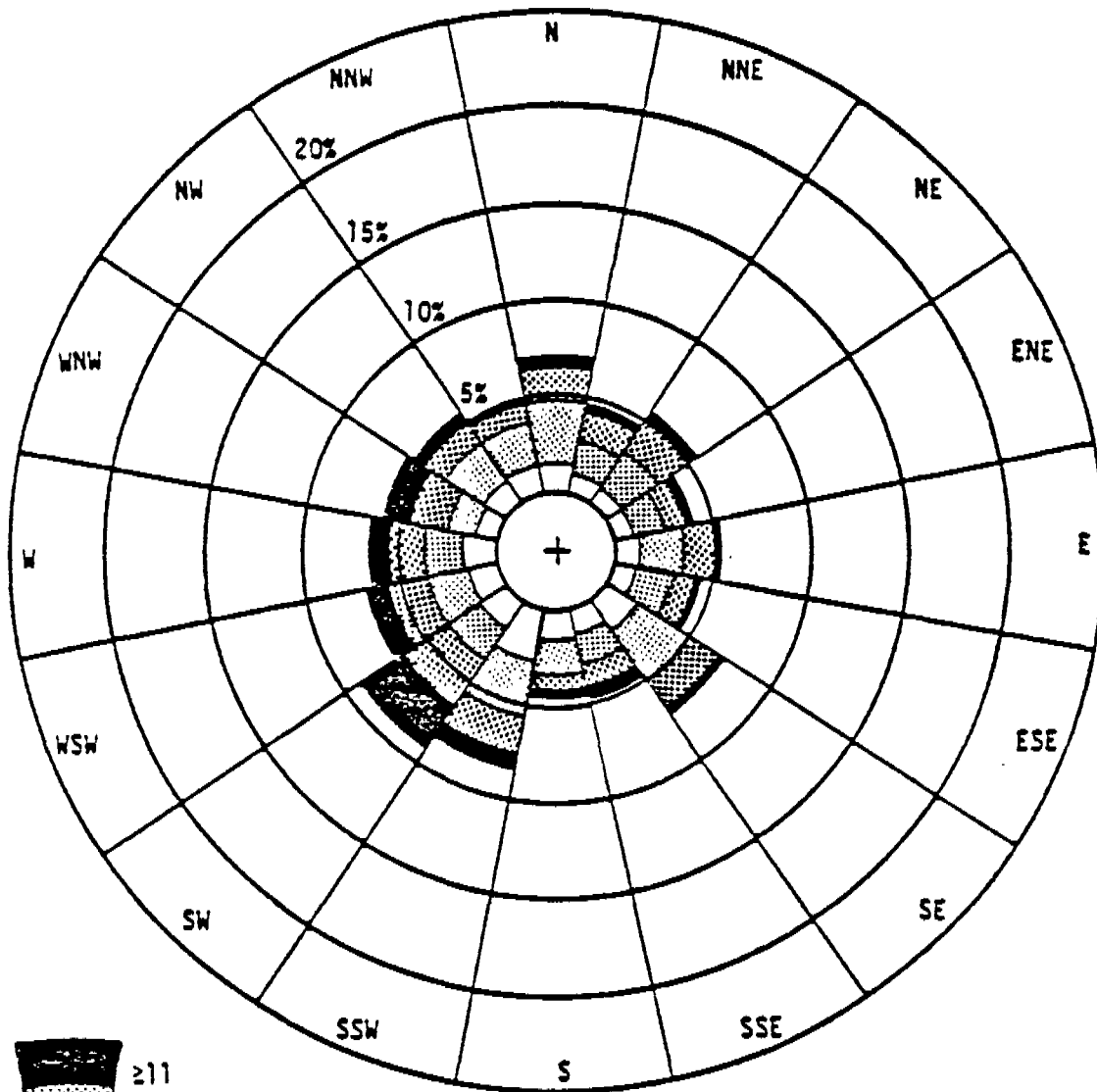


Figure 7. Surrounding land use.

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ANYTOWN, RHODE ISLAND
1965 - 1974

29,216 OBSERVATIONS
7.1% CALM



WIND SPEED, knots

Figure 8. Wind rose.

Buildings; Treatment, Storage, and Disposal Areas; Other Structures: Figure 3 shows the building and structures on the property as well as the waste storage areas.

Recreation Areas: Not applicable.

Runoff Control Systems: A combined sewer system with collection drains located throughout the facility collects runoff from the processing and warehouse areas (Figure 4). Runoff from the container and waste pile storage areas is collected in holding tanks prior to discharge to the sewer system. Section F-4b discusses runoff control in greater detail.

Access and Internal Roads: Figure 4 shows the roads within the plant area and the one road leading into the plant.

Storm, Sanitary and Process Sewers: Tankopile's combined sewer system, which collects sanitary sewage and storm water, has drains located in the office building, lunch room, first aid building, processing area, and warehouse area. The system also extends to the container storage area and waste pile storage area receiving runoff. Runoff collected in the container storage area and waste pile storage area does not mix with sanitary waste until it passes through the holding tanks as discussed in section F-4b. The combined sewer system is shown in Figure 4. There are no process sewers at this facility.

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Loading and Unloading Areas: Concrete loading/unloading areas are provided on the east side of the tank storage area and at the warehouse. A loading/unloading area is provided on the west side of the container storage area and a loading/unloading area will be located on the south side of the future waste pile.

Fire Control Facilities: The three fire hydrants provided are located near the lab, the processing area, and the warehouse.

Surface Waters: The only surface water within 1000 feet of the facility is the Queen River shown in Figures 4 through 6.

Flood Control/Drainage Barriers: General drainage on the property is toward the river. A fence surrounds the containers to keep them within the storage area during a minor flood. Alternatively, when a 100-year flood is evident, the containers will be removed to a disposal facility. Current plans call for the waste pile to be moved outside the 100-year floodplain. The tanks are already located outside the floodplain.

B-3 Location Information [40 CFR 122.25(a)(11) and 264.18]

B-3a Seismic Standard

Because this is an existing rather than a new facility, the seismic standard does not apply.

B-3a Floodplain Standard

The Tankopile Finishing Company, Inc., facility is located immediately west of the Queen River and 1.3 miles east of the Chipuxet River. The 100-year floodplain elevation at the facility is 125 feet mean sea level (MSL).

Figure 9 shows a portion of the Federal Insurance Administration (FIA) flood map for the city of Anytown. The zones labeled "AO" on the map indicate areas of 100-year shallow flooding with depths between 1 and 3 feet. (This refers to depth of flooding in a given area rather than rise of the river by one to three feet.) The Zone B portions of the facility property indicate areas between the limits of the 100-year flood and the 500-year flood or areas subject to 100-year flooding with average depths of less than one foot. The remainder (the most northern and western sections) of the property, designated as Zone C, is an area that is not subject to flooding. More than half of the facility property is located within the 100-year floodplain and is subject to floods of one to three feet in depth.

B-3b(1) Demonstration of Compliance

B-3b(1)(a) Flood Proofing and Flood Protection Measures

The slow-flowing Queen River may subject the property to occasional shallow (one to three foot depths) floods, but no wave action can reasonably be expected.

Waste containers (55-gallon drums) are stored in a fenced-in area located in Zone AO. Although the container storage

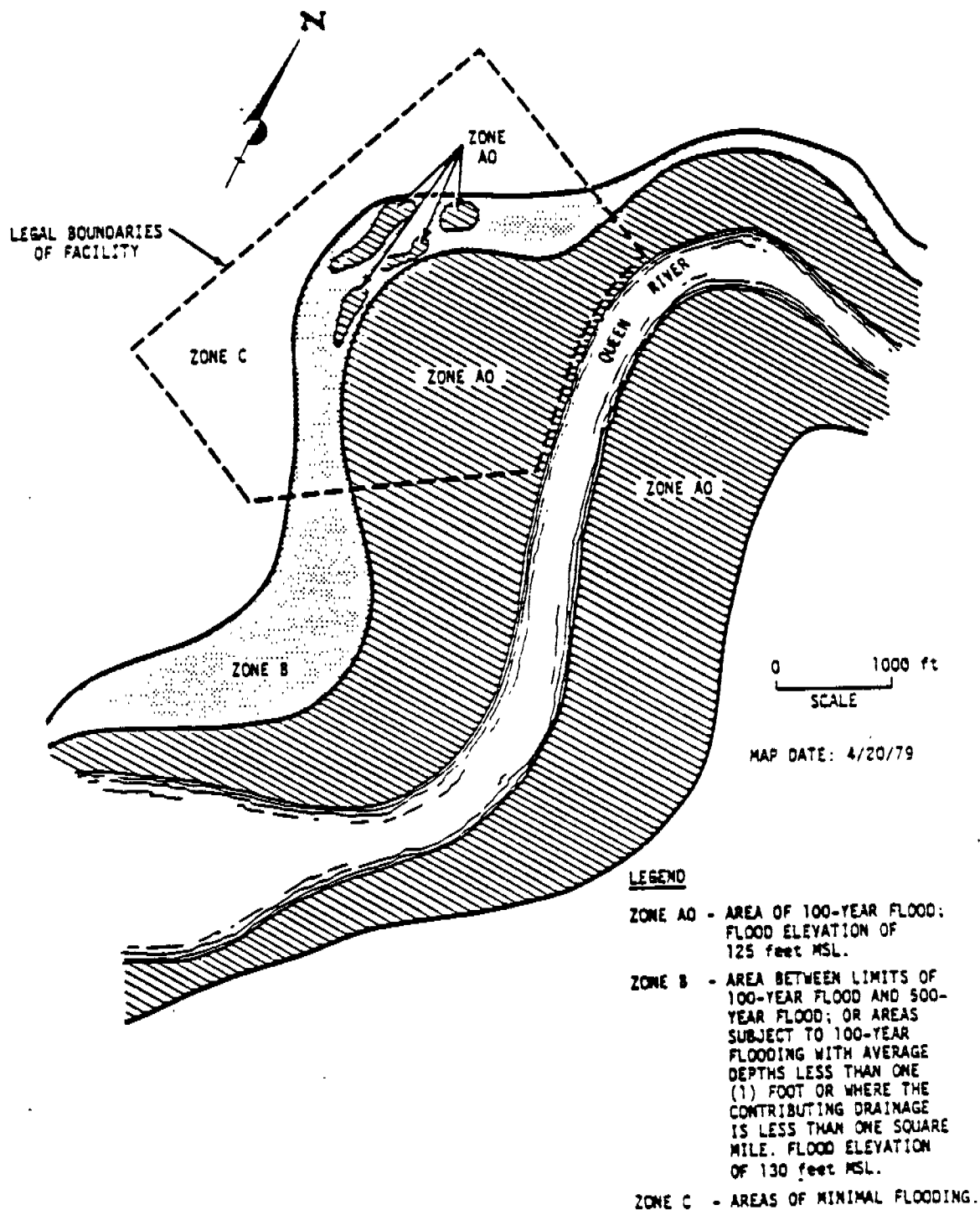


Figure 9. Federal Insurance Administration (FIA) 100-year floodplain map.

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area is subject to floods, the closed drums would be contained by the fence should a flood occur. In the event of a 100-year flood, the drums will be removed to a disposal facility.

B-10.1)(b) Flood Plan

The container storage area located in the east corner of the property, in zone AO, is in the 100-year floodplain. In the event of a 100-year flood, the drums will be moved by Hazardous Spills Cleaned (OSC), Inc. (EPA I.D. No. RI000000000) 1200 East Twelfth Street, Anytown, Rhode Island to Ace Storage, Inc., 4700 West Eleventh Street, Anytown Rhode Island (EPA I.D. No. RI009899999).

Tankopile has contracted with OSC, Inc., a firm that specializes in hazardous waste transport and hazardous spill cleanup activities. Tankopile has entered into a contractual agreement with OSC that guarantees that OSC will have the necessary personnel and equipment available to move our waste to Ace Storage within 4 hours notice. The contractual agreement is available at the facility for review. OSC will move the palletized drums by fork-lift truck onto a flat-bed truck, which will transport the drums 3 miles to Ace Storage. OSC has entered into a contractual agreement with Ace Storage that states that they will accept the Tankopile waste within 3 hours' notice.

It is estimated that it would take 8 hours to move 100 drums (4 per pallet), which is well within the warning time before the occurrence of a 100-year flood.

Some small likelihood of a potential accident is possible when moving the drums from the storage area and loading them onto the flat-bed trucks. Therefore, Tankopile's emergency coordinator will be responsible for ensuring that the contractor personnel follow all necessary safety procedures.

B-3b(2) Plan for Future Compliance

The waste pile currently located in the east corner of the property, in Zone AO, would be subject to washout should a 100-year flood occur. Plans are being completed for constructing a storage area for the waste pile in the northernmost corner of the property along the eastern boundary. This is a Zone C area, not subject to flooding (100-yr). The planned waste pile storage area will be constructed according to the production schedule provided in Table 2 and will meet the same design specifications as the existing waste pile storage area. Moving the waste pile from its current location will prevent material washout from the pile due to flooding. (See Section D-3a for design of waste pile.) The old waste pile will be closed in accordance with the procedures specified in the closure plan.

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TABLE 1 WASTE PILE CONSTRUCTION SCHEDULE

Item	Date of completion
Begin construction	March 1, 1982
Ground water table control system	March 25, 1982
Leachate collection system	April 15, 1982
Foundation	April 23, 1982
Liner	April 30, 1982
Leachate and runoff collection system	May 14, 1982
Base	May 21, 1982
Run-on diversion ditch	June 7, 1982
Begin receiving wastes	June 15, 1982

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This facility will be in compliance with 40 CFR Section 264.18(b) by June 1983 when the waste pile is moved to a nonflooding area.

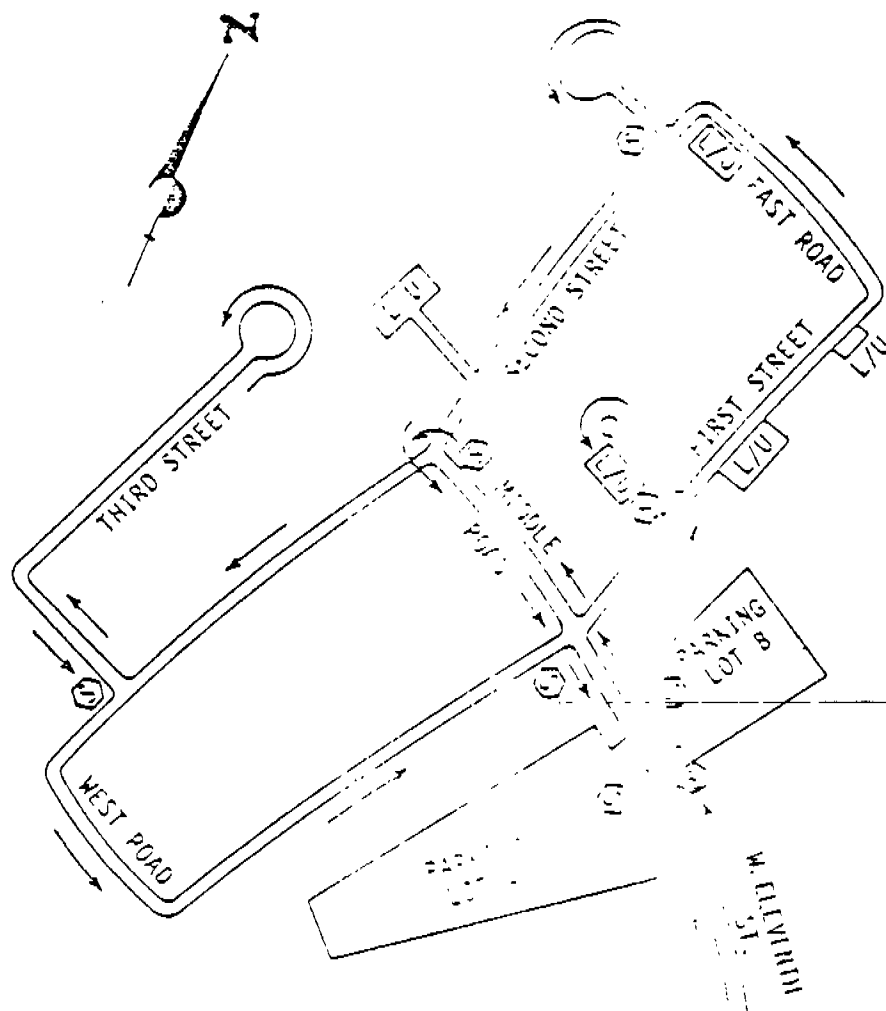
B-4 Traffic Patterns [40 CFR 122.25(a)(10)]

Access to Tankopile Finishing Company is from Interstate 95 to State Highway 102 east and right on River Road. After a distance of approximately 5 miles on River Road, a left-hand turn is made at West Eleventh Street, and the plant entrance is on the left about 1/2 mile from the intersection.

Figure 10 shows the onsite traffic pattern. The main road, parking lots, and dead-end roads are two-way; the two main loops within the property are one-way. Most cars are confined to the parking lot and entrance road. Within the plant, traffic vehicles consist mostly of front-end loaders and trucks. About five semitrailers enter the plant each day. Four front-end loaders are used throughout the plant on a constant basis; and two additional front-end loaders are used as needed.

Traffic Control: Traffic is controlled by one-way direction and stop signs. These are also indicated in Figure 10.

Access Road Surfacing: All roads are constructed of 5 in. of bituminous concrete pavement (blacktop), composed of 3½ in. of bituminous concrete base material and 1½ in. of bituminous concrete surface material; this overlays 9 in. of compacted aggregate base.



- (S) STOP SIGN
- (L/U) LOADING/UNLOADING AREA

Figure 10. Traffic Flow (not to scale).

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Load-Bearing Capacity: All roads are capable of bearing loads up to 50,000 pounds per axle. The bulk tanker truck used to remove inventory from the tank storage area has a curb weight of 28,000 lbs. Assuming removal of 7,500 gal from either of the storage tanks, the tanker will weigh approximately 91,000 lbs. The flatbed truck used to remove drums from the facility has a curb weight of 30,000 lbs. Assuming removal of 100 drums at 500 lbs/drum, the loaded flatbed truck will weigh about 80,000 lbs. Therefore, the facility roads can bear the weight of the trucks.

Traffic Control Signals: Not applicable.

SECTION C
WASTE CHARACTERISTICS

This section describes the chemical and physical nature of the hazardous wastes stored at the Tankopile facility and the Waste Analysis Plan for sampling, testing, and evaluating the wastes to assure that sufficient information is available for their safe handling. The information submitted is in accordance with the requirements of 40 CFR §122.25(a)(2) and (3).

C-1 Chemical and Physical Analyses [40 CFR 122.25(a)(2)]

List of Hazardous Wastes Stored at Facility: Hazardous wastes are stored at this facility in 55-gallon drum containers, 7500-gallon tanks, and a waste pile. Current inventory consists of

100 containers (55-gallon drums)
Two 7500-gallon tanks
One 50-yd³ waste pile

The containers (55-gallon drums) can be broadly classified into Group A, B, and C containers grouped separately due to incompatibility of the wastes. The contents of each group are listed below:

Group A	Yellow drums	Pickle liquor sludge (D001, D007, and D008)
Group B	Blue drums	Metal grindings (D007 and D008)

Group C White drums Vinyl acetate sludge (D001)
 Vinyl chloride sludge (D001)

The pickle liquor sludge is corrosive, and it is toxic because of its extractable lead and hexavalent chromium content. The vinyl acetate and vinyl chloride sludges are ignitable; both have flash points below 60°F. The metal grindings are toxic; they contain large amounts of extractable lead and hexavalent chromium.

Spent pickle liquor [hydrochloric acid (HCl)] and spent 1,1,1-trichloroethane solvent (also referred to as methyl chloroform) that have become contaminated and diluted through use in metal cleaning and finishing operations are stored separately in tanks. Spent pickle liquor is a listed hazardous waste, assigned hazardous waste number K062 (40 CFR 261.32) because of its corrosivity and EP toxicity. It is corrosive because it has a pH of less than 2; it is toxic because of its extractable hexavalent chromium and lead content. The 1,1,1-trichloroethane is also a listed hazardous waste, assigned number F001 (40 CFR 261.31) because of its toxicity.

A 50-yd³ (maximum) waste pile is used to store metal hydroxide sludges which are toxic due to their extractable lead and hexavalent chromium content. The EPA hazardous waste numbers assigned to these sludges are D007 and D008.

Waste Analyses: Table 3 lists the hazardous wastes stored

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TABLE 3
WASTES, ASSOCIATED HAZARDS, AND BASIS FOR HAZARD DESIGNATION

Chemical	Hazard	Basis for hazard designation
<u>Tanks</u>		
Pickle liquor (hydrochloric acid)	Corrosive, Toxic	Listed waste K062 has pH of 1 EP toxic, lead and hexavalent chromium
1,1,1-trichloroethane	Toxic	Listed waste F001
<u>Drums</u>		
Vinyl acetate sludge	Ignitable	Flash point of pure vinyl acetate is 19°F. Tested flash point for waste is 25°F.
Vinyl chloride sludge	Ignitable	Flash point of pure vinyl chloride is -108°F. Tested flash point for waste is 6°F.
Pickle liquor sludge	Corrosive, Toxic	Has pH of 1; EP toxic, lead and hexavalent chromium
Metal grindings	Toxic	EP toxic, lead and hexavalent chromium
<u>Waste pile</u>		
Metal hydroxide sludge	Toxic	EP toxic, lead and hexavalent chromium

at the Tankopile facility, their associated hazard classification, and the basis for the hazard classification. In most cases the classification is based on known characteristics of the wastes, such as ignitability, reactivity, corrosivity, or EP toxicity analyses. For listed wastes, the classification is based on the listing. Figures 11 through 17 show the waste analysis results.

Waste Handling: All wastes (except those in the waste pile) are labeled; the label describes the contents of each tank or container and its associated hazard (corrosivity, toxicity, or ignitability). This practice informs workers handling these wastes of the associated hazards so that appropriate precautions can be taken. Details regarding the tanks, containers, storage areas, and personnel training are presented in other sections of this application. General information and hazardous characteristics of the waste types are included in Appendix A.

C-2 Waste Analysis Plan [40 CFR 122.25(a)(3)]

C-2a Parameters and Rationale

Table 4 shows the hazardous wastes stored at the facility, the analytical parameters that apply to each, and the rationale for their selection.

C-2b Test Methods

Table 5 shows the test methods that are used to measure the analytical parameters. All test methods are from Test

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LABORATORY DATA

CLIENT Pinkerton ANALYSIS 1,1,1-trichloroethane
 RN 4000 DATE 1/4/82 METHOD NUMBER 808
 ANALYST E. Small CHECKER _____

[illegible]

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Figure 11. Laboratory analysis results - 1,1,1-Trichloroethane.

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RCRA HAZARD ASSESSMENT TEST REPORT

Client: Tankopile Finishing Company PN: 4000
Sample ID: 4601 (pickle liquor)
PEDCO Lab No.: CF 103 Date Received: 12/1/81 Date Reported: 1/12/82

1261.21 IGNITABILITY

Flash point _____ °F (Max. allowed 140°F)

1261.22 CORROSIVITY

pH 1.0 (2 < pH < 12.5 allowed)
NACE corrosion rate _____ mm/yr (Max. allowed 6.35 mm/yr)

1261.23 REACTIVITY

Acid labile cyanide _____
Acid labile sulfide _____

1261.24 EF TOXICITY

Sample type: Solid _____ Semisolid _____ Liquid X
If liquid or semisolid, non-filterable solids = 2 %

NOTE: If sample contains less than 0.5% nonfilterable solids,
the filtrate is the extract.

Analytical Results

Values are concentrations of constituent in extract.

Constituent	Concentration, mg/l	Maximum concentration allowed, mg/l
Arsenic	<0.01	5.0
Barium	<0.01	100.0
Cadmium	0.2	1.0
Chromium, total	86.0	5.0
Chromium, hexavalent	64.0	5.0
Lead	10.0	5.0
Mercury	<0.001	0.2
Selenium	<0.01	1.0
Silver	<0.001	5.0
Endrin	_____	0.02
Lindane	_____	0.4
Methoxychlor	_____	10.0
Toxaphene	_____	0.5
2,4-D	_____	10.0
2,4,5-TP	_____	1.0

PEDCO Environmental, Inc. Submitted by: _____

Figure 12. Laboratory analysis results for pickle liquor.

Q

FOIA b(7)(D) APPLICABLE TO THIS REPORT

Client: Easton's Electronics Company PN: 4000
Sample ID: 1000 (normal controls checked)
PEDCO Lab No.: 07-001 Date Received: 12/17/92 Date Reported: 1/17/93

1261.21 IDENTIFIITYFlash point 25 °F (Max. allowed 140°F)

1261.22 CORROSIVITY

pH _____ (2 < pH < 12.5 allowed)
 HACE corrosion rate _____ mm/yr (Max. allowed 6.35 mm/yr)

§261.23 REACTIVITY

Acid labile cyanide _____
Acid labile sulfide _____

J261.24 EP TOXICITY

Sample type: Solid _____ Semisolid _____ Liquid _____
If liquid or semisolid, non-filterable solids = _____

NOTE: If sample contains less than 0.5% nonfiltrable solids, the filtrate is the extract.

Analytical Results

Values are concentrations of constituent in extract.

Constituent	Concentration, mg/l	Maximum concentration allowed, mg/l
Arsenic	_____	5.0
Barium	_____	100.0
Cadmium	_____	1.0
Chromium, total	_____	5.0
Chromium, hexavalent	_____	5.0
Lead	_____	5.0
Mercury	_____	0.2
Selenium	_____	1.0
Silver	_____	5.0
Endrin	_____	0.02
Lindane	_____	0.4
Methoxychlor	_____	10.0
Toxaphene	_____	0.5
2,4-D	_____	10.0
2,4,5-TP	_____	1.0

DDCC Environmental, Inc. Submitted by: _____

Figure 13. Laboratory analysis results for vinyl acetate sludge.

C

RCRA HAZARD ASSESSMENT TEST REPORT

Client: Tankonile Finishing Company PN: 4000
Sample ID: 4662 (vinyl chloride sludge)
Penco Lab No.: CF 105 Date Received: 12/1/81 Date Reported: 1/12/82

1261.21 IGNITABILITY

Flash point 6 °F (Max. allowed 140°F)

§261.22 CORROSIVITY

PH (2 < pH < 12.5 allowed)
 NaCl corrosion rate mm/yr (Max. allowed 6.35 mm/yr)

§261.23 REACTIVITY

Acid labile cyanide _____
Acid labile sulfide _____

1261.24 EP TOXICITY

Sample type: Solid _____ Semisolid _____ Liquid _____
If liquid or semisolid, non-filterable solids = _____

NOTE: If sample contains less than 0.5% nonfiltrable solids, the filtrate is the extract.

Analytical Results

Values are concentrations of constituent in extract.

Constituent	Concentration, mg/l	Maximum concentration allowed, mg/l
Arsenic	_____	5.0
Barium	_____	100.0
Cadmium	_____	1.0
Chromium, total	_____	5.0
Chromium, hexavalent	_____	5.0
Lead	_____	5.0
Mercury	_____	0.2
Selenium	_____	1.0
Silver	_____	5.0
Endrin	_____	0.02
Lindane	_____	0.4
Methoxychlor	_____	10.0
Toxaphene	_____	0.5
2,4-D	_____	10.0
2,4,5-TP	_____	1.0

FEDCO Environmental, Inc. Submitted by: _____

Figure 14. Laboratory analysis results for vinyl chloride sludge.

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RCRA HAZARD ASSESSMENT TEST REPORT

Client: Tanpopple Finishing Company PN: 4000
Sample ID: test pickle liquor sludge
PEDCO Lab No.: 05-103 Date Received: 12/1/81 Date Reported: 1/11/82

1261.21 IGNITABILITY

Flash point _____ °F (Max. allowed 140°F)

1261.22 CORROSIVITY

pH 1.3 (2 < pH < 12.5 allowed)
NACE corrosion rate _____ mm/yr (Max. allowed 6.35 mm/yr)

1261.23 REACTIVITY

Acid labile cyanide _____
Acid labile sulfide _____

1261.24 EP TOXICITY

Sample type: Solid _____ Semisolid X Liquid _____
If liquid or semisolid, non-filterable solids = NA

NOTE: If sample contains less than 0.5% nonfilterable solids,
the filtrate is the extract.

Analytical Results

Values are concentrations of constituent in extract.

Constituent	Concentration, mg/l	Maximum concentration allowed, mg/l
Arsenic	<0.01	5.0
Barium	<0.01	100.0
Cadmium	<0.01	1.0
Chromium, total	<0.01	5.0
Chromium, hexavalent	<0.01	5.0
Lead	<0.01	5.0
Mercury	<0.001	0.2
Selenium	<0.01	1.0
Silver	<0.001	5.0
Endrin	_____	0.02
Lindane	_____	0.4
Methoxychlor	_____	10.0
Toxaphene	_____	0.5
2,4-D	_____	10.0
2,4,5-TP	_____	1.0

PEDCO Environmental, Inc. Submitted By: _____

Figure 15. Laboratory analysis results for pickle liquor
sludge.

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RCRA HAZARD ASSESSMENT TEST REPORT

Client: Tankopile Finishing Company PW: 4000
Sample ID: 4605 (metal grinding)
PEDCo Lab No.: CF 107 Date Received: 12/1/81 Date Reported: 1/13/82

1261.21 IGNITABILITY

Flash point _____ °F (Max. allowed 140°F)

1261.22 CORROSIVITY

pH _____ (2 < pH < 12.5 allowed)
NACE corrosion rate _____ mm/yr (Max. allowed 6.35 mm/yr)

1261.23 REACTIVITY

Acid labile cyanide _____
Acid labile sulfide _____

1261.24 EP TOXICITY

Sample type: Solid X Semisolid _____ Liquid _____
If liquid or semisolid, non-filterable solids = _____

NOTE: If sample contains less than 0.5% nonfilterable solids,
the filtrate is the extract.

Analytical Results

Values are concentrations of constituent in extract.

Constituent	Concentration, mg/l	Maximum concentration allowed, mg/l
Arsenic	<0.01	5.0
Barium	<0.01	100.0
Cadmium	0.6	1.0
Chromium, total	98.3	5.0
Chromium, hexavalent	85.6	5.0
Lead	52.1	5.0
Mercury	<0.001	0.2
Selenium	<0.01	1.0
Silver	<0.001	5.0
Endrin	_____	0.02
Lindane	_____	0.4
Methoxychlor	_____	10.0
Toxaphene	_____	0.5
2,4-D	_____	10.0
2,4,5-TF	_____	1.0

PEDCo Environmental, Inc. Submitted by: _____

Figure 16. Laboratory analysis results for metal grindings.

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RCRA HAZARD ASSESSMENT TEST REPORT

Client: Tankcoile Finishing Company PN: 4000
Sample ID: 4000 Metal Hydroxide Sludge
PEDCO Lab No.: 01108 Date Received: 12/1/81 Data Reported: 1/11/82

1261.21 IGNITABILITY

Flash point _____ °F (Max. allowed 140°F)

1261.22 CORROSIVITY

pH _____ (2 < pH < 12.5 allowed)
NACE corrosion rate _____ mm/yr (Max. allowed 6.35 mm/yr)

1261.23 REACTIVITY

Acid labile cyanide _____
Acid labile sulfide _____

1261.24 EP TOXICITY

Sample type: Solid _____ Semisolid X Liquid _____
If liquid or semisolid, non-filterable solids = _____

NOTE: If sample contains less than 0.5% nonfilterable solids,
the filtrate is the extract.

Analytical Results

Values are concentrations of constituent in extract.

Constituent	Concentration, mg/l	Maximum concentration allowed, mg/l
Arsenic	<0.01	5.0
Barium	<0.01	100.0
Cadmium	<0.01	1.0
Chromium, total	<0.01	5.0
Chromium, hexavalent	<0.01	5.0
Lead	<0.01	5.0
Mercury	<0.01	0.2
Selenium	<0.01	1.0
Silver	<0.01	5.0
Endrin	_____	0.02
Lindane	_____	0.4
Methoxychlor	_____	10.0
Toxaphene	_____	0.5
2,4-D	_____	10.0
2,4,5-TP	_____	1.0

PEDCO Environmental, Inc. Submitted By: _____

Figure 17. Laboratory analysis results for metal hydroxide sludge.

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TABLE 4
PARAMETERS AND RATIONALE FOR THEIR SELECTION

Hazardous waste	Parameter	Rationale
Pickle liquor (hydrochloric acid)	pH, EP toxicity (Pb, Cr ⁺⁶)	The waste is a listed hazardous waste (K062) due to its toxicity (lead and hexavalent chromium) and due to its corrosivity (pH <2).
1,1,1-trichloroethane	1,1,1- trichloro- ethane	This is a listed toxic waste (F001). There is no reason to believe this waste will contain any other toxic constituents in significant concentrations.
Vinyl acetate sludge	Flash point	This waste is ignitable. Practical grade vinyl acetate has a flash point of 18°F. Knowledge of this value helps to ensure the safe handling of these wastes.
Vinyl chloride sludge	Flash point	The waste is ignitable. Practical grade vinyl chloride has a flash point of -108°F. Knowledge of this value helps to ensure the safe handling of these wastes.
Pickle liquor sludge	pH, EP toxicity (Pb, Cr ⁺⁶)	The waste has an estimated pH value of less than 2, making it a corrosive waste. Also it may contain toxic levels of lead and hexavalent chromium.
Metal grindings	EP toxicity (Pb, Cr ⁺⁶)	The grindings contain lead and hexavalent chromium compounds.
Metal hydroxide sludge	EP toxicity (Pb, Cr ⁺⁶)	The sludge contains lead and hexavalent chromium compounds.

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TABLE 5
PARAMETERS AND TEST METHODS

Parameter	Test method	Reference
pH	Electrometric	Test Methods for Evaluating Solid Waste. Physical/Chemical Methods U.S. EPA SW-846
Flash point	Pensky-Martens closed-cap tester	ASTM Standard D-93-79 or D-93-80
EP toxicity	EP toxicity test procedure	40 CFR 261, Appendix II
1,1,1-trichloroethane	GC/FID	Test Methods for Evaluating Solid Waste. Physical/Chemical Methods U.S. EPA SW 846.
Lead	Atomic absorption	Methods for chemical analysis of water and wastes, EPA-600/4-79/020, March 1979.
Chromium	Atomic absorption	Methods for chemical analysis of water and wastes EPA-600/4-79/020 March 1979

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Methods for Evaluating Solid Waste, Physical/Chemical Methods (EPA Office of Water and Waste Management, SW-846, 1980), or other EPA-approved methods.

C-2c Sampling Methods

Table 6 lists the hazardous wastes stored at the facility and the methods used to sample each.

C-2d Frequency of Analyses

As Table 7 shows, each waste is analyzed yearly. Because wastes generated at this facility do not change significantly, this minimum frequency will continue as long as the quality control program indicates that the products are within 1 percent of specifications. Additional analyses will be performed if a process change should affect the hazardous characteristics of a waste. These analyses will be conducted at the discretion of the plant manager or the regulatory agency.

C-2e Additional Requirements for Waste Generated Offsite

This facility only handles on-site generated wastes; therefore, requirements for wastes received from off-site generators do not apply.

TABLE 6
METHODS USED TO SAMPLE HAZARDOUS WASTES

Hazardous waste	Sampling method	Description of sampling	Reference for sampler
Pickle liquor	Sampling a Storage Tank from "Samplers and Sampling Procedures for Hazardous Waste Streams," EPA-600/2-80-018, page 38, which appears in reference for sampler	Composite sample using a Coliwasa sampler from 3 grab samples at top, middle, and bottom of tank	Test Methods for the Evaluation of Solid Waste. Physical/Chemical Methods EPA-SW-846
1,1,1-trichloroethane	Sampling a Storage Tank from "Samplers and Sampling Procedures for Hazardous Waste Streams," EPA-600/2-80-018, page 38, which appears in reference for sampler	Composite sample using a Coliwasa sampler from 3 grab samples at top, middle, and bottom of tank	Test Methods for the Evaluation of Solid Waste. Physical/Chemical Methods EPA-SW-846
Vinyl acetate sludge	ASTM Standard D346-75. Soil or rock-like material	Representative composite sample from 3 grab samples at top, middle, and bottom of drum using a split tube thief sampler	Test Methods for the Evaluation of Solid Waste. Physical/Chemical Methods, EPA-SW-846 Section 3.2.4
Vinyl chloride sludge	ASTM Standard D346-75. Soil or rock-like material	Representative composite sample from 3 grab samples at top, middle, and bottom of drum using a split tube thief samplers	Test Methods for the Evaluation of Solid Waste. Physical/Chemical Methods, EPA-SW-846 Section 3.2.4

(continued)

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TABLE 4 (continued)

Hazardous waste	Sampling method	Description of sampling	Reference for sampler
Pickle liquor sludge	ASTM Standard D46-75. Soil or rock-like material	Representative composite sample from 3 grab samples at top, middle, and bottom of drum using a split tube thief sampler	Test Methods for the Evaluation of Solid Waste. Physical/Chemical Methods, EPA-SW-846 Section 3.2.4
Metal grindings	ASTM Standard D140-70. Crushed or powdered material	Representative composite sample from 3 grab samples at top, middle, and bottom of drum using a Trier scoop	Test Methods for the Evaluation of Solid Waste. Physical/Chemical Methods, EPA-SW-846 Section 3.2.5
Metal hydroxide sludge	ASTM Standard D346-75. Soil or rock-like material	Composite sample using a Trier scoop from 6 grab samples through three different points near the top of the pile to points diagonally opposite the point of entry	Test Methods for the Evaluation of Solid Waste. Physical/Chemical Methods, EPA-SW-846 Section 3.2.5

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TABLE 7
FREQUENCY OF ANALYSIS

Hazardous waste	Analysis	Frequency
Pickle liquor (hydrochloric acid)	pH, EP toxicity (Pb, Cr)	Annually
1,1,1-trichloroethane	1,1,1-trichloro- ethane	Annually
Vinyl acetate sludge	Flash point	Annually
Vinyl chloride sludge	Flash point	Annually
Pickle liquor sludge	pH, EP toxicity (Pb, Cr)	Annually
Metal grindings	EP toxicity (Pb, Cr)	Annually
Metal hydroxide sludge	EP toxicity (Pb, Cr)	Annually

SECTION D
PROCESS INFORMATION

The information provided in this section is submitted in accordance with the requirements of 40 CFR Part 122.25(b)(1), (2) and (4). Other regulations addressed to complete this section include 40 CFR §264.17, §264.175, §264.176, §264.177, §264.191, §264.192, §264.198, §264.199, §264.252, §264.253, §264.256, and §264.257.

This section discusses specific process information for the storage of containers, tanks, and waste piles. The Tankopile Finishing Company has a 1125-ft² container storage area, two 7500-gallon storage tanks, and one 50-yd³ waste pile. The waste pile containment system, container storage area, and tank storage area designs and specifications were all certified by a registered professional engineer.

D-1 Containers [40 CFR 122.25(b)(1)]

D-1a Containers

The maximum inventory of drums in storage at any given time during the operating life of the facility is not expected to exceed 100 drums. The container storage area, which is located outdoors at the northeast end of the facility, currently holds this amount. Drummed waste includes vinyl

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acetate sludge, vinyl chloride sludge, pickle liquor sludge, and metal grindings, all of which contain free liquids. Consequently, specific information provided in this section will follow a format required for containers storing free liquids.

There is 1125 ft² in the container storage area, 225 ft² for ramp areas providing forklift access to each of the storage sections, 27 ft² for sump areas, and 469 ft² for aisle space. The remaining 404 ft² is actual storage area, and is divided into three sections (storage areas A, B, and C) separated by curbs to permit the storage of incompatible wastes. A plan view and cross-sectional view of the container storage area is provided in Figures 18 and 19. Storage areas A, B, and C presently hold 44, 34, and 22 drums, respectively. Stacked three drums high, storage areas A, B, and C have the capacity to hold as many as 210, 102, and 51 drums, respectively, or a total of 363 drums, however 100 drums or less are stored in this area at any given time.

D-1a(1) Description of Containers

Steel 55-gallon drums are used at the facility to store the wastes listed above in D-1a. The drums are color coded and constructed of low carbon steel that meets U.S. Department of Transportation Specification No. 17C. The ignitable vinyl acetate and vinyl chloride sludges are contained in drums painted white to reflect solar heat as a possible

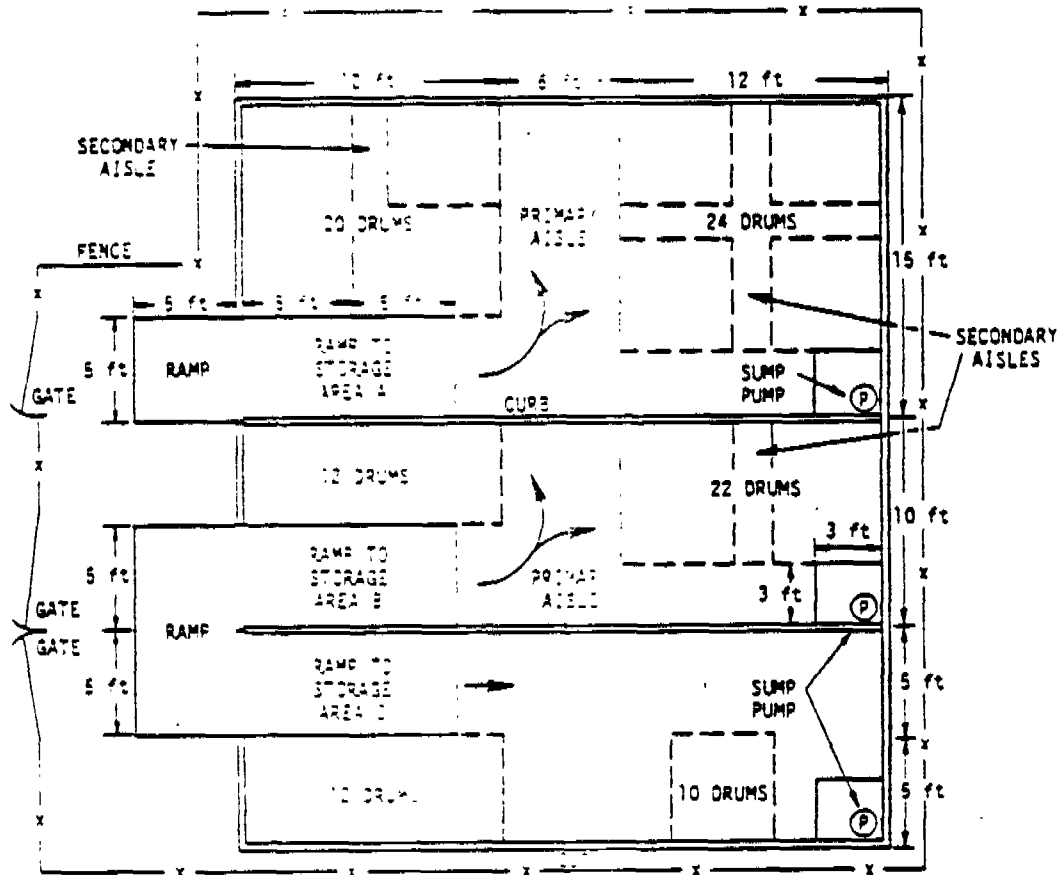
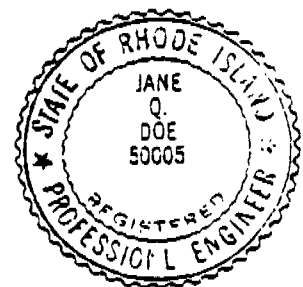


Figure 13. Plan view of container storage area.



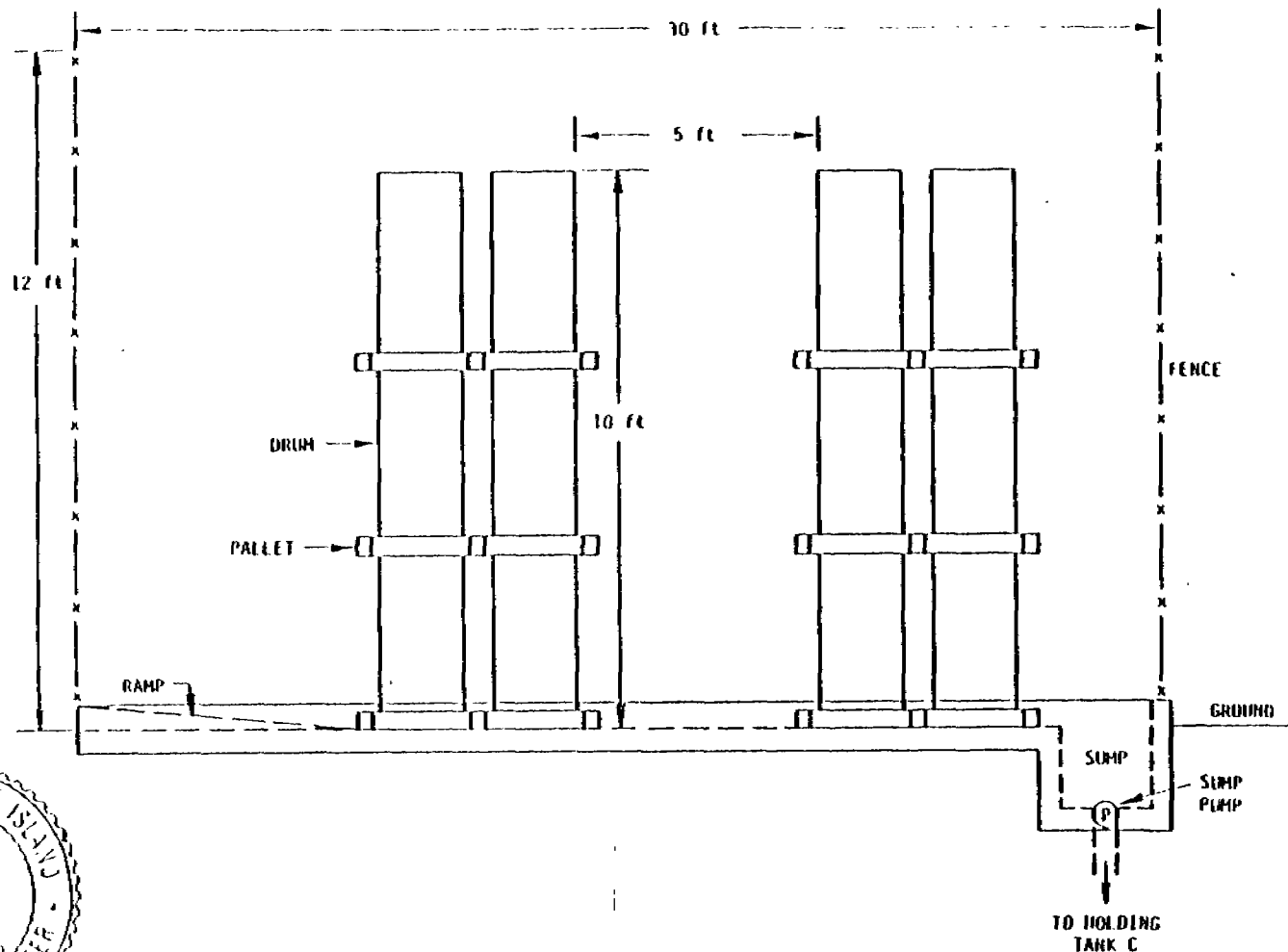


Figure 19. Cross-sectional view of container storage area.



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ignition source. These drums are protected against corrosion by epoxy phenolic linings. Yellow drums are used to store pickle liquor sludge are equipped with polyethylene liners. Blue drums used to store metal grindings do not require a liner for chemical protection.

D-1a(2) Container Management Practices

Prior to transfer to the container storage area, sludge and grinding wastes generated in the processing area are placed in the proper color-coded drums, sealed, and labeled according to Department of Transportation regulations for hazardous materials. Transfer of drums to the container storage area is performed by a forklift truck. The forklift operator accesses the storage area with a key and places the yellow (corrosive sludge) drums in storage area A, the blue (toxic metal grindings) drums in storage area B, and the white (ignitable sludges) drums in storage area C. During the transfer of drums from the process area to the container storage area, the yellow, blue, and white drums are always transferred separately from the other colors because of their incompatibility. At Tankopile there are no sources of ignition such as an open flame.

The drums are stored on pallets to elevate them from contact with standing liquids, and if necessary, the drums are stacked as high as 12 ft (3 drums). Primary aisle space of at least 5 ft is maintained at all times, and the container storage area is inspected regularly (see Section F-2).

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D-1a(3) Secondary Containment System Design and Operation

The container storage area pad is constructed of concrete, designed for loads of 25 lb/in². A 6-in.-high concrete curb lines the perimeter of the storage area to provide a holding capacity of 3276 gallons, or more than 50 percent of the total volume held by the estimated maximum inventory. Below are the calculations involved in determining holding capacity:

$$1125 \text{ ft}^2 - 225 \text{ ft}^2 \text{ (ramp areas)} = 875 \text{ ft}^2$$

$$750 \text{ ft}^2 \times 0.5 \text{ ft (curb height)} = 443 \text{ ft}^3$$

$$1 \text{ ft}^3 = 7.48 \text{ gal}$$

$$438 \text{ ft}^3 \times 7.48 \text{ gal} = 3276 \text{ gal}$$

The concrete pad is presently in good condition, free of any gaps holes or cracks. The concrete pad in area A is specially coated with epoxy to prevent damage in the event of a spill. Two other 6-in. curbs within the storage area were constructed as partitions to permit the storage of incompatible wastes in the same storage area. The base of the storage area is constructed of 6-in.-thick concrete, and the surface in each storage section is sloped 2 percent towards its respective sump area.

The pad will be regularly inspected as discussed in Section F-2 to ensure that it remains impervious and in good condition. Automatic sump pumps activated by level switches are installed in each of the sump areas. The pumps operate at 32 gallons per minute sending collected liquids to three

separate secondary holding tanks (see Section D-1a(4)). This prevents any possible overflow of the collection system from precipitation, leaks, or spills. To date, the secondary containment system has been able to hold rainfall from the most severe thunderstorms without risk of rising above the curb.

Run-on is prevented from entering the containment area by several means. Besides the presence of a 6-in. curb at the perimeter of the storage area, the land immediately surrounding the containment area is graded to encourage drainage away from the area. In addition, drain tiles at the perimeter of the containment curb drain any collected water to the sewer system.

A 12-ft-high, chain-link fence with two lockable gates was installed to ensure safety and security (Figure 18).

D-1a(4) Removal of Liquids From Collection System

Storage areas A, B, and C have separate sump areas and sump pumps to allow for the removal of any leaks or spills to three secondary holding tanks located just west of the processing area (Figure 4). A 10,000-gallon holding tank receives precipitation, leaks, or spills from storage area A, a 35,000-gallon holding tank receives discharges from storage area B and leachate runoff from the waste pile area, and a 5,000-gallon holding tank receives discharges from storage area C. These collection systems were designed

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to handle the maximum 24-hour rainfall recorded in Anytown (in 24 years). Discharges remain in the holding tanks until laboratory analyses indicate whether they are either hazardous or acceptable for release to the municipal sewer system. If laboratory analyses indicate that a holding tank contains hazardous waste, the material will be removed from the tank, drummed, labeled, and transferred to the appropriate container storage (A, B, or C).

D-1b Containers Without Free Liquids

The Tankopile Finishing Company does not currently manage containers without free liquids. Therefore, Permit Application Sections D-1b, D-1b(1), D-1b(2), D-1b(3), and D-1b(4) are not applicable.

D-2 Tanks [40 CFR 122.25(b)(2)]

D-2a Description of Tanks

Two 7500-gallon vertical tanks with a total holding capacity of 15,000 gallons provide storage for wastes generated from the degreasing, painting, and metal finishing operations. The two storage tanks, designated as ST-101 and ST-102, contain spent hydrochloric acid (pickle liquor) and 1,1,1-trichloroethane solvent, respectively (Figure 20). The pickle liquor waste has a specific gravity of 1.0507, and the 1,1,1-trichloroethane solvent waste has a specific gravity of 1.299. Both tanks have been fabricated and stamped in accordance with ASME Code Section VIII, 1971. Table 8 gives the individual tank dimensions and capacities.

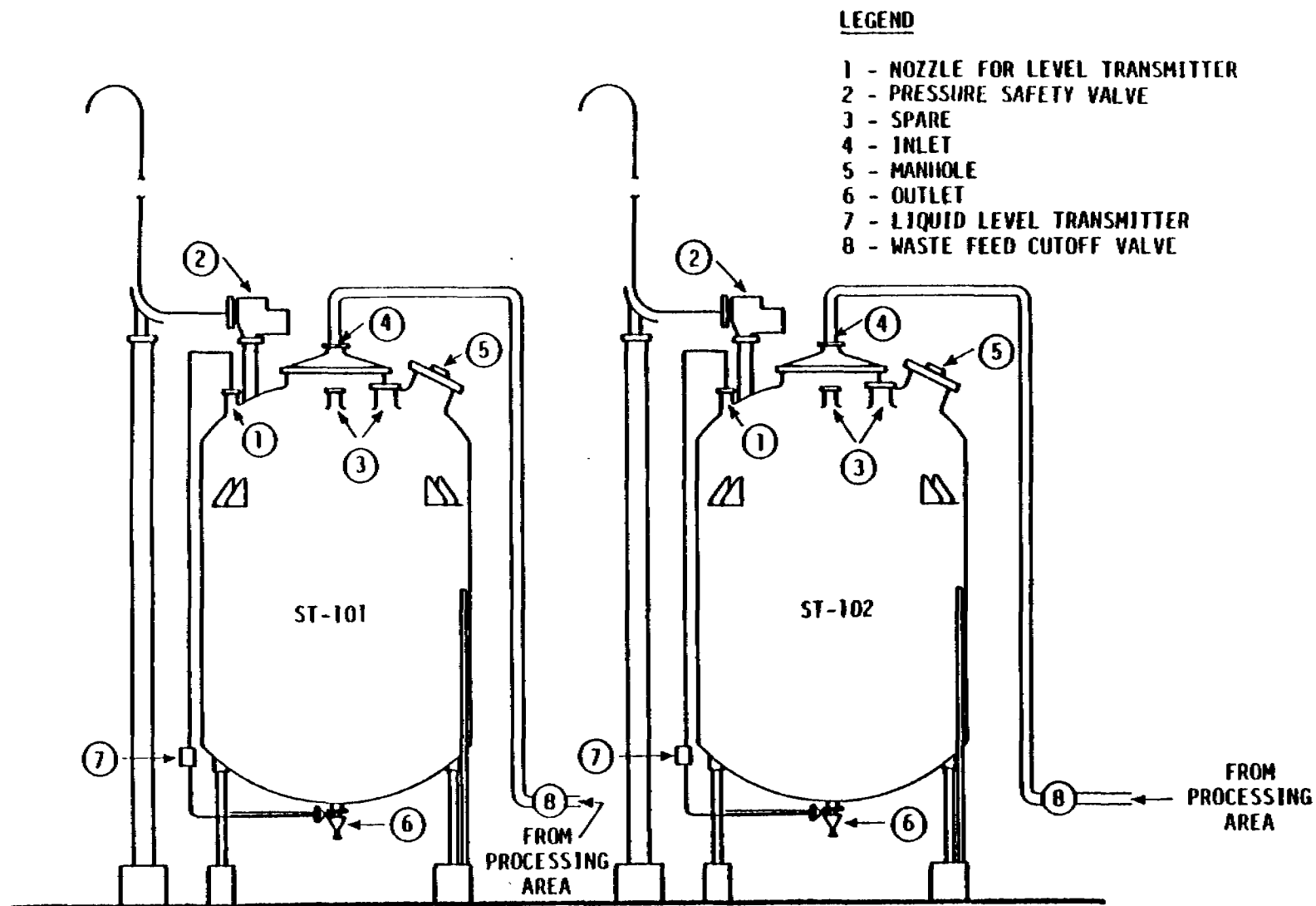


Figure 20. Waste storage tanks.

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TABLE 8
PHYSICAL CHARACTERISTICS OF STORAGE TANKS

Item	Tank identification No.	
	ST-101	ST-102
Capacity, gal	7500	7500
Shell thickness, in. (design)	0.703	0.703
Shell thickness, in. (present)	0.699	0.700
Dimensions, in.		
Straight side	200.4	200.4
Diameter	118.1	118.1

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The shells of Tanks ST-101 and ST-102 are constructed of standard A285 Grade B carbon steel (0.22% carbon) with a tensile strength of 50,000 to 70,000 psi.

Each tank is structurally supported in eight equally spaced locations on the concrete slab. The supports are raised 6 in., and each is secured to the slab by four No. 4 rods with three No. 3 ties. The tanks are secured to supports with 4-3/4-in. Type AB-3 anchor bolts. Tanks ST-101 and ST-102 are both equipped with an 18-in. manhole, a conservation vent, a liquid level transmitter, an inlet and outlet, and spare nozzles. The pad is designed for loads of 250 lb/in².

D-2b Tank Corrosion and Erosion

Storage tanks ST-101 and ST-102 are glass-lined (3/32-inch or 2 mm) for chemical and corrosion resistance. Glass-lined tanks have been shown to be very resistant to a variety of chemicals in a wide range of concentrations, including hydrochloric acid. Furthermore, water absorption is minimal, and organic liquids such as 1,1,1-trichloroethane produce no measurable chemical effect on the glass lining. According to manufacturer specifications, glass linings exposed to boiling hydrochloric acid solutions (20 percent) exhibit low corrosion rates of 0.01626 and 0.02108 mm/yr. At the range of rates, the expected lifetime for a 0.91 mm thick lining would be 43 to 56 years. Since Tankopile's tanks

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are lined with 2 mm of glass, their expected lifetime is roughly 90 - 120 years.

Weld seams on tanks ST-101 and ST-102 were examined by radiography and liquid penetrant. The radiographic inspection detected no discontinuities in the weld seams, such as porosity, tungsten inclusions, incomplete penetration, slag inclusions, lack of fusion, cracks, icicles, burnthrough, or undercut, that were judged unacceptable to the code. The liquid penetrant also failed to detect any discontinuities in the weld seams. The glass linings of the tanks were spark-tested at 6000 volts for discontinuities, and none were found.

D-2c Tank Management Practices

A simplified process flow diagram is shown in Figure 21. Spent 1,1,1-trichloroethane solvent wastes and spent hydrochloric acid wastes generated from the degreasing and metal finishing operations are pumped directly to ST 102 and ST101, respectively, storage tanks through separate piping systems (3-inch lines). When the tanks are filled to near capacity, the spent hydrochloric acid is pumped to a tanker (by use of a positive displacement pump) and transported to a local publicly owned treatment works (POTW) for treatment. The 1,1,1-trichloroethane solvent is pumped to a tanker in a similar manner, and the waste is transported to a reclamation facility.

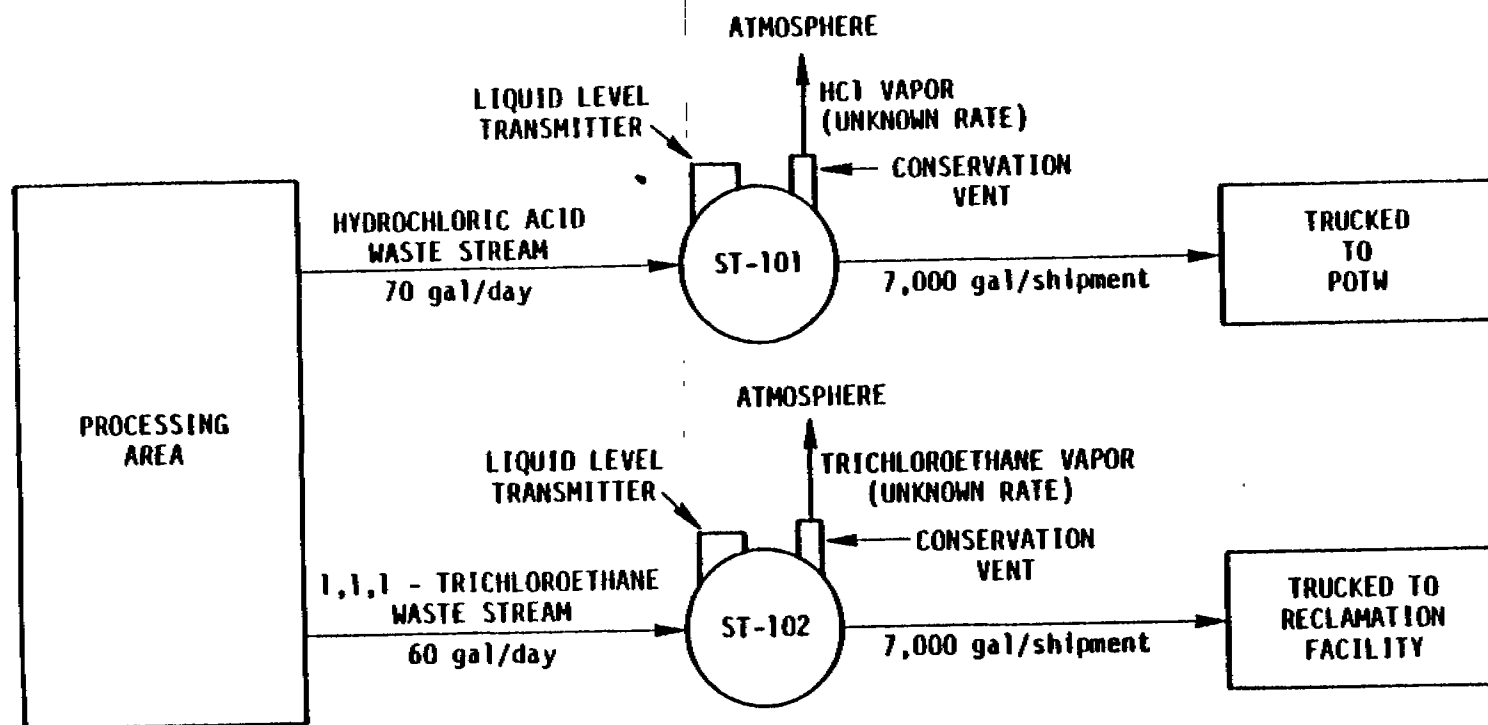


Figure 21. Process flow diagram.

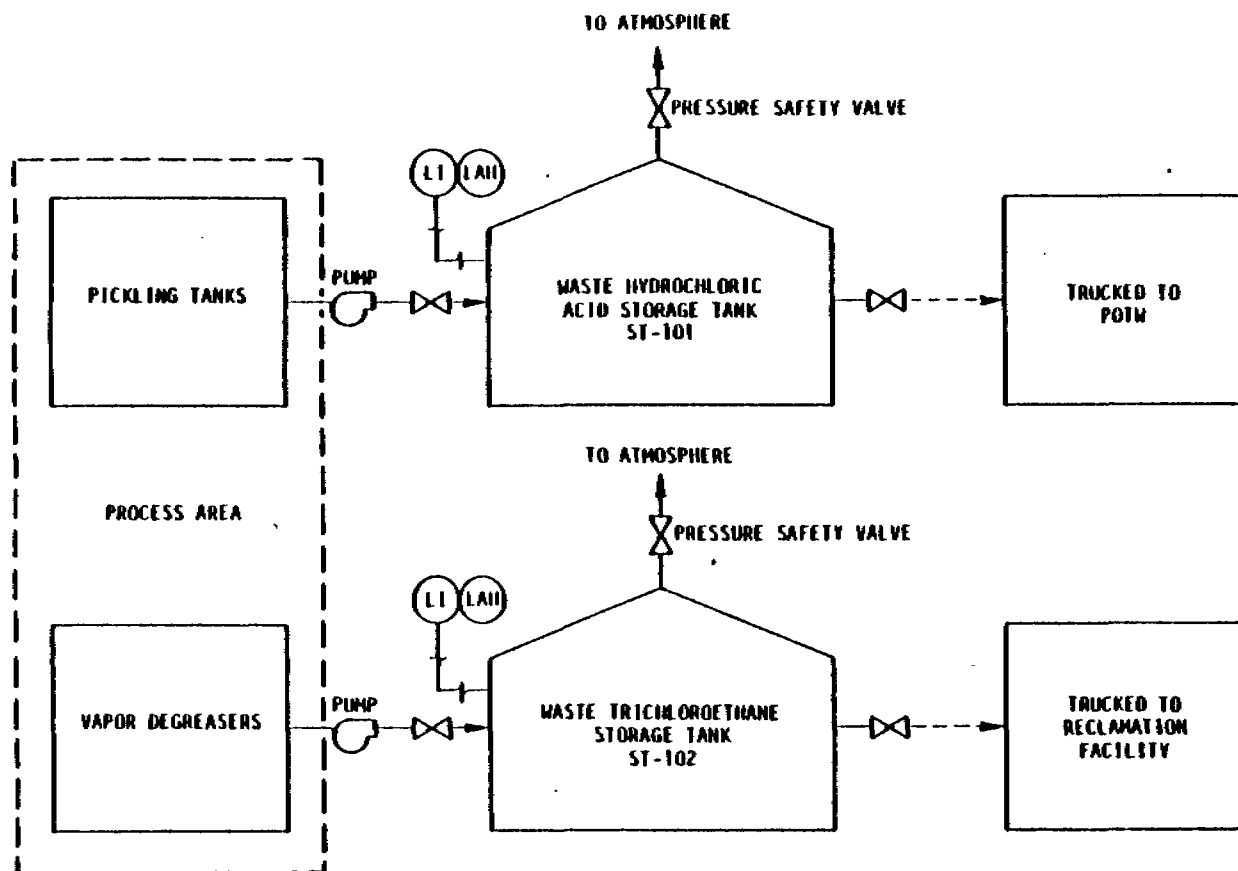
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A piping and instrumentation diagram showing the storage tanks, instrumentation, and waste feed cutoff valves is presented in Figure 22. Inlet valves are manually operated to control waste flow and prevent overfilling.

The waste storage tanks are situated on a 44-ft by 22-ft concrete pad. The pad is 1 ft thick and reinforced with No. 5 rods at the top and bottom spaced 12 in. apart.

The pressure safety valves installed on the storage tanks are Teflon-coated and spring-set to relieve pressures at 26 in. H₂O (0.22 psig). The required capacity of the vents is 7500 scf/h and they are pressure set at 110 percent over-pressure. Exit from the vents is connected directly to the atmosphere, which provides a constant back pressure. Under normal conditions the vents operate at 55°F, although their range is 0°F to 110°F.

The Taylor Model 3423 TD liquid-level transmitter is a remote seal instrument that measures liquid levels from 0 to 200 in. H₂O. The pressure differential in a closed tank actuates the transmitter and converts the differential pressure measurement into an electrical signal (level indicator) by a resistance-strain gage circuit. The transmitter is powered by 24V d.c. and has an output range of 4 to 20 mA d.c. Calibration accuracy of the instrument is ± 0.5 percent of span (0.25 percent ultimate capability). The measuring element operates at ambient temperatures of



LEGEND

LI - Level Indicator
LAH - Level Indicator Alarm

Figure 22. Piping and instrumentation diagram for hazardous waste storage in tanks.

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-40°F to 300°F, whereas the transmitter housing can withstand temperatures of -40°F to 185°F. The explosion-proof transmitter housing is made of aluminum with a low copper content and is mounted directly to the tank.

As discussed in Section F-2a(2), the tank level indicators are inspected daily. Since the tanks are slowly filled two to three times per year, the daily inspection should allow ample time to prepare for emptying the tanks. As a back-up precaution, level indicator alarms (LAH) have been added to each tank to warn of high fill levels. In such an unlikely event, the tank inlet valves can be manually closed to prevent the tanks from overfilling.

D-3 Waste Piles

The waste pile area presently located in the northeastern section of the facility, approximately 500 ft from the warehouse building, was installed in May 1978. This pile will be moved by June 1982 to a new location on the site which will meet the same design specifications and operating procedures as the existing waste pile.

Wastes generated by the processing operations at Tankopile Finishing Company and destined for the waste pile area consist of metal hydroxide sludge, which is classed as a toxic hazardous waste because of its hexavalent chromium and lead content. The waste pile contains free liquids; consequently, specific information provided in this section

follows the format required for waste piles with free liquids.

Several control systems and structural features of the waste pile area are discussed throughout this section; therefore, reference to section and plan views of the waste pile area (Figures 23 and 24) will greatly assist the reader. Some of the control systems and structures addressed are control of wind dispersal; control of run-on; collection of leachate and run-off; foundation; waste pile base; containment system design; vegetation and rodent control; and equipment and procedures for waste pile movement.

D-3a Piles With Free Liquids

D-3a(1) Control of Wind Dispersal

Two design factors were addressed to control wind dispersal of the hazardous waste pile. First, the slope of the pile was reduced to 7:1, which creates a relatively flat pile with less resistance to air flow. Second, the banks of the containment area, which were built to protect the liner and foundation, further reduce pile exposure to wind currents, because they rise one foot above ground level. As a result of both of these factors, only about 1½ ft of the waste pile is exposed to air flow. Furthermore, as a result of regular inspections, the waste pile will be moistened by a water truck before the waste pile becomes dry and fugitive emissions develop.

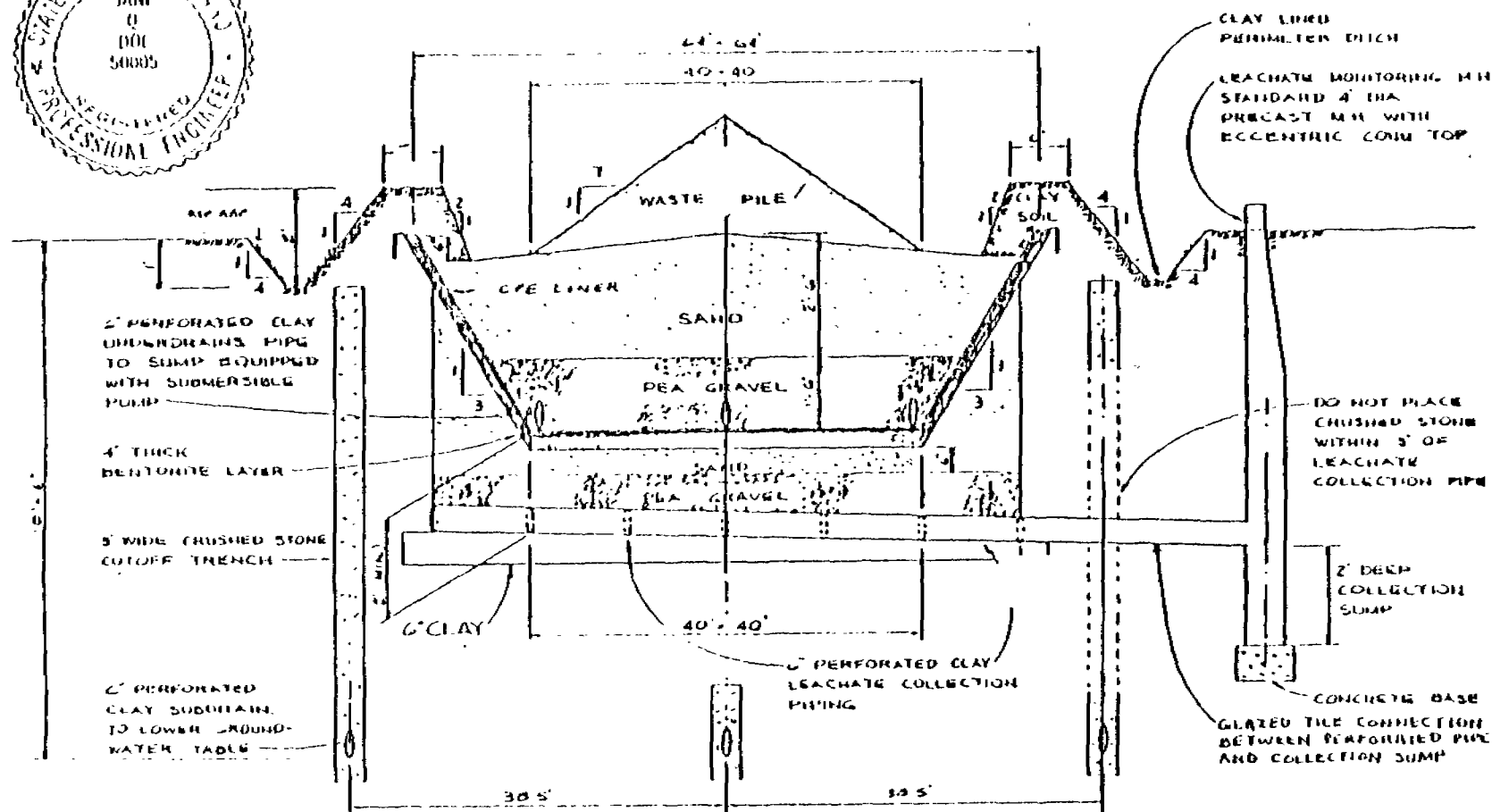


Figure 23. Containment system section.

CONTAINMENT SYSTEM SECTION	
	DATE: 2/25/92
	REVISED: 2/25/92
	BY: [Signature]
	CHECKED: [Signature]
A-E DESIGN ASSOCIATES ARCHITECTS AND ENGINEERS 1000 GARDEN RD., CINCINNATI, OHIO 45202 513 766 4567	

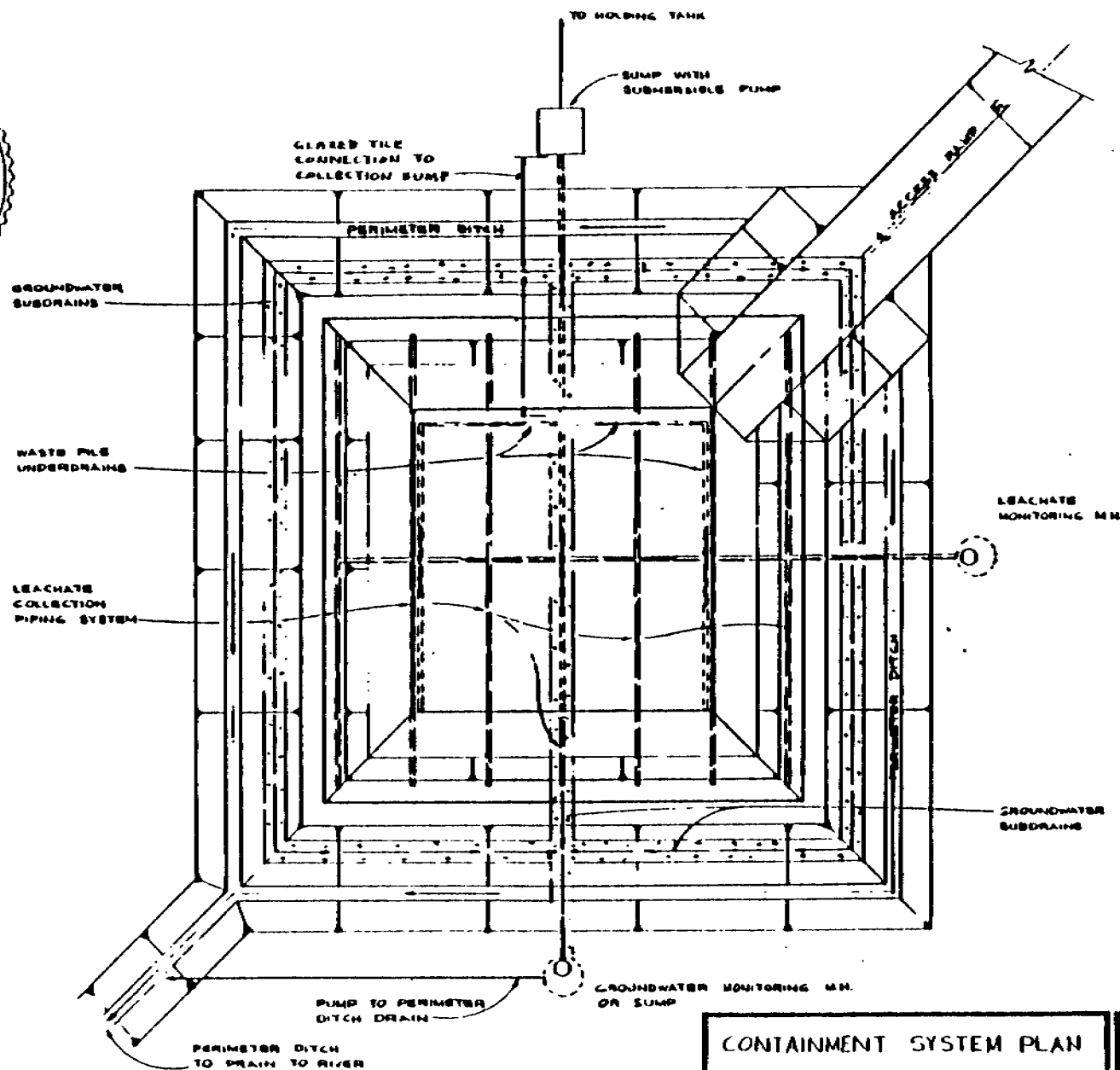
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CONTAINMENT SYSTEM PLAN



A-E DESIGN ASSOCIATES
ARCHITECTS AND ENGINEERS
 1400 GUNSTER RD., CINCINNATI, OHIO
 513-755-4887 48246

DATE	DESIGN NO.
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Figure 24. Containment system plan.

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D-3a(2) Control of Run-on

The run-on diversion system consists of a ditch (diversion canal) surrounding the waste pile containment system. The ditch is 10 ft wide and has 4:1 sloped banks. The banks of the diversion canal are lined with several inches of clay soil with a permeability of 10^{-3} cm/s (measured using a Double Ring Infiltrometer) to reduce infiltration (which could possibly reach the leachate and ground water collection systems). In addition to the moderate slope of the diversion canal banks, riprap was applied to the banks to reduce erosion. The diversion canal is sloped away from the waste pile area and drains by gravity directly to the Queen River.

D-3a(3) Collection of Leachate and Runoff

The leachate and runoff collection system is composed of a network of 6-in.-diameter, vitrified clay, perforated pipe connected together and then inserted through the liner and foundation to a sump area. Pipe leaving the foundation to the sump area is 6-in.-diameter, vitrified clay, nonperforated pipe that allows conveyance of runoff to the sump area without contaminating the soil and ground water. The piping network consists of three parallel sections of pipe at the bottom of the pea gravel, perpendicularly connected at one end by another section of pipe. Leachate and runoff collected in the perpendicular pipe is gravity-fed to an adjoining pipe and carried through the liner and foundation

to a sump area where it is automatically pumped to a 35,000-gallon holding tank. Waste in the holding tank will be analyzed for lead and hexavalent chromium and subsequently discharged to the sewer system if found not to be a hazardous. If the waste is hazardous, it will be trucked to Waste Treatment, Inc. located in Anytown, Rhode Island.

D-3a(4) Foundation

The foundation supporting the synthetic liner, base, runoff collection and removal system, and the waste pile is constructed of a Bentonite-treated soil 4 in. thick. The floor of the foundation covers 1600 ft² (40 feet square) and the walls are sloped 3:1, which results in an upper foundation opening of 4096 ft² (64 feet square). The manufacturer of the Bentonite material used for this waste pile projects that it will last for a period of 20 years.

D-3a(5) Waste Pile Base

The base material supporting the waste pile consists of 2½ ft of coarse sand on top of 1½ ft of pea gravel. The base materials serve several functions. First, the sand and gravel combination permits rapid percolation of runoff through the base to a holding tank via the runoff collection and removal system. This prevents precipitation and free liquids from overflowing the banks of the containment system. Secondly, the base material reduces both the concentration and contact time between contaminated runoff and the chlorinated polyethylene (CPE) liner, which in turn

increases the longevity of the liner. Finally, the base permits movement of mechanical equipment in the waste pile area without damage to the liner and prevents exposure of the liner to direct sunlight which can dry the liner and significantly reduce its life. After periodic removal of the waste pile to a disposal site, any lost sand will be replaced to the original design depth. The waste pile base is designed for loads up to 15 lb/in².

D-3a(5)(a) Containment System Design

Adjoined to the foundation with adhesive and mechanical fasteners is a chlorinated polyethylene (CPE), oil-resistant, reinforced liner (primary liner) 45 mil in thickness. The CPE liner, which has a permeability of less than 10^{-12} cm, was specifically recommended for the metal hydroxide sludge by the manufacturer because they are compatible. The existing liner has a project life of 10 years, which expires in May, 1998. The new liner, scheduled to be put under the waste pile when it is moved in June, 1982, is also projected to last 20 years, until June, 2002. Other pertinent characteristics of the CPE liner are provided in Table 9.

D-3a(5)(b) Leachate Detection, Collection, and Removal System

Directly underneath the foundation is a layer of sand and pea gravel, under which is a network of 6-in.-diameter, vitrified clay, perforated pipes. Under the pipes is a 6-in.-thick layer of bentonite clay. This backup leachate collection system is designed to operate in the event of

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TABLE 9
PROPERTIES OF CHLORINATED POLYETHYLENE
(CPE) OIL-RESISTANT LINER

Property	Minimum manufacturing specifications	Test method
1. Fabric (polyester)	Denier, 2½ tpi	
2. Laminate thickness	± 10% of specified thickness	ASTM D-751
3. Cold bend (36 mil)	-25°F No cracks	ASTM D-2136 1/8 in. mandrel
4. Tensile strength, lb Grab method	200	ASTM D-751
5. Tear strength, lb Tongue tear method	80	ASTM D-751
6. Puncture resistance, lbs.	NA ^a	FTM-101B 2031
7. Hydrostatic resistance	250	ASTM D-751
8. Dimensional stability 2 h at 150°F 1 h at 212°F	< ± 2%	ASTM D- 1204-54
9. Ozone resistance	No effect	ASTM D-1149 3 ppm at 30% strain at 104°F for 72 h
10. Seam strength, lb	170	ASTM D-751

^a NA - not available.

liner failure. If a leak develops in the containment system, the leachate will percolate rapidly through the sand and gravel to the leachate collection system and provide an early warning of liner failure. The piping network of the leachate collection system consists of seven 60-ft parallel sections of pipe spaced approximately 10 ft apart and an additional perpendicular pipe that connects all the pipes. The perpendicular pipe drains any collected leachate to a leachate-monitoring manhole. The perpendicular pipe, which extends from the side of the sand and pea gravel to the manhole, is glazed and has lipped connections secured with caulk. If the pipe were not impervious groundwater could penetrate the system and indicate false negative leachate quantities. The 4-ft-diameter manhole is equipped with a 2-ft-deep collection sump and ladder for manual measurement of leachate collection. The sump area has a capacity of 188 gallons. If leachate is collected and removal is desired, a portable sump pump is used to evacuate the manhole to 55-gallon drums for analyses, and if necessary, to storage and disposal.

D-3a(6) Ground Water Table Control

As described under separate cover in the "Hydrogeologic Evaluation Report", the ground water table in the Anytown, Rhode Island area is typically 10 ft below ground surface. Therefore, Tankopile Finishing Company constructed the following ground water table control system in an effort to

prevent the ground water table from rising to the leachate collection system (giving false positive leachate quantities). A network of 6-in.-diameter, vitrified clay, perforated pipes (subdrains) were installed at a depth of 10½ ft within 3-ft-wide cutoff trenches filled with crushed stone. The cutoff trenches extend vertically from a foot below ground surface to a depth of 11 ft. The network consists of five subdrain sections, four forming a square (80 ft to a side) around the containment area and another connecting two of the sides. All of the subdrains drain together, by gravity, to a ground water-monitoring manhole and sump. Ground water in the sump is automatically pumped to the outlet of the run-on diversion canal for discharge into the Queen River. Ground water discharged from the manhole is metered for informational purposes.

D-3a(7) Vegetation and Rodent Control

Prior to the construction of the waste pile containment system in May 1978, isopropyl N-phenylcarbamate (herbicide) was applied to the immediate area. If vegetation is observed during the life of the waste pile, weeds will be removed by hand or another herbicide treatment will be applied.

In an effort to control rodents in the area, chloralose (rodenticide) was applied in the vicinity of the waste pile area.

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D-3a(8) Equipment and Procedures for Waste Pile Movement

The waste pile is moved by using a front-end loader and a dump truck. The dump truck is equipped with sides and a cover to ensure that the load will not overflow or be exposed to wind or precipitation during loading, unloading, and transport. One front-end loader is used on the pile to ensure that the liner is not punctured by the dump truck.

D-3b Waste Piles Without Free Liquids

Presently, the Tankopile Finishing Company does not manage a waste pile without free liquids, therefore, Sections D-3b, D-3b(1), D-3b(2), D-3b(3), and D-3b(4) are not applicable.

D-4 Surface Impoundments

Presently, the Tankopile Finishing Company does not manage a surface impoundment, therefore, Section D-4 is not applicable.

D-5 Incinerators

Presently, the Tankopile Finishing Company does not manage an incinerator, therefore, Section D-5 is not applicable.

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SECTION E
GROUND WATER MONITORING SYSTEMS

The requirements for ground water monitoring are not applicable to a storage facility such as Tankopile Finishing Company, which stores containers and tanks and operates a waste pile (not intended for disposal).

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SECTION F

PROCEDURES TO PREVENT HAZARDS

The information provided in this section is submitted in accordance with the requirements of 40 CFR Part 122.25(a)(4), (5), (6), (8), and (9). Other regulations addressed to complete this section include 40 CFR §264.14, §264.15, §264.17, §264.174, §264.194, and §264.254.

Tankopile Finishing Company will address the following subject areas (referenced above): general security provisions; inspection schedule; request for a waiver of preparedness and prevention requirements; spill prevention, containment, and countermeasures plan; and prevention of accidental ignition or reaction of ignitable, reactive, or incompatible wastes.

F-1 Security

F-1a Security Procedures and Equipment

In addition to the general security provisions of fencing, gates, and guards discussed below, several other features contribute to the safety and security of the facility. Ample lighting is provided throughout the site, and guards and operators are equipped with hand-held, two-way radios to report upset conditions immediately. In addition to the two-way portable radios carried by guards and operators, a

base station for the public address system is located in the plant manager's office. An internal telephone system (with phones in most plant areas) is provided. The same telephone system is used for communications outside the plant.

Employees are required to show identification cards when reporting for work, and visitors and contractors entering the plant must sign a log sheet (Figure 25) and obtain visitor passes.

F-1a(1) 24-hour Surveillance System

Security at Tankopile Finishing Company is maintained by a staff of trained security guards, who primarily monitor entry and exit from the active portion of the facility and provide security measures within the plant premises.

The main entrance gate at the east end of the facility is operated by remote control from the guard house, which is occupied by two armed guards 24 hours a day, 7 days a week, except during plant shutdowns for holidays at which time the gates remain locked. Guards normally work an 8-hour shift with a crew of six guards per day. During each shift, one of the guards makes a walkthrough of the facility at scheduled intervals while the other remains in the guard house.

F-1a(2) Barrier and Means to Control Entry

Visitor/Contractor Entry Log Sheet

Date	Time		Name	Affiliation	Contact	Purpose of visit
	In	Out				

Figure 25. Log sheet.

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F-1a(2)(a) Barrier

Except for two company parking lots, the entire facility is enclosed within a 7-ft-high, chain-link fence topped by three strands of barbed wire. The fence has two gates; one located at the southwest end of the facility, which is locked at all times, and the other at the east end of the facility, which serves as the main entrance to the facility. In addition, a 12-ft-high, chain-link fence with two lockable gates was constructed around the container storage area to restrict unauthorized entry and to prevent drums from being washed downstream in the event of a minor flood.

F-1a(2)(b) Means to Control Entry

As discussed in Section F-1a(1), entry to the facility is controlled by two armed guards stationed at the main entrance gate. Employees are required to show identification cards when reporting for work, and visitors and contractors entering the plant must sign a log sheet and obtain visitor passes.

F-1a(3) Warning Signs

Signs which are legible from a distance of 25 feet are posted at all fence gates and several other fence locations around the active portion of the facility; these signs are visible from all angles of approach, and bear the legend "Danger - Unauthorized Personnel Keep Out." Also, "No Smoking" signs which are legible for a distance of 25 feet have been placed in the container storage area.

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F-1b Waiver

The Tankopile Finishing Company does not request a waiver of the requirements stated in Part 264.14(a)(1) and (2) regarding injury to intruder and violation by intruder.

F-2 Inspection Schedule

F-2a General Inspection Requirements

The Tankopile Finishing Company conducts regular inspections of the facility for equipment malfunctions, structural deterioration, operator errors, and discharges that could cause or lead to the release of hazardous waste constituents and adversely affect the environment or threaten human health.

F-2a(1) Types of Problems

Table 10 presents the schedule for inspecting monitoring equipment, safety and emergency equipment, security devices, operating and structural equipment, the container storage area, the tank storage area, tanks (internally and externally), and the waste pile area. The items listed in the table are considered important because of their role in preventing, detecting, or responding to environmental or human health hazards. Provided with each item is a list of problems normally encountered.

F-2a(2) Frequency of Inspection

Also provided in Table 10 is a recommended frequency of inspection for each item.

TABLE 10. INSPECTION SCHEDULE

Area/equipment	Specific item	Types of problems	Frequency of inspection
Monitoring equipment	Liquid level transmitters (tanks)	Transmitter signal, electrical circuitry, power	Daily
	Conservation vents (tanks)	Spring adjustment or sticking	Daily
	Leachate detection, collection, and removal system (waste pile)	Groundwater collected, groundwater contaminated, sump pump failure, external evidence of malfunction	Daily
	Ground water table control system (waste pile)	Level of groundwater, external evidence of malfunction, sump pump failure	Daily
	Runoff collection and removal system (waste pile)	Groundwater collected, groundwater contaminated, sump pump failure, external evidence of malfunction	Daily
	Ground water table water meter (located in sump)	Clogging, malfunction of digital display, rotor sticking, wearing of gears	Daily
Safety and emergency equipment	Standard industrial absorbents (Sorb-Ail, Vermiculite, etc.)	Out of stock	Monthly/as needed
	Sandbags	Leak or worn	At use
	Sand	Out of stock	Monthly/as needed
	Absorbent boom		Monthly/as needed
	Absorbent pads		Monthly/as needed
	Straw		Monthly/as needed
	Submersible pump	Power, clogging	Monthly
	Flexible hoses with quick couple fittings	Cracks or holes, fittings stick	Monthly
	55-gallon drums (steel, stainless steel)	Corrosion, structural damage	Monthly
	Emergency shower and eyewash	Water pressure, leaking, drainage	Weekly
	Face shields and extra protective eyeglasses	Broken or dirty equipment	Monthly
	Disposable respirators	Out of stock	Monthly/as needed
	Chemical cartridge respirators with cartridges for organic vapors and acid gases; half- and full-face types	Spent chemical adsorbent, seals	Monthly/after each use
	Chest-mounted gas mask canisters	Canisters become exhausted	Monthly/after each use
	Self-contained breathing apparatus (SCBA)	Air quantity in reserve, air delivery system, moisture in tank (cold weather)	Monthly/after each use
	Portable sump pump	Power, clogging	Monthly
	Fire blankets	Dispensing	As used
	Fire extinguishers	Needs recharging	Monthly/after each use
	Fire alarm system	Power failure	Per NFPA
	Telephone system	Power failure	Per NFPA
	Public address (PA) system	Power failure, speakers	Per NFPA
	Generators	Fuel supply, spark plugs, oil	As used
	Emergency lighting system	Battery failure, lights	Per NFPA
	First aid equipment and supplies	Items out of stock or inoperative	As used
	Steam cleaner	Water supply, fuel supply	As used
	Protective clothing (impermeable full body coveralls, gloves, and foot coverings)	Holes, normal wear and tear	As used
	Decontamination facility (showers, dirty room, clean room)	Water pressure, leaking, drainage, upkeep	As used

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TABLE 10 (continued)

Area/equipment	Specific item	Types of problems	Frequency of inspection
Security devices	Facility fence	Corrosion, damage to chain-link fence or barbed wire	Weekly
	East gate (main entrance)	Corrosion, damage to chain-link fence or barbed wire	Weekly
	West gate and lock	Corrosion, damage to chain-link fence or barbed wire, sticking or corroding lock	Weekly
	Container storage area fence	Corrosion, damage to chain-link fence or barbed wire	Weekly
	Container storage area gate and lock	Corrosion, damage to chain-link fence or barbed wire, sticking or corroding lock	Weekly
	Remote control to east gate Two way radios	Transmitter or receiver, sticking of gate Transmitter or receiver	Upon failure Upon failure
Operating and structural equipment	Sump pumps (automatic)	Setting adjustment, power, clogging	Weekly
	Dikes	Cracks, deterioration	Weekly
	Bases or foundations	Erosion; uneven settlement; cracks and spalling in concrete pads, base rings and piers, deterioration of water seal between tank bottom and foundation, wet spots	Weekly
	Sump pump (manual)	Power, clogging	Weekly
	Ramps	Erosion, uneven settlement, cracks and spalling in concrete	Weekly
	Sump areas	Erosion, uneven settlement, cracks and spalling in concrete, wet spots	Weekly
	Tank structural supports	Concrete deterioration and cracking, corrosion of pipe supports	Weekly
	Piping to holding tanks	Loss of metal thickness, leaks, corrosion or deterioration	Weekly
	Holding tanks	Corrosion, discoloration, cracks, buckles, and bulges	Weekly
	Storage areas	Leaks, spills	Daily
	Container placement and stacking	Aisle space, height of stacks	Weekly
	Sealing of containers	Open lids	Weekly
Container storage area	Labeling of containers	Improper identification, date missing	Weekly
	Containers	Corrosion, leakage, structural defects	Weekly
	Segregation of incompatible wastes	Storage of incompatible wastes in same area	Weekly
	Pallets	Damaged (e.g., broken wood, warping, nails missing)	Weekly
	Fence, gate and lock	Corrosion, damage to chain-link fence, sticking or corroding lock	Weekly
	Base or foundation	Cracks, spalling, uneven settlement, erosion, wet spots	Weekly
	Dikes	Cracks, deterioration	Weekly
	Sump area	Cracks, spalling, uneven settlement, erosion, wet spots	Weekly
	Sump pumps (automatic)	Setting adjustment, power, clogging	Weekly
	Debris and refuse	Clog sump pump, aesthetics, possible reaction with leaks	Weekly
	Ramps	Cracks, spalling, uneven settlement, erosion	Weekly
	Warning signs	Damaged	Weekly

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TABLE 10 (continued)

Area/equipment	Specific item	Types of problems	Frequency of inspection
Tank storage area and ancillary equipment	Dike	Cracks, deterioration	Weekly
	Base or foundation	Cracks, spalling, uneven settlement, erosion, wet spots	Weekly
	Sump pump (manual)	Power, clogging	Weekly
	Sump area	Cracks, spalling, uneven settlement, erosion, wet spots	Weekly
	Warning sign	Damaged	Weekly
	Pipes	loss of metal thickness, leaks, corrosion or deterioration	Weekly
	Valves	loss of metal thickness, leaks, corrosion or deterioration	Weekly
	Fittings	loss of metal thickness, leaks, corrosion or deterioration	Weekly
	Overfill control valve (manual) and level indicator	loss of metal thickness, leaks, corrosion or deterioration, sticking, damaged handle	Daily
Tank (externally)	Ladder	Damaged, structural stability	Weekly
	Foundation/structural supports	Cracks, spalling, uneven settlement, erosion, wet spots	Weekly
	Pipe connections	External corrosion, cracks, distortion	Weekly
	Protective coating	Rust spots, blisters, film lifting	Weekly
	Tank shell	Corrosion, discoloration, cracks, buckles, bulges	Weekly
	Tank roof	Malfunction of seals, blockage of water drains on roof, corrosion	Weekly
	Tank bottom	Corrosion, discoloration, cracks, buckles, bulges	Weekly
	Anchor bolts	Distortion, corrosion	Weekly
	Nozzles	Cracks, corrosion	Weekly
Tank (internally)	Tank roof	Malfunction of roof's seals, corrosion, loss of metal thickness	yearly
	Internal supports	Deterioration, depressions	yearly
	Tank shell	Corrosion of vapor space, and liquid level line, cracking, bulges, holes, loss of metal, thickness, seams	yearly
	Tank bottom	Corrosion pits, sprung seams, rivets, depressions, bottom thickness, unevenness of bottom	yearly
	Plate joints	Cracking	yearly
	Nozzle connection joints	Cracking	yearly
	Glass lining	Cracking, bubbles	yearly
	Rivets	tightness, corrosion	yearly
	Pipecell support	Depressions	yearly
Waste pile area	Run-on diversion ditch	Obstructions to flow, bank erosion, loose riprap	Weekly
	Entrance road and guard rails	loss of gravel, fugitive emissions, corrosion and tightness of guard rails	Weekly
	Runoff diversion canal and drain	Obstructions, drain clogged	Weekly
	Wind dispersal control system	frequency of water application, dryness and slope of pile	Daily
	Foundation	Cracks or breaks	At installation
	Synthetic liner	tears, holes, separation of layers, thin spots, cracks, shrinkage, hardness, excessive permeability, blisters	At installation
	Base	erosion, exposed area to liner, depth	Weekly
	liner seams	tear, tightness of seam	At installation
	Joints	tightness of connection	At installation

F-2b Specific Process Inspection Requirements

F-2b(1) Container Inspection

Inspections of the container storage area will be conducted per the inspection schedule provided in Table 10. Results of each inspection will be recorded on inspection log sheets entitled, "Operating and Structural Equipment Inspection Log Sheet," "Security Devices Inspection Log Sheet," and "Container Storage Area Inspection Log Sheet" (Supplement 1-3). Information requested on the log sheets, similar to that of log sheets for tanks, waste piles, etc., includes the inspector's name and title, date and time of inspection, item of inspection, typical problems encountered, status of the item, observations, and the date and nature of repairs and remedial action. Typical problems encountered with each item of inspection, included in the inspection schedule, are provided on the log sheet to serve as a reminder to the inspector and to ensure a complete inspection. The inspector is required to check the status of each item and indicate whether its condition is acceptable or unacceptable. Regardless of the status, observations are made as to the number of containers, aisle space, height of container stacking, inventory quantities, storage tank levels, observation of runoff in waste pile area, and more. If the status of a particular item is unacceptable, appropriate and complete information is recorded, including date and nature of repairs and remedial action.

F-2b(2) Tank Inspection

Tank inspections will be conducted per the inspection schedule provided in Table 10. Results of each inspection will be recorded on inspection log sheets entitled, "Monitoring Equipment Inspection Log Sheet," "Operating and Structural Equipment Inspection Log Sheet," "Tank Storage Area and Ancillary Equipment Inspection Log Sheet," "External Tank Inspection Log Sheet," and "Internal Tank Inspection Log Sheet" (Appendix). Upon completion of the inspection log sheets, they will be inserted in the inspection log three-ring binder previously discussed in Section F-2b(1).

F-2b(3) Waste Pile Inspection

During the installation of the waste pile liner system, strict quality assurance of the workmanship was part of standard installation procedure. The liner was inspected for uniformity, damage and imperfections. The waste pile inspections will be conducted per the inspection schedule provided in Table 10. Results of each inspection will be recorded on inspection log sheets entitled, "Monitoring Equipment Inspection Log Sheet," "Operating and Structural Equipment Inspection Log Sheet," and "Waste Pile Area Inspection Log Sheet." Upon completion of the inspection log sheets, they will be inserted in the inspection log three-ring binder previously discussed in Section F-2b(1).

F-2c Remedial Action

If inspections reveal that non-emergency maintenance is needed, they will be completed as soon as possible to preclude further damage and reduce the need for emergency repairs. If a hazard is imminent or has already occurred during the course of an inspection or any time between inspections, remedial action will be taken immediately. Tankopile Finishing Company personnel will notify the appropriate authorities per the Contingency Plan (see Section G) and initiate remedial actions. In the event of an emergency involving the release of hazardous constituents to the environment, efforts will be directed towards containing the hazard, removing it, and subsequently decontaminating the affected area. Refer to the Contingency Plan for further details.

F-2d Inspection Log

An inspection log is maintained for each calendar year in a three-ring binder that is subdivided by sections for each area/equipment. After an inspection, each log sheet is filed in the binder according to area/equipment, which provides a case history of a particular item. The inspection log notebook is always kept with the inspection schedule in the Environmental Engineer's office. As required, records of inspections are kept for at least 3 years from the date of inspection. A copy of the inspection log sheets may be found in the Appendix.

F-3 Waiver of Preparedness and Prevention Requirements

The applicant does not wish to request a waiver of the preparedness and prevention requirements under 40 CFR §264 Subpart C. Requirements of this Subpart are primarily addressed in Section D, Section F, and Section G of this application.

F-3a Equipment Requirements

Internal and external communications, emergency equipment, and fire control equipment are discussed in Section F and Section G.

F-3b Aisle Space Requirements

Aisle space requirements are addressed in Sections D-1a(2), F-5c, and G.

F-4 Preventive Procedures, Structures, and Equipment

F-4a Loading/Unloading Operations

Loading operations at the facility, other than removal operations at the container, tank, and waste pile storage areas, take place in the processing area. Except for tank storage wastes, wastes generated in the processing area are collected in hoppers and loaded into drums or front-end loader for transport to the appropriate storage area. During loading operations spills are unlikely; however, in the event of an accident the material will be contained with sandbags, standard industrial absorbents, absorbent boom and pads, or dirt. Contaminated materials will be contractor-hauled to a permitted hazardous waste landfill.

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and affected areas of the facility and equipment will be decontaminated.

The only areas that involve unloading operations at Tankopile Finishing Company are the container storage area and the waste pile area. Wastes stored in the tank area are piped directly from the processing area to the storage tanks.

Several precautions have been taken to reduce the potential for hazards during unloading operations in the container storage area. First, three ramps were designed and constructed to facilitate the smooth and accessible movement of a forklift truck in and out of each of the storage area sections (Figure 18): Second, at least 5 feet of aisle space is maintained at all times. Third, pallets are used in the transport of drum containers.

Unloading operations in the waste pile area involve the transport of wastes from the processing area to the waste pile via front-end loader or dump truck. The front-end loader is equipped with a cover to prevent hazardous waste dispersal. Entrance to the waste pile area is by a gravel road, which slopes away from the pile to prevent run-on from entering the waste pile area (Figure 24). At the intersection of the road entrance and the diversion canal, a guard rail was installed on both sides of the road to prevent the front-end loader from driving into the canal and spilling the waste. The front-end loader is driven up

the access ramp where its contents are emptied onto the waste pile.

F-4b Runoff

Runoff from the container storage area and waste pile area is collected and automatically pumped to three holding tanks located just east of the container storage area (Figure 4). Runoff from Storage Area A is diverted to Holding Tank A, runoff from Storage Area B and the waste pile area is collected in Holding Tank B, and runoff from Storage Area C is diverted to Holding Tank C. Runoff contained in Holding Tanks A and C is discharged to the municipal sewer system if no leaks or spills from containers are detected during inspection. Contents of Holding Tank B, which consists of runoff from Storage Area B and runoff and leachate from the waste pile area, will be examined by laboratory analyses and either discharged to the sewer system (if determined not to be a hazardous waste) or drummed and stored onsite for later disposal at a facility authorized to accept the waste types. In the event that a spill or leak is detected in Storage Areas A or C, runoff collected in their respective holding tanks will be managed similarly to waste received in Holding Tank B discussed above.

Runoff from all other areas of the facility drains directly into the municipal sewer system.

Because the Tankopile Finishing Company is located in a 100-year floodplain, provisions have been made to minimize flooding, and emergency procedures have been established for the possible but unlikely occurrence of a flood. These procedures are discussed in the Emergency Procedures section of the Contingency Plan (Section G).

F-4c Water Supplies

Ground water contamination is prevented by eliminating the discharge of hazardous materials onto the unprotected ground. The container storage area is constructed of a concrete base, dikes, sump areas, sump pumps, and holding tanks to contain leaks, spills, and precipitation. The waste pile area is also designed and constructed to prevent water supply contamination. Refer to Section D-3a for a complete description of the design and construction of the waste pile area, including a leachate collection system, wind dispersal control system, and runoff and run-on collection system.

F-4d Equipment and Power Failure

In the event of a brief power interruption, emergency generators will be started to maintain process operations, and the emergency lighting system will activate automatically supplying lighting to all facility buildings and property. If there is a prolonged power outage, the waste feed lines to the tank storage area will be manually shut off and all plant operations will be shut down. After

shutdown, maintenance personnel will check for malfunction and equipment failures, and the Anytown Power and Light will be contacted immediately for assistance. Refer to Emergency Procedures in the Contingency Plan for more details.

F-4e Personnel Protection Equipment

General information on the major chemical components of the wastes in the container, tank, and waste pile areas is provided in the Appendix under General Information and Hazardous Characteristics of Wastes. The sheets present information on various chemicals regarding toxicity, fire and explosion hazards, protective equipment recommendations, and first aid. Available protective equipment is presented under Emergency Equipment and Provisions of the Contingency Plan (see Section G). Use of protective equipment is covered in the initial and annual Personnel Training Programs (see Section H), which satisfies the Occupational Safety and Health Standards of 29 CFR Part 1910 Subpart I - Personal Protective Equipment.

F-5 Prevention of Reaction of Ignitable, Reactive, and Incompatible Wastes

F-5a Precautions to Prevent Ignition or Reaction of Ignitable or Reactive Wastes

The container storage area is the only area on the facility property where ignitable wastes are stored. No reactive wastes are stored at the facility. The containers, as discussed in Section D-1a(1), are compatible with the contained

wastes; therefore, the only source of ignition is external to the containers. To prevent a possible source of external ignition, drums containing ignitable wastes are painted white to reflect solar heat and signs are placed in the container storage area clearly marked with the legends, "No Smoking" and "Danger - Unauthorized Personnel Keep Out." Sparkproof tools (brass hammers, wrenches, etc.) are used on all containers and tanks storing ignitable materials.

F-5b General Precautions for Handling Ignitable or Reactive Wastes or Accidentally Mixing Incompatible Wastes

General precautions for handling ignitable or reactive wastes were discussed above. Incompatible wastes are not mixed at Tankopile Finishing Company.

F-5c Management of Ignitable or Reactive Wastes in Containers

Precautions taken in the container storage area to prevent accidental fire and explosion include the proper storage of containers (e.g., stacking, aisle space, and labeling and sealing of containers), dikes, sump areas and sump pumps, and appropriate warning signs.

Prior to storage, each container is sealed and labeled. This prevents precipitation from entering the drum, and identifies the contents of the container and the date wastes were generated. Containers are stored on pallets to minimize contact with precipitation, leaks, or spills, and they are never stacked more than three containers high. A minimum of 5 ft is maintained in the aisles to allow access

for a forklift without risk of damaging containers by scraping or puncturing.

The container storage area is located 700 ft from the closest company property line (Figure 4), which is in compliance with the National Fire Code Standards for outdoor storage of containers holding ignitable or reactive wastes.

F-5d Management of Incompatible Wastes in Containers

Drums used at Tankopile Finishing Company are color-coded white for vinyl acetate and chloride sludges, yellow for pickle liquor sludges, and blue for metal grindings. This system prevents an operator from placing waste in a container that previously held an incompatible waste.

Incompatible wastes stored in the container storage area are separated by 6-in.-high curbs, and each of the three storage area sections has a separate sump area, sump pump, and holding tank to prevent mixing of the wastes.

F-5e Management of Ignitable or Reactive Wastes in Tanks

Hazardous waste properties of storage tank waste materials generated from the finishing operations at the Tankopile Finishing Company are corrosivity and toxicity. No ignitable or reactive waste materials are stored in the tanks.

The location of the waste storage tanks complies with the buffer zone requirements for stable liquids (operating pressure 2.5 psig or less) contained in the National Fire

Protection Association's 1981 "Flammable and Combustible Liquids Code" for vertical tanks with emergency relief venting. The storage tanks are designed to relieve pressures in excess of 0.22 psig. The facility provides protection for exposures by location within the jurisdiction of the Anytown Fire Department and by operation of its own fire brigade.

F-5f Management of Incompatible Waste in Tanks

Waste materials stored in the tank storage area are incompatible. When 1,1,1-trichloroethane comes in contact with acid or acid fumes, highly toxic chloride fumes are generated. The tanks therefore have separate piping systems.

Pressure safety valves were installed on both tanks to relieve pressure buildup and prevent a possible explosion. Furthermore, regular inspections as discussed in section F-2b(2) will be conducted to ensure safe operations.

F-5g Management of Ignitable or Reactive Wastes in Waste Piles

Ignitable or reactive wastes are not stored in the waste pile at Tankopile Finishing Company.

F-5h Management of Incompatible Wastes in Waste Piles

Incompatible wastes are not stored in the waste pile at Tankopile Finishing Company.

SECTION G
CONTINGENCY PLAN

The information contained herein is submitted in accordance with the requirements for a Contingency Plan, as contained in 40CFR§122.25(a)(7) and §264 Subpart D.

Contingency Plan [40 CFR 122.25(a)(7)]

The intent of §264, Subpart D (Contingency Plan and Emergency Procedures), of RCRA is to ensure that facilities that treat, store, or dispose of hazardous wastes have established the necessary planned procedures to follow in the event an emergency situation should arise.

The intent of the requirements under 40 CFR §264, Subpart E (Preparedness and Prevention), which was described in Section F, is to ensure that the facility is properly designed and equipped to minimize the possibility of accidents and prevent the occurrence of emergency situations. The requirements under 40 CFR §264 Subpart D address the actions that are to be taken if an accident should occur.

3-1 General Information

This contingency plan is for the Tankopile Finishing Company, Inc., located at 3100 West 11th Street, Anytown, Rhode Island 02881. Tankopile is primarily a manufacturer of metal automotive parts (i.e., body parts, hubs, and trim) and household appliance housings and parts. Mary P. Jones is the owner and operator of the facility. Ms. Jones may be reached at (401) 555-6789 from 9 a.m. to 5 p.m. on weekdays. Mr. John Smith, Environmental Engineer, is the primary emergency coordinator at the facility and may be reached at (401) 555-3219 from 9 a.m. to 5 p.m. on weekdays. Other emergency coordinators may be reached at this telephone extension during other hours.

Tankopile stores hazardous waste in three locations. A waste pile with a maximum storage of 50 yd² is used to store metal hydroxide wastes. Two 7,500-gallon tanks are used to store 1,1,1-trichloroethane waste solvent and spent pickle liquor. A container storage area has an estimated maximum storage capacity of 100 drums. A general site plan and a full description of the facility is contained in Section B. A description of the wastes is contained in Section C. Included in the copies of the Contingency Plan provided to emergency organizations, these two sections (B and C) have been added as Appendices.

G-2 Emergency Coordinators

If an emergency situation develops at the facility, the discoverer should contact an emergency coordinator listed in Table 11. John Smith, primary Emergency Coordinator, should be contacted first, and if he is not available, the others should be called (in the order listed) until someone is reached. The primary Emergency Coordinator and alternates have complete authority to commit all resources of the company in the event of an emergency. Table 12 lists organizations that could possibly be contacted by the Emergency Coordinator in the event of an emergency.

TABLE 11

EMERGENCY COORDINATORS

Name	Title	Home address	Work phone No.	Home phone No.
John Smith	Environmental Engineer	453 Elm St.	Ext.3219	221-2932
Joseph Williams	Plant Manager	911 6th St.	Ext.3225	862-3801
Albert Brown	Vice President, Operations	1101 Main St.	Ext.3220	921-4410

G-3 Implementation of the Contingency Plan

The decision to implement the contingency plan depends upon whether or not an imminent or actual incident could threaten human health or the environment. The purpose of this section is to provide guidance to the emergency coordinator in making this decision by providing decision-making criteria.

Date: 2/26/82
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TABLE 12
EMERGENCY CONTACTS

Emergency	Organization/agency	Emergency No.
Injury	Anytown Hospital	911
	Washington County Hospital	Ambulance - 863-4800 Info. - 863-3232
	Rhode Island Medical College	821-8305
	Poison Control Center	724-5050
Fire/explosion	Washington County Fire Dept.	798-6818
	Anytown Fire Dept.	722-5351
Hazardous material spill or release	Anytown Fire Dept.	722-5351
	Washington County Fire Dept.	798-6818
If spill reaches navigable water	U.S. EPA Region I Response Center	24-hr. emergency No. - 617/472-3815
	Rhode Island Emergency Management	401/702-4895
	National Response Center	800/424-8802
Natural disaster	Washington County Emergency Management Agency*	911 or 724-4444
Potential flood	Army Corp of Engineers Engineer	401/704-4362
All of the above	Rhode Island Emergency Management Agency*	24-hr. No. - 401/826-4739
	American Red Cross	722-1821

* This agency may also be contacted in any emergency event if necessary.
They will coordinate the proper agencies/organizations as needed.

The contingency plan will be implemented in the following situations:

1. Fire and/or Explosion

- a. A fire causes the release of toxic fumes.
- b. The fire spreads and could possibly ignite materials at other locations onsite or could cause heat-induced explosions.
- c. The fire could possibly spread to offsite areas.
- d. Use of water or water and chemical fire suppressant could result in contaminated runoff.
- e. An imminent danger exists that an explosion could occur, causing a safety hazard because of flying fragments or shock waves.
- f. An imminent danger exists that an explosion could ignite other hazardous waste at the facility.
- g. An imminent danger exists that an explosion could result in release of toxic material.
- h. An explosion has occurred.

2. Spills or Material Release

- a. The spill could result in release of flammable liquids or vapors, thus causing a fire or gas explosion hazard.
- b. The spill could cause the release of toxic liquids or fumes.
- c. The spill can be contained onsite, but the potential exists for ground water contamination.
- d. The spill cannot be contained onsite, resulting in offsite soil contamination and/or ground or surface water pollution.

3. Floods

- a. The potential exists for surface water contamination.

G-4 Emergency Response Procedures

G-4a Notification [40 CFR 264.56(a)]

In the event of an emergency situation the emergency coordinator will be notified first; subsequently, all facility personnel, appropriate federal, state, or local agencies, and fire or police departments will also be notified. See Figures 26 and 27.

G-4b Identification of Hazardous Wastes [40 CFR 264.56(b)]

The emergency coordinator will immediately identify the character, exact source, amount and area extent of the release. The initial identification method will be to utilize visual analysis of the material and location of the release. The containers are color coded as to their contents and are in distinct separate locations. The tanks and piping from the process area to the tanks are labeled to identify whether they hold waste pickle liquor or trichloroethane. The waste pile area would only have metal hydroxide sludge. If for some reason the released material cannot be identified, visual samples will be taken for chemical analysis.

G-4c Assessment [40 CFR 264.56(c) and (d)]

The emergency coordinator will assess possible hazards, both direct and indirect, to human health or the environment.

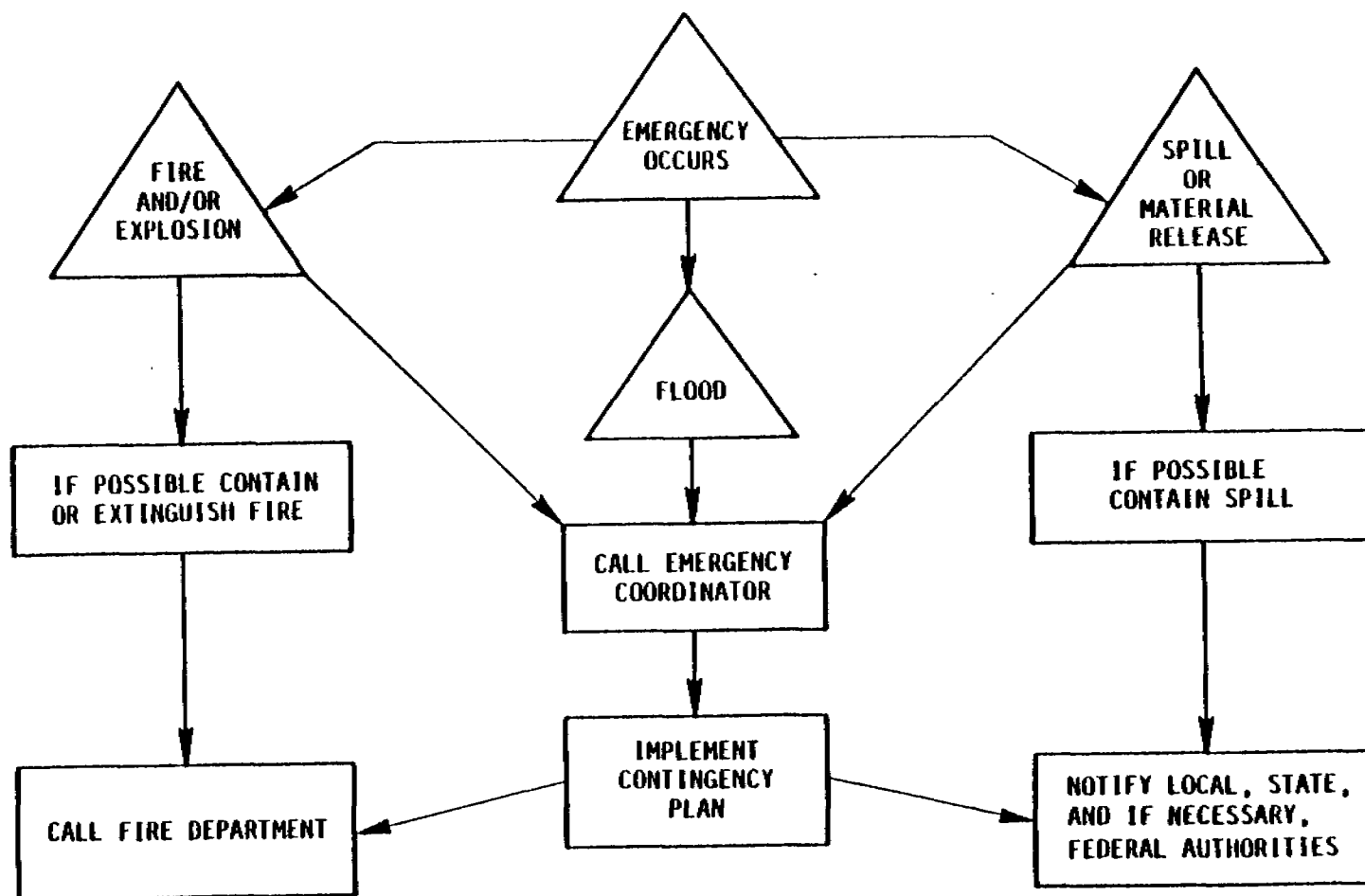
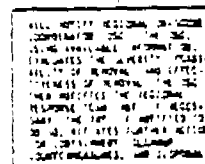


Figure 26. Overview of emergency plan of action.



MOBILE NUMBER: 81 292 36 173
TELEFAX NO.: 81 292 36 173
E-MAIL ADDRESS: info@mobitel.com

G-4d Control Procedures [40 CFR 264.52(a)]

Potential accidents fall under three general classifications: (1) fire and/or explosions, (2) spills or material release, (3) floods. Natural disasters such as earthquakes or hurricanes are assumed to fall into one of these three classifications. An overview of the emergency plan of action is outlined in Figure 26. Figure 27 is a more detailed emergency plan of action, including phone numbers.

Fire and/or Explosion

The storage tank, container, and waste pile areas can be easily accessed by fire-fighting and other emergency vehicles and equipment. A paved blacktop road, about 25 ft in width, passes within 100 ft of each of these areas. This road is kept clear at all times.

A company fire brigade will be on standby during all general plant emergencies. During times of power failure or severe weather, fire protection personnel will be assigned to protect personnel and property. If a fire should break out, concentration will be placed on preventing the fire from spreading to nearby areas. The fire-fighting effort will be carried out by the fire brigade until outside assistance has arrived.

The following actions will be taken in the areas affected by the fire or explosion:

1. Fire doors in buildings will be closed.
2. Hazardous work in all areas will be shut down immediately.
3. All feed lines and additional equipment will be shut down, as necessary and practical.
4. The Emergency Coordinator will be contacted (See Table 10.)
5. The area will be cleared of all personnel not actively involved in fighting the fire. These persons are to report to the designated rally points for accountability. Rally points are designated in Figure 28. All persons in Section 1 on Figure 28 proceed to Rally Point 1; those in Section 2 to Rally Point 2.
6. All injured persons will be removed, and medical treatment will be administered by qualified personnel.

Because fire is always a potential hazard in spills of flammable materials, possible sources of ignition have been eliminated. Vehicular traffic and hazardous work in the area will cease until the spill is contained and safety is restored. If spilled materials are flammable, the fire brigade will respond with foam equipment and hoses. Flushing with large quantities of water or foaming of the spill will be performed if advised by the fire brigade chief.

If a highly flammable material is released (e.g., propane or natural gas), all persons within at least a quarter-mile radius of the release will be notified. All ignition sources within this area will be eliminated. Use of motor vehicles within this area will be restricted or eliminated to avoid ignition of the vapor, which can cause a flashback to the source and an initial explosion of fire of wide

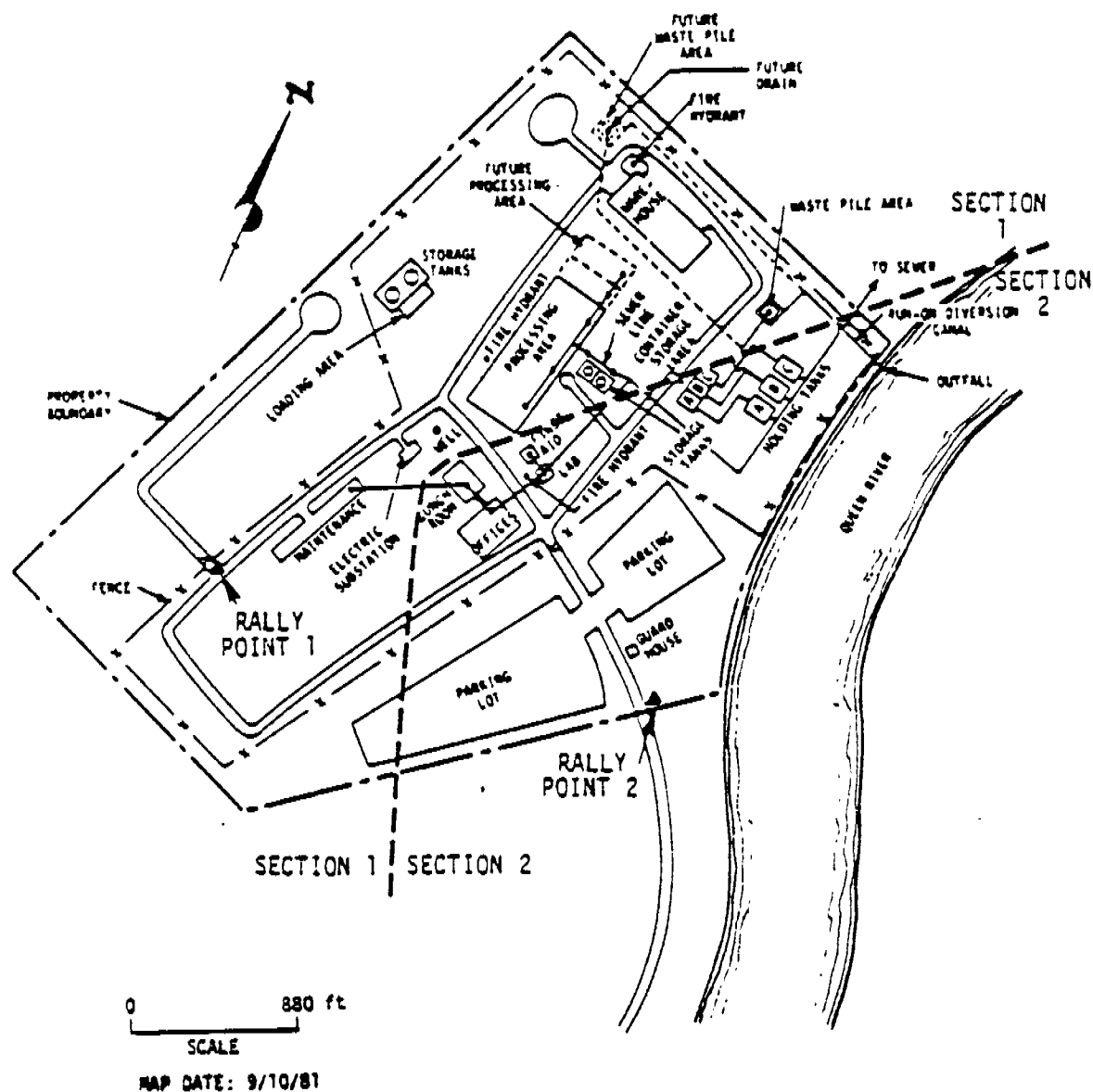


Figure 28. Rally points in the event of fire or explosion.

dimensions. If the chances of an impending explosion are high, the entire area within a 2000-ft radius of the source will be evacuated.

If a fire is involved and is concentrated at the source, people will be evacuated up to a half-mile downwind.

Fire fighting will not be done at the risk of injury to the persons involved; however, early containment of fires can significantly decrease total damage. Notification procedures are given in Figure 27.

The guard house or the plant receptionist will ^{not} be called unless absolutely necessary so that they remain free to handle only emergency calls.

Area or plant evacuation will be necessary in case of major fire or explosion. Specifics are outlined under general evacuation procedures. All personnel have been trained in evacuation procedures and means of exit from their respective work areas.

Until evacuation is signaled, personnel who are not in an affected area will stay in their respective work areas. Contract personnel and visitors will be cleared from the area and instructed to report to a guard house or office area.

The fire brigade chief will be responsible for all fire fighting efforts until outside help arrives. The fire

brigade chief is always the lead shift foreman. Supervisors of unaffected areas will stay with their personnel and be ready to evacuate and account for the persons under their supervision.

An "all clear" signal will be given when the fire has been extinguished and the safety of personnel is no longer endangered. The fire brigade chief will determine when the emergency has passed and consult with the Emergency Coordinator before the "all clear" signal is given. All emergency equipment used in the emergency must be cleaned and fit for use prior to resumption of plant operation in the affected areas.

Spills or Material Release

In the event of a major emergency involving a chemical spill, the following general procedures will be used for rapid and safe response and control of the situation. Emergency contacts found in Figure 27 provide a quick-reference guideline to follow in the event of a major spill.

If an employee discovers a chemical spill or process upset resulting in a vapor release, he or she will immediately report it to the area supervisor.

The area supervisor will contact the designated Emergency Coordinator at the time of the incident. When contacted,

the designated Emergency Coordinator will obtain information pertaining to the following:

1. The material spilled or released
2. Location of the release or spillage of hazardous material
3. An estimate of quantity released and the rate at which it is being released
4. The direction in which the spill or vapor or smoke release is heading
5. Any injuries involved
6. Fire and/or explosion or possibility of these events
7. The area and materials involved and the intensity of the fire or explosion.

This information will help the Emergency Coordinator to assess the magnitude and potential seriousness of the spill or release. If the accident is determined to lie within the company's emergency response capabilities, the Emergency Coordinator will contact and deploy the necessary plant personnel. If the accident is beyond plant capabilities, the Emergency Coordinator will contact the appropriate agencies. A list of agencies and phone numbers can be found in Table 12.

The initial response to any emergency will be to protect human health and safety, and then the environment. Identification, containment, treatment, and disposal assessment will be the secondary response.

In the event of a leak or spill in the tank area, all feed lines to the storage tanks will be closed. The dike surrounding the tank storage area has the capacity to hold the largest tank and any rainfall. Immediately after the spill is detected, a local contractor will be summoned to remove any standing liquids and haul the spilled material to a facility approved to handle that particular waste.

If for some reason a chemical spill is not contained within a dike or sump area, an area of isolation will be established around the spill. The size of the area will generally depend on the size of the spill and the materials involved. If the spill is large and involves a tank or a pipeline rupture, an initial isolation of at least 100 ft in all directions will be used. Small spills or leaks from a tank or pipe will require evacuation of at least 50 ft in all directions to allow cleanup and repair and to prevent exposure. When any spill occurs, only those persons involved in overseeing or performing emergency operations will be allowed within the designated hazard area. If possible the area will be roped or otherwise blocked off.

If the spill results in the formation of a toxic vapor cloud (by reaction with surrounding materials or by outbreak of fire) and its release (due to high vapor pressures under ambient conditions), further evacuation will be enforced. An area at least 500 ft wide and 1000 ft long

will be evacuated downwind if volatile materials are spilled.

Because the distance to the closest urban area is about 5 miles, it is unlikely that evacuation of its population will be necessary in the event of a release of toxic material. Industrial areas within a mile of the plant will be notified, however, if a large quantity of spilled material ignites. Because winds in the area tend to vary, the quickest and most accurate assessment of meteorological conditions is accomplished by calling the National Weather Service at 798-5558 or Anytown Airport at 861-6610.

If the control and cleanup of a spill, release, or fire is within the capabilities of company personnel and local response teams, the Rhode Island Department of Environmental Management or the National Response Center will not be notified unless one of the following occurs:

- ° A spill discharges to the Queen River and the quantity of hazardous material spilled is equal to or greater than the reportable quantity specified under 40 CFR Part 117.
- ° One thousand gallons or more of oil is spilled in a single event. If a lesser quantity has been spilled but has entered a storm sewer leading to the Queen River, it is advisable to contact local and state authorities for assistance if it is not possible to intercept the spill at the outfall or prevent the oil slick from moving downstream.
- ° The spill involves other hazardous materials not listed but used at the plant if they pose an actual or potential hazard to life or property.

As called for in regulations developed under the Comprehensive Environmental Liability and Compensation Act of 1980 (Superfund), our practice is to report a spill of a pound or more of any hazardous material for which a reportable quantity has not been established and which is listed under the Solid Waste Disposal Act, Clean Air Act, Clean Water Act, or TSCA. We also follow the same practice for any substances not listed in the Acts noted above but which can be classified as a hazardous waste under RCRA.

If the Emergency Coordinator determines that the company is unable to handle the emergency, then local, state, and Federal authorities will be notified of the situation. Evacuation of all potentially affected plant areas will be initiated as soon as possible.

The following guidelines will be used in case of an accidental episode involving waste materials. These are general guidelines, and circumstances may dictate some alterations to these procedures.

Most waste spills and leaks are easily contained within the dikes and sumps provided in the tank area. Small spills occurring in a diked area are flushed with plenty of water, to the sump provided in that area. If necessary, a portable sump pump is used to pump the diluted waste material into 55-gallon drums. Procedures for handling large spills were discussed earlier in this section.

For all large spills or serious leaks the following guidelines will be followed as closely as possible:

1. If a leak develops or a spill occurs from a waste storage tank, pipeline pump, etc., the person discovering the discharge will leave the immediate area and contact the Emergency Coordinator. The Emergency Coordinator will obtain the following information:
 - a. Person(s) injured and seriousness of injury.
 - b. Location of the spill or leak, material involved, and source (tank, pipeline, etc.).
 - c. The approximate amount spilled, an estimate of the liquid and/or gas discharge rate, and the direction the liquid flow or gaseous cloud is moving.
 - d. Whether or not a fire is involved.

~~Next, the Emergency Coordinator will:~~

- a. Initiate evacuation of the hazard area. For small spills or leaks, isolate at least 50 ft in all directions. For large spills, initially isolate at least 100 ft in all directions and keep all persons upwind of spill.
- b. Obtain medical attention for any injured persons. It may be helpful to instruct the caller in initial first aid procedures. Then call the hospital.
- c. Call the fire department if a fire is involved that cannot be extinguished by plant personnel. Fight small fires with dry chemicals, CO₂, or foam, and large fires with water spray, fog, or foam. Keep heat-exposed containers cooled with water spray and remove them from the fire if possible. IF A RISING SOUND COMES FROM A VENTING DEVICE OR THE TANK BEGINS TO DISCOLOR, WITHDRAW FROM THE AREA IMMEDIATELY.

- d. Dispatch emergency personnel to the site to take the appropriate action.
 - e. Contact the proper authorities (Figure 27 and Table 11) if the spill or release is large. Contact local authorities first so that, if necessary, downstream water users and/or persons downwind of the vapor can be notified and, if necessary, evacuated. If a large spill occurs, the initial evacuation area downwind should be 0.2 mile long (≈ 1000 ft) by 0.1 mile wide (≈ 500 ft). If a tank containing waste becomes involved in a fire, isolate an area $\frac{1}{4}$ mile in all directions.
3. Cleanup personnel will:
- a. Make sure all unnecessary persons are removed from the hazard area.
 - b. Put on protective clothing and equipment.
 - c. If the flammable waste is involved, remove all ignition sources, and use spark and explosion proof equipment and clothing in containment and cleanup.
 - d. If possible try to stop the leak. Special materials will be kept on hand for temporary repairs.
 - e. Remove all surrounding materials that could be especially reactive with materials in the waste. Determine the major components in the waste at the time of the spill.
 - f. Use absorbent pads, booms, earth, sandbags, sand, and other inert materials to contain, divert and clean up a spill if it has not been contained by a dike or sump. Most spills contained within the dike or sump can be pumped back into the appropriate storage tank or drum.
 - g. If wastes reach a storm sewer, try to dam the outfall to the Queen River by using sand, earth, sandbags, etc. If

this is done, dilute wastes in the storm sewer with large quantities of water and pump this material out into a temporary holding tank or drums as soon as possible. If a spill enters the river or has entered a storm drain, use absorbent booms and sweeps around the outfall to contain and absorb water-insoluble organics.

- h. Place all containment and cleanup materials in drums for proper disposal. Some items, such as absorbent rags or booms may have to be cut up.
- i. Place all recovered liquid wastes and contaminated soil in drums for removal to an approved disposal site.

Following are procedures to follow if a large amount of material spills onto unprotected ground and ground water is contaminated. Because the water table level onsite is only about 10 ft below the ground surface, cleanup and containment of spills reaching or likely to reach the groundwater will be accomplished by construction of interceptor trenches. Ground water flow is in the general direction of the Queen River. The trench will be constructed across the entire front of the migrating body of material (i.e., the trench will be a few feet wider on either side of the spill boundaries as can be determined from surface observations). Figure 29 illustrates this. This trench will be as narrow as the excavating equipment will allow. It will be constructed to a depth of 1 to 4 ft below the water table surface. The downstream wall of the trench will be lined with an impermeable and resistant material to prevent further migration of the spilled material. If the trench

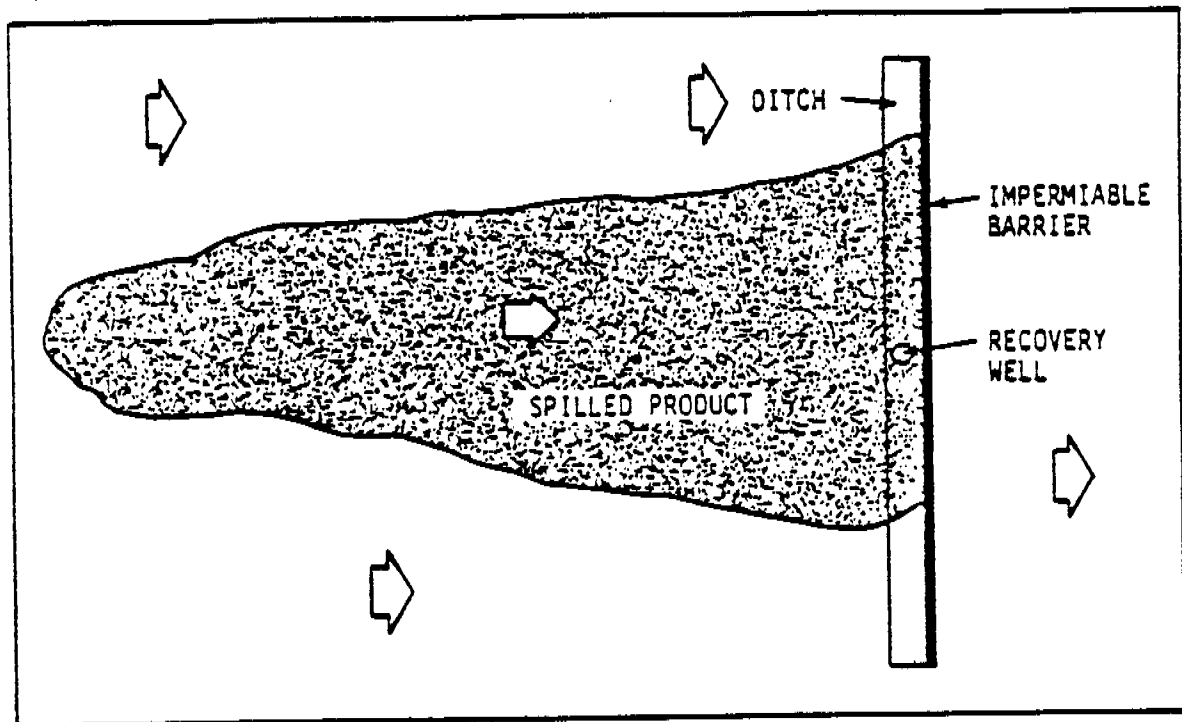


Figure 29. Interceptor trench.

is deep enough, the contaminated water will collect in the ditch and will be pumped out as required. A pump to create a zone of depression will be used to increase speed of recovery. This is accomplished by first placing a 16- to 18-in. diameter galvanized culvert pipe, slotted or perforated and capped on the bottom, in the bottom of the trench about midway from each end. Fiberglass or steel window screening is then wrapped around the pipe where it is slotted and then secured with wire. The trench is then backfilled within 2 ft of the ground surface with gravel and finished with native soil. Figure 30 shows a cross section of an interceptor trench. When pumping is required to prohibit contamination of the water table, a submersible pump is lowered into the culvert. Pumping will be done continuously to prevent the contaminant from moving around the ditch. When recovering a flammable material from the ground water, explosion- and spark-proof pumping equipment, tools, and clothing is used because of the possible presence of explosive vapors. Smoking, and heat sources in the area will be eliminated.

All emergency equipment used in the emergency must be cleaned and fit for use prior to resumption of plant operations in the affected areas.

Floods

Approximately half of the facility property is located within the 100-year flood plain and is subject to floods of

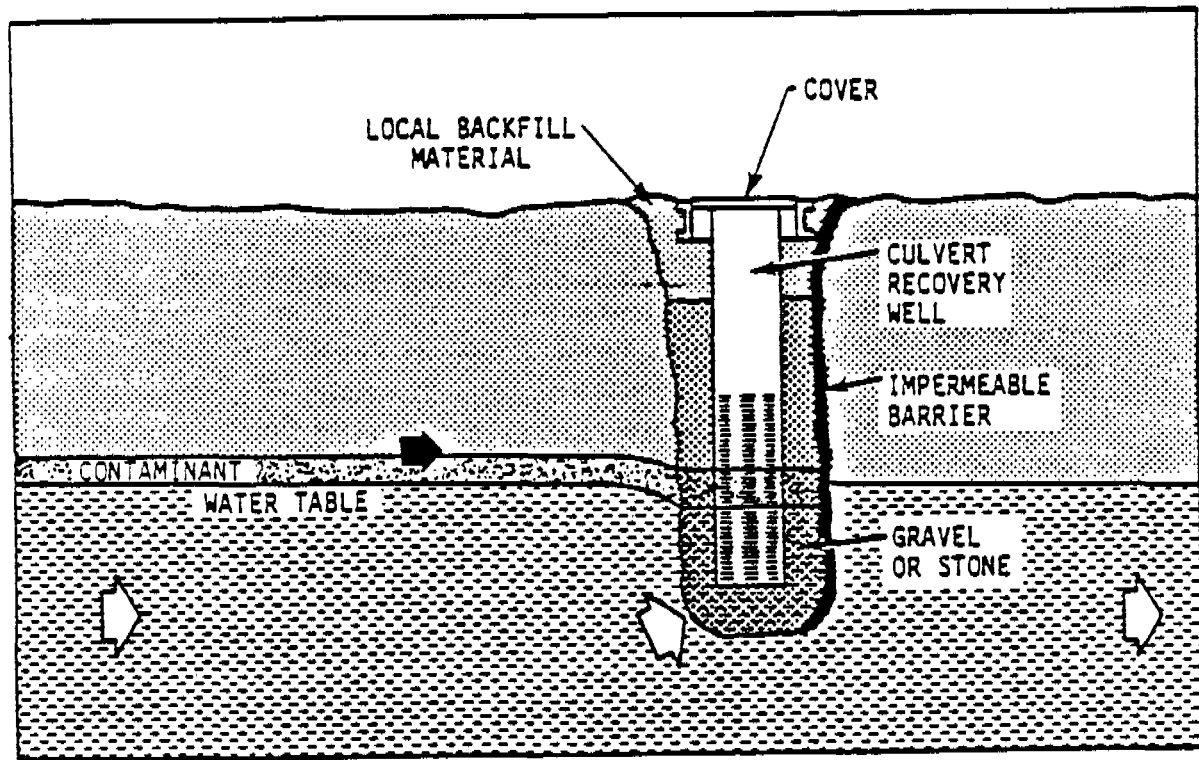


Figure 30. Interceptor trench
(cross-section).

1 to 3 feet in depth. The present waste pile and drum storage areas are within the 100-year flood plain.

The drum storage area and waste pile are both subject to flooding. The long-term solution is to move these functions to higher ground. If a flood occurs before this relocation, the following steps should be taken:

1. Check with the National Weather Service in Providence, Rhode Island, or the Army Corps of Engineers for a projected flood crest.
2. If the crest will result in less than 1 ft of water in the waste pile or drum area, the areas will be diked with sandbags up to a level 1 ft over the projected level.
3. If the crest will result in more than 1 ft of water in the waste pile and drum areas, the waste will be removed to a waste disposal facility. It is estimated the drums will take 3 to 4 hours to remove. The waste pile is expected to take up to 8 hours to remove; therefore a sandbag dike will be constructed to protect the site during the removal time.
4. Should a fire, explosion, spill or material release occur during the flooding, the sections addressing these occurrences will be consulted.

G-4e Prevention of Recurrence or Spread of Fires, Explosions or Releases [40 CFR 264.56(e)]

Actions to prevent the recurrence or spread of fires, explosions or releases include stopping processes and operations, collecting and containing released waste, and recovering or isolating containers. The onsite training manual addresses the specific actions to be taken in an emergency. In addition, if the facility stops operations

in response to an emergency, the emergency coordinator will monitor valves, pipes, and other equipment for leaks, pressure build up, gas generation or ruptures.

G-4f Storage and Treatment of Released Material [40 CFR 264.56(g)]

Immediately after an emergency, the emergency coordinator will make arrangements for treatment, storage, or disposal of recovered waste, contaminated soil, surface water, or any other contaminated material.

G-4g Incompatible Wastes [40 CFR 264.56(h)]

The emergency coordinator will ensure that wastes which may be incompatible with the released material are treated, stored or disposed of until cleanup procedures are completed.

G-4h Post-Emergency Equipment Maintenance [40 CFR 264.56(h)(2)]

After an emergency event, all emergency equipment listed in section G5 will be cleaned so that it is fit for use or it will be replaced. Before operations are resumed an inspection of all safety equipment will be conducted as discussed in section F-2. The Regional Administrator, state, and local authorities will be notified that post-emergency equipment maintenance has been performed and operations will be resumed.

G-4i Container Spills and Leakage [40 CFR 264.171]

Refer to section G-4d for a discussion of emergency response procedures for container spills and leakage.

G-4j Tank Spills and Leakage [40 CFR 264.194(c)]

Refer to section G-4d for a discussion of tank spills and leakage emergency response procedures.

G-4k Waste Piles

G-4k(1) Indication of Waste Pile Containment System Failures

Per the inspection schedule discussed in section F-2, the waste pile storage area will be inspected on a weekly basis. If during an inspection liquid is detected in the leachate monitoring manhole a sample will be collected and analyzed for lead and hexavalent chromium. If lead and/or hexavalent chromium is detected, the containment system evaluation and repair plan will be implemented. If inspection of the membrane liner indicates there are tears, holes, separation of layers, thin spots, cracks, shrinkage, hardness, excessive permeability, or blisters, the plan will also be immediately implemented. Other indications of waste pile containment system failure which would require implementation of the plan include: deterioration or loosening of the joint holding the liner to the foundation, loss of base material or soil covering liner, exposing the liner to direct sunlight, or foundation deterioration or cracking.

G-4k(2) Elements of a Containment System Evaluation and Repair Plan

If there are indications of waste pile containment system failure, the containment system evaluation and repair plan will be implemented immediately. The plan clearly outlines the steps necessary to evaluate the extent of damage to the containment system and measures necessary to correct a containment deficiency. Structures involved in the

containment system evaluation include: the foundation, liner, leachate, and runoff collection system, waste pile base, leachate monitoring manhole, and perimeter soil embankment. The most vulnerable unit of the containment system is the liner which will undergo the following tests to ensure integrity:

- ° visual inspection for cracks, holes, etc.
- ° laminate thickness
- ° cold bend
- ° tensile strength
- ° tear strength
- ° puncture resistance
- ° hydrostatic resistance
- ° dimensional stability
- ° ozone resistance
- ° seam strength

Other structures will require thorough visual inspection for deficiencies. Also included in the plan is a schedule of actions in the event of containment failure and a description of repair techniques.

G-4k(3) Criteria and Procedures for Removal of Waste Pile From Service in Case of Positive Failure of the Containment System [40 CFR 264.255(b), 264.255(c), and 264.255(d)(1)]

In the event there is a positive failure of the containment system the waste pile will be removed from service. Front-end loaders will be used to remove the waste pile from the containment system and load the haul trucks. Waste will be disposed of at a facility approved to handle that particular waste. Newly generated waste will be stored in 3 cu. yd. dumpsters until the containment system is repaired.

G-4k(4) Restoration of a Waste Pile to Service [40 CFR 264.255(e)]

After removing the waste pile from service and disposing of the waste pile, the containment system will be repaired as

soon as possible. Depending upon the severity of the repair work, a registered professional engineer will certify that the containment system still meets the design specifications approved in the RCRA permit.

G-4k(5) Course of Action After Waste Pile is Removed From Service (40 CFR 264.255(f) and 264.258)

When the waste pile containment system is permanently removed from service the following steps will be necessary to close the facility and restore the grounds to their original appearance:

1. Remove hazardous waste pile to a facility approved to handle that particular waste.
2. Remove base, liner, foundation, underdrains, underdrain collection sump, leachate collection system, and leachate monitoring manhole, and dispose of at a facility approved to handle that particular waste.
3. Remove any contaminated soil and dispose of at a facility approved to handle that particular waste.
4. Remove groundwater subdrains and store for reuse or resale.
5. Fill diversion ditch and pit from waste pile containment system with onsite soil and grade.
6. Apply seed and straw in an effort to reclaim the area.
7. Decontaminate front-end loaders, haul trucks, pumps, etc. in the container storage area and dispose of resulting wastes appropriately.
8. An independent registered professional engineer will certify closure of the waste pile containment system.

G-5 Emergency Equipment

Location of emergency equipment is shown on Figure 31. The plant employs several mechanisms for fire control. First, three fire hydrants are located in the plant area. Each hydrant will deliver 500 gal/min of water. Approximately 1000 ft of hose is stored in the warehouse.

Also available for fire control are portable fire extinguishers; at least one extinguisher is located in each of the following areas:

- ° Drum storage area
- ° Storage tank area
- ° Processing area
- ° Warehouse
- ° Electric substation
- ° Lab
- ° Offices

These fire extinguishers are dry chemical Types A, B, and C. Type A is capable of extinguishing fires involving ordinary combustible materials such as wood, cloth, paper, rubber, and many plastics; Type B is capable of extinguishing fires involving flammable liquids, oils, greases, tars, oil base paints, lacquers, and flammable gases; and Type C is capable of extinguishing fires involving energized electrical equipment. All extinguishers comply with National Fire Code standards for portable fire extinguishers, and they are inspected after each use or at least monthly. Records of these inspections are kept in the operating log.

Equipment for use in containing and cleaning up spilled hazardous wastes is stored in the warehouse. A list of

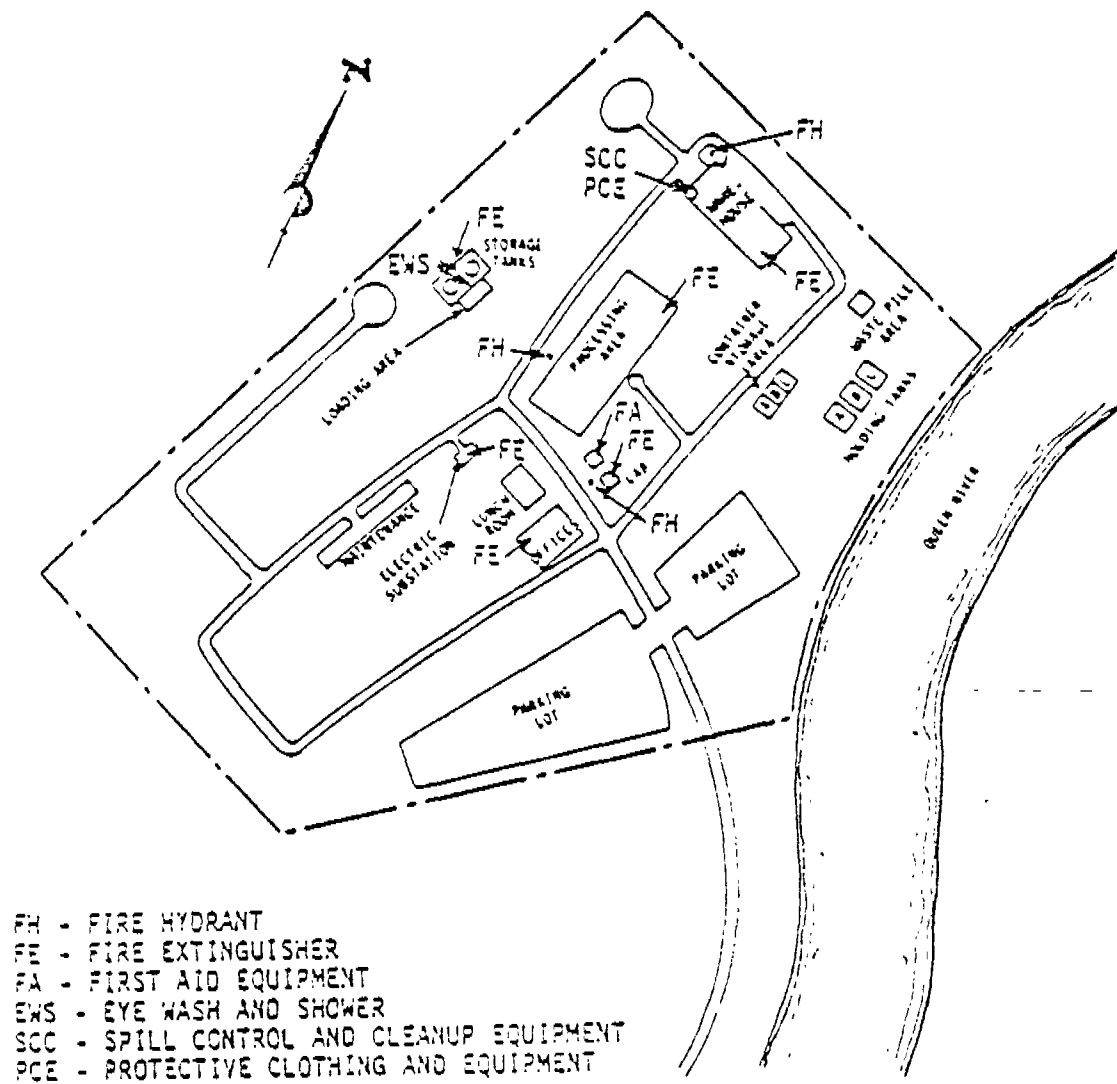


Figure 31. Location of emergency equipment.

equipment and materials stored and maintained in the warehouse is listed in Table 13, along with the function of each.

First aid supplies at the first aid station include the following:

- ° Bandage materials
 - band-aids
 - gauze pads and rolls
 - adhesive tape
 - butterfly bandages
- ° Antibacterial ointments
- ° Splints
- ° Aspirin
- ° Emetic - Syrup of Ipecac
- ° Local and topical anesthetics
- ° Eyewash bottle and solution

Emergency eyewash fountains and showers are located at the east and west ends of the waste storage tank area. Each unit consists of a drench showerhead with "panic bar"-operated frost-proof valve and an eyewash with a dirt cover and "panic bar"-operated frost-proof valve. A sign reading "EMERGENCY SHOWER AND EYEWASH FOUNTAIN" is posted at each unit. A hose station is also located near the eyewash/shower station at the west end of the tank storage area.

Protective clothing and equipment is provided to protect employees during normal and emergency operations. Hard hats, protective eyewear, and steel-toed boots or shoes are the minimum protective clothing required. Other protective clothing equipment available on site include:

- Clothing
 - Plastic aprons and gauntlets
 - Rubber and Neoprene boots

TABLE 13. MATERIALS AND EQUIPMENT FOR SPILL CONTAINMENT AND CLEANUP

Material(s)/equipment	Quantity	Substances contained/ absorbed/cleaned up	Notes
Standard industrial absorbents (Sorb-All, Vermiculite, etc.)	A drum should be placed in all plant areas where small spills are suspect.	For small spills of oil, solvents, aqueous materials. Do not use for acids or caustics unless first neutralized.	Each drum should be accompanied with broom (or shovel) and dustpan.
Sandbags	800-1000	Sand is unreactive with most any chemical except hydrofluoric acid.	Keep in readily accessible area(s) near most concentrated area(s) of tanks or drums.
Sand	50-100 yd ³	Sand is unreactive with most any chemical except hydrofluoric acid.	Use primarily for containment or large spills. Containment and cleanup of small spills. Also, keep in barrels in areas where small spills may occur more frequently (drum storage areas, process pads, etc.). Keep covered if outside.
Absorbent boom, weighted or with curtain or skirt	2	In water, most insoluble or slightly soluble organics. Most materials on land. Do not use for acids.	Employ one boom around out-fall discharge on permanent basis and one for backup.

(Continued)

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TABLE 13 (continued)

Material(s)/equipment	Quantity	Substances contained/ absorbed/cleaned up	Notes
Absorbent pads	Carton (100 pads- Conwed)	In water, most insoluble or slightly soluble organics. Most materials on land. Do not use for acids.	Will float on water so are most helpful in cleaning up materials contained within the boom boundaries or in diked areas where a chemical sheen has formed on water collected within. Also, place around equipment or in areas where leakage or spillage occurs frequently (i.e., pumps, loading/unloading areas).
213 Straw	15-20 bales	Petroleum, distillates, oil, organic solvents. Do not use for acids or caustics.	Can be used for diking and absorption for land spills. If booms become saturated, can be tied together and used to con- tain and absorb water spills. Since they sink partly below water surface, they are useful for substances slightly heavier than water.
Submersible pump	1	See manufacturers (Gould, Flygt, Peabody) for specifications on mate- rial-handling capabili- ties.	Can be used to remove diked liquids, etc.

(continued)

TABLE 13 (continued)

Material(s)/equipment	Quantity	Substances contained/ absorbed/cleaned up	Notes
Flexible (Neoprene) hoses with quick couple fittings.	75 ft minimum	N.A.	Neoprene is resistant to most acids and solvents, but not all. For instance, benzene will degrade Neoprene.
55-gallon drums; steel, stainless steel	Variable	Most organics (steel); acids, caustics, contaminated absorbent materials (stainless steel).	

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- Short and long rubber gloves
- Rain suits
- Chemical-resistant suits (Tyvek, polyurethane, polyethylene)
- Polyethylene gloves

Equipment

- Face shields and extra protective eyeglasses
- Disposable respirators
- Chemical cartridge respirators w/cartridges for organic vapors and acid gases; half- and full-face types
- Chest-mounted gas mask cannisters
- Self-contained breathing apparatus (SCBA) operated in pressure-demand mode

This equipment is located in the warehouse for easy access by personnel.

G-6 Coordination Agreements

Tankopile has made the following arrangements to assist in response to emergency situations.

1. An agreement has been made with a local disposal facility to provide a tank truck on a 24-hour basis.
2. Copies of the contingency plan have been given to the local police and fire departments, the hospital, and the state and local Emergency Response Teams. These agencies were asked to review and comment on the plan and have detailed the actions they will take in response to any emergency.

The following organizations have been sent copies of the contingency plan:

Fire Chief Charles Lang
Anytown Fire Department
6th and Main Streets
Anytown, Rhode Island 02881

Fire Chief David Kuntz
Washington County Fire Department
11934 State Route 43
Brixton, Rhode Island 02881

Dr. Joyce Henderson
Anytown Hospital
2914 Elm Street
Anytown, Rhode Island 02881

Dr. Joseph Smyth
Washington County Hospital
1293 State Route 43
Georgetown, Rhode Island 02881

Mr. Robert Burns
Rhode Island Emergency Management Agency
1200 Washington Boulevard
Providence, Rhode Island 02908

Ms. June Davidson
Washington County Emergency Management Agency
11850 State Route 43
Brixton, Rhode Island 02881

G-7 Evacuation Plan

All emergencies require prompt and deliberate action. In the event of any major emergency, it will be necessary to follow an established set of procedures. Such established procedures will be followed as closely as possible; however, in specific emergency situations, the Emergency Coordinator may deviate from the procedures to provide a more effective plan for bringing the situation under control. The Emergency Coordinator is responsible for determining which emergency situations require plant evacuation.

The facility employs a warning system with a specific alarm signal to initiate evacuation of all plant areas. In addition to the alarm, the internal telephone system is used to notify key plant personnel as to the nature of the emergency and recommended plan of action. Total plant evacuation is initiated only by an Emergency Coordinator.

A fire alarm system is installed with alarm boxes located at critical areas throughout the plant. The fire alarms can also be used to summon aid in other emergency situations. All applicable employees are familiar with alarm box locations.

In the event plant evacuation is called for by the Emergency Coordinator, the following actions will be taken:

1. The signal for plant evacuation will be activated.
2. The guards will immediately open the gates. No further entry of visitors, contractors, or trucks will be permitted. All vehicle traffic within the plant will cease to allow safe exit of personnel and movement of emergency equipment.
3. ALL personnel, visitors, and contractors will immediately leave through the exit gate.
4. No persons shall remain or reenter the location unless specifically authorized by the person or persons calling for the evacuation. In allowing this, the person in charge assumes responsibility for those persons within the perimeter. Those within the fenced area will normally only include fire brigade personnel or emergency teams.
5. ALL persons will be accounted for by their immediate supervisors. Supervisors will designate certain gates as the safest exits for his or her employees and will also choose an alternate exit if the first choice is inaccessible. To assist in this endeavor, the Emergency Coordinator will use the internal telephone system to call the area supervisor, to inform him or her of the nature of the emergency.
6. During exit, the supervisor should try to keep his or her group together. Rally points for specific areas are shown in Figure 28. Immediately upon exit through the gate, the highest ranking supervisor

will prepare a list of all personnel at the exit gate. All other personnel who have persons reporting to them should report immediately to the front gate for final accounting.

7. Upon completion of the employee list, the supervisor in charge will hand-carry the list to the Emergency Coordinator. All other personnel will remain at the gate area.
8. Contract personnel should also be listed with the name of their company. Contract foremen should report to the front gate.
9. The names of fire brigade and/or other emergency team members involved in emergency response will be reported, in writing, to the front gate by designated response team personnel.
10. A final tally of persons will be made by the Emergency Coordinator.
11. No attempt to find persons not accounted for will involve endangering lives of others by reentry into emergency areas.
12. A plant guard at each gate will also maintain an updated list of all personnel to aid in the accountability procedure.
13. Reentry into the fenced area will be made only after clearance is given by the Emergency Coordinator. At his direction, a signal or other notification will be given for reentry into the plant.
14. In all questions of accountability, immediate supervisors will be held responsible for those persons reporting to them. Visitors will be the responsibility of those employees they are seeing. Contractors are the responsibility of those persons administering the individual contracts. Truck drivers are the responsibility of the warehouse supervisor or the area supervisor where the truck is loading/unloading. The guards will aid in accounting for visitors, contractors, and truckers by reference to the sign-in sheets.

15. Drills are held to practice all of these procedures and are treated with the same seriousness as an actual emergency.

G-8 Required Reports [40 CFR 264.56(d) and 264.56(i)]

As required by §264.56(J), any emergency event (e.g., fire, explosion, etc.) that requires implementing the contingency plan will be reported in writing within 15 days to the EPA Regional Administrator. A reporting form for emergency events is shown in Figure 32.

In addition to these reporting requirements for state and Federal authorities, Tankopile also has internal reporting requirements. The following incidents require that an incident report be completed and returned to the safety director within 5 working days and made part of the operating record:

1. All fires
2. Rupture disc releases
3. Unusual gas or vapor releases
4. Chemical spills of more than 10 gallons (or smaller volumes if highly toxic materials are involved)
5. All injuries except minor cuts and bruises (all burns and chemical irritations)
6. All equipment damage due to malfunction or operating error
7. All "near misses" of the above variety that could have had serious consequences

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REPORTING FORM FOR EMERGENCY EVENTS

Name, address, and phone number of owner or operator

Name, address, and phone number of facility

Date, time, and type of incident (e.g., fire, explosion, etc.)

Name and quantity of material(s) involved

Extent of injuries (if any)

Assessment of actual or potential hazards to human health or the environment
(if applicable)

Estimated quantity and disposition of material recovered from the incident

Send to: (Name)
U.S. EPA, Region I
Regional Administrator (EPA)
JFK Federal Bldg.
Boston, Massachusetts 02203
(Name) Chief
Environmental Emergency Branch
U.S. EPA, Region I
JFK Federal Bldg.
Boston, Massachusetts 02203

Figure 32. Sample reporting form for emergency events.

Amendments to the Contingency Plan

The contingency plan will be reviewed and immediately amended, if necessary, whenever:

1. The facility permit is revised
2. The plan fails in an emergency
3. The facility changes in its design, construction, operation, maintenance, or other circumstances in a way that materially increases the potential for fires, explosions, or releases of hazardous waste or hazardous waste constituents, or changes in the response necessary in any emergency
4. The list of emergency coordinators change
5. The list of emergency equipment changes

G-9 Amendments to the SPCC Plan

The Tankopile Finishing Company, prior to the submission of this application, did not have a Spill Prevention, Control and Countermeasure (SPCC) Plan. Therefore, §264.52(b) is not applicable, and the requirements for spill prevention, control and countermeasures were addressed in various sections of this contingency plan.

SECTION H

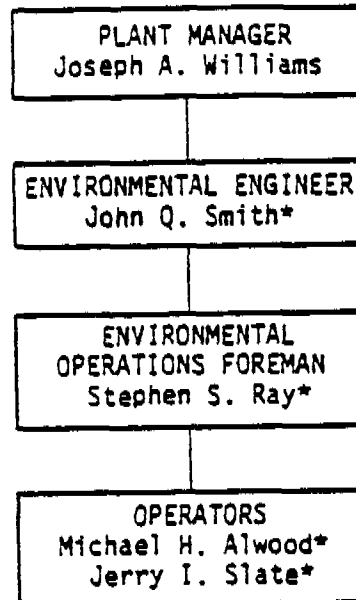
PERSONNEL TRAINING

The information contained in this section outlines the personnel training program for Tankopile's hazardous waste storage facility in accordance with the requirements of 40 CFR §122.25(a)(12) and §264.16.

H-1 Outline of Training Program [40 CFR 122.25(a)(12)]

H-1a Job Titles and Duties

Figure 33 shows the organization of personnel at the facility. Only four employees are directly involved with the handling of waste: The environmental engineer, the environmental operations foreman, and two operators. Management responsibilities involving compliance with RCRA regulations but not involving actual handling of the wastes are split between the environmental engineer and the plant manager. Maintenance personnel (i.e., electricians and mechanics) work in the waste handling area, but they do not handle wastes directly. The duties, responsibilities, and qualifications of each position follow:



*Indicates those personnel directly involved with hazardous waste activities.

Figure 33. Organization chart for Tankopile's HWM facility.

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Position Title: Environmental Engineer

Name of employee: John Q. Smith

Position Responsibilities and Duties:

- ° Emergency Coordinator for all hazardous waste activities.
- ° Training of plant personnel in the proper handling of raw materials, intermediates, finished products, and waste byproducts.
- ° Responsible for all air, water, and solid waste control systems on the site.
- ° Obtains all required permits and licenses or modifications of same from local, state, and Federal regulatory bodies.
- ° Resolves problems involving permits and licenses from local, state, and Federal regulatory agencies.
- ° Notifies proper authorities in emergency situations.
- ° Reports to Plant Manager.
- ° Regularly inspects plant grounds and all facilities for status of air, water, and solid/hazardous waste emissions and controls.
- ° Consults with maintenance foreman on questions involving emergency action.
- ° Drafts and submits to plant manager all required reports to EPA or the State.

Experience and Qualifications:

- ° B.S. degree in Chemical, Civil, or Environmental Engineering. B.S. Degree in Chemistry also acceptable.
- ° 1-3 years experience in industrial or municipal pollution control management.
- ° Training and/or experience in hazardous waste management is desirable.

Position Title: Environmental Operations Foreman

Name of employee: Stephen S. Ray

Position Responsibilities and Duties:

- ° Overall operation and maintenance of the hazardous waste storage facility.
- ° Maintains facility compliance with RCRA and other permits.
- ° Oversees operators and reviews their performance.
- ° Trains operators to:
 - Operate materials/drum handling equipment safely and effectively
 - Handle leaks, spills, and emergency situations
- ° Maintains operating log, monitoring records, maintenance records, inspection records, personnel training records, and all other required records.
- ° Notifies plant environmental engineer, plant manager, and if so directed, proper authorities in emergency situations.
- ° Schedules all maintenance and repairs to structures and equipment for HWM facility.
- ° Oversees mechanic/electrician doing both scheduled and unscheduled maintenance and repair work to be sure he is not releasing hazardous wastes to the environment or contaminating himself.
- ° Reports to environmental engineer.

Experience and Qualifications:

- ° Associate (2-yr) degree in Chemical, Civil, Environmental, or Mechanical Engineering.
- ° 2-3 years experience in plant operation.
- ° Hazardous waste management experience helpful but not required.

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Note: If applicant has no hazardous waste experience, special training in the functions and operation of a hazardous waste storage facility will be required before assuming job responsibilities. This training will be provided by Tankopile.

Position Title: Operator

Names(s) of employee(s): Michael E. Alwood
Jerry I. Slate

Position Responsibilities:

- ° Reports to environmental operations foreman.
- ° Operates waste handling equipment.
- ° Reviews all incoming wastes and assigns wastes to proper storage location.
- ° Inspects tanks, drums, and other storage equipment, and any gauges, dials, and recorders as required for proper operation and structural integrity.
- ° Inspects drum storage area for evidence of leaks and spills and inappropriately placed drums.
- ° Inspects emergency equipment on a regular basis.
- ° Assists in training of new operators and mechanics to handle hazardous waste spills and leaks safely and in such a way as to avoid exposures.
- ° Makes appropriate entries into operating log, monitoring records, inspection records, and maintenance records, and files them according to established system.
- ° Notifies foreman and other plant authorities as necessary in emergency situations.
- ° Takes emergency action on own authority in accordance with established procedures.

Experience and Qualifications:

- ° High school diploma
- ° 2-3 years experience as plant operator with related activities.

Note: Operator will also be required to maintain and inspect other pollution control equipment on the site.

H-1b Training Content, Frequency, and Technique

The program developed at Tankopile for training employees in the safe handling of hazardous wastes has been organized into a "training manual." Provisions are made for updating or revising the text as necessary to ensure compliance with the terms of the RCRA permit. Each employee has his or her own copy of the manual. An outline of the training manual is shown in Figure 34. This training manual is kept on file at the facility, and is available to EPA officials for review.

During the training program, employees are instructed on (1) the hazardous nature of chemicals and chemical wastes in general, (2) the purpose of RCRA and importance of maintaining compliance with RCRA regulations, (3) the hazardous nature of the wastes being stored in the facility, (4) proper handling and storage procedures for wastes, (5) emergency procedures and contingency plan.

The manual is used as the basis or framework for training Tankopile personnel in the proper procedures, equipment, and systems to be used in managing hazardous wastes.

Preface

1.0 Introduction

- 1.1 Chemical hazards
- 1.2 The Resource Conservation and Recovery Act - RCRA

2.0 Facility and Process Description

- 2.1 Description of wastes to be managed
- 2.2 Description of storage facility
- 2.3 Key terms of the permit
- 2.4 Normal/routine operations
- 2.5 Waste analysis
- 2.6 Recordkeeping and reporting requirements
- 2.7 Security
- 2.8 Inspections

3.0 Emergency Procedures and Contingency Plans

- 3.1 Emergency coordinator
- 3.2 Emergency procedures
- 3.3 Emergency communications/phone numbers and alarms
- 3.4 Location, maintenance, inspections, and use of emergency equipment
- 3.5 Procedures for waste feed cutoff systems
- 3.6 Spill control and response to groundwater contamination incidents
- 3.7 Fires and explosions
- 3.8 Power interruption or failure
- 3.9 Tornadoes, hurricanes, and severe storms

Appendix A Summary of RCRA Regulations for Hazardous Waste Storage Facilities

Appendix B Summary of Conditions Specific in Tankopila's RCRA Permit

Appendix C Training Programs in Hazardous Waste Management

Figure 34. Outline of Hazardous Waste Training Manual.

For key personnel, Tankopile plans to supplement the training outlined in the manual with attendance at one or more technical seminars or training programs on hazardous materials. A list of such seminars or programs is included in Appendix C of the training manual.

A brief description of each section of the training manual follows:

Section 1 - Introduction

This section of the manual introduces Tankopile employees to the general classes and characteristics of chemicals and chemical wastes that can be hazardous to health and property. In this context, the terms toxicity, reactivity, corrosivity, and ignitability are defined. It is Tankopile's policy that each employee handling chemical substances (raw materials, finished products, byproducts, and wastes) respect them and be aware of these potential hazards. The company's policy on the use of protective clothing and safety equipment to prevent accidental worker exposures and releases to the environment of hazardous chemicals and wastes is introduced.

The authority for regulating hazardous wastes under the Resource Conservation and Recovery Act (RCRA) also is discussed. The regulatory framework for classifying hazardous wastes, setting operational standards, and permitting procedures and achieving compliance is explored. The RCRA permit for Tankopile (once it is received) will

also be studied to be sure that each employee is familiar with its terms.

Section 2 - Storage of Hazardous Wastes at Tankopile

This section focuses on the types of hazardous wastes that are handled and stored at Tankopile, normal/routine storage operations, and procedures for maintaining compliance with the RCRA permit (e.g., waste analysis, recordkeeping, inspections, and security). A site diagram showing the dimensions, capacity, and relative position of each storage area (tanks, containers, and piles) is included.

Training for normal or routine operating conditions includes the following topics:

- ° Proper operation and maintenance of the storage facility
- ° Scheduled inspections
- ° Purpose and use of security and communications systems
- ° Monitoring requirements for tracking and recording the operation of the facility
- ° Recordkeeping requirements and procedures

Section 3 - Emergency and Contingency Plans

The third section of the training manual provides detailed instruction on steps to be taken in the event of an emergency such as a waste spill or fire, power outage, or damage from wind and storms. The emergency coordinator is clearly identified, as are emergency phone numbers and directions

for locating and using onsite emergency equipment, alarms, and communications. Contingency plans are also detailed.

This manual is used in classroom training for both introductory training and annual review. All personnel involved with hazardous waste are required to complete 20 hours of classroom training in addition to 6 weeks on-the-job training. Also personnel receive an 8-hour classroom review training session once a year. This is supplemented with attendance by the environmental engineer at seminars and conferences involving hazardous waste management.

H-1c Training Director

The personnel training program is directed by Mr. John Q. Smith, the plant Environmental Engineer. Mr. Smith has been with Tankopile for 10 years. He received a M.S. degree in Environmental Engineering from the University of Cincinnati in 1971. He has been trained in all aspects of Hazardous Waste Management and attended various seminars on this subject. Records of his previous and ongoing training are kept on file at the personnel office.

H-1d Relevance of Training to Job Position

Mr. John Q. Smith, the plant Environmental Engineer, is responsible for teaching hazardous waste management procedures, including contingency plan implementation, to all waste handling personnel. The training program is tiered (Figure 35) in some areas to provide training to personnel at levels that are relevant to their positions within the

	Personal safety	Release prevention and re- sponse	Contingency plan	Emergency procedures	Hazardous waste man- agement and prac- tices	Record keeping	Hazardous waste handling and operations
Environmental Engineer	B	B	B	B	B	B	B
Environmental Operations Foreman	B	B	B	B	B	L	B
Operators	B	B	L	B	L	L	B

B = broad instruction
L = limited instruction

Figure 35. Level of training for hazardous waste personnel.

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plant. For example, the foreman receives training in recordkeeping and other procedures required for compliance, whereas the operators do not. Operators are more specifically trained to maintain proper and safe operating procedures and to respond effectively in the event of a spill or other emergency.

H-1e Training for Emergency Response

This training program is designed to ensure that personnel not only handle hazardous wastes in a safe manner but also properly respond to emergency situations. The program trains hazardous waste handling/management personnel to maintain compliance under both normal operating conditions and emergency conditions.

Training elements addressing nonroutine and emergency situations (unscheduled shutdowns and startups related to storms, power outages, fires, explosions, spills) include:

- ° Procedures for locating, using, inspecting, repairing, and replacing facility emergency and monitoring equipment
- ° Key procedures for automatic waste feed cutoff systems
- ° Emergency communication procedures and alarm systems
- ° Response to fires or explosions
- ° Response to ground water contamination incidents and procedures for containing, controlling, and mitigating spills
- ° Shutdown of operations and power failure procedures
- ° Procedures for evacuation of nearby areas

In addition to the hazardous waste management personnel, a company fire brigade is on standby for response to all fires and other general plant emergencies. This fire brigade is trained both with classroom training methods and fire drills. The classroom training is required for introductory training and as an annual review for each member assigned to the fire brigade. The fire brigade training is not addressed in the hazardous waste training manual. For more information contact Tankopile's safety officer, George Shoe at 555-6790. The fire drills occur at a minimum of six times a year and are unannounced.

H-2 Implementation of Training Program

The director of the training program and all current waste-handling personnel have been fully trained at the time of this submittal. In the future, all new personnel will complete this training program within 6 months of assignment to the hazardous waste storage facility or within 6 months of their date of employment, whichever is later. No employee hired to work at this facility will work unsupervised prior to completion of the training program.

Employees are required to meet annually for review and update of this training program and to discuss and study the following subjects:

- 1) All hazardous wastes currently being handled at the facility, noting any changes in waste type, volume, source, characteristics, or location that have occurred during the past year.

- 2) The status of storage and operating conditions and procedures, noting any areas where there are problems or potential for problems. Employees participate in developing effective solutions.
- 3) The requirements contained in the facility's RCRA permit, noting any changes that have occurred during the past year. Areas where maintenance of compliance is a problem are identified and discussed, and effective solutions are sought.
- 4) Incidents that have occurred in the past year that warranted use of contingency plans and/or emergency action. This review focuses on the cause of the incident and identification of steps to be taken to prevent or to ensure better handling of such events in the future.

The annual review will also utilize the facility's annual report to EPA as a working document for the review.

Records documenting the job title for each position, job descriptions, names of employees, and completed training programs (both introductory and review) will be kept onsite in the personnel office of Tankopile Finishing Company. These records will be kept until closure of the facility for current employees and for 3 years from the date of the individual employee's termination for former employees.

SECTION I

CLOSURE PLAN, POST-CLOSURE PLAN, AND FINANCIAL REQUIREMENTS

This Section is submitted in accordance with the requirements of 40 CFR §122.25(a)(13), §264.112 through 115, §264.178, §264.197, and §264.258. This plan identifies all steps that will be necessary to partially close the facility at any point during its intended operating life and to completely close the facility at the end of its intended operating life. The plan also addresses the conditions and reasons under which partial closure will occur. A post-closure plan is not required because this is not a disposal facility and all wastes are being removed at closure.

Tankopile will maintain an onsite copy of the approved closure plan and all revisions to the plan until the certification of closure completeness has been submitted and accepted by EPA, Region I. The Tankopile owner will notify the Regional Administrator at least 180 days prior to the date we expect to begin final closure. The closure date for closure of the entire facility will be 2002. Upon completion of closure, the Tankopile owner will submit to the Regional Administrator a certification by both the Tankopile owner and by a local independent registered professional engineer that the facility has been closed in accordance with the specifications in the approved closure plan.

I-1 Closure Plan [40 CFR 122.25(a)(13)]

I-1a Closure Performance Standard [40 CFR 264.111]

This closure plan was designed to ensure that the facility will not require further maintenance and controls, minimizes or eliminates threats to human health and the environment, and avoids escape of hazardous waste, hazardous waste constituents, leachate, contaminated rainfall, or waste decomposition products to the ground or surface waters or to the atmosphere. If there is evidence of any spills or leaks, samples will be taken and analyzed to determine the extent of contamination in the soil and if necessary, in groundwater. Any contaminated soil will be excavated, removed, and disposed of at a proper disposal facility. Any contaminated groundwater will be remedied. The entire site will be regraded subsequent to closure to prevent erosion. The following sections discuss in detail efforts to be made at Tankopile to satisfy the closure performance standard.

I-1b Partial and Final Closure Activities

Tankopile expects to perform partial closure when we remove our waste pile from its current location in the eastern portion facility to a new location in the northern portion facility. Final closure activities on the waste pile will occur in 1982. Our procedures for final closure of the waste pile, including waste removal, cleanup and decontamination activities, are described in Section I-1d(3) of the

closure plan. Partial closure of the container storage and tank storage operations are not planned. However, in the event that future circumstances or decisions force us to discontinue our hazardous waste tank storage or hazardous waste container storage activities, Sections I-1d(2) and I-1d(1) of the closure plan present our procedures for final closure of each of the two storage areas. Any modifications to our existing facility equipment, structures, instruments or procedures related to the management of the three distinct portions of the facility will result in Tankopile updating the partial closure plan, and revising the closure plan accordingly.

At a maximum we expect the operation to consist of storage of 100 drums, 2 tanks and 1 waste pile during the life of the facility. Section I-1c of the closure plan describes the maximum inventory of wastes in storage at any given time during the operating life of Tankopile. Tankopile will secure permission to dispose of its wastes and enter into contractual agreements with XTC (an off-site surface impoundment) and the PFI hazardous waste landfill.

I-1c Maximum Waste Inventory

The following table shows the maximum inventory of wastes in storage at any given time during the operating life of Tankopile for 1 waste pile, 100 containers, and 2 tanks.

Waste pile:	
metal hydroxide sludge	50 yd ³
	<u>50 yd³ total</u>
Containers:	
metal grindings	1870 gal
vinyl acetate sludge	605 gal
vinyl chloride sludge	605 gal
pickle liquor sludge	2420 gal
	<u>5500 gal total</u>
Tanks:	
pickle liquor	7500 gal
1,1,1-trichloroethane	7500 gal
	<u>15000 gal total</u>

I-1d Inventory Removal and Disposal or Decontamination of Equipment

Following waste removal, all piping to and from the two storage tanks will be disconnected, dismantled and decontaminated. The work will be supervised and performed using qualified Tankopile personnel. Personnel will be equipped with acid/solvent resistant coveralls (olefin material, ~~coated with heavy polyethylene film~~), head protection, neoprene-coated gloves and boots resistant to solvents and acids. Both the wrists and ankles will be taped (electrical tape) to protect against upward and inward splash. Full face respirators with organic vapor and acid gases filter cartridges that seal directly to the mask will be used. Chemical neutralizers and spill control pillows will be employed in the event of any spills resulting from pipe drainage during the disconnection and dismantling process. Spill saturated spill control pillows will be placed in a 55-gallon polyethylene-lined, steel recovery drum located at the dismantling area for temporary storage.

Since contact of hydrochloric acid with some metals produces explosive hydrogen gas, extreme caution will be taken to utilize non-sparking tools and equipment during all cleanup and decontamination activities. Strict supervision will include provision for no open flames, hot surfaces, or smoking to be present in and surrounding the work areas.

The 3-in lines which transport the waste from the plant to the storage tanks will be dismantled. Positive displacement pumps, used to pump the wastes to tankers, and valves will be disconnected. In cases when it is difficult to remove all liquid or solid residues as these residues may be trapped behind heavy scale or rust or may be too viscous for pumping, the pipes, valves, pumps, dump trucks, and forklift trucks will be steam-cleaned to remove the residues. All contaminated wash waters, generated as a result of the steam-cleaning process, will be pumped by a positive displacement pump into a tanker truck and transported to the XTC facility (an off-site surface impoundment) located 30 miles from Tankopile in Cranville, Rhode Island (EPA I.D. Number RI0000020000).

Soils in the facility are not expected to be contaminated by the waste storage at Tankopile. However, the possibility of contamination occurring during the dismantling and cleaning of equipment and structures exists. An allowance has been made in the closure costs for removal and disposal

of approximately 20 yd³ using a front-end loader. If evidence of possible areas of soil contamination (in the form of soil discoloration or odor) exists, a soil sampling program will be instituted to determine the extent of soil contamination in those areas. At least one soil sample will be taken from the waste pile area (after removal of the liner) and one sample near the container storage area, where unloading operations occur. Auger soil borings with collected samples will be transported to a laboratory with GC/MS and atomic absorption capabilities. If contamination is found in the soil, those areas will be excavated to the depth at which no contamination is detected. All soils, contaminated equipment to be disposed, and solid residues will be loaded and transported by truck to the PEI landfill located 10 miles east of this facility in Newburg, Rhode Island (EPA I.D. Number RI0000010000).

Prior to leaving any of the site locations undergoing decontamination, decontamination of personnel protective clothing will be conducted by removing all bulk material from the boots and spraying, washing, and scrubbing with detergent solution all outside protective clothing materials as well as exposed skin surfaces (i.e., facial area).

I-1d(1) Closure of Containers

All the drum containers in the Tankopile container storage area will first be removed for transport to the PEI landfill. Because of the incompatibility of the types of wastes, the

corrosive sludge drums, toxic metal grindings drums, and ignitable sludges drums will each be transported along with the pallets on separate truck trips to the landfill. The drums will be moved utilizing a forklift.

The container storage area will then be decontaminated with a series of solvent washes and all waste water and residues generated will be collected in the sumps and pumped to the holding tanks for immediate analysis and, if laboratory analysis indicates that the waste is hazardous, the material will be pumped from the holding tanks into tanker trucks and sent for off-site disposal at the XTC surface impoundment. If laboratory analysis shows no evidence of contamination, waste water and residues in the holding tanks will be discharged to the sewer system. The automatic sump pumps in each of the sump areas will then be removed and decontaminated as described in Section I-1d.

Approximately 350 gallons of waste water and residue are anticipated to result from the container storage area decontamination process.

I-1d(2) Closure of Tanks

The final spent hydrochloric acid waste load stored in the tank is pumped to a tanker (by use of a positive displacement pump) and transported to the local publicly owned treatment works (POTW) for treatment. The 1,1,1-trichloroethane solvent is pumped to a tanker in a similar manner, and the waste is transported to a reclamation facility.

1,1,1-trichloroethane, upon contact with acid or acid fumes, can evolve highly toxic chloride fumes and HCl may react with water or steam to produce toxic and corrosive fumes. For safety considerations due to the proximity of the two tanks to each other, Tankopile elects not to perform dismantling, cleaning and decontamination of the two tanks and associated piping concurrently, but in a sequential manner. Using properly qualified Tankopile personnel protected as described in I-1d, the following procedures will be used to decontaminate each of the two tanks:

First, the waste outlet valve will be opened to allow waste residuals remaining on the bottom to drain from the tanks. The waste will be drained from the tanks into 55-gallon polyethylene-lined, steel recovery drums located directly beneath the outlet. When filled, the drums will be sealed and sent off-site by truck to the PEI landfill for disposal. The waste outlet valve will then be closed.

A 2,000 gallon-per-hour steam cleaning unit (capable of washing a 16,000-gallon area of storage capacity/hour) will be rented to decontaminate the tanks. This process will generate residues in the form of contaminated wash waters. The waste outlet valve will again be opened and contaminated wash waters will be drained into 55-gallon steel recovery drums, sealed, and sent off-site by truck to the XTC surface impoundment for disposal. Approximately 2000 gallons of

contaminated wash waters are anticipated to be generated during the steam cleaning of all tanks and equipment.

All the ancillary equipment associated with the tank will be detached from the tank. The equipment to be disconnected includes the nozzle for the level transmitter, piping inlets and piping exits. The pipes will be decontaminated by steam cleaning. Any visible spills or leakage detected during the disconnection process will immediately be remedied by spill saturation pillows, as discussed in Section I-1d.

To assess whether the tank steam cleaning process has been successful for the 1,1,1-trichloroethane storage tank, a member of the clean-up team will enter the tank with full protective gear and a combustible gas/oxygen detector. The team member will assess the hazard of the tank by local diffusion measurement of the percent of lower explosive limit of any residual 1,1,1-trichloroethane vapor in the tank. The detected presence of measured oxygen levels below 19.5%, or of combustible gas will result in rewashing the tank. For the HCl tank, litmus paper will be used for sampling the pH of the last drainage wash water. A neutral pH reading will indicate decontamination is complete.

Next, the concrete slab supporting the tank will be steam cleaned. The tank will then be dismantled from the foundation structure supports and either sold for scrap or resold.

I-1d(3) Closure of Waste Pile

The waste pile presently located in the northeastern section of the facility will be removed by June 1982. Closure of the waste pile will involve removal of the metal hydroxide sludge from the waste pile area. Tankopile personnel dressed in protective equipment described in Section I-1d will participate in the closure of the pile. Due to the design of the containment system of our waste pile storage area, the 2'6" of sand and the 1'6" of pea gravel underlying the pile must be removed since the waste pile has in all probability contaminated these layers. Extra precaution will be taken in removing the pea gravel to avoid damaging the CPE liner and the 4"-thick bentonite layer liner beneath the pea gravel. The waste materials, excavated by a front-end loader, will be loaded onto a dump truck equipped with equipment to avoid release of hazardous material over the sides. The material will be transported to the PEI landfill for disposal.

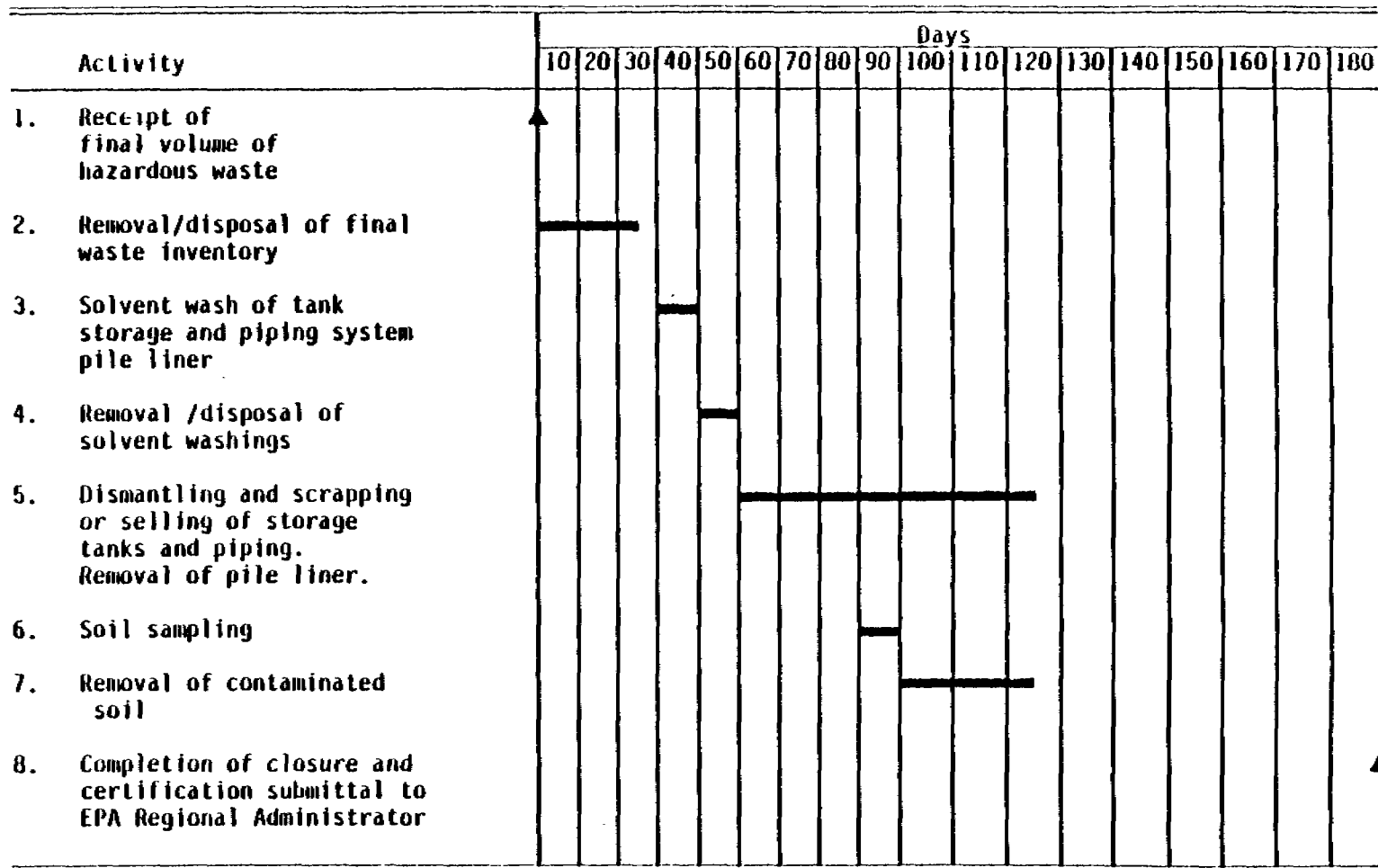
To avoid contamination of soils surrounding the piping due to cracking or stresses due to excavation, the surface of the bentonite liner will be flushed with water to drain and clean the perforated clay underdrains and remove residual materials from the pipe that goes to the collection sump. Leachate collected in the sump will be pumped into a tanker truck for transport to the XTC surface impoundment. After several flushings in this manner, the clay layer will be

excavated with a backhoe and the leachate collection piping system, waste pile underdrains, and the submersible pump will be removed. The materials (except for the pump) will be transported to the PEI landfill for disposal. The pump will be steam cleaned for reuse. Soils in the excavated zone and within the perimeter ditch will be examined for signs of contamination and at least one soil core sample taken, as discussed in Section I-1d. If there is no proven contamination of the area, the excavation will be backfilled with fill soil from local sources and regraded. The collection sump will be backfilled to prevent collection of rainwater and erosion.

I-1e Schedule for Closure

Within 90 days after receipt of the final volume of hazardous wastes, final closure activities will be initiated. Completion of closure will be within 180 days of this occurrence. All financial calculations are based on a closure date in the year 2002. The Regional Administrator will be notified by Tankopile 180 days before beginning final closure. The proposed schedule for closure is shown in Figure 36. Final closure will be supervised and certified by a professional engineer, in addition to the owner or operator.

I-1f Extensions for Closure Time [40 CFR 264.113(a) and 264.113(b)]
Tankopile Finishing Company will not require an extension for closure time.



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Figure 36. Anticipated closure schedule.

I-2 Post-closure Plans [40 CFR 122.25(a)(13)]

Post-closure care will not be needed for this facility because this is not a disposal facility.

I-3 Notice in Deed and Notice to Local Land Authority [40 CFR 122.25(a)(14)]

Because Tankopile is only a hazardous waste storage facility and not a disposal facility, notation is not necessary in the deed informing potential purchasers of restrictions associated with a disposal site, as required by 40 CFR 264.120.

I-4 Closure Cost Estimate [40 CFR 122.25(a)(15) and 264.142]

The closure cost information presented is submitted in accordance with the requirements of 40 CFR §122.25(a)(15), §264.142, and §264.143.

An estimated \$57,500 (March 1982 cost estimate) will be needed to close the Tankopile hazardous waste storage facilities. The closure costs are presented by activity in Table 14. Activities include removal of waste inventory, decontamination, disposal of wash solvents, disposal of contaminated soil, and closure certification.

The assumptions made in the cost estimate are as follows:

1. Removal of final waste inventory. The waste volume is 100 drums of assorted wastes; 7500 gallons of waste HCl, 7500 gallons of waste 1,1,1-trichloroethane, and 50 yd³ of metal hydroxide sludges. Disposal cost estimates are based on land disposal of the drums and waste pickle liquor, incineration of the waste 1,1,1-trichloroethane.

TABLE 14. CLOSURE COST ESTIMATE^a

A. Tanks

1. Removal of final waste inventory

a.	Disposal cost (7,500 gal HCl waste @ \$0.10/lb)	\$ 6,000
b.	Disposal cost (7,500 gal 1,1,1-trichloroethane @ \$0.15/lb)	9,000
c.	Plant labor (8 h @ \$12/h)	96
d.	Hauling (2 trips @ \$350/trip)	<u>700</u>

Subtotal \$15,000

2. Decontamination of storage tanks, piping, and pipe liner

a.	Solvent (100 gal @ \$2/gal)	\$ 200
b.	Supervision (20 h @ \$20/h)	400
c.	Labor (40 h @ \$12/h)	480
d.	Dismantling of two 7500-gal tanks and ancillary equipment (80 h @ \$12/h)	960
e.	Disposal cost of solvent, water washes and spill control pillows (35 drums @ \$40/drum)	1,400
f.	Discharge cost to the city sewer system	<u>260</u>

Subtotal \$3,700

B. Containers

1. Removal of final waste inventory

a.	Disposal cost (100 drums of various chemicals @ \$40/drum)	\$ 4,000
b.	Plant labor (8 h @ \$12/h)	96
c.	Hauling (3 trips @ \$350/trip)	1,050
d.	Disposal of contaminated container storage area decontamination washes (1 trip @ \$250/trip)	<u>250</u>

Subtotal \$5,400

C. Waste Pile

1. Removal of final waste inventory

a.	Disposal cost (50 yd ³ metal hydroxide sludges @ \$80/ton)	\$ 4,000
b.	Plant labor (24 h @ \$12/h)	288
c.	Hauling (1 trip @ \$350/trip)	<u>350</u>

Subtotal \$ 4,700

(continued)

TABLE 14 (continued)

2. Disposal of contaminated base material, liner, foundation, and contaminated soil		
a.	Removal (50 tons: 80 h @ \$62/h)	\$ 4,960
b.	Hauling (2 trips @ \$350/trip)	700
c.	Disposal (50 tons @ \$80/ton)	4,000
d.	Disposal of residual liquid from sump	<u>250</u>
	Subtotal	\$9,900
3. Decontamination of equipment		
a.	Rental of steam cleaner (2 day @ \$75/day)	\$ 150
b.	Disposal of decontamination residues (5 drum @ \$40/drum)	<u>200</u>
	Subtotal	\$ 350
D. Soil Sampling and Analysis		
1.	Core samples	\$ 400
2.	Core analyses	<u>600</u>
	Subtotal	\$ 1,000
E. Closure Certification		
1.	Labor (P.E. 48 h @ \$60/h)	\$ 2,880
2.	Expenses (6 days @ \$75/day)	450
3.	Transportation (300 mi @ \$0.23/mi)	<u>69</u>
	Subtotal	\$ 3,400
F. Subtotal		\$44,300
1.	Plus 15% administration	6,600
2.	Plus 15% contingencies	<u>6,600</u>
G. Total Closure Cost		\$57,500

^a1982 dollars.

2. Decontamination of storage tanks, piping, and pile liner. Tanks and piping for the HCl tank will be washed with water, whereas the 1,1,1-trichloroethane tank will be washed with an alcohol wash. After removal of the waste pile, the pile liner will also be removed by plant personnel.
3. Removal of solvent washings. It is estimated that two drums of water wash and two drums of alcohol solvent wash will require disposal. Cost is estimated at \$40/drum.
4. Disposal of soil in contaminated area. Although the soil is not expected to be contaminated by the waste storage at Tankopile, an allowance has been made in the closure costs for removal and disposal of approximately 20 yd³. It is assumed that 1 yd³ of soil will weigh approximately 1 ton.
5. Closure certification. The cost of certification of closure by a professional engineer (P.E.) is estimated on the basis of a labor rate of \$40 per hour and an estimate of other expenses for a 6-day period.
6. Total costs were calculated by adding 15 percent administrative costs and 15 percent for contingencies.

This closure cost estimate will be kept on file at the Tankopile facility. It will be revised whenever a change in the closure plan affects the cost of closure. It will be adjusted annually (from the date of its original development) to reflect changes in closure cost brought about by inflation. The Department of Commerce's Annual Implicit Price Deflator for Gross National Product* will be used to make this adjustment.

* Published by U.S. Dept. of Commerce in its monthly publication "Survey of Current Business."

I-6 Financial Assurance Mechanism for Closure [40 CFR Sections 122.25(a)(1), 264.143, and 264.150]

I-6a Closure Trust Fund [40 CFR Sections 264.143(a) and 264.151(a)(1)]

Tankopile will establish a closure trust fund as the selected financial assurance mechanism at the Anytown National Bank. An originally signed duplicate of the trust agreement will be sent to the Regional Administrator by certified mail. A copy of the agreement is attached as appendix C. A payment of one-tenth of the estimated closure cost will be deposited annually in this account. Although the expected life of the facility is 20 years, the duration of the permit is expected to be 10 years. Consequently, the payment period will be 10 years.

I-6f Combinations

I-6 Post-Closure Cost Estimate [40 CFR Sections 122.25(a)(16) and 264.144]

Since all wastes will be disposed of offsite, there will be no post-closure activities or costs.

I-7 Financial Assurance Mechanism for Post-Closure [40 CFR Sections 122.25(a)(16) and 264.145]

Since all wastes will be disposed of offsite, there will be no post-closure activities or costs.

I-8 Liability Insurance [40 CFR Sections 122.25(a)(17) and 264.147]

I-8a Sudden Insurance [40 CFR Sections 264.147(a), 264.151(i), and 264.151(j)]

Tankopile has obtained liability insurance for sudden and accidental occurrences in the amount of \$1 million per

occurrence with an annual aggregate of \$2 million exclusive of legal defense costs. An originally signed certificate of liability insurance has been sent to the Regional Administrator by certified mail. The certificate is worded as specified in 40 CFR 264.151(g).

I-8b Nonsudden Insurance [40 CFR 264.147(b), 264.151(i), and 264.151(j)]

Tankopile is a storage facility, therefore, no liability insurance is required for a nonsudden accidental occurrence.

I-8c Financial Test [40 CFR 264.147(f) and 264.151(j)]

Tankopile has an insurance policy for sudden and accidental occurrences, therefore, the financial test is not necessary.

I-8d Variance Procedures [40 CFR Section 264.147(c)]

Tankopile will not request the Regional Administrator for a reduction of liability amounts.

I-8e Adjustment Procedures [40 CFR Section 264.147(d)]

If the Regional Administrator increases the amounts of liability coverage or elects to improve nonsudden liability coverage requirements, Tankopile will immediately seek an adjustment to the insurance policy discussed above.

I-9 State Assumption of Responsibility [40 CFR 264.150]

Tankopile will not request state assumption of the legal or financial responsibilities.

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SECTION J

OTHER FEDERAL LAWS

Information will be provided in accordance with the requirements of 40 CFR Part 122.25(a)(20) at the request of the EPA Region I office. At this time, however, we believe this facility is in compliance with the following Federal laws; Wild and Scenic Rivers Act, National Historic Preservation Act of 1966, Endangered Species Act, Coastal Zone Management Act, and the Fish and Wildlife Coordination Act.

CERTIFICATION

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all attachments and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment.

Date: March 26, 1982 Signature: Mary P. Jones
Mary P. Jones, President

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Date: 2/26/82
Revision: 0

APPENDIX A
GENERAL INFORMATION AND HAZARDOUS
CHARACTERISTICS OF WASTES

Excerpted from: Dangerous
Properties of Industrial
Materials, Fourth Edition, 1975
by N. Irving Sax

HYDROCHLORIC ACID

General Information

Synonyms: muriatic acid; chlorohydric acid; hydrogen chloride.

Colorless gas or colorless, fuming liquid; strongly corrosive.

Formula: HCl

Mol wt: 36.47, mp: -114.3°C, bp: -84.3°C, d: 1.439 g/liter (gas) at 0°C; 1.196 at -36°C (liquid), vap. press: 4.0 atm at 17.3°C

Hazard Analysis

Toxic Hazard Rating:

Acute Local: Irritant 3.

Acute Systemic: Ingestion 3; Inhalation 1.

Chronic Local: Irritant 2.

Chronic Systemic: U.

Toxicology: Hydrochloric acid is an irritant to the mucous membranes of the eyes and respiratory tract, and a concentration of 15 ppm causes irritation of the throat after short exposure. Concentrations of 50 to 100 ppm are tolerable for 1 hour. More severe exposures result in pulmonary edema, and often laryngeal spasm. Concentrations of 1,000 to 2,000 ppm are dangerous, even for brief exposures. Mists of hydrochloric acid are considered less harmful than the anhydrous hydrogen chloride, since the droplets have no dehydrating action. In general, hydrochloric acid causes little trouble in industry, other than from accidental splashes and burns. It is used as a general purpose food additive (Section 10). It is a common air contaminant.

Disaster Hazard: Dangerous; see chlorides; will react with water or steam to produce toxic and corrosive fumes.

VINYL ACETATE

General Information

Colorless, mobile liquid, polymerizes to solid on exposure to light.

Formula: CH₃COOCH=CH₂

Mol wt: 86.09, mp: -100.2°C, bp: 73°C, flash p.: 12°F, d: 0.9335 at 20°C, autoign. temp.: 100°F, vap. press: 100 mm at 21.5°C, rel = 2.6%, vol = 13.4%, vap. d: 1.0.

Hazard Analysis

Toxic Hazard Rating:

Acute Local: Irritant 1.

Acute Systemic: Inhalation 1.

Chronic Local: Irritant 1.

Chronic Systemic: U.

Toxicology: May act as a skin irritant by its defatting action. High concentrations of vapor are narcotic but are formed only if an inhibitor is present.

Fire Hazard: Highly dangerous when exposed to heat or flame.

Spontaneous Heating: No.

Explosion Hazard: Unknown.

Disaster Hazard: Dangerous; when heated to decomposition, it burns and emits acrid fumes; can react with oxidizing materials.

TRICHLOROETHANE

General Information

Synonyms: 1,1,1-trichloroethane; methyl chloroform.

Colorless liquid.

Formula: CH₂Cl₃

Mol wt: 133.42, bp: 74.1°C, sp: -32.5°C, flash p.: none.

d: 1.349 at 20°C, vap. press: 100 mm at 20.0°C

Hazard Analysis

Toxic Hazard Rating:

Acute Local: Irritant 1; Ingestion 1.

Acute Systemic: Inhalation 2.

Chronic Local: Irritant 1.

Chronic Systemic: Ingestion 1; Inhalation 1.

Toxicity: Narcotic in high concentrations.

Disaster Hazard: Dangerous; see chlorides.

VINYL CHLORIDE

General Information

Synonyms: chloroethylene; chloroethene.

Colorless liquid or gas (when liquified); faintly sweet odor.

Formula: CH₂CHCl

Mol wt: 62.50, bp: -13.4°C, rel = 4%, vol = 22%, flash p.: -104°F (CO C), bp: -13.3°C, sp: -159.7°C, d liquid: 0.9195 at 15°C, vap. press: 1600 mm at 25°C, vap. d: 2.13, autoign. temp.: 882°F.

Hazard Analysis

Toxic Hazard Rating:

Acute Local: Irritant 2.

Acute Systemic: Inhalation 2.

Chronic Local: Irritant 2.

Chronic Systemic: Inhalation 1.

Toxicology: In high concentrations it acts as an asphyxiant. Causes skin burns by rapid evaporation and consequent freezing. Chronic exposure has shown liver injury in rats and rabbits. Circulatory and bone changes in the finger tips reported in workers handling unpolymerized materials. A recognized carcinogen (Section 3), of the liver.

Caution: May cause local irritation or frostbite due to rapid evaporation from skin or tissues.

Fire Hazard: Dangerous, when exposed to heat or flame. Large fires of this material are practically unextinguishable.

Spontaneous Heating: No.

Explosion Hazard: Severe, in the form of vapor when exposed to heat or flame.

Disaster Hazard: Very dangerous; when heated to decomposition, it emits highly toxic fumes of phosgene; can react vigorously with oxidizing materials. Before storing or handling this material, instructions for its use should be obtained from the supplier.

TOXIC HAZARD RATING CODE (For detailed discussion, see Section 9.)

1 NONE: (a) No harm under any conditions; (b) Harmful only under unusual conditions or overwhelming dosage.

2 SLIGHT: Causes readily reversible changes which disappear after end of exposure.

3 MODERATE: May cause both reversible and irre-

versible changes not severe enough to cause death or permanent injury.

4 HIGH: May cause death or permanent injury after very short exposure to small quantities.

5 UNKNOWN: No information on human considered valid by authors.

LEAD

General Information

Synonym: plumbum.

Bluish-gray, soft metal.

Formula: Pb.

At wt: 207.21, mp: 327.43°C, bp: 1620°C, Δ 11.238 at 20°/20°C, vap. press.: 1 mm at 973°C.

Element Analysis

Toxic Hazard Rating:

Acute Local: 0.

Acute Systemic: Inhalation 3.

Chronic Local: 0.

Chronic Systemic: Ingestion 3; Inhalation 3.

Toxicology: See lead compounds. A common air contaminant. It is a suspected carcinogen of the lungs and kidney (Section 8).

Radiation Hazard: For permissible levels, see Section 5, Table 5. Artificial isotope ^{210}Pb , $T_{1/2}$ = 52h. Decays to stable ^{210}Bi by electron capture. Emits γ 's of 0.40 MeV and X-rays. Natural isotope ^{210}Pb (Radium-D, Uranium Series), $T_{1/2}$ = 21y. Decays to radioactive ^{210}Bi by emitting β 's of 0.015 (81%), 0.061 (19%) MeV. Also emits γ 's of 0.046 MeV. ^{210}Pb usually exists in equilibrium with its daughters ^{210}Bi and ^{210}Po . Natural isotope ^{232}Pb (Thorium-232, Thorium Series), $T_{1/2}$ = 10.6h. Decays to radioactive ^{232}Bi by emitting β 's of 0.16 (5%), 0.34 (81%), 0.38 (14%) MeV. Also emits γ 's of 0.24, 0.30 MeV and X-rays.

Fire Hazard: Moderate, in the form of dust when exposed to heat or flame. See also powdered metals.

Explosion Hazard: Moderate, in the form of dust when exposed to heat or flame.

Disaster Hazard: Dangerous; when heated it emits highly toxic fumes; can react vigorously with oxidizing materials.

CHROMIUM COMPOUNDS

Hazard Analysis

Acute Hazard Rating:

Acute Local: Irritant 3; Ingestion 3; Inhalation 3.

Acute Systemic: U.

Chronic Local: Irritant 3; Ingestion 3; Inhalation 3.

Chronic Systemic: Ingestion 3; Inhalation 3.

Toxicology: Chromic acid and its salts have a corrosive action on the skin and mucous membranes. The lesions are confined to the exposed parts, affecting chiefly the skin of the hands and forearms and the mucous membranes of the nasal septum. The characteristic lesion is a deep, penetrating ulcer, which, for the most part, does not tend to suppurate, and which is slow in healing.

Small ulcers, about the size of a matchhead or end of a lead pencil may be found, chiefly around the base of the nails, on the knuckles, dorsum of the hands and forearms. These ulcers tend to be clean, and progress slowly. They are frequently painless, even though quite deep. They heal slowly, and leave scars. On the mucous membrane of the nasal septum the ulcers are usually accompanied by purulent discharge and crusting. If exposure continues, perforation of the nasal septum may result, but produces no deformity of the nose. Chromate salts are recognized carcinogens of the lungs, nasal cavity and paranasal sinus also experimental carcinogens of the stomach and larynx (Section 8).

Hexavalent compounds are said to be more toxic than the trivalent. Eczematous dermatitis due to trivalent chromium compounds has been reported.

LEAD COMPOUNDS

Hazard Analysis

Toxic Hazard Rating:

Acute Local: 0.

Acute Systemic: Ingestion 3; Inhalation 1.

Chronic Local: 0.

Chronic Systemic: Ingestion 3; Inhalation 3; Skin Absorption 3.

Toxicology: Lead poisoning is one of the commonest of occupational diseases. The presence of lead-bearing materials or lead compounds in an industrial plant does not necessarily result in exposure on the part of the workman. The lead must be in such form, and so distributed, as to gain entrance into the body or tissues of the workman in measurable quantity, otherwise no exposure can be said to exist. It is a suspected carcinogen of the lungs and kidneys (Section 8).

Mode of entry into body:

1. By inhalation of the dusts, fumes, mists or vapors. (Common air contaminants).
2. By ingestion of lead compounds trapped in the upper respiratory tract or introduced into the mouth on food, tobacco, fingers or other objects.
3. Through the skin: this route is of special importance in the case of organic compounds of lead, as lead tetraethyl. In the case of the inorganic forms of lead, this route is of no practical importance.

Physiological Action and Toxicity: When lead is ingested, much of it passes through the body unabsorbed, and is eliminated in the feces. The greater portion of the lead that is absorbed is caught by the liver and excreted, in part, in the bile. For this reason, larger amounts of lead are necessary to cause poisoning if absorption is by this route, and a longer period of exposure is usually necessary to produce symptoms. On the other hand, when lead is inhaled, absorption takes place easily from the respiratory tract and symptoms tend to develop more quickly. From the point of view of industrial poisoning, inhalation of lead is much more important than ingestion.

Lead is a cumulative poison. Increasing amounts build up in the body and eventually a point is reached where symptoms and disability occur. Lead produces a brittleness of the red blood cells so that they hemolyze with but slight trauma: the hemoglobin is not affected. Due to their increased fragility, the red cells are destroyed more rapidly in the body than normally, producing an anemia which is rarely severe. The loss of circulating red cells stimulates the production of new young cells which, on entering the blood stream, are acted upon by the circulating lead, with resultant coagulation of their basophilic material. These cells after unstable staining, are recognized as "stippled cells." As regards the effect of lead on the white blood cells, there is no uniformity of opinion. In addition to its effect on the red cells of the blood, lead produces a damaging effect on the organs or tissues with which it comes in contact. No specific or characteristic lesion is produced. Autopsies of deaths attributed to lead poisoning and experimental work on animals, have shown pathological lesions of the kidneys, liver, male gonads, nervous system, blood vessels and other tissues. None of these changes, however, have been found consistently.

In cases of lead poisoning, the amount of lead found in the blood is frequently in excess of 0.07 mg per 100 cc of whole blood. The urinary lead excretion generally exceeds 0.1 mg per liter of urine.

The toxicity of the various lead compounds appears to depend upon several factors: (1) the solubility of the compound in the body fluids; (2) the fineness of the particles of the compound; solubility is greater, of course, in proportion to the fineness of the particles; (3) conditions under which the compound is being used; where a lead compound is used as a powder, contamination of the atmosphere will be much less where the powder is kept damp. Of the various lead compounds, the carbonate, the monoxide and sulfate are considered

to be more toxic than metallic lead or other lead compounds. Lead arsenate is very toxic, due to the presence of the arsenic radical.

Signs and Symptoms: Industrial lead poisoning commonly occurs following prolonged exposure to lead or its compounds. The common clinical types of lead poisoning may be classified according to their clinical picture as (a) alimentary; (b) neuromotor; and (c) encephalic. Some cases may show a combination of clinical types. The alimentary type occurs most frequently, and is characterized by abdominal discomfort or pain. Severe cases may present actual colic. Other complaints are constipation and/or diarrhea, loss of appetite, metallic taste, nausea and vomiting, lassitude, insomnia, weakness, joint and muscle pains, irritability, headache and dizziness. Pallor, lead line on the gums, pyorrhea, loss of weight, abdominal tenderness, basophilic stippling, anemia, slight albuminuria, increased urinary excretion, and an increase in the lead content of the whole blood, are signs which may accompany the above symptoms.

In the neuromotor type, the chief complaint is weakness, frequently of the extensor muscles of the wrist and hand, unilateral or bilateral. Other muscle groups which are subject to constant use may be affected. Gastroenteric symptoms are usually present, but are not as severe as in the alimentary type of poisoning. Joint and muscle pains are likely to be more severe. Headache, dizziness and insomnia are frequently prominent. True paralysis is uncommon, and usually is the result of prolonged exposure.

Lead encephalopathy is the most severe but the rarest manifestation of lead poisoning. In the industrial worker it follows rapid and heavy lead absorption. Organic lead compounds, such as tetraethyl lead, are absorbed rapidly through the skin as well as through the lungs, and are selectively absorbed by the central nervous system. The clinical picture in these cases is usually an encephalopathy. With inorganic lead compounds, comparable concentrations in the central nervous system are reached only when the workplace is heavily contaminated with vapor, fume and dust. Encephalopathy begins abruptly, and is characterized by signs of cerebral and meningeal involvement. There is usually stupor, progressing to coma, with or without convulsion, and often terminating in death. Excitation, confusion and mania are less common. In milder cases of short duration, there may be symptoms of headache, dizziness, somnolence and insomnia. The cerebrospinal pressure may be increased. See also specific compound.

Diagnosis: A diagnosis of lead poisoning should not be made on the basis of any single clinical or laboratory finding. There must be a history of significant exposure, signs, and symptoms (as described above) compatible with the diagnosis, and confirmatory laboratory tests. Increase of stippled red blood cells, mild anemia, and elevated lead in blood and urine, i.e., more than 0.07 mg/100 ml blood and similar values per liter of urine. An increase of coproporphyrins and certain amino acids in urine may be present. Diagnostic mobilization of lead with calcium EDTA may be useful in questionable cases.

Treatment of Lead Poisoning: It has been found that the chelating agent, calcium ethylenediamine-triacetate, and related compounds are highly effective in removing absorbed lead from the tissues of the body. (The therapeutic agents of this group are also known as versene, versenate, edathamil and Ca EDTA.)

Ca EDTA is effective only when administered intravenously. Various dosage schedules have been proposed. An effective regime is 3 to 6 grams of Na Ca EDTA in 300 cc to 500 cc of 5 percent glucose by intravenous drip over a period of 3 to 8 hours. Treatment may be given daily for 5 to 10 days with an interval of one week between courses. Another plan is to give treatment at intervals of 3 to 5 days until deleading has been accomplished.

Disaster Hazard: See lead.

Date: 2/26/82
Revision: 0

APPENDIX B
INSPECTION LOG SHEETS

MONITORING EQUIPMENT INSPECTION LOG SHEET

Inspector's name/title _____ /
 Date of inspection _____ (month/day/year)
 Time of inspection _____ (military time)

Item	Types of problems	Status (/)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Liquid level transmitters (tanks)	Transmitter signal, electrical circuitry, power				
Conservation vents (tanks)	Spring adjustment or sticking				
Leachate detection, collection, and removal system (waste pile)	Broken pipe or connection, lack of gravel in pipes, clogged holes in pipe, angle of drainage, ground water collected, sump pump failure				
Ground water table control system (waste pile)	Broken pipe or connection, lack of gravel in pipe, clogged holes in pipe, angle of drainage				
Runoff collection and removal system (waste pile)	Broken pipe or connection, lack of gravel in pipe, clogged holes in pipe, angle of drainage, sump pump failure				
Ground water table water meter (located in sump)	Clogging, malfunction of digital display, rotor sticking, wearing of gears				

Figure B-1. Monitoring equipment inspection log sheet.

Date: 2/26/82
 Revision No.: 0

SAFETY AND EMERGENCY EQUIPMENT INSPECTION LOG SHEET

Inspector's name/title _____

Date of inspection _____ (month/day/year)

Time of inspection _____ (military time)

Item	Types of problems	Status (f)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Standard industrial absorbents (Sorb-Aid, Vermiculite, etc.)	Out of stock				
Sandbags	Torn or worn				
Sand	Out of stock				
Absorbent boom	Out of stock				
Absorbent pads	Out of stock				
Straw	Out of stock				
Submersible pump	Power, clogging				
Flexible hoses with quick couple fittings	Cracks or holes, fittings stick				
55-gallon drums (steel, stainless steel)	Corrosion, structural damage				
Emergency shower and eyewash	Water pressure, leaking, drainage				
Face shields and extra protection eyeglasses	Broken or dirty equipment				
Disposable respirators	Out of stock				
Chemical cartridge respirators with cartridges for organic vapors and acid gases, half and full face types	Spent chemical adsorbent, seals				

Figure B-2. Safety and emergency equipment inspection log sheet.

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Figure B-2(continued)

Item	Types of problems	Status (✓)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Chest-mounted gas mask canisters	Canisters become exhausted				
Self-contained breathing apparatus (SCBA)	Air quantity in reserve, air delivery system, moisture in tank (cold weather)				
Portable sump pump	Power, clogging				
Fire blankets	Dispensing				
Fire extinguishers	Needs recharging				
Fire alarm system	Power failure				
Telephone system	Power failure				
Public address system	Power failure, speakers				
Generators	Fuel supply, spark plugs, oil				
Emergency lighting system	Battery failure, lights				
First aid equipment and supplies	Items out of stock or inoperative				
Sleam cleaner	Water supply, fuel supply				
Protective clothing (impermeable full-body coveralls, gloves, and foot coverings)	Holes, normal wear and tear				
Decontamination facility (showers, dirty room, clean room)	Water pressure, leaking, drainage, upkeep				

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SECURITY DEVICES INSPECTION LOG SHEET

Inspector's name/title _____ /
 Date of inspection _____ (month/day/year)
 Time of inspection _____ (military time)

Item	Types of problems	Status (✓)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Facility fence	Corrosion, damage to chain link fence or barbed wire				
East gate (main entrance)	Corrosion, damage to chain link fence or barbed wire				
West gate and lock	Corrosion, damage to chain link fence or barbed wire; sticking or corroding lock				
Container storage area fence	Corrosion, damage to chain link fence or barbed wire				
Container storage area gate and lock	Corrosion, damage to chain link fence or barbed wire; sticking or corroding lock				
Remote control to east gate	Transmitter or receiver; sticking of gate				
Two-way radios	Transmitter or receiver				

Figure B-3. Security devices inspection log sheet.

Date: 2/26/92
 Revision No.: 0

OPERATING AND STRUCTURAL EQUIPMENT INSPECTION LOG SHEET

Inspector's name/title _____ / _____

Date of inspection _____ (month/day/year)

Time of inspection _____ (military time)

Item	Types of problems	Status (f)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Sump pumps (automatic)	Setting adjustment, power, clogging				
Sump pumps (manual)	Power, clogging				
Dikes	Cracks, deterioration				
Bases or foundations	Erosion; uneven settlement; cracks and spalling in concrete pads, base rings and piers; deterioration of water seal between tank bottom and foundation, wet spots				
Ramps	Erosion, uneven settlement, cracks and spalling in concrete				
Sump areas	Erosion, uneven settlement, cracks and spalling in concrete, wet spots				
Tank structural supports	Concrete deterioration and cracking, corrosion of pipe supports				
Piping to holding tanks	Loss of metal thickness, leaks, corrosion, or deterioration				
Holding tanks	Corrosion, discoloration, cracks, buckles, and bulges				

Figure B-4. Operating and structural equipment inspection log sheet.

Date: 2/26/82
Revision No.: 0

CONTAINER STORAGE AREA INSPECTION LOG SHEET

Inspector's name/title _____ / _____
 Date of inspection _____ (month/day/year)
 Time of inspection _____ (military time)

Item	Types of problems	Status (✓)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Container placement and stacking	Aisle space, height of stacks				
Sealing of containers	Open lids				
Labeling of containers	Improper identification, date missing				
Containers	Corrosion, leakage, structural defects				
Segregation of incompatible wastes	Storage of incompatible wastes in same area				
Pallets	Damaged (e.g., broken wood, warping, nails missing)				
Fence, gate and lock	Corrosion, damage to chain link fence, sticking or corroding lock				
Base or foundation	Cracks, spalling, uneven settlement erosion, wet spots				
Dikes	Cracks, deterioration				
Sump area	Cracks, spalling, uneven settlement erosion, wet spots				
Sump pumps (automatic)	Setting adjustment, power, clogging				

Figure B-5. Container storage area inspection log sheet.

Date: 2/25/82
 Revision No.: 0

Figure B-5(continued)

Item	Types of problems	Status (d)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Debris and refuse	Clog sump pump, aesthetics, possible reaction with leaks				
Ramps	Cracks, spalling, uneven settlement, erosion				
Warnings signs	Damaged				

TANK STORAGE AREA AND ANCILLARY EQUIPMENT INSPECTION LOG SHEET

Inspector's name/title _____ / _____

Date of inspection _____ (month/day/year)

Time of inspection _____ (military time)

Item	Types of problems	Status (✓)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Blake	Cracks, deterioration				
Base or foundation	Cracks, spalling, uneven settlement, erosion, wet spots				
Sump pump (manual)	Power, clogging				
Sump area	Cracks, spalling, uneven settlement, erosion, wet spots				
Warning signs	Damaged				
Pipes	Loss of metal thickness, leaks, corrosion, or deterioration				
Valves	Loss of metal thickness, leaks, corrosion, or deterioration				
Fittings	Loss of metal thickness, leaks, corrosion, or deterioration				
Overfill control valve (manual)	Loss of metal thickness, leaks, corrosion, or deterioration, sticking, damaged handle				

Figure B-6. Tank storage area and ancillary equipment inspection log sheet.

Date: 2/25/92
Revision No.: 0

EXTERNAL TANK INSPECTION LOG SHEET

Inspector's name/title _____ / _____

Date of inspection _____ (month/day/year)

Time of inspection _____ (military time)

Item	Types of problems	Status (✓)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Ladder	Damaged, structural stability				
Foundation/structural supports	Cracks, spalling uneven settlement, erosion, wet spots				
Pipe connections	External corrosion, cracks, distortion				
Protective coating	Rust spots, blisters, film lifting				
Tank shell	Corrosion, discoloration, cracks, buckles, bulges				
Tank roof	Malfunction of seals, blockage of water drains on roof, corrosion				
Tank bottom	Corrosion, discoloration, cracks, buckles, bulges				
Anchor bolts	Distortion, corrosion				
Nozzles	Cracks, corrosion				

Figure B-7. External tank inspection log sheet.

Date: 2/26/82
Revision No.: 0

INTERNAL TANK INSPECTION LOG SHEET

Inspector's name/title _____ / _____
 Date of inspection _____ (month/day/year)
 Time of inspection _____ (military time)

Item	Types of problems	Status (//)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Tank roof	Malfunction of roof's seals, corrosion, loss of metal thickness				
Internal supports	Deterioration, depressions				
Tank shell	Corrosion of vapor space, and liquid level line, cracking, bulges, holes, loss of metal thickness, seams				
Tank bottom	Corrosion pits, sprung seams, rivets, depressions, bottom thickness, unevenness of bottom				
Plate joints	Cracking				
Nozzle connection joints	Cracking				
Glass lining	Cracking, bubbles				
Rivets	Tightness, corrosion				
Pipecoil support	Depressions				

Figure B-8. Internal tank inspection log sheet.

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Date: 2/26/82
 Revision No.: 0

WASTE PILE AREA INSPECTION LOG SHEET

Inspector's name/title _____ / _____
 Date of inspection _____ (month/day/year)
 Time of inspection _____ (military time)

Item	Types of problems	Status (/)		Observations	Date and nature of repairs/remedial action
		Acceptable	Unacceptable		
Run-on diversion ditch	Obstructions to flow, bank erosion, loose riprap				
Entrance road and guard rails	Loss of gravel, fugitive emissions, corrosion and tightness of guard rails				
Runoff diversion canal and drain	Obstructions, drain clogged				
Wind dispersal control system	Frequency of water application, dryness and slope of pile				
Foundation	Cracks or breaks				
Synthetic liner	Tears, holes, separation of layers, thin spots, cracks, shrinkage, hardness, excessive permeability, blisters				
Base	Erosion, exposed area to liner, depth				
Liner seams	Leak, tightness of seam				
Joints	Tightness of connection				

Figure B-9. Waste pile area inspection log sheet.

Date: 2/26/82
 Revision No.: 0

Date: 2/26/82
Revision No.: 0

APPENDIX C
TRUST AGREEMENT

Trust Agreement

Trust Agreement, the "Agreement," entered into as of July 10, 1982 by and between Mary P. Jones, a Rhode Island corporation, the "Grantor," and John Victor, an Anytown National Bank, the "Trustee".

Whereas, the United States Environmental Protection Agency, "EPA," an agency of the United States Government, has established certain regulations applicable to the Grantor, requiring that an owner or operator of a hazardous waste management facility shall provide assurance that funds will be available when needed for closure and/or post-closure care of the facility.

Whereas, the Grantor has elected to establish a trust to provide all or part of such financial assurance for the facilities identified herein.

Whereas, the Grantor, acting through its duly authorized officers, has selected the Trustee to be the trustee under this agreement, and the Trustee is willing to act as trustee.

Now, Therefore, the Grantor and the Trustee agree as follows:

Section 1. Definitions. As used in this Agreement:

(a) The term "Grantor" means the owner or operator who enters into this Agreement and any successors or assigns of the Grantor.

(b) The term "Trustee" means the Trustee who enters into this Agreement and any successor Trustee.

Section 2. Identification of Facilities and Cost Estimates. This Agreement pertains to the facilities and cost estimates identified on attached Schedule A (on Schedule A, for each facility list the EPA Identification Number, name, address, and the current closure and/or post-closure cost estimates, or portions thereof, for which financial assurance is demonstrated by this Agreement).

Section 3. Establishment of Fund. The Grantor and the Trustee hereby establish a trust fund, the "Fund," for the benefit of EPA. The Grantor and the Trustee intend that no third party have access to the Fund except as herein provided. The Fund is established initially as consisting of the property, which is acceptable to the Trustee, described in Schedule B attached hereto. Such property and any other property subsequently transferred to the Trustee is referred to as the Fund, together with all earnings and profits thereon, less any payments or distributions made by the Trustee pursuant to this Agreement. The Fund shall be held by the Trustee, IN TRUST, as hereinafter provided. The Trustee shall not be responsible nor shall it undertake any responsibility for the amount or adequacy of, nor any duty to collect from the Grantor, any payments necessary to discharge any liabilities of the Grantor established by EPA.

Section 4. Payment for Closure and Post-Closure Care. The Trustee shall make payments from the Fund as the EPA Regional Administrator shall direct, in writing, to provide for the payment of the costs of closure and/or post-closure care of the facilities covered by this Agreement. The Trustee shall reimburse the Grantor or other persons as specified by the EPA Regional

Administrator from the Fund for closure and post-closure expenditures in such amounts as the EPA Regional Administrator shall direct in writing. In addition, the Trustee shall refund to the Grantor such amounts as the EPA Regional Administrator specifies in writing. Upon refund, such funds shall no longer constitute part of the Fund as defined herein.

Section 5. Payments Comprising the Fund. Payments made to the Trustee for the Fund shall consist of cash or securities acceptable to the Trustee.

Section 6. Trustee Management. The Trustee shall invest and reinvest the principal and income of the Fund and keep the Fund invested as a single fund, without distinction between principal and income, in accordance with general investment policies and guidelines which the Grantor may communicate in writing to the Trustee from time to time, subject, however, to the provisions of this Section. In investing, reinvesting, exchanging, selling, and managing the Fund, the Trustee shall discharge his duties with respect to the trust fund solely in the interest of the beneficiary and with the care, skill, prudence, and diligence under the circumstances then prevailing which persons of prudence, acting in a like capacity and familiar with such matters, would use in the conduct of an enterprise of a like character and with like aims; except that:

(i) Securities or other obligations of the Grantor, or any other owner or operator of the facilities, or any of their affiliates as defined in the Investment Company Act of 1940, as amended, 15 U.S.C. 80a-2(a), shall not be acquired or held, unless they are securities or other obligations of the Federal or a State government;

(ii) The Trustee is authorized to invest the Fund in time or demand deposits of the Trustee, to the extent insured by an agency of the Federal or State government; and

(iii) The Trustee is authorized to hold cash awaiting investment or distribution uninvested for a reasonable time and without liability for the payment of interest thereon.

Section 7. Commingling and Investment. The Trustee is expressly authorized in its discretion:

(a) To transfer from time to time any or all of the assets of the Fund to any common, commingled, or collective trust fund created by the Trustee in which the Fund is eligible to participate, subject to all of the provisions thereof, to be commingled with the assets of other trusts participating therein; and

(b) To purchase shares in any investment company registered under the Investment Company Act of 1940, 15 U.S.C. 80a-1 et seq., including one which may be created, managed, underwritten, or to which investment advice is rendered or the shares of which are sold by the Trustee. The Trustee may vote such shares in its discretion.

Section 8. Express Powers of Trustee. Without in any way limiting the powers and discretions conferred upon the Trustee by the other provisions of this Agreement or by law, the Trustee is expressly authorized and

empowered:

(a) To sell, exchange, convey, transfer, or otherwise dispose of any property held by it, by public or private sale. No person dealing with the Trustee shall be bound to see to the application of the purchase money or to inquire into the validity or expediency of any such sale or other disposition;

(b) To make, execute, acknowledge, and deliver any and all documents of transfer and conveyance and any and all other instruments that may be necessary or appropriate to carry out the powers herein granted;

(c) To register any securities held in the Fund in its own name or in the name of a nominee and to hold any security in bearer form or in book entry, or to combine certificates representing such securities with certificates of the same issue held by the Trustee in other fiduciary capacities, or to deposit or arrange for the deposit of such securities in a qualified central depository even though, when so deposited, such securities may be merged and held in bulk in the name of the nominee of such depository with other securities deposited therein by another person, or to deposit or arrange for the deposit of any securities issued by the United States Government, or any agency or instrumentality thereof, with a Federal Reserve bank, but the books and records of the Trustee shall at all times show that all such securities are part of the Fund;

(d) To deposit any cash in the Fund in interest-bearing accounts maintained or savings certificates issued by the Trustee, in its separate corporate capacity, or in any other banking institution affiliated with the Trustee, to the extent insured by an agency of the Federal or State government; and

(e) To compromise or otherwise adjust all claims in favor of or against the Fund.

Section 9. Taxes and Expenses. All taxes of any kind that may be assessed or levied against or in respect of the Fund and all brokerage commissions incurred by the Fund shall be paid from the Fund. All other expenses incurred by the Trustee in connection with the administration of this Trust, including fees for legal services rendered to the Trustee, the compensation of the Trustee to the extent not paid directly by the Grantor, and all other proper charges and disbursements of the Trustee shall be paid from the Fund.

Section 10. Annual Valuation. The Trustee shall annually, at least 30 days prior to the anniversary date of establishment of the Fund, furnish to the Grantor and to the appropriate EPA Regional Administrator a statement confirming the value of the Trust. Any securities in the Fund shall be valued at market value as of no more than 60 days prior to the anniversary date of establishment of the Fund. The failure of the Grantor to object in writing to the Trustee within 90 days after the statement has been furnished to the Grantor and the EPA Regional Administrator shall constitute a conclusively binding assent by the Grantor, barring the Grantor from asserting any claim or liability against the Trustee with respect to matters disclosed in the statement.

Section 11. Advice of Counsel. The Trustee may from time to time consult with counsel, who may be counsel to the Grantor, with respect to any question arising as to the construction of this Agreement or any action to be taken hereunder. The Trustee shall be fully protected, to the extent permitted by law, in acting upon the advice of counsel.

Section 12. Trustee Compensation. The Trustee shall be entitled to reasonable compensation for its services as agreed upon in writing from time to time with the Grantor.

Section 13. Successor Trustee. The Trustee may resign or the Grantor may replace the Trustee, but such resignation or replacement shall not be effective until the Grantor has appointed a successor trustee and this successor accepts the appointment. The successor trustee shall have the same powers and duties as those conferred upon the Trustee hereunder. Upon the successor trustee's acceptance of the appointment, the Trustee shall assign, transfer, and pay over to the successor trustee the funds and properties then constituting the Fund. If for any reason the Grantor cannot or does not act in the event of the resignation of the Trustee, the Trustee may apply to a court of competent jurisdiction for the appointment of a successor trustee or for instructions. The successor trustee shall specify the date on which it assumes administration of the trust in a writing sent to the Grantor, the EPA Regional Administrator, and the present Trustee by certified mail 10 days before such change becomes effective. Any expenses incurred by the Trustee as a result of any of the acts contemplated by this Section shall be paid as provided in Section 9.

Section 14. Instructions to the Trustee. All orders, requests, and instructions by the Grantor to the Trustee shall be in writing, signed by such persons as are designated in the attached Exhibit A or such other designees as the Grantor may designate by amendment to Exhibit A. The Trustee shall be fully protected in acting without inquiry in accordance with the Grantor's orders, requests, and instructions. All orders, requests, and instructions by the EPA Regional Administrator to the Trustee shall be in writing, signed by the EPA Regional Administrators of the Regions in which the facilities are located, or their designees, and the Trustee shall act and shall be fully protected in acting in accordance with such orders, requests, and instructions. The Trustee shall have the right to assume, in the absence of written notice to the contrary, that no event constituting a change or a termination of the authority of any person to act on behalf of the Grantor or EPA hereunder has occurred. The Trustee shall have no duty to act in the absence of such orders, requests, and instructions from the Grantor and/or EPA, except as provided for herein.

Section 15. Notice of Nonpayment. The Trustee shall notify the Grantor and the appropriate EPA Regional Administrator, by certified mail within 10 days following the expiration of the 30-day period after the anniversary of the establishment of the Trust,

if no payment is received from the Grantor during that period. After the pay-in period is completed, the Trustee shall not be required to send a notice of nonpayment.

Section 16. Amendment of Agreement. This Agreement may be amended by an instrument in writing executed by the Grantor, the Trustee, and the appropriate EPA Regional Administrator, or by the Trustee and the appropriate EPA Regional Administrator if the Grantor ceases to exist.

Section 17. Irrevocability and Termination. Subject to the right of the parties to amend this Agreement as provided in Section 16, this Trust shall be irrevocable and shall continue until terminated at the written agreement of the Grantor, the Trustee, and the EPA Regional Administrator, or by the Trustee and the EPA Regional Administrator, if the Grantor ceases to exist. Upon termination of the Trust, all remaining trust property, less final trust administration expenses, shall be delivered to the Grantor.

Section 18. Immunity and Indemnification. The Trustee shall not incur personal liability of any nature in connection with any act or omission, made in good faith, in the administration of this Trust, or in carrying out any directions by the Grantor or the EPA Regional Administrator issued in accordance with this Agreement. The Trustee shall be indemnified and saved harmless by the Grantor or from the Trust Fund, or both, from and against any personal liability to which the Trustee may be subjected by reason of any act or conduct in its official capacity, including all expenses reasonably incurred in its defense in the event the Grantor fails to provide such defense.

Section 19. Choice of Law. This Agreement shall be administered, construed, and enforced according to the laws of the State of [insert name of State].

Section 20. Interpretation. As used in this Agreement, words in the singular include the plural and words in the plural include the singular. The descriptive headings for each Section of this Agreement shall not affect the interpretation or the legal efficacy of this Agreement.

In Witness Whereof the parties have caused this Agreement to be executed by their respective officers duly authorized and their corporate seals to be hereunto affixed and attested as of the date first above written. The parties below certify that the wording of this Agreement is identical to the wording specified in 40 CFR 354.251(a)(1) as such regulations were constituted on the date first above written.

Gregory P. Jones
President, Transpacific Finishing Co., Inc.

John H. Jones
President, Anytown National Bank

SUPERFUND REGULATIONS

The following are regulations required or authorized by the Superfund law. In addition to these regulations, the statute requires revision of the National Contingency Plan. It is likely that this will be the responsibility of the Council on Environmental Quality in consultation with the National Response Team. Those listed below which have an asterisk (*) are regulations EPA is planning to initiate.

- §102: *Requires promulgation of regulations designating hazardous substances and reportable quantities (but contains interim procedure).
- *Authorizes promulgation of regulations specifying records to be kept regarding sites. Types of records are statutorily described.
- *Requires promulgation of regulations on waiver of recordkeeping requirements.
- §104: *Claims of confidentiality may be raised by designating those records believed entitled to protection when submitting them. Designation must be made in accordance with regulations promulgated by the President.
- *Upon determination that emergency procurement procedures are necessary the President must promulgate regulations detailing the circumstances and procedures.
- §107: Liability limits may be adjusted by the President. If done, it must be by regulation.
- *Within 18 months, the President must, by rule, determine feasibility of optional insurance for post closure.
- *If the system is feasible, the President must publish minimum standards within 6 months of the determination.
- §108: Requires vessels to establish financial responsibility in accordance with regulations promulgated by the President.
- Requires DOT to promulgate regulations for denial of entry and detention of vessels without financial responsibility certification.
- Beginning 5 years after enactment, the President must promulgate financial responsibility requirements for classes of facilities (excluding RCRA); but classes must be identified in Federal Register within 3 years.
- §111: *The President may promulgate regulations designating those who may obligate funds.

*Requires promulgation of regulations concerning notice to potential injured parties by responsible parties (provides for interim procedures).

§112: *Requires that President prescribe appropriate forms and procedures for claims.

§301: Requires President's designee under the NCP to promulgate regulations for natural resource damage assessment.

§302: Requires Treasury to promulgate regulations providing for termination of taxes at \$1.38 billion.

* In addition, EPA plans to promulgate a regulation regarding State programs under Superfund.

For further information contact:

Sylvia Lowrance -- (202) 382-2188
Coke Cherney ----- (202) 755-0760

PUBLIC PARTICIPATION IN SUPERFUND POLICY DEVELOPMENT

1. The Deputy Assistant Administrator and the staff of the Office of Hazardous Emergency Response will make every effort to continue the current practice of responding to requests for meetings from interest groups and individuals affected by or interested in Superfund.

2. The Office of Hazardous Emergency Response will have weekly informal meetings at its offices in Waterside Mall, 401 M Street, SW. at 12:00 p.m. every Friday. The format will be as follows:

- o A Superfund Manager will present a brief (10 minute) update of a key Superfund activity.
- o During the second half hour of the session, attendees (by pre-arrangement with EPA) could make a presentation.

3. The Deputy Assistant Administrator will schedule regular meetings with State and local government interest groups, environmental, and business interest groups.

4. In the next several months, we plan to hold two meetings similar to the January 19th meeting:

- o In mid-April, a meeting to discuss early draft copies of Superfund regulations.
- o In mid-May, a meeting to discuss a draft of the revised National Contingency Plan.

5. Toward the end of the formal public comment period for Superfund regulations we will hold a series of public meetings around the country to discuss the proposed regulations and the National Contingency Plan. These sessions will be information exchange meetings.

6. After these public meetings are completed, we will hold a single, public hearing in Washington to receive comment on the regulations.

7. In accordance with current EPA policy, we will invite and carefully consider written comments on the regulations and all other issues.

Subject Area: Public Participation/Community Relations

Basic Premises

A. Public participation or community relations is as major element of the Superfund program.

B. Community relations functions will be organizationally integrated within the operational units of the Superfund organization.

C. In many communities, abandoned hazardous waste sites are extremely serious political issues, and the subject of considerable local concern.

D. The public does not always have a clear understanding of the abandoned site issue, the precise nature of the hazardous waste threat, and the nature of the Superfund program.

E. An inadequate community relations program will hamper overall program implementation. In order to insure sensible policies, EPA needs to actively consult with all individuals and groups affected by the policies.

F. EPA has a great deal to learn about managing community relations during environmental emergencies.

Working Assumptions

A. Information should be released to the public rapidly, accurately, and in comprehensible form.

B. Local governments, interests, and citizens will be consulted as often as possible during Superfund planning.

C. National interest groups and interested members of the public should be consulted as often as possible during Superfund planning.

D. Community and local government involvement is a major program element under Superfund, and resources adequate to carry out this program element should be provided.

E. We must develop a program to train EPA personnel responsible for public involvement.

F. We need to research citizen-government interaction during hazardous waste incidents in order to learn from past mistakes and successes.

G. The attitudes and perceptions of local residents and officials will be carefully considered when planning response actions.

H. EPA Headquarters should publish understandable descriptions of the Superfund program.

Rationale

If we wish to ensure a successful Superfund program we must recognize that abandoned waste sites and spills of hazardous materials are not simply environmental problems but are political, economic, psychological, social and health problems as well. EPA will be judged on its ability to deal with all aspects of the hazardous waste problem. Although we might prefer to limit our activities to engineering technical solutions to environmental problems, such a narrow focus is politically and practically unrealistic.

The existence of uncontrolled hazardous wastes or a spill of chemicals or oil is an environmental emergency for the affected community. When responding to environmental emergencies government must act both rapidly and effectively.

Our response actions must both remove the peril to the environment and human health, and address the perceived threat to human and ecological well-being.

Source of Additional Information

Steve Cohen, (202) 755-9685

SUBJECT AREA: Interagency Cooperation

Basic Premises

Interagency cooperation is crucial to effective Superfund implementation. The National Response Team (NRT) of the National Oil and Hazardous Substances Pollution Contingency Plan will serve as the focus for national interagency communication and the Regional Response Teams (RRT) for local interagency communication.

Preliminary Program Decisions

A. The President will issue an Executive Order which will delegate general areas of responsibility of each agency.

B. The National Contingency Plan will be revised and republished to reflect the legislative mandates cited in P.L. 96-510. The revised National Contingency Plan will be the primary mechanism for defining specific Agency responsibilities.

C. Interagency Agreements (IAG) and Memoranda of Understanding will be used only to supplement the NCP, particularly when the transfer of funds or use of personnel are involved.

Source of Additional Information

Bonnie Casper, 755-9685

Subject Area: State Programs

Basic Premises

A. The more States contribute and participate the better off the Superfund program will be.

B. Generally, existing State resources and capabilities are not yet adequate. As a result, only a few States will play a major role during the first few program years, and EPA will need to assist the States in developing their programs.

C. State and local governments will end up bearing responsibility for dealing with the great majority of spills and abandoned hazardous waste sites.

D. Superfund implementation must avoid, to the extent possible, competing with or undermining other State environmental programs, especially RCRA.

Working Assumptions/Preliminary Decisions

A. EPA will develop a strong Federal program to ensure effective action at major problem sites during the initial years of program implementation.

B. A program for upgrading State and local capabilities must be developed within the first two years after legislative enactment.

C. EPA Regional offices will have primary responsibility for evaluating State readiness, negotiating agreements or contracts, and providing program development support to State and local governments.

D. States must play a major role in setting response priorities. EPA will require an initial list from the States within three months of enactment.

E. States will be able to assure they will meet the cost-share and other support preconditions for remedial action in several ways. They will be able to enter into formal contracts for specific sites or in general, or they can arrange less strict working agreements, again for specific sites or in general.

F. State governments will conduct emergency or remedial actions with Superfund money wherever feasible. Money from the fund will be available for paying overhead costs for State programs similar to those which would be paid to a contractor.

Rationale

There is a tremendous demand for prompt action under Superfund. The Federal Government must be ready to shoulder the large part of the burden initially. However, the hazardous waste spill and abandoned site problem is much bigger than the Federal Government alone can handle. Consequently, the Superfund program must be designed to enable EPA to take advantage of whatever State and local capabilities exist. Encouraging State and local participation is critical to effective program implementation. Thus, EPA will be as flexible as possible in setting requirements for State participation so that it can secure the maximum amount of cooperation.

Source of Additional Information

Harry Butler, 245-3045

Subject Area: Contracts - Operating Contracts to Support and Carry Out
Emergency and Remedial Response Action

Basic Premises

A. Most of field work performed under Superfund (investigation, lab analysis, design, construction, etc.) will be done by contractors supervised by deputy project officers situated in EPA's Regional offices.

B. EPA staff for field operations work will be severely limited.

C. EPA staff for management staff resources will be most effectively utilized if we have management contracts with the activities to be performed under contract.

Working Assumptions

A. Federal emergency response activities will be carried out primarily by a single, national management contract with prenegotiated subcontractors for specific geographic areas. The national management contractor will be required to provide up to ten deputy managers to work with Superfund field personnel at the regional level. The on-scene-coordinator and deputy managers will select the proper mix of subcontract response skills needed in each particular emergency situation. Consistent with the emergency nature of the activity, subcontractors must have the capability to respond immediately when the OSC or deputy project manager requests services.

B. The Technical Assistant Team (TAT) contract will continue to be used to provide certain types of technical support to the emergency response actions performed under the emergency response national management contract. These services provided under the TAT contract primarily will consist of the following: rapid lab analyses, hot lab analyses, and natural resource and economic damage assessments.

C. The Remedial Response Program will obtain contract support from several contracts, each primarily devoted to assisting different phases of the program.

(1) The Field Investigation Team (FIT) contract will continue and a second, large FIT-type contract will be let. These two contracts will handle field work up through preliminary investigation and site inspection.

(2) Lab analyses will continue to be obtained from a number of labs through Invitations for Bids (IFBs). A national laboratory services management contract may be let if needed.

(3) A national remedial response management contract, managed at the regional level by deputy project officers, will provide full field investigation, engineering feasibility, design work, environmental analysis, public involvement, construction monitoring and construction contract administration. The method of subcontracting within the national remedial response contract framework is still under study. Two possibilities are prenegotiated or prequalified subcontractors.

(4) Construction work at remedial sites will be contracted directly by regional deputy project officers using IFBs based on detailed plans and specifications produced under the remedial response management contract. Larger sites will be bid separately or bundled into one IFB.

(5) A national expert technical and scientific support contract will be let to provide OSC's with uniquely qualified expert advice at especially difficult sites or spills.

D. No decisions have been reached on a disposal contract for "EPA-owned" wastes acquired by the Agency from emergency response actions.

E. To the extent possible, States will be able to use Federal contracts for the work they are managing. (The precise mechanism for this has not been determined).

Rationale

The contract network described above was developed after considering limitations on EPA resources, the types of contracting mechanisms available, and the structure of the private sector from which services must be obtained. It is intended to compensate for expected limitations on Federal personnel while meeting emergency needs for extremely rapid response, remedial response needs for timely and cost-effective provision of site containment, and the total program's needs for effective prevention or mitigation of health and environmental hazards.

Sources of Additional Information

Harry Butler, 245-3045
Bill Hanson, 245-3154

SUPERFUND -

A SUMMARY OF THE COMPREHENSIVE ENVIRONMENTAL RESPONSE,
COMPENSATION AND LIABILITY ACT OF 1980

o Notification:

- Spills: Requires notification to the National Response Center for releases of reportable quantities (RQ) of designated substances.

RQ's of 1 lb. or existing 311.

- Sites: Requires notification by persons disposing of, owning, or transporting for disposal (but not interim or final RCRA sites).

Stop during transportation is not a site.

Records on facility must be kept for 50 years. EPA can designate what must be kept, and will promulgate waiver procedures.

o Response:

- Allowed to releases or substantial threats (hazardous substances only - no oil) or to pollutants or contaminants presenting an imminent and substantial endangerment.
- Hazardous substances includes: RCRA 311 CWA, 112 CAA, 307 CWA toxics, 7 of TSCA, and any others designated under Superfund.
- Remedial action or removal is authorized if consistent with the NCP and the responsible party takes inadequate or no action.
- Whenever response authority is used, or the President believes a release has occurred or illness, etc., may be caused, he may monitor, investigate, etc., and may take action to plan and direct response actions (these actions are not subject to the 6 month \$1 million limitation).
- Two or more related facilities may be treated as one.

o Conditions for Response (State Programs)

- Response cannot continue after \$1 million or 6 months in absence of a cost sharing agreement unless there is a continuing need to prevent or limit an emergency, there is an immediate risk to public health or the environment or response would not otherwise be provided in a timely manner.
- States must be consulted on remedial action, but none may be taken until the State assures all future maintenance (for the expected life), availability of an acceptable disposal facility, and 10% cost sharing (50% for government owned).

- A credit for direct, documented costs from January 1, 1978, to enactment is provided (NTE response costs).
- States may take over the program through contract or cooperative agreement if they have the capability.
- o Public Health: A new agency is created to coordinate activities - including a national registry, literature inventory, medical testing, and screening.
- o National Contingency Plan: Must be promulgated within 180 days - includes a new sites section.

Hazardous Substance Plan must include:

1. Methods for discovery and investigation.
2. Methods for evaluation and remedy of releases.
3. Methods and criteria concerning the appropriate extent of response.
4. Roles of all parties including private entities.
5. Provision for equipment and supplies.
6. Provision for Federal facilities (reporting).
7. Cost-effectiveness.
8. Priority Criteria - to be based on a variety of health, environmental, and other appropriate factors.

Priority List - is part of plan - State must submit a list for consideration within one year based on criteria in Plan. President will revise list at least annually. At least 400 will be designated. One in each State must be in the top 100.

o Enforcement:

- Relief may be sought by AG when there is an imminent and substantial endangerment.
- President may issue orders necessary to protect public health and the environment (violation costs up to \$5,000 a day).
- Consolidated guidance on use of imminent hazard, enforcement and emergency response must be published within 180 days (EPA in cooperation with AG).

- o Liability - Owners, operators (including those at time of disposal, persons who arranged for disposal or transported for disposal) are liable in accordance with Section 311 of the Clean Water Act, for (1) responsible costs not inconsistent with the NCP, and (2) natural resource damage.
 - Defenses include: (1) an act of God, (2) and act of war, and (3) third party actions (but not employees, agents, contractors, etc.), if the defendant can show due care and precautions against foreseeable acts.
 - Monetary limits to liability are provided for vessels, motor vehicles, aircraft, pipelines, and rolling stock. The President is authorized to establish other limits by regulation.
 - Defenses and limits are lost in cases of willful misconduct or willful negligence; knowingly violating standards or regulations or refusing to cooperate under the NCP.
 - Contains a good samaritan provision.
- o Financial Responsibility:
 - DOT will enforce for vessels.
 - Other facilities must be classified within 3 years; then requirements must begin to be promulgated 5 years after enactment.
- o Fund:
 - Approximately \$1.6 billion over 5 years; at least 85% clean up; no more than 15% claims.
 - Approximately 86% tax, 14% appropriations.
- o Uses (all subject to appropriations in the aggregate):
 1. Response costs.
 2. Claims for response costs by any persons consistent with the NCP.
 3. Outstanding 311 claims.
 4. Assessment, restoration, and rehabilitation of natural resources.
 - Enforcement and abatement (specifically limited to appropriations).

- Epidemiologic studies, registry, and diagnostic testing (not otherwise available).
- Equipment and similar overhead for this act, and §311 (subject to appropriations).
- Worker health and safety program.
- No remedial action funds for Federal facilities (except under #4 above).
- There is authorized to be appropriated advances to the fund, subject to certain limitations.

o Claims:

- Procedure:
 - a. First presented to RP, if unsatisfied in 60 days, claimant may go to court or to the fund.
 - b. Upon receipt of a claim, President will expeditiously seek to negotiate a settlement between claimant and RP (settlements are final); if there is not RP, the fund will negotiate a settlement with claimant.
 - c. Upon payment, the fund is subrogated claimants' rights to recover costs paid by the fund.
- No claims for natural resource damage occurring wholly before enactment or for ambient air.
- Claims will be paid first come, first serve.
- Statute of limitations is 3 years from the date of enactment or discovery of the loss, whichever is later.

o Preemption:

- No contribution can be required to any State fund for claims for response or damages which may be compensated under Superfund.
- No double compensation.

o Post Closure:

- A post closure fund is created.

- Liability under the act is transfered to a post closure fund when facilities close properly and have been monitored for 5 years. Effective 90 days after.
- Secretary of Treasury must conduct a study and submit a report on the feasibility of an optional private insurance system.

I. SITE MANAGEMENT PLAN

A. Discovery

1. Site Search

- a) Obtain and review State inventory - Access national inventory developed under the National Contingency Plan and review information relevant to the site.
- b) Compile and search remote sensing data - Analyze available aerial reconnaissance data available for site.
- c) Search existing data bases - Query other existing sources for site relevant information.
 - Federal/State/local
 - SIA/RCRA

2. Notification - Design and implement notification system as required under the Act.

- a) Design and issue notification forms - Develop, obtain approval and issue forms.
- b) Process notifications - Receive and encode information into national data base as received from the following sources.
 - Public
 - Government
 - Industry

3. Sites into national inventory of potential sites - Consolidate information from all known sources on sites into a comprehensive list.

B. Screen Incident Discovery

- 1. Compile/review data - Analyze information for accuracy and completeness, as received.
- 2. Assess need for emergency action/NO action/legal action/or further study - Evaluate reported incident to determine disposition.
- 3. Assign initial ranking for preliminary investigation - evaluate adequacy of data to determine position of site for later preliminary investigation.
- 4. Initial assessment of risks/damages - Based on limited information, appraise potential threat to health and safety.

C. Preliminary investigation consists primarily of review of existing documents, possible interviews, and visually examine site.

- 1) Search records and interview - Review all existing Federal, State, local and other data bases which may contain relevant information on the site and conduct personal interviews with individuals who may be familiar with the site.
- 2) Identify potential responsible party - For site, locate an individual or firm which may undertake voluntary clean-up or be liable for legal action.
- 3) Determine permit status - The effort to determine if an EPA or State permit is involved, which may provide a basis for acting.
- 4) Define problem
 - technical
 - fiscal
 - legal
 - environmental
 - institutional
- 5) Conduct visual inspection of site - A visual inspection which may take place on or just outside the site/spill.
- 6) Conduct remote sensing - Aerial or other physically removed inspection.
- 7) Characterize preliminary risks/damages - Based on new information.
- 8) Assess need for immediate action (emergency or enforcement)/no action/or further study - Evaluate reported incident to determine appropriate disposition.
- 9) Rank site for preliminary assessment - Based on additional information, rerank sites for inspection.
- 10) Control site access - limit all unauthorized access to site.
- 11) Determine need for emergency action -- Yes - If no, determine appropriate disposition.

D. Preliminary Assessment

- 1) Assign initial priority for site inspection - Evaluate data to determine position of site in ranking scheme.
- 2) Initial assessment of risks/damages - Based on limited information, appraise potential threat to health and safety.

E. Site Inspection

- 1) Plan inspection parameters - Determine methodology under which site inspection will be conducted.
 - Structure sampling and inspection to satisfy both potential remedial and enforcement needs.
- 2) Acquire permission to enter site - Display official ID and obtain permission to enter site.
- 3) Inspect and sample - Collect, analyze, quality assure and quality control in order to meet both enforcement and remedial needs.
 - characterize waste
 - track samples
 - ensure chain of custody for potential evidentiary uses
- 4) Develop project schedule - Develop milestone calendar for controlling site inspection; includes provision for management decision on additional activities.
- 5) Continue responsible party search - Review new or updated information in order to establish ownership and/or liability.
- 6) Assess risks/damages - Estimate current danger to public health and safety and natural resource damage.
- 7) Complete initial priority ranking forms - encode data for input into national information system.
- 8) Determine need for emergency action/no action/enforcement/ or full-field investigation.
- 9) ~~Develop and maintain State responsibility - identify responsible party, in accordance with State law~~

F. Assign to national priority list - Assign priority based upon relative risk or damage to health or welfare or the environment; population at risk; potential of hazardous substances; potential impact on drinking water supply; potential for direct human contact and potential for destruction of sensitive ecosystems; State readiness to assume responsibilities; and other appropriate factors.

- 1) Evaluate against priority criteria - Determine condition relative to the above criteria.
- 2) Set priority and review with State - Upon determination of ranking, review with State prior to public notice.

G. Use Fund or Enforcement Actions

- 1) Determine threat to public health or the environment - Decide on need for emergency action, normal process or inactive status based on available information.
- 2) Make legal judgment regarding responsible party - Identify existence of deep pocket party.
- 3) Assign initial site ranking - Rank site based upon assessment of risks/damages.
- 4) Direct responsible party to take action and negotiate consent decree-assuming voluntary action, negotiate course of action and monitor implementation of solution.
- 5) Designation and advertising of financial responsibility - Identify responsible party and indicate process for filing claims.
- 6) Select use of fund or legal remedy, if no voluntary action - Invoke fund using Federal directed action or State directed action.

H. Field Investigation - Determining in detail the environmental health problems.

- 1) Conduct field studies to further specify problem - Investigate fully the extent of the environmental problem requiring remedy. (Sample and evaluate across all media; from soil samples to monitoring wells; modeling).
 - a. For all media, collect information on:
 - detailed site conditions (includes samples)
 - activities of potentially responsible parties
 - nature of pollution problem
 - b. Perform lab analysis
 - collect samples to satisfy both remedial and cost recovery needs
 - track to ensure chain of custody and quality control
 - analyze and report results
- 2) Prepare required reports - Prepare labs reports, ADP systems input and reports to management.

I. Feasibility studies - Develop remedial measures (e.g., construction, relocation, transportation of waste) to mitigate site hazards.

- 1) Develop options - Develop appropriate alternative courses of action to mitigate site hazards.
 - least cost analysis
 - remedial level attained
 - risks associated with each option, including no action.

- 2) Prepare and disseminate Statement of Environmental Assessment.
 - 3) Conduct preliminary design and feasibility studies - For a limited number of options, develop tentative site solutions.
 - 4) Develop State cost sharing provisions - Develop State participation requirements.
- J. Select remedy - Decision point through which remedial measures to mitigate site is selected.
- 1) Review feasibility studies - Comprehensive review of feasibility studies developed above.
 - 2) Provide for public participation - Hold informal public meeting with governmental and citizens groups to inform public on alternative and obtain preferences.
 - 3) Finalize State cost-sharing and monitoring - Negotiate agreement with State government on State share of costs and role in monitoring site.
 - 4) Select remedy - Choose mitigation option to be implemented, and determine implementation phases.
- K. Final site improvement design - For selected option, develop full project schedule.
- 1) Develop contingency provision - Construct back-up plans for possible accidents on site.
 - 2) Develop site improvement schedule - Construct project schedule with milestones.
 - 3) Secure required permits - Obtain all necessary Federal, State and local permits.
 - 4) Prepare required reports - Provide periodic reports on status of site improvement design.
- L. Site improvements - Implement solution developed under design phase.
- 1) Complete procurements - Obtain bids for provision of service(s).
 - 2) Prepare and contain site(s) - Engineer and construct site improvement through contractor(s).
 - 3) Manage/oversee construction - Perform oversight function of various phases of construction.
 - 4) Process payment requests for construction work - Disburse funds and audit final project.

- 5) Operation and maintenance of site
- 6) Monitoring site condition - Provide for continuous monitoring (wells, remote sensing, etc.) of site.
- M. Recover costs for Federal remedial action under fund - Take enforcement actions to recover Federal expenditures.
- N. Post-Closure Monitoring
 - 1) Monitor State or responsible party maintenance - Provide oversight of long term operation and maintenance of site.

Source of Additional Information

Bill Hanson, 245-3154

OVERVIEW OF REPORTING REQUIREMENTS UNDER THE COMPREHENSIVE
ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT OF
1980 (PL 96-510); OUTLINE OF FEDERAL REGISTER NOTICE

Information on Federal Register Notice

1. The notice is not a regulation, but rather is designed to provide information to the public on the notification requirements of Section 103(a) and (b) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (P.L. 96-510) (hereafter referred to as "the Act").

2. The intent of the notice is to provide helpful information on when notification of a release is required, who is required to notify, and what hazardous substances are subject to reporting requirements.

3. The notice will present an initial preliminary interpretation of the notification requirement. Additional informational notices will be published in the Federal Register as required.

Why is Notification of a Spill Required

1. Notification is designed simply to "trigger" an emergency response. Early warning of a release can often avoid or mitigate potential damage to public health and the environment.

2. The Agency's spill response and prevention program has been in place for a number of years, and the notice provisions of the Clean Water Act have been very successful. The statutory requirements of the Act contain the same basic mechanism for notification, but substantially expand the coverage for release of hazardous substances to all media.

To Whom is Notification Required?

Notification must be made to the National Response Center.

800-424-8802

For Washington, D.C. area: 202-426-2675

When is Notification Required

1. Notification is immediately required whenever there is a release of a hazardous substance into the environment in amounts equal to or greater than the reportable quantity. This is to all media: air, land, water, and applies to releases which may enter groundwater.

2. The term "release" includes virtually all ways that substances may enter the environment. The Act defines

"release" to mean any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment.

3. Such notification should be made immediately upon knowledge of the release. A 24-hour time frame is utilized for determination of the amount of substance released.

4. The "Reportable Quantity" of each listed substance is set forth in the "Comprehensive Hazardous Substance List" which will be attached to the Federal Register Notice.

Who is Required to Notify?

1. Anyone in charge of a vessel, or onshore or offshore facility, unless specifically exempted. The definition of onshore facility includes, but is not limited to motor vehicles and rolling stock.

2. Certain discharges are excluded from the definition of a release (See Section 101(22) of the Act):

(a) workplace exposures for which persons may assert claims against the employer or other persons;

(b) emissions from engine exhaust from a motor vehicle, rolling stock, aircraft, vessel, or pipeline pumping station;

(c) releases of source, byproduct, or special nuclear material from a nuclear incident subject to Nuclear Regulatory Commission (NRC) requirements for financial protection under Section 170 of the Atomic Energy Act of 1954;

(d) any release of source, byproduct or special nuclear material from a processing site designated under Section 102(a)(1) or 302 (a) of the Uranium Mill Tailings Radiation Control Act of 1978;

(e) the normal application of fertilizers.

3. The following releases are exempted from the reporting requirements:

(a) Federally permitted releases as defined in section 101(10)

(b) the application of pesticide products registered under the Federal Insecticide, Fungicide, and Rodenticide Act (Section 103(e));

(c) releases of hazardous waste subject to the notification provisions of the Resource Conservation and Recovery Act as defined in Section 103(f)(1) and which have been reported to the National Response Center;

(d) continuous releases for which section 103(a) and (b) notification has already been given for a period sufficient to determine continuity, quantity, and regularity of such release (See Section 103 (f)(2));

(e) continuous releases from sites notifying pursuant to Section 103(c) of the Act (relating to sites of hazardous substances) See Section 103(f)(2)).

What Hazardous Substances are Included

1. Hazardous Substances

(a) Those listed on the Comprehensive Hazardous Substance List. At present, this list is compiled from the following lists:

1. Clean Water Act, Section 311
2. Clean Water Act, Section 307(a)
3. RCRA, Section 3001
4. Clean Air Act, Section 112
5. Toxic Substances Act, Section 7

Additions to the list may be made by future regulation under Section 102 of the Act.

(b) In addition to hazardous wastes listed under Section 3001 of RCRA, hazardous substances include any waste meeting the characteristics set forth in regulations implementing Section 3001 of RCRA for flammability, corrosivity, toxicity and reactivity.

2. The term "Hazardous Substances" does not include petroleum (including crude oil or any fraction not otherwise listed), natural gas, natural gas liquids, liquified natural gas or synthetic gas useable for fuel (or mixtures of natural gas and such synthetic gas).

COMPREHENSIVE HAZARDOUS SUBSTANCES LIST

To be used in the implementation
of the reporting requirements
of the Comprehensive Environmental
Response, Compensation, and Liability
Act of 1980 (P.L. 96-510)

Emergency Response Division
U.S. Environmental Protection Agency

January 19, 1980

CMA 047832

COMPREHENSIVE HAZARDOUS SUBSTANCE LIST

In defining hazardous substances the Congress was specific in defining the initial list of hazardous substances. Section 101(14) calls for the list to be comprised of those materials already designated as being hazardous under any one of five statutes. Specifically, these substances are designated pursuant to:

- (a) Section 311(b)(2)(A) of the Clean Water Act
- (b) Section 3001 of the Solid Waste Disposal Act (RCRA 3001)
- (c) Section 307(a) of the Federal Water Pollution Control Act (CWA 307(a))
- (d) Section 112 of the Clean Air Act (CAA 112)
- (e) Section 7 of the Toxic Substances Control Act (TSCA 7)

Additional substances can be added to the list by the EPA Administrator under Section 102 of the Act. Substances that have designated reportable quantities (RQ) under Section 311 of the Clean Water Act retain those designations for all media. A reportable quantity of one (1) pound will be assigned initially for all other hazardous substances.

Requirements for the comprehensive list are therefore set until superseded by future regulation. For the convenience of the reporting community and the agencies involved in spill response, a master list has been compiled. This list is attached. This preliminary list of hazardous substances is provided at this time in draft form for information only, and should not be considered to be a final document until it is published in the Federal Register.

Part I of the list contains those specific chemicals designated as hazardous substances, and show the applicable reportable quantity and the list(s) in which each material was originally designated. Both the CWA 307(a) list and the RCRA 3001 list contain numerous general categories of materials. Wherever possible these were broken into a complete designation of compounds (e.g. chlorinated ethanes --> chloroethane, dichloroethane, trichloroethane, tetrachloroethane). For "infinite" categories (e.g. phthalate esters), selected compounds already appearing on the individual lists were included. No effort has yet been made to determine whether the applicability of additional compounds should be included on the list. The Agency believes that a finite list of compounds provides a more useful tool to all involved parties than one including large generic groups of substances. This list is intended to be only interim, pending investigation into the

designation of additional compounds and the adjustment of reportable quantities.

Part II designates the specific hazardous wastes defined by RCRA regulations. Any waste, however, that meets the EPA characteristics of hazardous waste (i.e. corrosivity, ignitability, reactivity or toxicity), while not specifically delineated in this part, is subject to the reporting requirements.

It must be recognized that this list has been compiled in a short period of time and that typographical errors or duplication or omission of compounds may still be present. In particular the designations as to the appropriate source lists may not be completed in this draft of the list. Future versions of the list will also be cross-referenced to Chemical Abstracts Services (CAS) Registry Numbers. Comments on the list, the format, and the designation of reportable quantities will be solicited in the upcoming Federal Register Notice.

PART I

COMPREHENSIVE HAZARDOUS SUBSTANCE LIST

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Acenaphthene	X	1 (0.454)			X	X		
Acenaphthalene	X	1 (0.454)			X	X		
Acetaldehyde	C	1,000 (454)		X		X		
Acetic acid	C	1,000 (454)		X	X	X		
Acetic anhydride	C	1,000 (454)		X				
Acetone cyanohydrin	A	10 (4.54)		X				
Acetonitrile	X	1 (0.454)				X		
3-(alpha-Acetonylbenzyl) -4-hydroxycoumarin and salts	X	1 (0.454)				X		
2-Acetylaminofluorene	X	1 (0.454)				X		
Acetyl bromide	D	5,000 (2,270)		X				
Acetyl chloride	D	5,000 (2,270)		X		X		
1-Acetyl-2-thiourea	X	1 (0.454)				X		
Acrolein	X	1 (0.454)		X	X	X		
Acrylamide	X	1 (0.454)				X		
Acrylonitrile	B	100 (45.4)		X				
Adipic acid	D	5,000 (2,270)		X				
Aflatoxins	X	1 (0.454)				X		
Aldrin	X	1 (0.454)		X		X		
Allyl alcohol	B	100 (45.4)		X		X		
Allyl chloride	C	1,000 (454)		X				
Aluminum phosphide	X	1 (0.454)				X		
Aluminum sulfate	D	5,000 (2,270)		X				
4-Aminobiphenyl	X	1 (0.454)				X		
6-Amino-1,1a,2,8,8a,8b- hexahydro-8-(hydroxymethyl)- 8a-methoxy-5-methylcarbamate								
azirino(2',3':3,4) pyrrolo (1,2-a)indole-4,7-dione(ester)								
(Mitomycin C)	X	1 (0.454)				X		
5-(Aminomethyl)-3-isoxazolol	X	1 (0.454)				X		
4-Aminopyridine	X	1 (0.454)				X		
Amitrole	X	1 (0.454)				X		
Ammonia	B	100 (45.4)		X				

CMA 047835

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Ammonium acetate	D	5,000 (2,270)		X				
Ammonium benzoate	D	5,000 (2,270)		X				
Ammonium bicarbonate	D	5,000 (2,270)		X				
Ammonium bichromate	C	1,000 (454)		X				
Ammonium bifluoride	D	5,000 (2,270)		X				
Ammonium bisulfite	D	5,000 (2,270)		X				
Ammonium carbamate	D	5,000 (2,270)		X				
Ammonium carbonate	D	5,000 (2,270)		X				
Ammonium chloride	D	5,000 (2,270)		X				
Ammonium chromate	C	1,000 (454)		X				
Ammonium citrate	D	5,000 (2,270)		X				
Ammonium fluoborate	D	5,000 (2,270)		X				
Ammonium fluoride	D	5,000 (2,270)		X				
Ammonium hydroxide	C	1,000 (454)		X				
Ammonium oxalate	D	5,000 (2,270)		X				
Ammonium silicofluoride	C	1,000 (454)		X				
Ammonium sulfamate	D	5,000 (2,270)		X				
Ammonium sulfide	D	5,000 (2,270)		X				
Ammonium sulfite	D	5,000 (2,270)		X				
Ammonium tartrate	D	5,000 (2,270)		X				
Ammonium thiocyanate	D	5,000 (2,270)		X				
Ammonium thiosulfate	D	5,000 (2,270)		X				
Amyl acetate	C	1,000 (454)		X				
Aniline	C	1,000 (454)		X				
Anthracene	X	1 (0.454)			X	X		
Antimony	X	1 (0.454)				X		
Antimony pentachloride	C	1,000 (454)		X				

Note: The abbreviation N.O.S. signifies those members of the general class "not otherwise specified" by name in this listing.

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Antimony potassium tartrate	C	1,000 (454)		X				
Antimony tribromide	C	1,000 (454)		X				
Antimony trichloride	C	1,000 (454)		X				
Antimony trifluoride	C	1,000 (454)		X				
Antimony trioxide	D	5,000 (2,270)		X				
Aramite	X	1 (0.454)					X	
Arsenic	X	1 (0.454)					X	
Arsenic acid	X	1 (0.454)					X	
Arsenic disulfide	D	5,000 (2,270)		X				
Arsenic pentoxide	D	5,000 (2,270)		X		X		
Arsenic trichloride	D	5,000 (2,270)		X				
Arsenic trioxide	D	5,000 (2,270)		X		X		
Arsenic trisulfide	D	5,000 (2,270)		X				
Asbestos	X	1 (0.454)			X			
Auramine	X	1 (0.454)					X	
Azaserine	X	1 (0.454)					X	
Barium	X	1 (0.454)					X	
Barium cyanide	A	10 (4.54)		X			X	
Benz[c]acridine	X	1 (0.454)					X	
Benz[a]anthracene	X	1 (0.454)			X		X	
Benzene	C	1,000 (454)		X	X		X	
Benzeneearsonic Acid	X	1 (0.454)					X	
Benzenethiol	X	1 (0.454)					X	
Benzydine	X	1 (0.454)			X		X	
Benzo[a]anthracene	X	1 (0.454)			X		X	
Benzo[b]fluoranthene	X	1 (0.454)			X		X	
Benzo[j]fluoranthene	X	1 (0.454)			X		X	
Benzo[anti]perylene	X	1 (0.454)			X		X	
Benzo[a]pyrene	X	1 (0.454)			X		X	

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Benzole Acid	D	5,000 (2,270)		X				
Benzonitrile	C	1,000 (454)		X				
Benzoquinone (all isomers)	X	1 (0.454)				X		
Benzotrichloride	X	1 (0.454)				X		
Benzoyl chloride	C	1,000 (454)		X				
Benzyl chloride	B	100 (45.4)		X		X		
Beryllium	X	1 (0.454)				X		
Beryllium chloride	D	5,000 (2,270)		X				
Beryllium fluoride	D	5,000 (2,270)		X				
Beryllium nitrate	D	5,000 (2,270)		X				
Bis(2-chloroethoxy)methane	X	1 (0.454)			X	X		
Bis(2-chloroethyl) ether	X	1 (0.454)			X	X		
N,N-Bis(2-chloroethyl)- 2-naphthylamine	X	1 (0.454)				X		
Bis(2-chloroisopropyl) ether	X	1 (0.454)				X		
Bis(chloromethyl) ether	X	1 (0.454)			X	X		
Bis(chloroethyl) ether	X	1 (0.454)			X	X		
Bis(2-ethylhexyl) phthalate	X	1 (0.454)			X	X		
Bromoacetone	X	1 (0.454)				X		
Bromomethane	X	1 (0.454)			X	X		
4-Bromophenyl phenyl ether	X	1 (0.454)			X	X		
Brucine	X	1 (0.454)				X		
2-Butanone peroxide	X	1 (0.454)				X		
Butyl acetate	D	5,000 (2,270)		X				
Butyl benzyl phthalate	X	1 (0.454)			X	X		
2-sec-Butyl-4,6-dinitrophenol(DNBP)	X	1 (0.454)				X		
n-Butyl phthalate	B	100 (45.4)		X	X	X		
Butylamine	C	1,000 (454)		X				
Butyric acid	D	5,000 (2,270)		X				

CMA 047838

10/10/77

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Cadmium	X	1 (0.454)				X		
Cadmium acetate	B	100 (45.4)		X				
Cadmium bromide	B	100 (45.4)		X				
Cadmium chloride	B	100 (45.4)		X				
Calcium arsenate	C	1,000 (454)		X				
Calcium arsenite	C	1,000 (454)		X				
Calcium carbide	D	5,000 (2,270)		X				
Calcium chromate	C	1,000 (454)		X		X		
Calcium cyanide	A	10 (4.54)		X		X		
Calcium dodecylbenzenesulfonate	C	1,000 (454)		X				
Calcium hydroxide	D	5,000 (2,270)		X				
Calcium hypochloride	B	100 (45.4)		X				
Calcium oxide	D	5,000 (2,270)		X				
Captan	A	10 (4.54)		X				
Carbaryl	B	100 (45.4)		X				
Carbofuran	A	10 (4.54)		X				
Carbon disulfide	D	5,000 (2,270)		X		X		
Carbon tetrachloride	D	5,000 (2,270)		X	X			
Chlordane	X	1 (0.454)		X				
Chlorambucil	X	1 (0.454)				X		
Chlordane (alpha and gamma isomers)	X	1 (0.454)				X		
Chlorine	A	10 (4.54)		X				
Chloroacetaldehyde	X	1 (0.454)				X		
p-Chloroaniline	X	1 (0.454)				X		
Chlorobenzene	B	100 (45.4)		X	X	X		
Chlorobenzilate	X	1 (0.454)				X		

CMA 047839

10/1/80

MATERIAL	CATEGORY	RQ IN POUNDS {KILOGRAMS}	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
1-(p-Chlorobenzoyl)-5-methoxy- 2-methylindole-3-acetic acid	X	1 (0.454)				X		
p-Chloro-m-cresol	X	1 (0.454)			X	X		
1-Chloro-2,3-epoxybutane	X	1 (0.454)				X		
Chloroethane	X	1 (0.454)			X	X		
2-Chloroethyl vinyl ether	X	1 (0.454)			X	X		
Chloroform	D	5,000 (2,270)		X	X	X		
Chloromethane	X	1 (0.454)			X	X		
Chloromethyl methyl ether	X	1 (0.454)				X		
Chloronaphthalene (all isomers)	X	1 (0.454)				X		
2-Chloronaphthalene	X	1 (0.454)				X		
Chlorophenol	X	1 (0.454)				X		
2-Chlorophenol	X	1 (0.454)			X	X		
4-Chlorophenyl phenyl ether	X	1 (0.454)			X	X		
1-(o-Chlorophenyl)thiourea	X	1 (0.454)			X	X		
3-Chloropropionitrile	X	1 (0.454)				X		
Chlorpyrifos	X	1 (0.454)		X				
Chlorosulfonic acid	C	1,000 (454)		X				
Chlorotoluene (all isomers)	X	1 (0.454)				X		
alpha-Chlorotoluene	X	1 (0.454)				X		
Chromium	X	1 (0.454)			X	X		
Chromic acetate	C	1,000 (454)		X				
Chromic acid	C	1,000 (454)		X				
Chromic sulfate	C	1,000 (454)		X				
Chromous chloride	C	1,000 (454)		X				
Chrysene	X	1 (0.454)			X	X		
Citrus red No. 2	X	1 (0.454)				X		
Coal tar	X	1 (0.454)				X		
Cobaltous bromide	C	1,000 (454)		X				
Cobaltous formate	C	1,000 (454)		X				
Cobaltous sulfamate	C	1,000 (454)		X				
Copper	X	1 (0.454)			X	X		
Copper cyanide	X	1 (0.454)				X		
Coumaphos	A	10 (4.54)		X				
Cresol	C	1,000 (454)		X				
Creosote	X	1 (0.454)				X		
Cresylic Acid	X	1 (0.454)				X		

CMA 047840

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Crotonaldehyde	B	100 (45.4)		X		X		
Cupric acetate	B	100 (45.4)		X				
Cupric acetoarsenite	B	100 (45.4)		X				
Cupric chloride	A	10 (4.54)		X				
Cupric nitrate	B	100 (45.4)		X				
Cupric oxalate	B	100 (45.4)		X				
Cupric sulfate	A	10 (4.54)		X				
Cupric sulfate ammoniated	B	100 (45.4)		X				
Cupric tartrate	B	100 (45.4)		X				
Cyanides (soluble salts and complexes), N.O.S.	X	1 (0.454)				X		
Cyanogen	X	1 (0.454)				X		
Cyanogen bromide	X	1 (0.454)				X		
Cyanogen chloride	A	10 (4.54)		X		X		
Cycasin	X	1 (0.454)				X		
Cyclohexane	C	1,000 (454)		X				
2-Cyclohexyl-4,6-dinitrophenol	X	1 (0.454)				X		
Cyclophosphamide	X	1 (0.454)				X		
2,4-D Acid	B	100 (45.4)		X				
2,4-D Esters	B	100 (45.4)		X				
Daunomycin	X	1 (0.454)				X		
DDD	X	1 (0.454)			X	X		
DDE	X	1 (0.454)			X	X		
DDT	X	1 (0.454)			X	X		
Diallate	X	1 (0.454)				X		
Diazinon	X	1 (0.454)		X				
Dibenz[a,h]acridine	X	1 (0.454)				X		
Dibenz[a,j]acridine	X	1 (0.454)				X		

CMA 047841

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA	CWA	CWA	RCRA	CAA	TSCA
			102	311K	307a	3001	112	7
Dibenz[a,h]anthracene								
(Dibenzo[a,h]anthracene)	X	1 (0.454)		X				
7H-Dibenzo[c,g]carbazole	X	1 (0.454)				X		
Dibenzo[a,e]pyrene	X	1 (0.454)				X		
Dibenzo[a,h]pyrene	X	1 (0.454)				X		
Dibenzo[a,i]pyrene	X	1 (0.454)				X		
1,2-Dibromo-3-chloropropane	X	1 (0.454)				X		
1,2-Dibromoethane	X	1 (0.454)				X		
Dibromomethane	X	1 (0.454)				X		
Di-n-butyl phthalate	X	1 (0.454)				X		
Dicamba	C	1,000 (454)		X				
Dichlobenil	C	1,000 (454)		X				
Dichlone	X	1 (0.454)		X				
Dichlorobenzene (all isomers)	B	100 (45.4)		X	X	X		
Dichlorobenzidine (all isomers)	X	1 (0.454)			X			
3,3'-Dichlorobenzidine	X	1 (0.454)				X		
Dichlorobromomethane	X	1 (0.454)			X	X		
Dichloroethane (all isomers)	X	1 (0.454)				X		
1,1-Dichloroethane	X	1 (0.454)				X		
1,2-Dichloroethane	X	1 (0.454)				X		
trans-1,2-Dichloroethane	X	1 (0.454)				X		
Dichloroethylene (all isomers)	X	1 (0.454)			X	X		
1,1-Dichloroethylene	X	1 (0.454)			X	X		
Dichloromethane	X	1 (0.454)				X		
Dichloronaphthalene (all isomers)	X	1 (0.454)				X		
Dichlorophenol (all isomers)	X	1 (0.454)				X		
2,4-Dichlorophenol	X	1 (0.454)				X		
2,6-Dichlorophenol	X	1 (0.454)				X		
Dichlorophenylarsine	X	1 (0.454)				X		
Dichloropropane (all isomers)	D	5,000 (2,270)		X				
Dichloropropene-								
Dichloropropane Mixture	D	5,000 (2,270)		X				

CMA 047842

DATA

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Dichloropropanol(s) (all isomers)	X	1 (0.454)				X		
Dichloropropene(s) (all isomers)	D	5,000 (2,270)		X	X	X		
1,3-Dichloropropene	X	1 (0.454)			X	X		
2,2-Dichloropropionic acid	D	5,000 (2,270)		X				
Dichlorvos	A	10 (4.54)		X				
Dieldrin	X	1 (0.454)		X	X	X		
Diepoxybutane	X	1 (0.454)				X		
Diethylamine	C	1,000 (454)		X				
Dimethylamine	C	1,000 (454)		X				
Diethylarsine	X	1 (0.454)					X	
0,0-Diethyl-S-(2-ethylthio)ethyl ester of phosphorothioic acid	X	1 (0.454)					X	
1,2-Diethylhydrazine	X	1 (0.454)					X	
0,0-Diethyl-S-methylester phosphorodithioic acid	X	1 (0.454)					X	
0,0-Diethylphosphoric acid, O-p-nitrophenyl ester	X	1 (0.454)					X	
Diethyl phthalate	X	1 (0.454)			X	X		
0,0-Diethyl-O-(2-pyrazinyl) phosphorothioate	X	1 (0.454)					X	
Diethylstilbestrol	X	1 (0.454)					X	
Dihydrosafrole	X	1 (0.454)					X	
3,4-Dihydroxy-alpha-(methylamino)- methyl benzyl alcohol	X	1 (0.454)					X	
Di-isopropylfluorophosphate (DFP)	X	1 (0.454)					X	
Dimethoate	X	1 (0.454)					X	
3,3'-Dimethoxybenzidine	X	1 (0.454)					X	
p-Dimethylaminoazobenzene	X	1 (0.454)					X	
7,12-Dimethylbenz[a]anthracene	X	1 (0.454)					X	

CMA 047843

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
3,3'-Dimethylbenzidine	X	1 (0.454)				X		
Dimethylcarbamoyl chloride	X	1 (0.454)				X		
1,1-Dimethylhydrazine	X	1 (0.454)				X		
1,2-Dimethylhydrazine	X	1 (0.454)				X		
3,3-Dimethyl-1-(methylthio)-2-butanone-O-((methylamino)carbonyl)oxime	X	1 (0.454)				X		
Dimethylnitrosoamine	X	1 (0.454)			X	X		
alpha,alpha-Dimethylphenethylamine	X	1 (0.454)				X		
2,4-Dimethylphenol	X	1 (0.454)				X		
Dimethyl phthalate	X	1 (0.454)				X		
Dimethyl sulfate	X	1 (0.454)				X		
Dinitrobenzene (all isomers)	C	1,000 (454)		X		X		
4,6-Dinitro-o-cresol and salts	X	1 (0.454)				X		
Dinitrophenol (all isomers)	C	1,000 (454)		X		X		
Dinitrotoluene (all isomers)	C	1,000 (454)		X	X	X		
2,4-Dinitrotoluene	X	1 (0.454)				X		
2,6-Dinitrotoluene	X	1 (0.454)				X		
Di-n-octyl phthalate	X	1 (0.454)				X		
1,4-Dioxane	X	1 (0.454)				X		
1,2-Diphenylhydrazine	X	1 (0.454)				X		
Di-n-propylnitrosamine	X	1 (0.454)				X		
Diquat	C	1,000 (454)		X				
Disulfoton	X	1 (0.454)		X		X		
2,4-Dithiobiuret	X	1 (0.454)				X		
Diuron	B	100 (45.4)		X				
Dodecylbenzenesulfonic acid	C	1,000 (454)		X				
Endosulfan (all isomers)	X	1 (0.454)		X	X	X		
Endosulfan sulfate	X	1 (0.454)			X			
Endrin and metabolites	X	1 (0.454)		X	X	X		
Epichlorohydrin	C	1,000 (454)		X		X		
Ethion	A	10 (4.54)		X				

CMA 047844

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA	CWA	CWA	RCRA	CAA	TSCA
			102	311K	307a	3001	112	7
Ethylbenzene	C	1,000 (454)		X	X			
Ethyl cyanide	X	1 (0.454)				X		
Ethylenediamine	C	1,000 (454)		X		X		
Ethylene dibromide	C	1,000 (454)		X				
Ethylene dichloride	D	5,000 (2,270)		X				
Ethylene bis dithiocarbamate (EBDC)	X	1 (0.454)				X		
EDTA	D	5,000 (2,270)		X				
Ethyleneimine	X	1 (0.454)				X		
Ethylene oxide (I)	X	1 (0.454)				X		
Ethylenethiourea	X	1 (0.454)				X		
Ethyl methanesulfonate	X	1 (0.454)				X		
Ferric ammonium citrate	C	1,000 (454)		X				
Ferric ammonium oxalate	C	1,000 (454)		X				
Ferric chloride	C	1,000 (454)		X				
Ferric fluoride	B	100 (45.4)		X				
Ferric nitrate	C	1,000 (454)		X				
Ferric sulfate	C	1,000 (454)		X				
Ferrous ammonium sulfate	C	1,000 (454)		X				
Ferrous chloride	B	100 (45.4)		X				
Ferrous sulfate	C	1,000 (454)		X				
Fluoranthene	X	1 (0.454)			X	X		
Fluorene	X	1 (0.454)			X			
Fluorine	X	1 (0.454)				X		
2-Fluoroacetamide	X	1 (0.454)				X		
Fluoroacetic acid, sodium salt	X	1 (0.454)				X		
Formaldehyde	C	1,000 (454)		X		X		
Formic acid	D	5,000 (2,270)		X				
Fumaric acid	D	5,000 (2,270)		X				
Furfural	C	1,000 (454)		X				

CMA 047845

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA	CWA	CWA	RCRA	CAA	TSCA
			102	311K	307a	3001	112	7
Glycidyl aldehyde	X	1 (0.454)				X		
Guthion	X	1 (0.454)		X				
Heptachlor	X	1 (0.454)		X	X	X		
Heptachlor epoxide (alpha, beta, and gamma isomers)	X	1 (0.454)			X	X		
Hexachlorobenzene	X	1 (0.454)			X	X		
Hexachlorobutadiene	X	1 (0.454)			X	X		
Hexachlorocyclohexane (all isomers)	X	1 (0.454)			X	X		
Hexachlorocyclopentadiene	X	1 (0.454)		X		X		
Hexachloroethane	X	1 (0.454)				X		
Hexachlorophene	X	1 (0.454)				X		
Hexachloropropene	X	1 (0.454)				X		
Hexaethyl tetraphosphate	X	1 (0.454)				X		
Hydrazine	X	1 (0.454)				X		
Hydrochloric acid	D	5,000 (2,270)		X				
Hydrocyanic acid	X	1 (0.454)				X		
Hydrofluoric acid	D	5,000 (2,270)		X				
Hydrogen cyanide	A	10 (4.54)		X				
Hydrogen sulfide	B	100 (45.4)		X		X		
Indeno(1,2,3-cd)pyrene	X	1 (0.454)				X		
Iodomethane	X	1 (0.454)				X		
Iron Dextran	X	1 (0.454)				X		
Isocyanic acid, methyl ester	X	1 (0.454)				X		
Isophrone	X	1 (0.454)			X	X		
Isoprene	C	1,000 (454)		X				
Isopropylamine								
dodecylbenzenesulfonate	C	1,000 (454)		X				
Isosafrole	X	1 (0.454)				X		

CMA 047846

1/2/87

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA	CWA	CWA	RCRA	CAA	TSCA
			102	311K	307a	3001	112	7
Kelthane	D	5,000 (2,270)		X				
Kepon	X	1 (0.454)		X		X		
Lasiocarpine	X	1 (0.454)				X		
Lead	X	1 (0.454)			X	X		
Lead acetate	D	5,000 (2,270)		X		X		
Lead arsenate	D	5,000 (2,270)		X				
Lead chloride	D	5,000 (2,270)		X				
Lead fluoborate	D	5,000 (2,270)		X				
Lead fluoride	C	1,000 (454)		X				
Lead iodide	D	5,000 (2,270)		X				
Lead nitrate	D	5,000 (2,270)		X				
Lead phosphate	X	1 (0.454)				X		
Lead stearate	D	5,000 (2,270)		X				
Lead subacetate	X	1 (0.454)				X		
Lead sulfate	D	5,000 (2,270)		X				
Lead sulfide	D	5,000 (2,270)		X				
Lead thiocyanate	D	5,000 (2,270)		X				
Lindane	X	1 (0.454)		X				
Lithium chromate	C	1,000 (454)		X				
Malathion	A	10 (4.54)		X				
Maleic acid	D	5,000 (2,270)		X				
Maleic anhydride	D	5,000 (2,270)		X		X		
Malononitrile	X	1 (0.454)				X		
Melphalan	X	1 (0.454)				X		
Mercaptodimethur	B	100 (45.4)		X				
Mercury	X	1 (0.454)			X	X	X	
Mercuric cyanide	X	1 (0.454)		X				
Mercuric nitrate	A	10 (4.54)		X				

DRAFT

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Mercuric sulfate	A	10 (4.54)		X				
Mercuric thiocyanate	A	10 (4.54)		X				
Mercurous nitrate	A	10 (4.54)		X				
Methoxychlor	X	1 (0.454)		X				
Methapyrilene	X	1 (0.454)				X		
Methomyl	X	1 (0.454)				X		
2-Methylaziridine	X	1 (0.454)				X		
3-Methylcholanthrene	X	1 (0.454)				X		
4,4'-Methylene-bis-(2-chloroaniline)	X	1 (0.454)				X		
Methyl ethyl ketone (MEK)	X	1 (0.454)				X		
Methyl hydrazine	X	1 (0.454)				X		
2-Methylactonitrile	X	1 (0.454)				X		
Methyl mercaptan	B	100 (45.4)		X				
Methyl methacrylate	D	5,000 (2,270)		X		X		
Methyl methanesulfonate	X	1 (0.454)				X		
Methyl parathion	B	100 (45.4)		X		X		
2-Methyl-2-(methylthio) propionaldehyde-o(methylcarbonyl) oxime	X	1 (0.454)				X		
N-Methyl-N'-nitro-N-nitrosoguanidine	X	1 (0.454)				X		
Methylthiouracil	X	1 (0.454)				X		
Mevinphos	X	1 (0.454)		X				
Maxacarbate	C	1,000 (454)		X				
Monoethylamine	C	1,000 (454)		X				
Monomethylamine	C	1,000 (454)		X				
Mustard gas	X	1 (0.454)				X		
Naled	A	10 (4.54)		X				
Naphthalene	D	5,000 (2,270)		X				

CMA 047848

1984-11

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Naphthenic acid	B	100 (45.4)		X				
1,4-Naphthoquinone	X	1 (0.454)				X		
1-Naphthylamine	X	1 (0.454)				X		
2-Naphthylamine	X	1 (0.454)				X		
1-Naphthyl-2-thiourea	X	1 (0.454)				X		
Nickel	X	1 (0.454)				X		
Nickel ammonium sulfate	D	5,000 (2,270)		X				
Nickel chloride	D	5,000 (2,270)		X				
Nickel carbonyl	X	1 (0.454)				X		
Nickel cyanide	X	1 (0.454)				X		
Nickel hydroxide	C	1,000 (454)		X				
Nickel nitrate	D	5,000 (2,270)		X				
Nickel sulfate	D	5,000 (2,270)		X				
Nicotine and salts	X	1 (0.454)				X		
Nitric acid	C	1,000 (454)		X				
Nitric oxide	X	1 (0.454)				X		
p-Nitroaniline	X	1 (0.454)				X		
Nitrobenzene	C	1,000 (454)		X	X	X		
Nitrogen dioxide	C	1,000 (454)		X		X		
Nitrogen mustard and hydrochloride salt	X	1 (0.454)				X		
Nitrogen mustard N-oxide and hydrochloride salt	X	1 (0.454)				X		
Nitrogen peroxide	X	1 (0.454)				X		
Nitrogen tetroxide	X	1 (0.454)				X		
Nitroglycerine (R)	X	1 (0.454)				X		
Nitrophenol (all isomers)	C	1,000 (454)		X	X	X		
2-Nitrophenol	C	1,000 (454)		X	X	X		
4-Nitrophenol	C	1,000 (454)		X	X	X		
4-Nitroquinoline-1-oxide	X	1 (0.454)		X	X	X		

CMA 047849

42.2.1

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
N-Nitrosodi-n-butylamine	X	1 (0.454)				X		
N-Nitrosodiethanolamine	X	1 (0.454)				X		
N-Nitrosodiethylamine	X	1 (0.454)				X		
N-Nitrosodimethylamine	X	1 (0.454)			X	X		
N-Nitrosodiphenylamine	X	1 (0.454)			X	X		
N-Nitrosodi-n-propylamine	X	1 (0.454)			X	X		
N-Nitroso-N-ethylurea	X	1 (0.454)				X		
N-Nitrosomethylethylamine	X	1 (0.454)				X		
N-Nitroso-N-methylurea	X	1 (0.454)				X		
N-Nitroso-N-methylurethane	X	1 (0.454)				X		
N-Nitrosomethylvinylamine	X	1 (0.454)				X		
N-Nitrosomorpholine	X	1 (0.454)				X		
N-Nitrosomornicotine	X	1 (0.454)				X		
N-Nitrosopiperidine	X	1 (0.454)				X		
N-Nitrosopyrrolidine	X	1 (0.454)				X		
N-Nitrososarcosine	X	1 (0.454)				X		
5-Nitro-o-toluidine	X	1 (0.454)				X		
Nitrotoluene	C	1,000 (454)		X				
Octachloronaphthalene	X	1 (0.454)				X		
Octamethylpyrophosphoramide	X	1 (0.454)				X		
Oleyl alcohol condensed with 2 moles ethylene oxide	X	1 (0.454)				X		
Osmium tetroxide	X	1 (0.454)				X		
7-Oxabicyclo[2.2.1]heptane-2,3- dicarboxylic acid	X	1 (0.454)				X		
Paraformaldehyde	C	1,000 (454)		X				
Parathion	X	1 (0.454)		X				
Pentachlorobenzene	X	1 (0.454)				X		

CMA 047850

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Pentachloroethane	X	1 (0.454)				X		
Pentachloronitrobenzene (PCNB)	X	1 (0.454)				X		
Pentachlorophenol	A	10 (4.54)		X	X	X		
Phenacetin	X	1 (0.454)				X		
Phenanthrene	X	1 (0.454)			X			
Phenol	C	1000 (454)		X	X	X		
Phenyl dichloroarsine	X	1 (0.454)				X		
Phenylenediamine	X	1 (0.454)				X		
Phenylmercury acetate	X	1 (0.454)				X		
N-Phenylthiourea	X	1 (0.454)				X		
Phosgene	D	5,000 (2,270)		X		X		
Phosphine	X	1 (0.454)				X		
Phosphoric acid	D	5,000 (2,270)		X				
Phosphorothioic acid, O,O-dimethyl ester, O-ester with N,N-dimethyl benzene sulfonamide	X	1 (0.454)				X		
Phosphorus	X	1 (0.454)		X				
Phosphorus oxychloride	D	5,000 (2,270)		X				
Phosphorus pentasulfide	B	100 (45.4)		X				
Phosphorus trichloride	D	5,000 (2,270)		X				
Phthalic anhydride	X	1 (0.454)				X		
2-Picoline	X	1 (0.454)				X		
Polychlorinated biphenyl(s) (PCBs)	A	10 (4.54)		X	X	X		
Potassium arsenate	C	1,000 (454)		X				
Potassium arsenite	C	1,000 (454)		X				
Potassium bichromate	C	1,000 (454)		X				
Potassium chromate	C	1,000 (454)		X				
Potassium cyanide	A	10 (4.54)		X		X		

CMA 047851

12/1/82

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA	CWA	CWA	RCRA	CAA	TSCA
			102	311K	307a	3001	112	7
Potassium hydroxide	C	1,000 (454)		X				
Potassium permanganate	B	100 (45.4)		X				
Potassium silver cyanide (R)	X	1 (0.454)				X		
Pronamide	X	1 (0.454)				X		
1,2-Propanediol	X	1 (0.454)				X		
1,3-Propane sultone	X	1 (0.454)				X		
Propargite	A	10 (4.54)		X				
Propionic acid	D	5,000 (2,270)		X				
Propionic anhydride	D	5,000 (2,270)		X				
Propionitrile	X	1 (0.454)				X		
Propylene Oxide	D	5,000 (2,270)		X				
Propylthiouracil	X	1 (0.454)				X		
2-Propyn-1-ol	X	1 (0.454)				X		
Pyrene	X	1 (0.454)			X	X		
Pyrathrins	C	1,000 (454)		X				
Pyridine	X	1 (0.454)				X		
Quinoline	C	1,000 (454)		X				
Radionuclides	X	1 (0.454)					X	
Reserpine	X	1 (0.454)				X		
Resorcinol	C	1,000 (454)		X				
Saccharin	X	1 (0.454)				X		
Safrole	X	1 (0.454)				X		
Selenious acid	X	1 (0.454)				X		
Selenium	X	1 (0.454)				X		
Selenium oxide	C	1,000 (454)		X				
Selenium sulfide (R)	X	1 (0.454)				X		
Selenourea	X	1 (0.454)				X		
Silver	X	1 (0.454)			X	X		
Silver cyanide	X	1 (0.454)				X		
Silver nitrate	X	1 (0.454)		X				

CMA 047852

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA	CWA	CWA	RCRA	CAA	TSCA
			102	311K	307a	3001	112	7
Sodium	C	1,000 (454)		X				
Sodium arsenate	C	1,000 (454)		X				
Sodium arsenite	C	1,000 (454)		X				
Sodium bichromate	C	1,000 (454)		X				
Sodium bifluoride	D	5,000 (2,270)		X				
Sodium bisulfite	D	5,000 (2,270)		X				
Sodium chromate	C	1,000 (454)		X				
Sodium cyanide	A	10 (4.54)		X		X		
Sodium dodecylbenzenesulfonate	C	1,000 (454)		X				
Sodium fluoride	D	5,000 (2,270)		X				
Sodium hydrosulfide	D	5,000 (2,270)		X				
Sodium hydroxide	C	1,000 (454)		X				
Sodium hypochlorite	B	100 (45.4)		X				
Sodium methylate	C	1,000 (454)		X				
Sodium nitrite	B	100 (45.4)		X				
Sodium phosphate, dibasic	D	5,000 (2,270)		X				
Sodium phosphate, tribasic	D	5,000 (2,270)		X				
Sodium selenite	C	1,000 (454)		X				
Streptozotocin	X	1 (0.454)				X		
Strontium chromate	C	1,000 (454)		X				
Strontium sulfide	X	1 (0.454)				X		
Strychnine and salts	A	10 (4.54)		X		X		
Styrene	C	1,000 (454)		X				
Sulfuric acid	C	1,000 (454)		X				
Sulfur monochloride	C	1,000 (454)		X				
2,4,5-T acid	B	100 (45.4)		X				
2,4,5-T amines	B	100 (45.4)		X				

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
2,4,5-T esters	B	100 (45.4)		X				
2,4,5-T salts	B	100 (45.4)		X				
2,4,5-TP acid	B	100 (45.4)		X				
2,4,5-TP acid esters	B	100 (45.4)		X				
Tetrachlorobenzene	X	1 (0.454)				X		
1,2,4,5-Tetrachlorobenzene	X	1 (0.454)				X		
2,3,7,8-Tetrachlorodibenzo-p-dioxin	X	1 (0.454)				X		
Tetrachloroethane (all isomers)	X	1 (0.454)				X		
1,1,1,2-Tetrachloroethane	X	1 (0.454)				X		
1,1,2,2,-Tetrachloroethane	X	1 (0.454)				X		
Tetrachloroethene								
(Tetrachloroethylene)	X	1 (0.454)				X		
Tetrachloromethane	X	1 (0.454)				X		
Tetrachlorophenol (all isomers)	X	1 (0.454)				X		
2,3,4,6-Tetrachlorophenol	X	1 (0.454)				X		
TDE	X	1 (0.454)		X				
Tetraethyldithiopyrophosphate	X	1 (0.454)				X		
Tetraethyl lead	B	100 (45.4)		X		X		
Tetraethylpyrophosphate	B	100 (45.4)		X		X		
Thallium	X	1 (0.454)				X		
Thallio oxide	X	1 (0.454)				X		
Thallium (I) acetate	X	1 (0.454)				X		
Thallium (I) carbonate	X	1 (0.454)				X		
Thallium (I) chloride	X	1 (0.454)				X		
Thallium (I) nitrate	X	1 (0.454)				X		
Thallium selenite	X	1 (0.454)				X		
Thallium (I) sulfate	C	1,000 (454)		X		X		
Thioacetamide	X	1 (0.454)				X		
Thiosemicarbazide	X	1 (0.454)				X		
Thiourea	X	1 (0.454)				X		

CMA 047854

191 513

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Thiuram	X	1 (0.454)				X		
Toluene	C	1,000 (454)		X	X	X		
Toluenediamine	X	1 (0.454)				X		
o-Toluidine hydrochloride	X	1 (0.454)				X		
Tolylene diisocyanate	X	1 (0.454)				X		
Toxaphene	X	1 (0.454)		X	X	X		
Tribromomethane	X	1 (0.454)			X	X		
Trichlorobenzene (all isomers)	X	1 (0.454)				X		
1,2,4-Trichlorobenzene	X	1 (0.454)				X		
Trichlorfon	C	1,000 (454)		X	X			
Trichloroethane (all isomers)	X	1 (0.454)				X		
1,1,1-Trichloroethane	X	1 (0.454)			X	X		
1,1,2-Trichloroethane	X	1 (0.454)			X	X		
Trichloroethylene	C	1,000 (454)		X	X	X		
Trichloromethanethiol	X	1 (0.454)				X		
Trichlorophenol (all isomers)	A	10 (4.54)		X	X			
2,4,5-Trichlorophenol	X	1 (0.454)				X		
2,4,6-Trichlorophenol	X	1 (0.454)				X		
1,2,3-Trichloropropane	X	1 (0.454)				X		
Triethanolamine								
dodecylbenzenesulfonate	C	1,000 (454)		X				
Triethylamine	D	5,000 (2,270)		X				
0,0,0-Triethyl phosphorothioate	X	1 (0.454)				X		
Trimethylamine	C	1,000 (454)		X				
Trinitrobenzene	X	1 (0.454)				X		
Tris(1-azridinyl)phosphine sulfide	X	1 (0.454)				X		
Tris(2,3-dibromopropyl) phosphate	X	1 (0.454)				X		
Trypan blue	X	1 (0.454)				X		
Uracil mustard	X	1 (0.454)				X		
Uranyl acetate	D	5,000 (2,270)		X				
Uranyl nitrate	D	5,000 (2,270)		X				
Vanadic acid, ammonium salt	X	1 (0.454)				X		

1000000

MATERIAL	CATEGORY	RQ IN POUNDS (KILOGRAMS)	CERCLA 102	CWA 311K	CWA 307a	RCRA 3001	CAA 112	TSCA 7
Vanadium pentoxide	C	1,000 (454)		X		X		
Vanadyl sulfate	C	1,000 (454)		X				
Vinyl acetate	C	1,000 (454)		X				
Vinyl chloride	X	1 (0.454)			X	X	X	
Vinylidene chloride	D	5,000 (2,270)		X		X		
Xylene	C	1,000 (454)		X				
Xylenol	C	1,000 (454)		X				
Zinc	X	1 (0.454)			X			
Zinc acetate	C	1,000 (454)		X				
Zinc ammonium chloride	D	5,000 (2,270)		X				
Zinc borate	C	1,000 (454)		X				
Zinc bromide	D	5,000 (2,270)		X				
Zinc carbonate	C	1,000 (454)		X				
Zinc chloride	D	5,000 (2,270)		X				
Zinc cyanide	A	10 (4.54)		X				
Zinc fluoride	C	1,000 (454)		X				
Zinc formate	C	1,000 (454)		X				
Zinc hydrosulfite	C	1,000 (454)		X				
Zinc nitrate	D	5,000 (2,270)		X				
Zinc phenolsulfonate	D	5,000 (2,270)		X				
Zinc phosphide	C	1,000 (454)		X				
Zinc silicofluoride	D	5,000 (2,270)		X		X		
Zinc sulfate	C	1,000 (454)		X				
Zirconium nitrate	D	5,000 (2,270)		X				
Zirconium potassium fluoride	D	5,000 (2,270)		X				
Zirconium sulfate	D	5,000 (2,270)		X				
Zirconium tetrachloride	D	5,000 (2,270)		X				

PART II
LIST OF HAZARDOUS WASTES

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- Hazardous waste from nonspecific sources

Industry	EPA Hazardous Waste Number	Hazardous Waste	Hazard Code
Generic	F001	The following spent halogenated solvents used in degreasing: tetrachloroethylene, trichloroethylene, methylene chloride, 1,1,1-trichloroethane, carbon tetrachloride, and chlorinated fluorocarbons; and sludges from the recovery of these solvents in degreasing operations	(T)
	F002	The following spent halogenated solvents: tetrachloroethylene, methylene chloride, trichloroethylene, 1,1,1-trichloroethane, chlorobenzene, 1,1,2-trichloro-1,2,2-trifluoroethane, ortho-dichlorobenzene, and trichlorofluoromethane; and the still bottoms from the recovery of these solvents	(T)
	F003	The following spent non-halogenated solvents: xylene, acetone, ethyl acetate, ethyl benzene, ethyl ether, methyl isobutyl ketone, n-butyl alcohol, cyclohexanone, and methanol; and the still bottoms from the recovery of these solvents	(I)
	F004	The following spent non-halogenated solvents: cresols and cresylic acid, and nitrobenzene; and the still bottoms from the recovery of these solvents	(T)
	F005	The following spent non-halogenated solvents: toluene, methyl ethyl ketone, carbon disulfide, isobutanol, and pyridine; and the still bottoms from the recovery of these solvents	(I,T)
	F006	Wastewater treatment sludges from electroplating operations except from the following processes: (1) sulfuric acid anodizing of aluminum; (2) tin plating on carbon steel; (3) zinc plating (segregated basis) on carbon steel; (4) aluminum or zinc-aluminum plating on carbon steel; (5) cleaning/stripping associated with tin, zinc and aluminum plating on carbon steel; and (6) chemical etching and milling of aluminum	(T)

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Industry	EPA Hazardous Waste Number	Hazardous Waste	Hazard Code
	F019	Wastewater treatment sludges from the chemical conversion coating of aluminum	(T)
	F007	Spent cyanide plating bath solutions from electroplating operations (except for precious metals electroplating spent cyanide plating bath solutions)	(R,T)
	F008	Plating bath sludges from the bottom of plating baths from electroplating operations where cyanides are used in the process (except for precious metals electroplating plating bath sludges)	(R,T)
	F009	Spent stripping and cleaning bath solutions from electroplating operations where cyanides are used in the process (except for precious metals electroplating spent stripping and cleaning bath solutions)	(R,T)
	F010	Quenching bath sludge from oil baths from metal heat treating operations where cyanides are used in the process (except for precious metals heat-treating quenching bath sludges)	(R,T)
	F011	Spent cyanide solutions from salt bath pot cleaning from metal heat treating operations (except for precious metals heat treating spent cyanide solutions from salt bath pot cleaning)	(R,T)
	F012	Quenching wastewater treatment sludges from metal heat treating operations where cyanides are used in the process (except for precious metals heat treating quenching wastewater treatment sludges)	(T)
	F014	Cyanidation wastewater treatment tailing pond sediment from mineral metals recovery operations	(T)
	F015	Spent cyanide bath solutions from mineral metals recovery operations	(R,T)

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Hazardous waste from specific sources

Industry	EPA Hazardous Waste Number	Hazardous Waste	Hazar Code
Wood Preservation	K001	Bottom sediment sludge from the treatment of wastewater from wood preserving processes that use creosote and/or pentachlorophenol	(T)
Inorganic Pigments	K002	Wastewater treatment sludge from the production of chrome yellow and orange pigments	(T)
	K003	Wastewater treatment sludge from the production of molybdate orange pigments	(T)
	K004	Wastewater treatment sludge from the production of zinc yellow pigments	(T)
	K005	Wastewater treatment sludge from the production of chrome green pigments	(T)
	K006	Wastewater treatment sludge from the production of chrome oxide green pigments (anhydrous and hydrated)	(T)
	K007	Wastewater treatment sludge from the production of iron blue pigments	(T)
	K008	Oven residue from the production of chrome oxide green pigments	(T)
Organic Chemicals	K009	Distillation bottoms from the production of acetaldehyde from ethylene	(T)
	K010	Distillation side cuts from the production of acetaldehyde from ethylene	(T)
	K011	Bottom stream from the wastewater stripper in the production of acrylonitrile	(R)

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Industry	EPA Hazardous Waste Number	Hazardous Waste	Hazard Code
	K013	Bottom stream from the acetonitrile column in the production of acrylonitrile	(R,T)
	K014	Bottoms from the acetonitrile purification column in the production of acrylonitrile	(T)
	K015	Still bottoms from the distillation of benzyl chloride	(T)
	K016	Heavy ends or distillation residues from the production of carbon tetrachloride	(T)
	K017	Heavy ends (still bottoms) from the purification column in the production of epichlorohydrin	(T)
	K018	Heavy ends from the fractionation column in ethyl chloride production	(T)
	K019	Heavy ends from the distillation of ethylene dichloride in ethylene dichloride production	(T)
	K020	Heavy ends from the distillation of vinyl chloride in vinyl chloride monomer production	(T)
	K021	Aqueous spent antimony catalyst waste from fluoromethanes production	(T)
	K022	Distillation bottom tars from the production of phenol/acetone from cumene	(T)
	K023	Distillation light ends from the production of phthalic anhydride from naphthalene	(T)
	K024	Distillation bottoms from the production of phthalic anhydride from naphthalene	(T)
	K093	Distillation light ends from the production of phthalic anhydride from ortho-xylene	(T)
	K094	Distillation bottoms from the production of phthalic anhydride from ortho-xylene	(T)

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Industry	EPA Hazardous Waste Number	Hazardous Waste	Hazard Code
	K025	Distillation bottoms from the production of nitrobenzene by the nitration of benzene	(T)
	K026	Stripping still tails from the production of methyl ethyl pyridines	(T)
	K027	Centrifuge and distillation residues from toluene diisocyanate production	(R,T)
	K028	Spent catalyst from the hydrochlorinator reactor in the production of 1,1,1-trichloroethane	(T)
	K029	Waste from the product steam stripper in the production of 1,1,1-trichloroethane	(T)
	K095	Distillation bottoms from the production of 1,1,1-trichloroethane	(T)
	K096	Heavy ends from the heavy ends column from the production of 1,1,1-trichloroethane	(T)
	K030	Column bottoms or heavy ends from the combined production of trichloroethylene and perchloroethylene	(T)
	K083	Distillation bottoms from aniline production	(T)
	K103	Process residues from aniline extraction from the production of aniline	(T)
	K104	Combined wastewater streams generated from nitrobenzene/aniline production	(T)
	K085	Distillation or fractionation column bottoms from the production of chlorobenzenes	(T)
	K105	Separated aqueous stream from the reactor product washing step in the production of chlorobenzenes	(T)

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Industry	EPA Hazardous Waste Number	Hazardous Waste	Haza. Code
Inorganic Chemicals	K071	Brine purification muds from the mercury cell process in chlorine production, where separately prepurified brine is not used	(T)
	K073	Chlorinated hydrocarbon waste from the purification step of the diaphragm cell process using graphite anodes in chlorine production	(T)
	K106	Wastewater treatment sludge from the mercury cell process in chlorine production	(T)
Pesticides	K031	By-product salts generated in the production of MSMA and cacodylic acid	(T)
	K032	Wastewater treatment sludge from the production of chlordane	(T)
	K033	Wastewater and scrub water from the chlorination of cyclopentadiene in the production of chlordane	(T)
	K034	Filter solids from the filtration of hexachloro-cyclopentadiene in the production of chlordane	(
	K097	Vacuum stripper discharge from the chlordane chlorinator in the production of chlordane	(T)
	K035	Wastewater treatment sludges generated in the production of creosote	(T)
	K036	Still bottoms from toluene reclamation distillation in the production of disulfoton	(T)
	K037	Wastewater treatment sludges from the production of of disulfoton	(T)
	K038	Wastewater from the washing and stripping of phorate production	(T)

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Industry	EPA Hazardous Waste Number	Hazardous Waste	Hazar Code
	K039	Filter cake from the filtration of diethylphosphorodithioic acid in the production of phorate	(T)
	K040	Wastewater treatment sludge from the production of phorate	(T)
	K041	Wastewater treatment sludge from the production of toxaphene	(T)
	K098	Untreated process wastewater from the production of toxaphene	(T)
	K042	Heavy ends or distillation residues from the distillation of tetrachlorobenzene in the production of 2,4,5-T	(T)
	K043	2,6-Dichlorophenol waste from the production of 2,4-D	(T)
	K099	Untreated wastewater from the production of 2,4-D	(T)
Explosives	K044	Wastewater treatment sludges from the manufacturing and processing of explosives	(R)
	K045	Spent carbon from the treatment of wastewater containing explosives	(R)
	K046	Wastewater treatment sludges from the manufacturing, formulation and loading of lead-based initiating compounds	(T)
	K047	Pink/red water from TNT operations	(R)
Petroleum Refining	K048	Dissolved air flotation (DAF) float from the petroleum refining industry	(T)
	K049	Slop oil emulsion solids from the petroleum refining industry	(T)

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Industry	EPA Hazardous Waste Number	Hazardous Waste	Ha C
	K050	Heat exchanger bundle cleaning sludge from the petroleum refining industry	(
	K051	API separator sludge from the petroleum refining industry	(
	K052	Tank bottoms (leaded) from the petroleum refining industry	(
Iron and Steel	K061	Emission control dust/sludge from the primary production of steel in electric furnaces	(
	K062	Spent pickle liquor from steel finishing operations	(
Primary Copper	K064	Acid plant blowdown slurry/sludge resulting from the thickening of blowdown slurry from primary copper production	(
Primary Lead	K065	Surface impoundment solids contained in and dredged from surface impoundments at primary lead smelting facilities	(
Primary Zinc	K066	Sludge from treatment of process wastewater and/or acid plant blowdown from primary zinc production	(
	K067	Electrolytic anode slimes/sludges from primary zinc production	(
	K068	Cadmium plant leachate residue (iron oxide) from primary zinc production	(
Secondary Lead	K069	Emission control dust/sludge from secondary lead smelting	(
	K100	Waste leaching solution from acid leaching of emission control dust/sludge from secondary lead smelting	(

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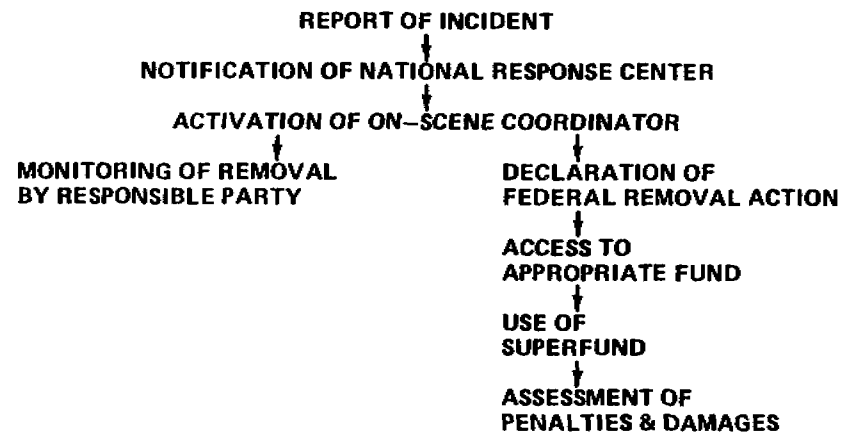
Industry	EPA Hazardous Waste Number	Hazardous Waste	Haza Co
Veterinary Pharmaceuticals	K084	Wastewater treatment sludges generated during the production of veterinary pharmaceuticals from arsenic or organo-arsenic compounds	(T)
	K101	Distillation tar residues from the distillation of aniline-based compounds in the production of veterinary pharmaceuticals from arsenic or organo-arsenic compounds	(T)
	K102	Residue from the use of activated carbon for decolorization in the production of veterinary pharmaceuticals from arsenic or organo-arsenic compounds	(T)
Ink Formulation	K086	Solvent washes and sludges, caustic washes and sludges, or water washes and sludges from cleaning tubs and equipment used in the formulation of ink from pigments, driers, soaps, and stabilizers containing chromium and lead	(T)
Coking	K060	Ammonia still lime sludge from coking operations	(T)
	K087	Decanter tank tar sludge from coking operations	(T)

CMA 047865

**EMERGENCY RESPONSE
UNDER THE
"SUPERFUND ACT"
OF 1980**

CMA 047866

**EMERGENCY RESPONSE
PROCEDURES**



CMA 047867

REPORT OF INCIDENT

OLD REPORTING REQUIREMENT

- OIL AND DESIGNATED 311 HAZARDOUS SUBSTANCES
- REPORTABLE QUANTITIES
- NAVIGABLE WATERS AND ADJOINING SHORELINES

NEW REPORTING REQUIREMENT

- OIL TO NAVIGABLE WATERS AND ADJOINING SHORELINES
- COMPREHENSIVE LIST OF HAZARDOUS SUBSTANCES INTO ALL MEDIA (WATER, LAND, AIR, GROUNDWATER)
- REPORTABLE QUANTITIES

* FAILURE TO NOTIFY CAN RESULT IN ASSESSMENT OF CRIMINAL PENALTIES *

**NOTIFICATION OF
NATIONAL RESPONSE CENTER**

- **RECEIVES REPORTS OF ALL DISCHARGES**
 - **OIL TO NAVIGABLE WATERS**
 - **HAZARDOUS SUBSTANCES TO ALL MEDIA
(WATER, LAND, AIR, GROUNDWATER)**
- **DISSEMINATES REPORT TO APPROPRIATE
RESPONSE AGENCY/ON-SCENE COORDINATOR**
- **TOLL FREE CALL WITHIN CONTINENTAL U.S.A.
1-800-424-8802**

ACTIVATION OF
ON-SCENE COORDINATOR

COASTAL AREAS (EXCEPT SITES)	INLAND AREAS
USCG OSC	EPA OSC

CMA 047870

DECISION BY OSC

**MONITOR REMOVAL EFFORT
BY RESPONSIBLE PARTY**

—OR—

**DECLARE FEDERAL
REMOVAL ACTION**

- **FAILURE OR INABILITY OF RESPONSIBLE
PARTY TO RESPOND PROPERLY**
- **DISCHARGER IS UNKNOWN**
- **CAUSED BY AN ACT OF GOD, WAR, OR
THIRD PARTY**

CMA 047871

ACCESS TO APPROPRIATE FUND

BEFORE SUPERFUND--DOLLARS AVAILABLE

311(k) FUND

- OIL AND "311 DESIGNATED" HAZARDOUS SUBSTANCES
- REPORTABLE QUANTITIES
- NAVIGABLE WATERS AND ADJOINING SHORELINE

AFTER SUPERFUND--DOLLARS AVAILABLE

311(k) FUND

+

SUPERFUND

- OIL IN REPORTABLE QUANTITY
- NAVIGABLE WATERS AND ADJOINING SHORELINE
- COMPREHENSIVE HAZARDOUS SUBSTANCES LIST IN REPORTABLE QUANTITIES
- SUBSTANTIAL THREATS BY ANY SUBSTANCE
- ALL MEDIA (WATER, LAND, AIR, GROUNDWATER)

**USE OF SUPERFUND
FOR EMERGENCY RESPONSE**

REMOVAL

- EVALUATION, MONITORING, AND INITIATION OF ACTION
- CONTAINMENT, SECURITY, AND COUNTERMEASURE
- CLEAN-UP, MITIGATION, AND DISPOSAL
- EVACUATION AND EMERGENCY ASSISTANCE
- DOCUMENTATION AND COST RECOVERY

DAMAGE ASSESSMENT AND RESTORATION

- BROADENED USE OF DIRECT FUND PAYMENTS

ASSESSMENT OF PENALTIES AND DAMAGES

CLEAN WATER ACT (OIL)

- CRIMINAL PENALTY FOR FAILURE TO NOTIFY = \$10,000 OR 1 YEAR IMPRISONMENT OR BOTH
- CIVIL PENALTY FOR EACH DISCHARGE = \$5,000
- REIMBURSEMENT OF FEDERAL REMOVAL AND NATURAL RESOURCES' RESTORATION COSTS INCURRED

SUPERFUND ACT (HAZ SUB)

- CRIMINAL PENALTY FOR FAILURE TO NOTIFY = \$10,000 OR 1 YEAR IMPRISONMENT OR BOTH
- REIMBURSEMENT OF FEDERAL REMOVAL AND NATURAL RESOURCES' RESTORATION COSTS INCURRED
- PUNITIVE DAMAGES FOR FAILURE TO PROVIDE REMOVAL = 3 x AMOUNT OF FEDERAL REMOVAL COSTS
- DESTRUCTION OF RECORDS = \$20,000 OR 1 YEAR IMPRISONMENT OR BOTH

78.41

BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
WASHINGTON, D.C.

In Re:

The Proposed Regulation of the United
States Occupational Safety and Health
Administration for the Identification,
Classification and Regulation of Toxic
Substances Posing a Potential Occupa-
tional Carcinogenic Risk to Humans.

OSHA Docket
No. H-090

POST HEARING BRIEF FOR
THE AMERICAN INDUSTRIAL HEALTH COUNCIL

ROBERT C. BARNARD
ERIC SCHWARTZ
PRICE O. GIELEN
ROBERT L. GLICKSMAN

Counsel for the American
Industrial Health Council

Of Counsel:

Cleary, Gottlieb, Steen & Hamilton
1250 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 223-2151

October 23, 1978

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BEFORE THE
UNITED STATES DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
WASHINGTON, D.C.

In Re:

The Proposed Regulation of the United
States Occupational Safety and Health
Administration for the Identification,
Classification and Regulation of Toxic
Substances Posing a Potential Occupa-
tional Carcinogenic Risk to Humans.

OSHA Docket

No. H-090

POST HEARING BRIEF FOR
THE AMERICAN INDUSTRIAL HEALTH COUNCIL

Preliminary Statement

On October 4, 1977, the Occupational Safety and Health Administration ("OSHA") published the Proposed Regulation for the "Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk", 42 Fed. Reg. 54148 [hereinafter referred to as the "Proposed Regulation"], under the Occupational Safety and Health Act, 29 U.S.C. § 651 et seq. [hereinafter referred to as the "Act"].

OSHA began work on the Proposed Regulation in January 1976. (Wrenn Tr. 164.)^{1/} In October 1976 a contract was entered into with Clement Associates, Inc. ("Clement"), a consulting firm to, inter alia, "examine and furnish alternative approaches and policies for the regulation of carcinogens" (Ex. 12A.) The contract also provided that Clement would "[d]evelop prototype regulations for controlling employee exposure to carcinogens found in the occupational environment."^{2/} Id.

In January 1977 OSHA released a draft of proposed regulations substantially identical to the Proposed Regulation for comment by the National Advisory Committee on Safety and

^{1/} References to the transcript of the hearing will be indicated as "Tr. ____." Exhibits to the Preamble to the Proposed Regulation will be indicated as "Preamble Ex. ____." Exhibits offered at the hearing will be indicated as "Ex. ____."

The statements filed on or before February 28, 1978, by persons wishing to testify, written statements by members of the public, and statements by OSHA witnesses were offered together as a single exhibit, Ex. 6. Additional statements or comments were filed during the hearing and as post hearing evidence was filed. For convenience the written statements of individual witnesses and written prepared testimony by witnesses will be referred to as "S. ____." Post hearing evidence will be identified by the person submitting the data as follows, e.g., "AIHC P.H."

^{2/} The National Institute for Occupational Safety and Health ("NIOSH") is designated under Section 20 of the Act, 29 U.S.C. § 669, as the research arm of OSHA. NIOSH is charged with, among other things, developing criteria for dealing with toxic materials, but was not consulted by OSHA when the Proposed Regulation was being drafted. (Tr. 2979.)

Health ("NACOSH"). ^{1/} This draft was not published in the Federal Register but was made available to the public on request. Two brief public meetings of NACOSH were held at which public comments were invited. ^{2/} 42 Fed. Reg. 54182-54183. At these very brief hearings testimony was received from a number of witnesses. ^{3/} On May 5, 1977, NACOSH adopted a resolution recommending that the draft be published for "information gathering and that neither the document nor the process be engaged for a rulemaking purpose at this time." ^{4/} 42 Fed. Reg. 54183.

1/ NACOSH is an advisory committee established under Section 7(a) of the Act. 29 U.S.C. § 656(a).

2/ NIOSH received notice of the draft regulation when it was released to NACOSH. NIOSH filed a letter with NACOSH stating its intention to comment on the draft, but no such comments were filed.

3/ The transcript of the proceedings of the Subcommittee on Environmental Carcinogenesis of the National Cancer Advisory Board was filed as part of the record in the NACOSH proceedings.

4/ The NACOSH resolution stated:

"1. The document can be adopted by OSHA as an administrative policy, and there should be such flexibility.

2. The document, even if adopted as a policy through the rulemaking process, would not deprive due process challenges when subsequent standards are promulgated.

3. The document identifies those issues upon which much debate has evolved and should continue, including the concept that some substances, although not always scientifically definable as carcinogens, must be addressed because of a regulatory obligation.

(Footnote continued on p. 4)

On July 13, 1977, OSHA entered into another contract with Clement to undertake a preliminary classification of substances in the 1976 Edition of the NIOSH Subfile of Suspect Carcinogens of the Registry of Toxic Effects of Chemical Substances ("NIOSH List" or "NIOSH Subfile") into OSHA's proposed Categories I, II, and III. (Ex. 12C.) On July 14, 1978, OSHA released the lists prepared by Clement placing substances in the NIOSH subfile in the OSHA categories on a tentative basis. (Ex. 132.)

The hearing began May 16, 1978, and ended July 25, 1978.

Statutes Involved

The relevant statutory provisions of the Act are Sections 3(8), 6, 7, 8(c), 8(g), 9, 13, and 20. 29 U.S.C. §§ 652(8), 655, 656, 657(c) and (g), 658, 662, and 669. The text of these sections of the statute is set out in Appendix A to this brief.

(Footnote continued from p. 3)

ISSUES WHICH NEED TO BE EXPANDED

1. Address adequacy of classification system.
2. Address carcinogenicity of impurities and mixtures.
3. Expand discussion on "other than animal testing" routes.
4. Anatomic and metabolic fate.
5. Decision on rate retention issue."

42 Fed. Reg. 54183.

Introductory Statement

The American Industrial Health Council ("AIHC") was formed with the objective of cooperating with government, labor, and the public in developing a sound policy for the control of exposure to carcinogens in the work place. ^{1/} To that end the AIHC developed "Recommended Alternatives to OSHA's Generic Carcinogen Proposal" [hereinafter referred to as "AIHC Alternative" or "the Alternative"]. The Alternative was originally released in draft form on January 9, 1978, to OSHA, unions, and the public for comment. A final copy reflecting comments on the draft was filed in these proceedings on February 28, 1978.

At the time of publication of the Proposed Regulation, OSHA published a one and one-half page pro forma Environmental Impact Statement.

OSHA did not undertake an economic analysis of the Proposed Regulation. OSHA stated that such an analysis would be made in rulemaking on individual substances. 42 Fed. Reg. 54182. In AIHC's view, an economic analysis of the Proposed Regulation should have been undertaken not only in compliance with the requirements of the National Environmental Policy Act of 1969, 42 U.S.C. § 4321 et seq. ("NEPA"), but also pur-

^{1/} The membership of AIHC as of June 26, 1978, appears as Exhibit 81. A number of companies have joined AIHC since that date and membership is now approximately 120 companies. In addition to these member companies, AIHC has cooperative relationships with some 50 trade associations.

suant to directives of the President in Executive Orders No. 11821, 39 Fed. Reg. 41501 (November 28, 1974) and No. 12044, 43 Fed. Reg. 12660 (March 27, 1978).^{1/} Consequently AIHC commissioned the Foster D. Snell Division of Booz, Allen and Hamilton, Inc., to undertake such an analysis. That analysis, - discussed infra, at 105, is entitled "Preliminary Estimates of Direct Compliance Costs and Other Economic Effects of OSHA's Generic Carcinogen Proposal on Substance Producing and Using Industries" [hereinafter referred to as the "Snell Report"].

Significant Post Hearing Developments

Regulatory Analysis. As pointed out above, OSHA did not undertake an economic analysis of the Proposed Regulation. On June 14, 1978 Organization Resource Counselors ("ORC") wrote to the Office of Management and Budget ("OMB"), the agency responsible for the implementation of the President's Regulatory Analysis Program, pointing out that OSHA's position that an economic analysis was not required under Executive Order 12044 was erroneous and requesting OMB to use its good offices to require OSHA to prepare an economic analysis. On July 25, 1978 OMB notified ORC that OSHA had "agreed that a regulatory analysis will be done for the generic standards and that [OMB] will

^{1/} OSHA's failure to comply with NEPA and the Executive Orders is discussed infra, at 100.

continue to work with [OSHA] on the design of the analysis."
(AIHC P.H.)

In a memorandum to Assistant Secretary Bingham dated August 3, 1978, Messrs. Morris and Wrenn summarized the agreement by OSHA to undertake a regulatory analysis of the Proposed Regulation, including an examination of "realistic alternative approaches." (AIHC P.H.) The memorandum continued:

"In addition to this comparison of alternative approaches, the analysis would also look at alternative criteria for the categorization of substances within the generic standard. OSHA also will set forth for review the parameters which are included in a determination of feasibility. We think the analysis will demonstrate what issues are intended in the generic approach to be foreclosed from further rulemaking." Id.

As of the date of this brief, neither the regulatory analysis nor a draft or outline of the analysis has been made public.

The Benzene Decision. On October 5, 1978 the Fifth Circuit Court of Appeals unanimously decided to set aside the Occupational Safety and Health Standard for Benzene (the "Benzene Standard"). American Petroleum Institute v. Occupational Safety and Health Administration, ___ F.2d 80 (5th Cir. 1978). (A copy of the decision is attached as Appendix B. The decision will hereinafter be referred to as the "Benzene decision".) The decision bears directly upon many of the policy determinations being considered as part of the Proposed Regulation and demonstrates that OSHA should withdraw the Proposed Regulation and repromulgate a new proposal which complies with the statute. Because

of the importance of the decision, we are discussing it at the outset rather than piecemeal in various sections of the brief.

The core policy determination of the Proposed Regulation -- the control of exposure to confirmed or suspected carcinogens to the "lowest feasible level" -- was incorporated into the Benzene Standard and was the primary focus of the Fifth Circuit's decision. The factual premise for that policy determination in the Proposed Regulation -- that there presently exists no known safe level for exposure to a carcinogen -- also was the basis for the control of benzene in accordance with that policy. The provisions of the Benzene Standard clearly track the provisions of the model standards found in the Proposed Regulation.^{1/}

The Court's ruling is particularly germane to the Proposed Regulation in light of the assumptions the court made in deciding to set the Benzene Standard aside. The Court accepted OSHA's determination that benzene is a leukomogen and that it is impossible to determine a safe or no-effect level for exposure to benzene or any other carcinogen. The Court accepted OSHA's cost estimates for industry implementa-

^{1/} Compare 43 Fed. Reg. 5918 (February 10, 1978) with 42 Fed. Reg. 54148 (October 4, 1977) regarding adoption of policy to control exposure to lowest feasible level; 29 C.F.R. § 1910.1028(c)(1) and (c)(2) (published at 43 Fed. Reg. 5964) with Proposed Section 1990.160(c)(1) and (c)(2) (published at 43 Fed. Reg. 54189) regarding control of exposure from airborne concentrations and from dermal contact; and 29 C.F.R. § 1910.1028(k)(2)-(5) (published at 43 Fed. Reg. 5966) with Proposed Section 1990.160(p)(3) regarding labelling.

tion of the Benzene Standard and did not reach or discuss the petitioners' arguments concerning the infeasibility of the standard. The decision thus is based on statutory grounds rather than the particular facts pertaining to benzene.

In setting aside the Benzene Standard, the Fifth Circuit rejected OSHA's effectuation of the policy determination "to limit employee exposure to carcinogens to the lowest feasible level" where (as is the case with benzene and the Proposed Regulation) that determination is based simply upon factual findings that the substance is a carcinogen and that there is no known safe or threshold effect level of exposure for the substance. ___ F.2d at 88. The Court found that for an occupational safety and health standard to be "reasonably necessary and appropriate to provide safe or healthful employment and places of employment," as required by Section 3(8) of the Act, 29 U.S.C. § 652(8), OSHA must "assess the expected benefits" from the standard and "determine whether [those benefits] bear a reasonable relationship to the costs imposed by the standard." ___ F.2d at 90-91. In other words, OSHA must conduct some form of cost/benefit analysis, as advocated by AIHC and others.

The Court specifically found that in making the assessment of benefits OSHA could not assume "appreciable" benefits would accrue to employees by lowering exposure to a carcinogen, in this case benzene. Rather, OSHA must make a factual determination, supported by substantial evidence, as to the benefits to employees from the reduction of exposure required by the

standard:

"Until OSHA can provide substantial evidence that the benefits to be achieved by reducing the [PEL] from 10 ppm to 1 ppm bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces." ___ F.2d at 92.

In short, OSHA must "regulate on the basis of knowledge rather than on the unknown." Id.

The Court explained that sufficient "knowledge" of the benefits provided by a standard could be secured through appropriate risk assessment and quantification.^{1/} While recognizing that "OSHA's assertion that present knowledge is insufficient to construct a valid dose-response curve for benzene may be correct," the Court found that "the record

1/ Because the word "risk" was used with different meanings by the Fifth Circuit and various witnesses in this proceeding, it is important as a preliminary matter to define "risk" as that word is used in this brief and to distinguish "risk" from "hazard". "Risk" is used in this brief to refer to the scientific evaluation of data to determine its validity to establish qualitative human risk of cancer. "Risk" also encompasses evaluation of potency in relation to human risk, identification of the scientific extrapolation techniques, and an evaluation of the probability of occurrence.

"Hazard", in contrast, is used in the regulatory context, to mean the social danger presented by exposure to the substance. The determination by the Agency whether to regulate or not is based on the analysis of the Agency of the "hazard". "Hazard" thus encompasses the number of workers exposed, the level of exposure, and the characteristics of the substance to which the worker is exposed - both the physical characteristics and the relative potency of the substance. Hazard assessment is the function of the Agency.

See generally AIHC Alternative at 78-82.

reflects that preliminary assessments are now being made and that valid extrapolations will be possible as more is known about the effects of past exposure at higher levels." __ F.2d at 92 n. 23. Furthermore, until "rough but educated estimates of the extent of benefits" from reducing exposure could be developed based on human exposures or animal data, there would be insufficient evidence upon which to find a standard reasonably necessary. __ F.2d at 93.^{1/}

The PEL for airborne concentrations of benzene was the primary focus of the Court's opinion, but challenges to the dermal contact and labelling provisions in the standard were considered and the Court's ruling setting aside these provisions was significant. The disposition of these challenges clearly demonstrates that each provision in a standard must be the subject of a finding, supported by substantial evidence, that the provision is "reasonably necessary" to provide workers protection.

The dermal contact provision in the Benzene Standard was set aside upon a finding that OSHA failed to demonstrate that it was "reasonably necessary" for the protection of workers:

"Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene will result

^{1/} The court's decision underlines the conclusion (see discussion beginning infra, at 197) that OSHA should modify the Proposed Regulation to provide for risk quantification and hazard assessment.

in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too." — F.2d at 94 (emphasis added).^{1/}

The Court stated that it would have applied the same criterion to the labelling provisions of the Benzene Standard but such an analysis became unnecessary once the provisions concerning the reduction of the PEL and the prohibition of dermal contact were set aside. These provisions were correctly viewed by the Court as tied to all the Benzene Standard's other requirements. However, in an effort to provide guidance to OSHA in promulgating future standards, the Court addressed the labelling issue.

The Fifth Circuit opined that OSHA could forbid employers from removing caution labels upon containers of benzene and benzene-containing products sold, distributed or otherwise leaving the employer's workplace; that authority, however, is limited to circumstances where "the labelling requirement as a whole is shown to be reasonably necessary to provide safe workplaces." — F.2d at 99 (emphasis added). In short, just as for exposure limits and restrictions on dermal contact, OSHA must

^{1/} It is notable that the Court reached this determination having before it information on costs which was made uncertain by OSHA's amendment of the Benzene Standard (promulgated on June 21, 1978, the day before oral argument) exempting from the scope of the standard work operations where the only dermal exposure to benzene is from liquid mixtures containing 0.5 percent or less of benzene by volume. Thus, the lack of a supportable finding of appreciable benefits was the primary basis for setting the provision aside.

find on the basis of substantial evidence that labelling will achieve a quantifiable health benefit for workers and that the benefits achieved will be reasonably related to the cost of such labelling. As in the Court's analysis of the PEL and dermal contact provisions, the Court stressed that a valid finding by OSHA that appreciable benefits would accrue to workers was the indispensable predicate to regulation. Thus, OSHA must as a threshold matter find that labelling is reasonably necessary or appropriate to inform employees of the danger of the substance found in the container and second, that it is reasonably necessary or appropriate for the labels to remain on the container to inform downstream employees of the danger of the substance found in the container.

Another aspect of the Court's decision is of great importance as it bears on OSHA's obligation to take affirmative action to secure data upon which to act. The analysis performed by the Court in determining that OSHA failed to establish dermal contact as a mode of entry of benzene into the body strongly suggests the invalidity of the primary procedural concept embodied in the Proposed Regulation. The Court recognized that there was evidence in the hearing record providing some support for OSHA's determination that benzene could enter the body through the skin. But testimony also established that through modern testing techniques a definitive answer could be provided to the question regarding the conditions under which skin absorption might occur and the nature of the substance which actually could be absorbed. The failure of OSHA to conduct the tests

necessary to answer these questions was viewed by the Court as directly contrary to the will of Congress:

"OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the 'best available evidence,' 'research, demonstrations, experiments, and such other information as may be appropriate,' and 'the latest available scientific data in the field.' 29 U.S.C.A. § 655(b)(5)."
— F.2d at 96.

Thus, the primary procedural concept in the Proposed Regulation -- OSHA's expressed intention to generically resolve many principles and concepts in this proceeding and to rigidly apply these principles and concepts in future rulemaking proceedings on specific substances -- flies in the face of the Fifth Circuit's ruling. It is clear that not only significant new data, but data reasonably obtainable must be considered by OSHA in promulgating occupational safety and health standards. Furthermore, assuming the answers to factual questions, such as whether a carcinogen may be absorbed through the skin, will be grounds for invalidating a standard. Rather than create such rebuttable presumptions, OSHA must find on the basis of substantial evidence that the carcinogen may be absorbed through the skin.

The Benzene decision underlines basic weaknesses of the Proposed Regulation. OSHA must find on the basis of valid supporting evidence that there are benefits in terms of reduced risk from control to the lowest feasible levels and those benefits must be quantified. OSHA has not done so. OSHA must then make the

determination whether the benefits justify the costs of the Proposed Regulation. OSHA has not done so. Finally, OSHA has the obligation to consider the best available evidence and to take affirmative steps to secure data reasonably available before making regulatory decisions. OSHA has done the opposite; the proposed policy decisions and presumptions of fact are designed to exclude new data and there is no procedure to secure reasonably available data. In short, if OSHA wishes to speed up its regulation of carcinogens in a valid manner, it must withdraw the Proposed Regulation and create a new regulatory scheme. OSHA has been provided such a scheme in the AIHC Alternative.

A R G U M E N T

Introduction

The AIHC Alternative and OSHA's Proposed Regulation agree on a number of very important points. However, in AIHC's view, the record shows that OSHA's proposal is deficient both legally and scientifically. The purpose of this brief is two-fold: First, to point out the shortcomings of the Proposed Regulation and to indicate how the regulation can be brought into conformity with the law. Second, to demonstrate that the AIHC Alternative avoids the shortcomings of the Proposed Regulation.

The discussion in this brief is divided into five

general parts.

In Part One (Sections I - VII) we shall discuss the statutory and constitutional issues arising under OSHA's proposal. As a background to this discussion and in order to clarify the nature of the problem OSHA is addressing, we shall discuss briefly the evidence in the record as it bears on the issue of whether there is an occupational cancer epidemic due to industrial exposure of workers.

In Part Two of the brief (Sections VIII - X) we shall discuss the shortcomings, both scientific and legal, of OSHA's proposed classification system. We will address the evidence in the record which demonstrates that OSHA's proposal to make generic scientific decisions by administrative fiat is unsound and would "freeze" science in a way inconsistent with the statute.

Part Three (Sections XI - XIV) addresses the issues which arise by reason of the automatic and inflexible way in which OSHA proposes that regulatory action be taken. We shall discuss OSHA's lack of authority to issue an Emergency Temporary Standard without an appraisal of the risk as required by law. We shall review the evidence in the record which demonstrates that OSHA should undertake a quantitative risk analysis and consider how such an analysis should be used in setting exposure levels. And we shall also refer to the record and the statute regarding OSHA's obligation to establish priorities.

Part Four (Sections XV - XVII) deals with the impor-

tance of providing in the regulation for a determination in subsequent standards for exclusion of mixtures containing small quantities of a carcinogen and for determination of an action level. It also discusses three matters which are inappropriate in the Proposed Regulation: rate retention, a permit system and limitations on the use of company doctors. Finally, we point out that key words in both the Proposed Regulation and the proposed standards are impermissibly vague.

Part Five (Sections XVIII - XIX) will address the inadequacies of the proposed model standards.

AIHC believes that the defects in the Proposed Regulation are fundamental. Significant issues such as risk assessment are being decided in the Interagency Regulatory Liaison Group, not in this proceeding. The Agency's interpretation of the basic concept of feasibility will only be made public when the Regulatory Analysis is made public. Similarly, the Agency has not indicated clearly which issues it proposes to decide generically. To make these basic disclosures only in the Regulatory Analysis, as the Agency proposes, renders the notice meaningless since the record is closed. OSHA has commenced overlapping proceedings on access to medical records. AIHC believes that the only prudent course is for OSHA to propose a new revised regulation which corrects the deficiencies of the present proposal and allow public comment on that new proposal.

PART ONE

I

THERE IS NO OCCUPATIONAL CANCER EPIDEMIC

In the Preamble to the Proposed Regulation OSHA discusses the increase in cancer since 1900. 42 Fed. Reg. 54150. Unfortunately, the ambiguous way in which OSHA used the term "environmental factors" as the cause of cancer, together with the way in which OSHA discussed exposure to "man-made chemicals" in the context of a burgeoning "environmental" cancer problem, created the impression that OSHA was attributing the growth in cancer since 1900 to industrial exposure. This has lead to a significant volume of testimony addressed to the issue of whether there is an epidemic of cancer related to workplace exposure to man-made chemicals.

It is not our purpose to review this testimony in any detail. While cancer from industrial exposure is only a small part of the total cancer problem, nonetheless the part industrial exposure plays is important because any cause of cancer is important. It is AIHC's position that whenever a confirmed or highly probable cause of cancer is found in the workplace, there is good and sufficient reason to take prompt and stringent protective action prior to OSHA's promulgation of a standard. Should OSHA conclude that protective action taken by industry is insufficient, it can then insti-

tute regulatory proceedings. It is unnecessary to show that there is an actual or threatened epidemic in order to justify control over worker exposure to identified carcinogens.

Until the post hearing filing by OSHA on September 15, 1978, the statements in the record of government officials (not industry representatives) indicated that the relative contribution of occupational exposure to the total cancer burden was small: 1% to 5% was the most frequent estimate.^{1/} Dr. Gori of the NCI and Dr. Wynder of the American Health Foundation in a study prior to this controversy concluded that most of the cancer burden was attributable to life style: diet, tobacco, alcohol and sunbathing, and attributed only about 4% to industrial exposure.^{2/}

^{1/} The British Royal Society Study Group on Lay Term Toxic Effects, of which Sir Richard Doll is chairman, issued a report dated July, 1978. (A copy has been filed in Docket 090). That report states:

"Many specific hazards of cancer have been traced to occupational exposures to chemicals in industry, though such hazards are not likely to account for more than about 1% of all cancers now occurring in the U.K. A few other cancers could be attributed to pollution by industrial products or industrial waste (e.g. respiratory cancer attributable to asbestos dust). New rapid tests for the detection of the carcinogenic potential of chemicals should enable sources of hazard to be reduced even further." (Id. at 7)(emphasis added).

^{2/} Ernest L. Wynder and Gio B. Gori "Contribution of the Environment to Cancer Incidence; an Epidemiologic Exercise," 58 J. Natl. Can. Inst. 825, 831 (1977). Reprint in AIHC Bibliography.

On September 15 OSHA filed a document in the record entitled "Estimates of the Fraction of Cancer in the United States Related to Occupational Factors" [hereinafter referred to as the "Estimates Paper"].^{1/} This paper purports to set forth a basis for revising the estimated cancer burden attributable to occupational exposure and concludes that an estimated 20% of cancer mortality will be occupationally related in forthcoming decades. (Estimates Paper at 24.)^{2/}

AIHC believes that the Estimates Paper is fundamentally flawed and presents a false picture. It is doubly unfortunate that such a new frightful forecast should be presented on the last day for filing evidence without opportunity to question the contributors or to demonstrate the flaws in the estimate. A separate memorandum [hereinafter referred to as the "AIHC Reply"], filed with this brief, contains an analysis by AIHC of the Estimates Paper. In this brief we will summarize the

^{1/} The contributors are: Kenneth Bridbord, M.D., NIOSH; Pierre Decoufle, Sc.D., NCI; Joseph F. Fraumeni, Jr., M.D., NCI; David G. Hoel, Ph.D., NIEHS; Robert N. Hoover, M.D., Sc.D., NCI; David P. Rall, M.D., Ph.D., NIEHS, Director; Umberto Saffiotti, M.D., NCI; Marvin A. Schneiderman, Ph.D., NCI; Arthur C. Upton, M.D., NCI, Director. Contributor to the Appendix: Nicholas Day, Ph.D., NCI, IARC.

^{2/} This figure was selected without explanation as a conservative estimate from a range of estimates of cancer as occupationally related varying from 18% to 38%. The Estimates Paper appears to conclude that there is no way to ameliorate this tragic and frightful forecast. The estimates are "future consequences of past exposure" (Estimates Paper at 16, emphasis in the original). Thus apparently no action by OSHA or any other agency can alter this terrible forecast.

points made in the AIHC Reply.

At the outset it is important to point out that the Estimates Paper rejects the "one effect-one cause" explanation of cancer and embraces the concept of associated risk while calling it attributable risk. An inevitable consequence of this approach is that attributable causes of cancer exceed 100%. (Estimates Paper at 23.) Thus, for example, worker A who had exposure to asbestos and in uranium mining would have his death of lung cancer attributed both to asbestos and radioactivity exposures. Assume a ten worker cohort with workplace exposure as indicated in the following table and that all died of lung cancer:

<u>Worker</u>	<u>Smoker?</u>	<u>Asbestos?</u>	<u>Uranium?</u>
1	+	+	+
2		+	
3	+		+
4	+	+	
5			
6	+	+	+
7			
8	+	+	
9			
10	<u>+</u>	<u>—</u>	<u>—</u>
	6	5	3

Six deaths would be attributable to smoking, five to asbestos and three to uranium - a total of 14 attributable deaths in 10 workers. The Estimates Paper would claim smoking accounted for 60% of the deaths, asbestos for 50% and uranium for 30%. We now have "attributed" 140% of the deaths without taking into account the attributable risk from genetic susceptibility, diet, alcohol, or exposure to other natural or synthetic carcinogens

in the environment or the body.^{1/} Since cancer has attributable causes exceeding 100%, the 20% estimate of occupationally related cancer should not be considered in relation to 100% of the cases of cancer, as is the case with most previous estimates, but to some higher percentage number of all attributable causes. If one conservatively assumes that the total of attributable causes do not exceed 500%, the 20% figure translated to the normal 100% usage would be 4%.

In addition, the Estimates Paper has not addressed the critical question of prevention: whether removal or reduction of one attributable cause has any meaning, if the remaining attributable causes still exceed 100%.

In the same discussion, the Estimates Paper urges that the focus be on "causative factors". (Estimates Paper at 23.) However, the methodology of the Estimates Paper injects a note of confusion with regard to recommendations that OSHA make a risk estimate of the causative factors as part of the regulatory process. No meaningful risk estimate can be made

^{1/} Several of OSHA's post hearing filings, including one by Dr. Saffiotti, a contributor to the Estimates Paper, were designed to show that the bionutrients, selenium, cobalt, calcium and estrogens which are essential to life are also contributors to the human cancer burden even at low essential levels. In addition, the calculations by Dr. Nisbet in his comment filed as part of the OSHA post-hearing evidence would indicate a very high risk for non-smokers from exposure to sidestream smoke. Thus each individual inherently has attributable risks from essential bionutrients and an inevitable risk from exposure to tobacco directly as a smoker or indirectly from sidestream smoke.

until a clear distinction is made between associated risk and attributable risk, between association and causation, and between preventable and attributable.

An increased associated risk does not necessarily mean the risk is attributable to exposure in a certain industry. Thus, hypothetical workers in a certain industry may have an increased relative risk of stomach cancer. If the etiological agent is diet, then the deaths are not attributable to occupational exposure. If the stomach cancer were truly attributable to occupational exposure, the mortality should drop by correcting the work environment. In this hypothetical example, correcting the work environment would have no effect because the workers carry an excessive relative risk which is associated with, but not caused by, workplace exposure. Removal of exposure would not prevent the cancer, but adding refrigeration might.

The lack of differentiation between relative risk and attributable risk must be eliminated in a sound methodology of risk analysis. Moreover, the methodology of quantification in the Estimates Paper has the following serious flaws which must be corrected before a sound risk assessment can be made:

(1) The Estimates Paper virtually disregarded dose-response relationships. The estimates were based on relative risk observations in select very high exposure cohorts and then that same risk ratio was applied to all potentially exposed workers without regard to the duration or level or probability of exposure for those individuals.

(2) The estimates of the number of individuals exposed are inappropriately large. The Estimates Paper relied largely on estimated numbers of potentially exposed workers from the National Occupational Hazard Survey ("NOHS") conducted by NIOSH between 1972 and 1974. The NOHS numbers are based on a survey of 5000 establishments and extrapolated to the entire workforce. The NOHS made no distinction between potentially and actually exposed workers or of levels of exposure.

(3) The calculated incidence rates are used in the Estimates Paper to approximate mortality without adjustments for cure rate, or competing causes of death, or shifts in the age structure of the U.S. population.

(4) The methodology of the Estimates Paper makes no attempt to eliminate multiple counting. The NOHS study identified 4.38 billion exposures for 38.2 million employees - an average of 115 potential exposures per worker out of the 198 hazards investigated. The Estimates Paper made no attempt to deal with this multiple counting. If the exposed population numbers in Table II are multiplied by the factor of 5 suggested in the Estimates Paper (Estimates Paper at 13), 59 million workers over 20 have been exposed to the six substances alone. In 1970, the total U.S. worker population over 20 was about 75 million.

(5) The risk ratios were calculated from select highly exposed cohorts and estimates on recent workplace conditions were ignored.

Asbestos. The principal example used for the analysis in the Estimates Paper is asbestos. This analysis is based on an estimated 8-11 million population exposed since World War II ("WW II"), including a cohort of 4,500,000 of WW II shipyard workers.^{1/} Of this 8-11 million, 4,000,000 are estimated to have been heavily exposed and "probably" one million have died. (Estimates Paper at 8-9.) The invalidity of the methodology embraced by the Estimates Paper can be demonstrated by applying that methodology to the WW II cohort of shipyard workers.

Assuming conservatively that all the "probable" million deaths occurred in the WW II cohort, one would conclude that 3.5 million exposed workers are still alive. While it appears probable that the WW II cohort was heavily exposed, it is reasonable to allocate the 3.5 million by assigning only 4/10 or 4/7 as heavily exposed and the balance as lightly exposed.^{2/} The heavily exposed sub-cohort then is between 1.4 million and 2 million. Using standard mortality rates and assuming the shipyard cohort had the same distribution of men and women workers as the WW II civilian workforce there would be 131,000 deaths expected in

^{1/} The basis for the figure of 8-11 million exposed workers has not been explained. In the Estimates Paper the number is referenced through reference (9) to reference (11), which is a speech by Secretary Califano, a rather unusual form of circular reference.

^{2/} Total exposed 8-11 million less one million dead leaves 7-10 million of which 4 million were heavily exposed. 4/10 of 3.5 million equals 1.4 million; 4/7 of 3.5 million equals 2 million.

this cohort in 1976.^{1/} The period since WW II is a long enough latency period (see Estimates Paper reference 15) for a significant number of deaths to have occurred as a result of asbestos exposure. Seven-to-ten percent of the deaths would be expected to be due to mesothelioma, the "marker" disease for asbestos exposure. On this assumption there would have been 5,200 deaths predicted from mesothelioma among the heavily exposed and over 900 among the less heavily exposed for a total of more than 6,100 deaths annually in the WW II cohort.^{2/} This projected epidemic has not materialized.

Surveillance Epidemiology and End Results ("SEER") data for total incidence of mesothelioma for all sites, sexes and races are as follows:

SEER Areas	Total	1973	1974	1975	1976
Connecticut	52	9	13	16	14
New Orleans	12	-- ^{3/}	1	7	4
Atlanta	2	--	--	--	2
Detroit	63	10	22	14	17
Iowa	43	10	15	11	7
Hawaii	6	1	1	4	0
New Mexico	21	5	5	7	4
San Francisco	95	26	22	20	27
Seattle	41	--	11	15	15
Utah	17	2	4	6	5
Total	352	63	94	100	95

- ^{1/} On this assumption one third of the shipyard cohort would be women, a conservative estimate since women live longer than men. The detailed calculations to derive the number of deaths is set out in the analysis in the AIHC Reply.
- ^{2/} This is the lower bound depending on whether 7% or 10% is used and depending on whether the total exposed population is 7 million or 10 million. The range is about 6,000 to nearly 9,000.
- ^{3/} Dashes indicate the area was not in the SEER program in that year.

The SEER population represent about 10% of the U.S. population. Disregarding the fact that the SEER population may have an unusually large number of cases of mesothelioma since five of the areas have a significant shipbuilding industry, these data would indicate a national incidence in 1976 of about 900-1000 cases of mesothelioma, compared to the 6,000 expected deaths in the WW II cohort alone forecast by the methodology in the Estimates Paper.^{1/} While the gross cancer statistics may not be "inconsistent" as the Estimates Paper asserts with its total estimates of occupationally related cancer (Estimates Paper at 22), it is extremely difficult to reconcile the forecast of mesothelioma incidence using the methodology in the Estimates Paper with the SEER data.

If one assumed that the WW II cohort had a higher proportion of heavily exposed workers the number of mesotheliomas forecast for 1976 could easily exceed 10,000. However, the assumption that a large number were heavily exposed would also lead to the conclusion that most of the cohort would now be dead.^{2/} In

^{1/} See "Lung Cancer After Employment in the Shipyards During World War II" published by Blot, Harrington, Toledo, Hoover, Heath and Fraumeni, September 21, 1978 in the New England Journal of Medicine. The authors, two of whom are contributors to the Estimates Paper, found an excess of lung among shipyard workers but the incidence of mesothelioma was no higher than the national average, thus indicating that something other than asbestos exposure may be involved.

^{2/} See Selikoff, I.J. and Hammond, E.C. "Multiple Risk Factors In Environmental Cancer", "Persons at High Risk of Cancer" at 467-483 (1975). Dr. Selikoff reported that 71% of his cohort of New Jersey asbestos insulation workers on the union rolls in 1943 had died by 1973 and 56% of the cohort of amosite workers first employed in 1941 had died by 1973.

that event, predictions for the future in the Estimates Paper are in error, since the predicted number that "probably" died before 1978 would exceed 1,000,000. Moreover, if the shipyard cohort had the high risks attributed to the heavily-exposed sub-cohort in the Estimates Paper, mesothelioma should have appeared in epidemic proportions in the Third National Cancer Survey, which was not the case.

Chromium (VI). The risk ratio used by the Estimates Paper is questionable. The risk ratio is based on studies of workers heavily exposed between 1945-1955 in the manufacture of chromates from chrome ore using the alkali roasting process. Such exposure conditions no longer exist. Moreover, the Enterline study (referenced in the Estimates Paper) showed a steady decline in the Standard Mortality Rate ("SMR") over the period of observation from 2090 in 1941-1955 to 475 in 1956-1960. Further, the NIOSH Criteria Document for chromium (VI) confirms the pattern of decreased risk at Allied's Baltimore chrome works. There the SMR declined from 680 in 1932-1941 to 160 in 1952-1961, with no cases observed for the period 1961-1974.^{1/}

The Estimates Paper uses the NOHS figure of 1.5 million workers exposed to chromium. The NIOSH Criteria Docu-

^{1/} A recent report on chrome pigment workers found no excess risk among workers with "low exposure" in two factories (exposure dates 1932-1954 and 1948-1967); nor was excess risk found over all exposure levels in a cohort employed during 1955-1967. Some excess of respiratory cancer was found in men with early and heavy exposures. Hayes, R., "A Study of Chromate Production Workers" 1978 Ph.D. (Epidemiology) Thesis, the Johns Hopkins University (I. Press) (1978).

ment (1975) concluded that only 175,000 workers are directly exposed to chromium (VI). Even that figure includes exposure to chromium (VI) compounds where carcinogenesis is merely "inferred". (Criteria Document Table III-5.)^{1/}

There is no reasonable basis for using a risk ratio derived from a cohort of workers highly exposed under conditions not found in the industry for many years and apply that risk ratio to a highly inflated exposed-population figure.

Arsenic.^{2/} In 1974 OSHA instituted regulatory proceedings to set exposure standards for arsenic. After extensive hearings a standard was published May 5, 1978. 43 Fed. Reg. 19583. The Estimates Paper neither referred to nor cited the extensive data in that record. In the Inflationary Impact Analysis filed April 28, 1976, OSHA made the following estimates of employee exposure to arsenic:

"4. Employment and Exposure Figures

Employment in all industries directly or indirectly involved in the commercial cycle of arsenic is about 660,000 employees. About 70 to 75 percent of these are production workers and, therefore, potentially exposed to inorganic arsenic. However, a large number of employees included in these figures work in areas where exposures to inorganic arsenicals are very low or non-existent. Relatively few employees are

^{1/} The NIOSH Criteria Document (Table XI-3) lists a large number of occupations where there is potential chromium exposure including downstream users where exposure is low and of shorter duration. The National Academy of Sciences study on chromium (1975) found no increased lung cancer risk in the user industries.

^{2/} There is scientific controversy as to whether arsenic is a carcinogen.

directly exposed to inorganic arsenicals. Estimates of the affected industries at any one time currently ranges from 1500-1700, for exposure levels of 0.1 mg As/m³ and above, to almost 7000 for exposure levels of 0.004 mg As/m³ and above. Most of the exposed workers are in the copper smelters (especially ASARCO-Tacoma) and wood preserving industries, where exposure levels are also the highest."

OSHA considered and rejected the NOHS 1,500,000 exposed population figure used by the Estimates Paper. That number, OSHA noted, may include some industries that have discontinued use of arsenicals or which involved exposure to organic arsenic.^{1/} It is also apparent from the range of exposures which OSHA found that use of a risk ratio derived from smelter workers grossly overstates the risk to "the large number of workers" in OSHA's 660,000 exposed worker population where OSHA found exposures "to inorganic arsenicals are very low or non-existent." The error is doubled by the use of the NOHS estimate in the Estimates Paper.

Nickel. The risk factor used in estimates for nickel is also exaggerated. A 1977 study by Doll, a reassessment of the study referenced in the report, states that the 6-fold excess was confined to persons exposed before 1930 and that no significant excess was seen among persons first exposed during the period 1930-1944 after process changes had been implemented.^{2/}

^{1/} The use of arsenic in agriculture and glassmaking has significantly declined in recent years. Organic arsenic has not been implicated as a carcinogen.

^{2/} Doll, R., Matthews, J.D., Morgan, L.G. "Cancers of the Lung and Nasal Sinuses in Nickel Workers; A Reassessment of the Period of Risk," Brit. J. of Industr. Med. 34:102-105 (1977).

Moreover, recent work on U.S. workers exposed to nickel since WW II has found no increased association with lung cancer.^{1/}

Benzene. The Estimates Paper uses the NOHS figure of 2,000,000 as the exposed population. However, only 48,500 of that population are employees with "full time" exposure. Moreover, the Economic Impact Statement in which Arthur D. Little assesses the economic impact of an OSHA proposed regulation of benzene, estimates that there are 800,000 employees in service stations where exposure is "well below 1 ppm on an 8-hour basis" (at D-4, 4-21).

The Estimates Paper proposes to apply a single risk ratio derived from a single study of highly exposed workers to this heterogeneous population. That study of some workers exposed in a pliofilm plant in Ohio 1940-1949 has been severely criticized. Seven cases of leukemia of various cell types were found among 746 workers. The study, however, did not report the absence of cases among 404 other workers at the plant. There is serious doubt as to the level of exposure at the plant. Records from the Ohio State Laboratory indicate levels of 500 ppm in places where workers spent considerable amounts of time and testimony at the OSHA hearing indicated clothing of workers were drenched, containers of benzene were open and direct contact with benzene was frequent. This would indicate an exposure

^{1/} Bernacki et al., "Investigation of Exposure to Nickel and Lung Cancer Mortality: Case Control Study at Aircraft Engine Factory," Am. Clin. Lab. Sci. 8(3):190-194 (1978).

considerably above 10-15 ppm assumed in the study, a level which requires sophisticated equipment for detection.

Thus a risk ratio derived from a flawed study was applied to a population with widely varying exposures, a large segment of which had exposures at very low levels.

Petroleum Products, Including Aromatic Hydrocarbons.

The Estimates Paper uses an estimate of 3,900,000 as the exposed population.^{1/} On the assumption that this population coincides with the NOHS category, this population includes only about 60,000 workers with a "full time" exposure in about 30 different industries.

The unreliability of an estimate using a risk ratio derived from a study of coke workers exposed to arsenic, aromatic amines, and ammonia in addition to PNA's, across industries with very different exposures is apparent. The observations in reference 16 are based merely on association in a survey of Los Angeles County. A cross section study of this kind provides no basis for extrapolation across the United States.

Thus an inappropriate risk ratio was applied across a wide range of industries with unexplored ranges of exposure.

^{1/} This number is stated to be derived from reference 16 but there are no such estimates in that article. Reference 18 gives 2.9 million as the estimated exposed population, a number which is taken from the NOHS data. The Draft Summary of the Estimates Paper released four days earlier gives 3,000,000 as the estimated exposed population.

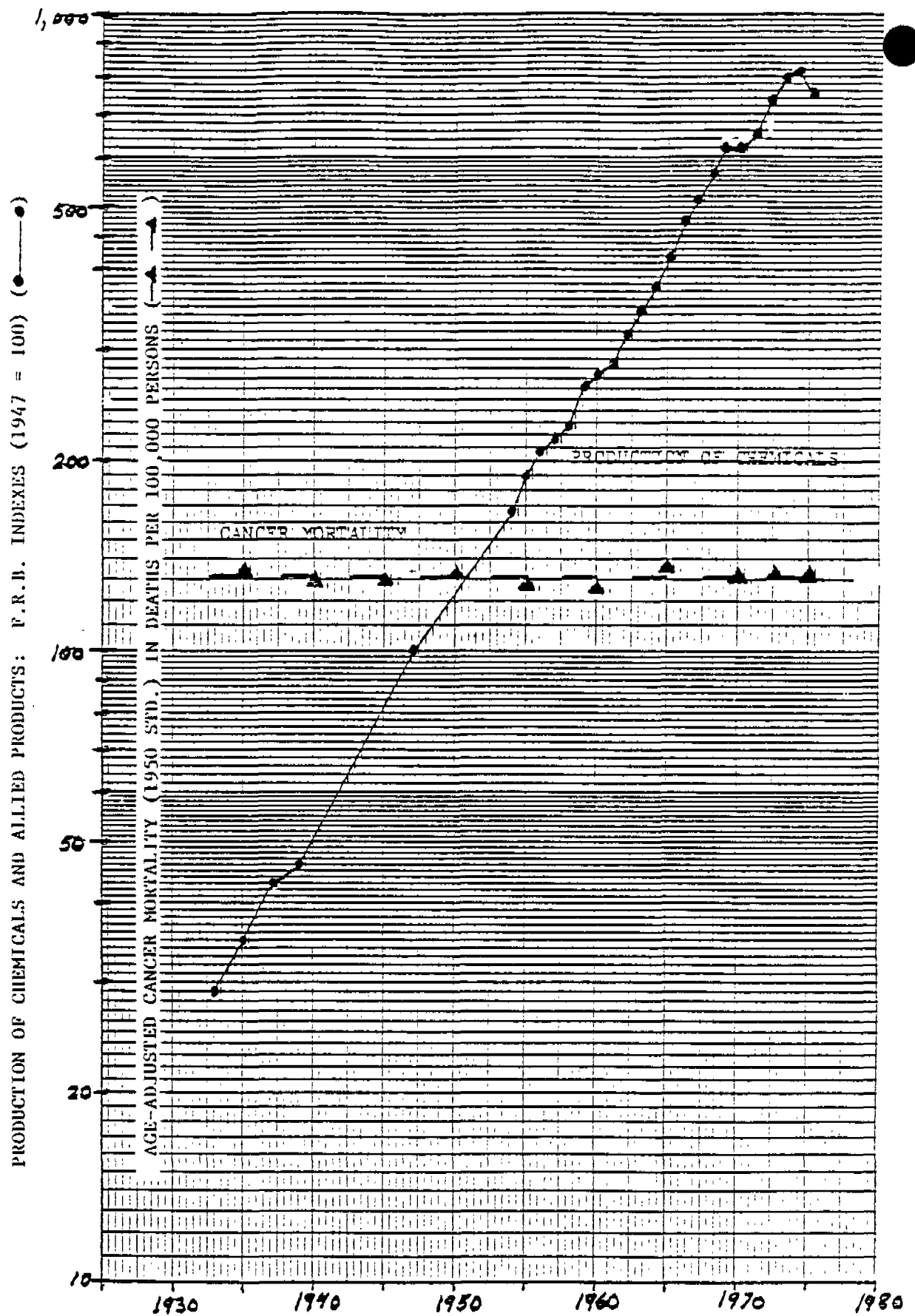
Four days before the Estimates Paper was made part of the record a "Draft Summary" was released. There are significant unexplained differences between the Draft Summary and the final document. Most important, the Draft Summary contained estimates for excess deaths from exposure to (1) coal tar pitch volatiles and coke oven emissions, (2) vinyl chloride, and (3) iron oxide. The Estimates Paper states that these were excluded from the final document because of difficulty in matching data on relative risk to the number of workers exposed. (Estimates Paper at 15.) Vinyl chloride illustrates why the Estimates Paper had difficulties relating relative risk to the number of workers exposed. On the basis of a NOHS exposed population of 2,260,000, the Draft Summary predicted 1940 excess cancers per year most of which would be hemangiosarcoma, the "marker" disease for vinyl chloride monomer exposure. The NOHS data used in the Draft Summary include exposure in some 30 to 40 industries most of which are downstream handling polyvinyl chloride rather than the monomer. The forecast in the Summary of yearly deaths using the NOHS population exceeds by a factor of almost 30 all the known cases of angiosarcoma world wide (about 70) since vinyl began to be manufactured more than 30 years ago. It is to be regretted that the data on other substances in the Estimates Paper were not also re-examined since those data suffer from the same difficulties which led to the withdrawal of estimates on the three substances.

Finally, the Estimates Paper asserts that the increase in production of synthetic organic chemicals is too recent to be

reflected in current cancer statistics. The chart prepared by Professor Jandl indicates that there is no detectible relationship between cancer mortality in the U.S. and the spectacular growth in the chemical industry since 1930.

A chart reproduced on page 35 prepared by Dr. Jandl compares the annual production of chemicals and allied products (using the Federal Reserve Board indices rather than simple poundage) and cancer mortality in the United States. The chart shows that the growth of the chemical industry in the United States has not been associated in any way with an increase in cancer mortality.

FIGURE 10B.
ANNUAL PRODUCTION OF CHEMICALS (1933-1975) VS.
ANNUAL CANCER MORTALITY (1935-1975)



II

OSHA'S AUTHORITY DOES NOT EXTEND TO PROMULGATION OF AN INFLEXIBLE "GENERIC" RULE FOR A WIDE VARIETY OF SUBSTANCES FOUND IN DIVERSE INDUSTRIES

The Proposed Regulation is broad and sweeping. It proposes to establish a single generic classification for all substances which under its inflexible criteria present a human carcinogenic risk. It would apply to all employment covered by the Act, "including general industry, construction, maritime and agriculture." 42 Fed. Reg. 54148. It purports to cover not only this enormous diversity of workplaces, but substances which range in form from solids, liquids, dusts and gases, and range in potency by a factor of a millionfold and more. 42 Fed. Reg. 54165. (Dr. Upton Tr. 318-319.) There are more than 2,400 substances in the NIOSH subfile of "Suspect Carcinogens" to which the Preamble to the Proposed Regulation refers. The variety and range are enormous.

Moreover, the Proposed Regulation proposes to establish a rigid and inflexible set of regulatory consequences which will flow automatically from the classification system without regard to the enormous diversity of workplaces and substances. No distinction is made in the regulatory scheme between exposure to the substances themselves as distinguished from exposure to minute quantities of the substance which may be present in mixtures.

While AIHC believes that it is appropriate for OSHA to issue generic regulations within the limits and subject to

the criteria approved by the courts (see discussion infra, at 43), the OSHA proposal fails to comply with those limitations and criteria.

A. The Inclusion Of Laboratory, Construction And Maritime Workplaces Makes The Proposed Regulation Unreasonably Broad

OSHA proposes to treat laboratory workplaces, both research and other types, and construction and maritime workplaces, in precisely the same manner as other industrial workplaces. OSHA offered no evidence concerning the application of these regulations to the construction industry, maritime industry or agriculture. AIHC believes, and we believe the record shows, that there is a need to exempt these kinds of workplaces from this regulation and deal with these workplaces in appropriate separate regulations.

Laboratories. Industrial and academic quality control and research laboratories, unlike most industrial workplaces, typically handle many substances in very small quantities for short periods of time. It is these conditions which make the Proposed Regulation inappropriate for laboratories.^{1/}

^{1/} For a discussion of the laboratory problem, see the comments filed by the University of Rochester, University of Minnesota, the California Institute of Technology, Johns Hopkins University, Mayo Clinic, Association of American Cancer Institute and Johns Hopkins University School of Medicine.

See also NIOSH Answer to OSHA Question 8; AIHC Tr. 3836-3839. Further, the persons working in laboratories are usually well-educated scientists who appreciate the hazard with which they are working. See, e.g., UpJohn Tr. 4233-4239, 4265-4273; Uniroyal Tr. 8260-8261.

If the Proposed Regulation is adopted without modification of its scope, laboratories, which typically handle many of the substances that might be subject to this regulation, apparently would be required to monitor each time a carcinogen (typically in a very small quantity) is introduced into the laboratory workplace; they would be required to keep innumerable records and to file innumerable notices of use with OSHA; they would be required to have separate vacuums for each substance used in the laboratory; and further, they would be required to clutter the laboratory with dozens of signs.^{1/} It is requirements such as these which independent, university and other laboratory representatives stated would significantly impede their research efforts; including, ironically, in some instances cancer research. See, e.g., American Industrial Hygiene Association Tr. 8492. Not only would these provisions reduce laboratory productivity, they would also be extremely costly. See Snell Report, Chapter VII; see also Dr. Campbell Tr. 3306-3308.

AIHC is not suggesting that laboratory workplaces are not in need of regulation. We are, however, suggesting that what is appropriate for a large chemical plant may not be appropriate for an academic or industrial research or quality control laboratory. Representatives from labor also acknowledged

^{1/} Many of the provisions of the standards are inappropriate for most laboratory situations, such as the provisions requiring a compliance program for each substance even though it may be used infrequently and in very small quantities.

that it might be more appropriate to set vertical standards for laboratories rather than proceed in the manner suggested by OSHA. (Tr. 5765.) Dr. Squire also favored separate regulations for laboratories which do not regularly use a particular chemical. (S. 31-32.)

In this connection it is significant that the Committee to Coordinate Toxicology and Related Programs of the Department of Health, Education and Welfare ("DHEW") has just released a document entitled "Guidelines for the Laboratory Use of Chemical Substances Posing a Potential Occupational Carcinogenic Risk." (AIHC P.H.) An open meeting for comment was held on September 25, 1978 and written comments have been invited. It is clear that the special problems of laboratories are being addressed by DHEW. Certainly OSHA should await the results of the work of that committee before adopting any regulation for laboratories.

OSHA offered no evidence to show that this inflexible generic standard is appropriate for control of exposure in laboratories. Those organizations which operate laboratories presented facts showing that the Proposed Regulation was unreasonable in its application to laboratories. See also AIHC P.H. (Dr. Campbell's submission). The special problems of laboratories are being addressed by DHEW. Upon this record, it is unreasonable to apply the Proposed Regulation to laboratories. OSHA should publish a new proposed regulation for laboratories and provide a reasonable opportunity for comment.

Construction and Maritime. The National Constructors Association, the Asbestos Information Association of North America and the West Gulf Maritime Association presented evidence demonstrating that construction and maritime workplace characteristics differ markedly from typical industrial workplaces. Construction workplaces and workforces are often temporary and transitory. Turnover rates may be as high as 600% per year for large industrial contractors and even higher for smaller construction contractors. Workplace conditions also vary considerably depending on the precise nature of the project and the particular task in question. (Nat'l Constructors Ass'n Tr. 7123-7124; Asbestos Info. Ass'n Tr. 7696-7714; West Gulf Maritime Ass'n Tr. 7171-7172.) -

Among the many provisions which seem out of place are those which require employee notification and recordkeeping, without regard to the transitory nature of the workforce. (Asbestos Info. Ass'n Tr. 7709-7710.) In addition, for construction workplaces, particularly remote ones, the kinds of hygienic facilities demanded by the model standards are simply often not realistically available. Certainly it is not possible to maintain, as the regulations would require, construction surfaces free of accumulations. Further, it seems to make little sense to require, as the regulations would, a separate compliance report reviewing engineering controls for each substance in such workplaces.

OSHA has in previous standards recognized the need

for special consideration for construction and other workplaces. Indeed, OSHA has appointed a separate Advisory Committee on Construction Safety and Health to address the peculiarities of this industry. We would urge that similar consideration be given here. ^{1/}

Agriculture. The record is virtually barren of evidence by OSHA concerning the need for, or the reasonableness of, the Proposed Regulation as it applies in agriculture. There is no discussion of agricultural workplaces in the Preamble nor are the special problems of agriculture addressed. If in a separate proceeding OSHA presents facts showing the need for, and reasonableness of, a generic regulation applicable to the agricultural workplace, a generic regulation may be authorized. No such showing has been made here.

B. OSHA's Sweeping And Inflexible Proposed Regulation Is Unauthorized Under The Statute

As its authority for promulgating the Proposed Regulation, OSHA has cited Sections 6(b), 8(c), and 8(g) of the Act, 29 U.S.C. §§ 655(b), 657(c) and (g). 42 Fed. Reg. 54148. None of these sections (except to the extent that Section 8(c) permits OSHA to promulgate general rules on recordkeeping and notices) speaks to OSHA's authority finally to decide in one massive proceeding the many technical, scientific, procedural and legal

^{1/} OSHA has dealt with exposure to asbestos in the maritime and construction industries. 29 C.F.R. § 1910.1001. Regulation of exposure to other specific substances may be appropriate prior to the issuance of a generic standard for these industries.

issues underlying the Proposed Regulation. To the contrary, Section 6(b) requires that OSHA proceed, as it has consistently in the past, to resolve these issues in the context of the promulgation of occupational safety and health standards for specific toxic substances. While there is room, as we shall discuss infra, at 51, for OSHA to issue limited generic regulations, any such regulations must be based on the statutory plan embodied in Section 6(b), under which issues as to the regulation of specific substances will be resolved in the context of the promulgation of standards for each of those substances. OSHA cannot depart from the statutorily mandated procedure under which it must consider each standard in the light of feasibility and on the basis of the "latest available scientific data" with respect to the particular substance. Moreover, by excluding evidence on generically determined issues in subsequent Section 6(b) rulemakings for the issuance or modification of standards, OSHA will deny affected parties their legal right to comment upon, or offer evidence on, these issues as they relate to specific toxic substances.

In view of the diversity of the underlying subject matter, OSHA does not have authority, under the Act or otherwise, to adopt a generic regulation of the type that it has proposed, in which inflexible standards are set for all substances meeting predetermined criteria.^{1/} The Proposed Regu-

^{1/} The present rulemaking differs fundamentally from situations in which agencies have promulgated rules of

(Footnote continued on p. 43)

lation fails to comply with the provisions of Section 6(b)(5) of the Act, 29 U.S.C. § 655(b)(5), regarding the promulgation of standards for toxic materials, which require specific consideration of "the latest available scientific data in the field, the feasibility of the standards, and experience gained under [the Act] and other health and safety laws."

In the Preamble to the Proposed Regulation, OSHA cites three cases as authority for its departure from the statutory procedure set forth in Section 6(b). 42 Fed. Reg. 54154. These are United States v. Storer Broadcasting Co., 351 U.S. 192 (1956), Federal Power Commission v. Texaco, Inc., 377 U.S. 33 (1964), and Airline Pilots Association v. Quesada, 276 F.2d 892 (2d Cir. 1960). These cases, however, deal with situations fundamentally different from the present rulemaking.

Each of these cases cited by OSHA involved an agency to which Congress had delegated broad powers of control over an area of economic activity to which access was made subject to agency authorization by license or permit. The reviewing courts found the broad rulemaking authority exercised by the agencies to be within Congress' intent. In contrast, nothing in the Act or in its legislative history suggests that Congress

(Footnote continued from p. 42)

general application to cover a variety of items or situations that are essentially uniform in the features affected by the rule. Whether OSHA has authority to make inflexible rules for a particular category of substances where true uniformity in fact exists would depend on the facts in the particular case.

intended to delegate sweeping and unrestricted authority to OSHA to regulate by an inflexible generic scheme all industrial and business activity without adherence to the carefully delimited procedures and criteria set forth in Section 6(b) of the Act.

In each of the cases cited by OSHA, the administrative agency, after affording opportunities for interested parties to comment, issued a regulation relating to a single specific act: ownership of a sixth television station (Storer), inclusion of certain price escalation clauses in contracts for sale of natural gas (Texaco), and piloting a commercial airliner after age sixty (Quesada). The situations covered by the regulation in each case, while not totally identical, are both simple and uniform. The interested parties could easily determine the effect of the regulation upon their businesses or profession and frame their comments accordingly. Thus, each of the regulations in question was adopted after the agency received as complete a picture as possible concerning its effect on the regulated parties, who were easily identified. The reviewing courts found the parties' hearing rights satisfied because they could be identified and hence had an opportunity to effectively comment upon the proposed regulation as it would apply to them. The present case stands in stark contrast. Rather than a single specific prohibition, OSHA has proposed a complex regulation which effectively would decide in an inflexible manner a myriad of scientific, technical, procedural and legal issues to be

automatically applied in the subsequent promulgation of occupational safety and health standards for specific substances which are in no fashion uniform, or even similar. It is therefore virtually impossible for interested parties in these circumstances to anticipate fully the potential effect of the Proposed Regulation on their business.

OSHA has compounded the difficulties faced by interested persons wishing to meaningfully comment upon the Proposed Regulation by failing to identify clearly the many principles and concepts which OSHA intends to generically resolve in the proceeding. OSHA's stating that its forthcoming regulatory analysis "will demonstrate what issues are intended in the generic approach to be foreclosed from further rulemakings" is a clear admission by OSHA of its failure to date to provide such information to the public. (Memorandum from Messrs. Morris and Wrenn to Ms. Bingham and Mr. Wellford, dated August 3, 1978 (AIHC P.H.).) Thus, the public has been forced to comment upon the broad-ranging Proposed Regulation in a general manner, without any real notice as to the specific issues OSHA intends to resolve generically in this proceeding.

The fact that OSHA failed to make a regulatory analysis of the significant issues involved in the Proposed Regulation, as required by Executive Order 12044, also denied members of the public the benefit of OSHA's discussion of the particular issues and alternatives which OSHA considered. The fact that OSHA has agreed after the hearings were closed to make an

analysis of the regulatory issues and "realistic alternatives" (see supra, at 6-7) underlines the inadequacy of the notice which the public received and their inability to participate meaningfully in a hearing on generic issues. In its proposed review, OSHA will also "look at alternative criteria for the classification of substances within the generic standard." There was no way that participants could meaningfully participate in these hearings without this information.

C. The Provisions In The Proposed Regulation For Waiver Or Amendment Are Inadequate

In both Storer and Texaco, supra, the Supreme Court found that the parties' statutory hearing rights also were satisfied, in part, by the agencies' providing procedures by which parties could seek waivers or amendments to the respective regulations. United States v. Storer Broadcasting Co., supra, at 201, 205; Federal Power Commission v. Texaco, Inc., supra, at 40-41. OSHA has made no comparable provision in the Proposed Regulation. It is difficult to conceive how OSHA could entertain such requests in view of its expressed intention to foreclose future discussion of the many issues being generically addressed in this proceeding. It is equally difficult to conceive how a fair waiver procedure could be created in the face of the vast range of carcinogenicity issues, the great diversity of physical properties exhibited by substances, and the wide variations among workplaces (including farms, ships, factories, laboratories and

and construction sites) in which the Proposed Regulation would be applied.

OSHA has stated in a footnote in the Preamble to the Proposed Regulation that it "will encourage petitions for amendments to these regulations, including the model standards, as conditions so warrant." 42 Fed. Reg. 54149 n.2. OSHA has issued no guidelines indicating how it will handle amendments. More importantly, however, Mr. Wrenn's testimony clearly demonstrates that OSHA has no intention of considering requests for waivers or amendments in the context of a rulemaking proceeding for a specific substance. Rather, such requests would be considered in a separate rulemaking proceeding convened for consideration of the requested waiver or amendment. (Wrenn Tr. 148-149, 151.) By definition the classification system would apply to a particular substance unless there was an amendment to the Proposed Regulation. While the standard setting proceedings on the substance and the proceedings to amend the Proposed Regulation could be parallel, the person involved in the standard setting proceeding could not seek an amendment to the Proposed Regulation which his facts justify in the proceeding on the individual substance. The proposed procedure is legally improper under the Storer and Texaco decisions since the affected parties would be denied the right to seek an amendment or variance as to a particular substance, an essential element of a valid generic regulation.

D. The Proposed Regulation Violates The Due Process Clause

The conclusion that the Proposed Regulation is unlawful is reinforced by the decisions of the Supreme Court holding that a regulation based on irrebuttable presumptions of fact which do not give parties adversely affected an opportunity to demonstrate the incorrectness of the presumption is a violation of the Due Process Clause of the Constitution. Stanley v. Illinois, 405 U.S. 645 (1974); Vlandis v. Kline, 412 U.S. 441 (1973); Cleveland Board of Education v. La Fleur, 414 U.S. 632 (1974). The Vlandis case involved an irrebuttable presumption of non-residence for a student who initially matriculated as a non-resident, thus charging the student at the higher non-resident tuition rate. Rejecting this presumption which barred the student from showing he had become a resident, the Court said:

"[I]t is forbidden by the Due Process Clause to deny an individual the resident rates on the basis of a permanent and irrebuttable presumption of non-residence, when that presumption is not necessarily or universally true in fact, and when the State has reasonable alternative means of making the crucial determination." 412 U.S. at 452.

Many of the generic administrative policy decisions proposed by OSHA are irrebuttable presumptions of fact under the Proposed Regulation. Thus the policy determination that a safe level or threshold cannot be determined for a carcinogen is a presumption of fact which is not necessarily universally true. But the policy determination will prevent presentation

of evidence that as a matter of fact there is a threshold for a particular substance until the generic policy has been amended. Thus Grover Wrenn testified that a scientific breakthrough, such as "strong evidence" of a threshold for a particular substance, would be rejected in a rulemaking on that substance; the data would be considered only after the generic regulation had been amended. (Tr. 148-149, 151.) OSHA's position on this amendment procedure effectively prevents presentation of evidence of a threshold, even if the regulatory action on the particular substance and the petition to amend are conducted simultaneously. There is no realistic possibility of an amendment to the generic regulation within the mandatory six-month time frame for regulation of particular substances under the proposal. The generic determinations therefore become irrebuttable presumptions of fact which violate the Due Process Clause. Moreover, as the Supreme Court recently held, administrative convenience is not a valid basis for disregard of Constitutional rights. Marshall v. Barlows, Inc., ___ U.S. ___, 44 L.W. 4483 (decided May 23, 1978). In addition, the Benzene decision confirms that the use of a generic standard to exclude data contrary to the generic policy determinations violates the Act.

Apart from the constitutional issues raised by the irrebuttable presumptions of fact incorporated into the Proposed Regulation, the classification procedure inherently results in the denial of due process to affected persons. Under that procedure, classification of substances will occur based

on generically resolved and woodenly applied criteria prior to a scientific evaluation of the evidence of carcinogenicity. Considerable adverse publicity and a substantial drop in business may occur for any substance labeled a carcinogen, yet OSHA demonstrates an intent to apply such labels before an appropriate scientific review is undertaken. The AIHC Alternative avoids this violation of due process rights by providing for review of the evidence of carcinogenicity by the Data Evaluation and Classification Panel prior to any provisional classification.

The putative classification of substances in the NIOSH "Suspect Carcinogens" list by Clement issued July 14, 1978 (Ex. 132) well demonstrates the violation of due process rights which is inherent in the classification procedure in the Proposed Regulation. Persons now producing or using the substances found on that list face great uncertainty regarding the future production and distribution of their products. The use of these substances, many of which serve valuable functions, could be effectively restricted or banned as industry and the public reacts to the listing of these substances as carcinogenic. Errors in the Clement list may eventually be demonstrated but significant, irreparable harm to industry and to the public may have been done in the interim. In short, the Clement list is likely to operate as a carcinogen "blacklist". Similarly, proceedings on individual substances will "blacklist" those substances for the months between provisional classification and the operation of the artificial rebuttal process where an appropriate scienti-

fic review will first be undertaken.

E. The AIHC Alternative Satisfies The Criteria For A Valid Generic Regulation

The AIHC Alternative, while it has the same objective as OSHA's proposal -- regulation of workplace exposure to carcinogens -- differs from the OSHA proposal in significant ways relevant here.

First, the AIHC proposal would apply only to industrial workplaces. Until OSHA proposes valid generic standards, regulation of workplace exposure in agricultural, transportation, and construction industries and in laboratories would be on an individual substance basis under Section 6(b).

Second, in contrast to the Proposed Regulation, the AIHC Alternative sets forth a system for identifying and regulating suspected carcinogens in the industrial workplace which would operate expeditiously while maintaining sufficient flexibility to regulate substances in light of their different properties. The Alternative would not attempt to freeze science nor exclude relevant facts from consideration in a rulemaking proceeding. The criteria for categorizing substances set forth in the Alternative would require the proposed Data Evaluation and Classification Panel to exercise scientific judgment on the basis of all the relevant evidence, rather than by applying rigid, overly simplistic criteria which are proposed for their supposed ease of administration.

Nor does categorization under the AIHC Alternative dictate an automatic regulatory response. Instead, sufficient flexibility is maintained by calling for risk/hazard/benefit analyses, providing for mixtures and action levels, and not mandating the control of exposure to the "lowest feasible level" regardless of the factual showing as to the danger of exposure.

Finally, the Alternative specifically authorizes the Panel to propose revisions of the categorization scheme or the criteria in light of scientific advancements, additional information, or experience with the categorization scheme. Reasonable notice of intended changes and an opportunity to comment are to be afforded the public, in accordance with the Administrative Procedure Act. Thus a reasonable method of providing for variances and amendments is provided as required by Storer and Texaco.

III

SINCE OSHA INTENDS TO ENLARGE THE PROPOSED
REGULATION IN UNDISCLOSED BUT SIGNIFICANT WAYS,
A HEARING ON THE INCOMPLETE REGULATION IS WITHOUT
MEANING AND DENIES DUE PROCESS

In his opening statement Mr. Wrenn stated that "OSHA's proposed classification scheme involves the development of criteria for conducting and ultimately evaluating animal and human studies." (Wrenn S. 4.) During his testimony Mr. Wrenn expressed the hope that ambiguous terms would be clarified and criteria be more firmly set after the hearing. He agreed that to the extent criteria for well conducted tests can be identified, it would be desirable to set forth such criteria in the regulations. (Tr. 227.) However, Mr. Wrenn was unable to identify the criteria being considered or to indicate how the impact of the criteria could be examined in the course of the hearing. None of OSHA's witnesses was able to describe or identify these criteria. ^{1/}

It is apparent from Exhibit 34 ^{2/} that the criteria

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- ^{1/} With respect to risk assessment procedures, Dr. Albert stated that he had reviewed a first draft being considered by the Interagency Regulatory Liaison Group on risk assessment, but was unwilling to describe the draft because it was being changed significantly and a second draft was being circulated. (Tr. 2319.) See discussion of risk assessment infra, at 56.
- ^{2/} Exhibit 34 consists of the prepared statements of Douglas M. Costle, Administrator, Environmental Protection Agency, Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health Administration, John Byington, Chairman, Consumer Product Safety Commission, and Donald Kennedy,

(Footnote continued on p. 54)

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which are being considered by OSHA are in fact of great significance and could have a major impact on the operation of the Proposed Regulation. On August 2, 1977, OSHA, the Environmental Protection Agency ("EPA"), the Food and Drug Administration ("FDA") and the Consumer Product Safety Commission ("CPSC") entered into an agreement to form an Interagency Regulatory Liaison Group ("IRLG") to coordinate the activities of the four agencies.^{1/} In the written agreement dated September 26, 1977, the four agencies agreed to endeavor to develop, inter alia, "common, consistent, or compatible":

- "1. Testing protocols, criteria for interpretation, quality assurance procedures, and other policies relating to the testing of toxic and hazardous substances;
2. Epidemiological practices and procedures;
3. Approaches to the assessment of risk presented by a toxic or hazardous substance and to the estimation of benefits associated with a substance."

(Footnote continued from p. 53)

Commissioner, Food and Drug Administration before the Subcommittee on Environment and Atmosphere, House Committee on Science and Technology, April 25, 1978. Attached to the prepared statements are materials furnished by the witnesses as supporting materials consisting of the Interagency Agreement, President Carter's letter to the IRLG, the IRLG work plans set out in the Federal Register for February 17, 1978 (43 Fed. Reg. 7174), a memorandum entitled "Examples of IRLG Accomplishments," and press clippings and news releases.

^{1/} The agreement is included as supporting materials in Exhibit 34.

Thus two months before the Proposed Regulation was published, OSHA, as part of the IRLG, was participating in an inter-agency program to develop outside this regulatory proceeding criteria and standards essential to the operation of the Proposed Regulation. The progress of the IRLG toward these objectives is apparent from the IRLG work plan published February 17, 1978.^{1/} In that Work Plan, the IRLG disclosed the formation of eight working groups and detailed the functions of each group.

Mr. Costle described the objectives of the IRLG at the hearing on April 25, 1978:

"Based on their investigation and discussions, the IRLG presented us with a report suggesting seven possible initiatives which they felt would contribute to the goals we had set ourselves. They included an attempt to evolve common, consistent, or compatible approaches to testing criteria and policies, risk assessment, information acquisition and exchange, research and development policies (possibly including methods of sharing costs and facilities), joint regulation and regulatory development activities, compliance and enforcement procedures and policies, and public communication and education. We added an eighth, the coordination of epidemiological practices and procedures. We decided to implement them all." (Ex. 34, Costle S. 3.)

A. IRLG Work Group Activities Closely Parallel And Involve Subjects Which Are Under Consideration In This Proceeding

The objectives of three IRLG work groups are of

^{1/} The Work Plan as published in the Federal Register on February 17, 1978 (43 Fed. Reg. 7174), is attached as supporting material in Exhibit 34.

particular interest here: Epidemiology, Risk Assessment, and Testing Standards and Guidelines.

Epidemiology. The objectives of this work group are described in the IRLG Work Plan as follows:

"While it is not intended that a standard model would be developed against which epidemiologists would mold their research, we believe it is necessary to develop minimum criteria by which submitted studies can be objectively evaluated." (Ex. 34, 43 Fed. Reg. 7186.)

Mr. Costle advised Congress that the IRLG hopes to have the epidemiology criteria complete by late 1978. (Ex. 34, Costle S. 8.)

Risk Assessment. In the Preamble to its Proposed Regulation OSHA invites comments on the question whether a risk assessment should be employed by OSHA. 42 Fed. Reg. 54167. There has been extensive testimony in the record on risk assessment and the methods and procedures to be used. See the discussion of risk assessment beginning infra, at 197.

In the meantime the IRLG Risk Assessment Group under the chairmanship of Assistant Secretary Bingham is pursuing the following objective:

"The Risk Assessment Work Group will develop procedures and criteria that can be uniformly applied by the four agencies for purposes of characterizing and quantifying human health risks associated with certain chemicals." (Ex. 34, 43 Fed. Reg. 7195.)

The task of the Work Group was described as follows:

"5. Task of the Work Group - An objective of the Work Group might be the development of systems to insure that the agencies routinely work together to conduct risk assessments on specific substances of mutual interest. However, the Work Group holds that such an objective is far less important than the broader one of developing and selecting general procedures and criteria for risk assessment that can be uniformly applied to all chemicals regulated by the agencies, including those substances for which only one agency is responsible.

Until the rules for risk assessment are clearly laid out and agreed upon, efforts to reach a consensus of the type and degree of risk associated with specific substances of mutual concern will in many instances be thwarted. Furthermore, in the absence of uniform criteria and procedures, the risks associated with chemicals that are the responsibility of only one agency will continue to be estimated in a different manner than those associated with chemicals regulated only by a second agency. This undesirable situation will not be remedied if the task of the Work Group is limited to the joint conduct of risk assessments on substances of mutual interest." Id.

This work group is addressing specific subjects being considered in this hearing.

"R.A.1.3 - Procedures for Quantifying Carcinogenic Risk.

Output: Procedures for treating available dose-response relationships to estimate risk at expected or known levels of human exposure.

Task - The subgroup will survey the risk estimation procedures currently in use by the agencies. Reasons for the use of specific procedures, including relevant legal matters, will be detailed.

An updated review and discussion of all current mathematical models will be undertaken, including consideration of time-to-tumor analyses as a preface to the final selection of a model(s). The final document will include procedures for combining data from

several experiments, use of human data, and modifications based on metabolic and kinetic data." (Ex. 34, 43 Fed. Reg. 7197.)

In her testimony before the House Committee Dr.

Bingham said:

"This Work Group is now developing a carcinogenesis risk assessment guideline that is to be reviewed by the IRLG member agencies next month. The guideline will then be published in the Federal Register for public comment. We expect the final document to be ready by October. The carcinogenesis guideline is a general educational device to alert the public to the dangers of chemical carcinogens as well as a manual for Federal agency scientists. This guideline will contain specific criteria for judging the likelihood that a chemical is a human carcinogen, procedures for treating available data to estimate human exposure to suspect chemicals, and procedures for attempting to quantify carcinogenic risk." (Ex. 34, Bingham S. 3 (emphasis added).)

The progress made by the group is set out in the memorandum entitled "Examples of IRLG Accomplishments." ^{1/} In that memorandum the carcinogenic risk assessment was described as follows: ^{2/}

"The carcinogenesis document contains three parts:

- (1) criteria for judging the likelihood that a chemical is a human carcinogen, including a review of the significance of various types of data;
- (2) procedures for treating available data to estimate type, level, and extent of human exposure to suspect chemicals, including a survey of approaches used by the four agencies; and

^{1/} Attached as supporting materials to Exhibit 34.

^{2/} Id. at 5.

- (3) procedures for quantifying carcinogenic risk, i.e., procedures for treating available dose-response relationships to estimate risk at expected or known levels of human exposure."

In a joint letter dated June 8, 1978 to Mr. W. Bowman Cutter, Executive Associate Director for Budget, Office of Management and Budget, the heads of the four IRLG agencies described the objective of the Risk Assessment Group:

"As mentioned previously, procedures and criteria for identifying carcinogens are being developed by the IRLG Risk Assessment Work Group; a draft document will be circulated to the agencies this summer and to the public in early fall. The document will define the criteria for the use of scientific evidence in determining carcinogenic risk as a basis for establishing regulatory policies. It will deal with at least the following issues:

1. The extent to which, and the circumstances under which, mammalian animal studies will be relied upon in identifying potential carcinogenic substances and in evaluating their impact upon human health.
2. Appropriate species of animals for carcinogenic testing.
3. Whether threshold or safe levels of exposure to carcinogens can be established.
4. The types of tumors and other lesions that indicate a carcinogenic effect or potential.
5. The appropriate routes of administration used in animal testing and the circumstances under which the route of administration affects the extrapolation of data from animals to humans.
6. The circumstances under which the use of high doses in animal tests is appropriate and valid.
7. The implications of similarities in chemical structure.

8. The relative weights that should be given to different types of evidence (e.g., epidemiological and animal studies) where the results reinforce or contradict each other.
9. The extent to which results from various in vitro tests can be applied to the assessment of risk." (AIHC P.H.)

Testing Standards and Guidelines. The Work Group on Testing Standards and Guidelines has the following objectives:

"The Work Group has agreed that the following tenets will be applied as it proceeds with the task to develop testing guidelines, criteria for interpretations, quality assurance procedures, and other policies relating to the testing of toxic and hazardous substances." (Ex. 34, 43 Fed. Reg. 7197.)

The work of this group is supplemented by the Risk Assessment Group:

"As a first task, the subgroup will address the significance of various types of data including those from epidemiologic studies, animal bio-assay studies, short term, in vitro tests, chemical structure, metabolic data, etc. Statistical procedures for treating animal data to establish significance will also be detailed.

The subcommittee will identify those problems attendant to the evaluation of data as evidence that an agent poses a carcinogenic risk and, where guidance is not available, will make recommendations for resolving difficult issues. A particularly troublesome issue to be treated is that of deciding the extent of testing required before a chemical can be classified as posing no carcinogenic threat. This matter is important for substances (e.g., food additives) requiring pre-market clearance." (Ex. 34, 43 Fed. Reg. 7196.)

B. Key Issues Being Decided In Another Forum Will Be Unlawfully Applied Here

It is perfectly plain from this brief summary of the

work of the IRLG that the criteria, methods and procedures of risk assessment and quantification being developed by the IRLG go to the heart of the Proposed Regulation.

In a speech entitled "Goals of the Risk Assessment Work Group of the Interagency Regulatory Liaison Group," Dr. Rodericks (Special Assistant to the Bureau Director for Science Policy, Food and Drug Administration, Bureau of Drugs) stated:

"We intend to provide detailed guidance on the evaluation of the various types of scientific data. Several such guidelines are available, but they do not supply the specificity needed to ensure a high degree of uniformity in the evaluation of test data. For example, some guidelines state that animal bioassays can be profitably evaluated only if they have been 'adequately designed and conducted.' We have no disagreement with such a guideline, but, if it is the only guidance available, it is almost certain that different scientists will have different notions of the term 'adequately'. Uniform evaluation of bioassays cannot be achieved without development of guidelines with greater specificity. We are attempting to add the necessary specificity and a large part of our guideline will be devoted to fairly detailed discussions of the dozen or so important bioassay variables and how they are each to be evaluated in reaching conclusions about the evidential value of a bioassay." (Ex. 147 at 6-7 (emphasis added).)

Until it is possible to examine these criteria and standards, there is no way to assess the Proposed Regulation.

The hearing therefore is being held in a vacuum. While witnesses are addressing the questions, the key issues are being decided in another forum. No adequate or valid hearing can be held until the parties know what criteria and standards essential to the operation of the Proposed Regulation are being considered and adopted in the IRLG.

Nor can the participants be afforded due process by being provided with an opportunity to comment on the work product of the IRLG at some later date. There will be no opportunity in such a hearing to demonstrate that the Proposed Regulation should, upon consideration of the new criteria and risk assessment procedures, be amended. Thus, for example, while risk assessment, as OSHA recognizes, is relevant to the level of control for a particular substance (42 Fed. Reg. 54167), comment on the use of risk assessment for that purpose would be frustrated by the policy determination that control shall uniformly be imposed to achieve lowest feasible exposure. 42 Fed. Reg. 54166. Similarly, comment on the criteria for carcinogenicity adopted by the IRLG would have no meaning if OSHA has already adopted the criteria for its categories.

IV

THE PROPOSED REGULATION IS AN OPEN-ENDED
ASSERTION OF REGULATORY AUTHORITY LACKING IN
THE NECESSARY CONSTRAINING CRITERIA AND GUIDELINES
WHICH MIGHT LIMIT ARBITRARY AGENCY ACTION

The foregoing section discussing the work of the IRLG makes clear that the Proposed Regulation is skeletal and incomplete. No standards or criteria are set forth for judging the validity of animal tests or human epidemiological studies. The need for such criteria is underscored by the provisions in §§ 1990.110(b) and 1990.120(b) which permit categorization of a substance on an open-ended basis of "evidence sufficient to convince" the Secretary that the substance should be classified in Category I or II. This open-ended unrestricted basis for classification finds no support in law or in the record.

The need for criteria for the conduct of tests and for identification and evaluation of data is made clear by the IRLG Work Plan discussed supra, at 55.^{1/} Nor does OSHA lack the resources to set out relevant criteria. In July 1977, three months before the Proposed Regulation was published, OSHA entered into a contract with Clement Associates to screen the NIOSH list of suspect carcinogens and to evaluate, prioritize and categorize

^{1/} In a post-hearing statement Dr. Heston listed environmental factors which influence the incidence of tumors in inbred mice: age, hormonal status, diet, temperature, parasites, etc. (Ex. 224-G.) He stressed the importance of performance standards in relation to validity of the test results.

suspect workplace carcinogens. (Ex. 12.) The Agreement dated July 13, 1977 provides:

"Within six (6) months from the approval of the initial plan, the contractor shall have initially screened the substances to determine the preliminary OSHA Categories I, II, and III. In the interest of orderly regulation, those that exhibit extreme and/or confirmed carcinogenic effects should naturally take primary importance, but those with weak effects should also be thoroughly screened to reduce uncertainty. Scientific expertise and judgment will play a great part in this step of the process. . . .

(1) Contractor's experts in chemical carcinogenesis shall establish criteria for categorization, with the realization that this material does not lend itself to rapid systemization. Again, expert judgment will largely determine these criteria.

(2) The scientists will then critically analyze and review all carcinogenicity and other data. These data will be systematically screened and evaluated on the following points:

- * the appropriateness of the method and route of exposure to test animals for indicated occupational exposure risk in humans and the suitability of the experimental animal species used
- * the adequacy of test protocols for determining carcinogenicity, particularly with regard to:
 - the experimental design and its conformity to accepted protocols
 - sample size
 - the quality of the pathology review
 - statistical significance of positive results
 - adequacy of reporting results
- * for epidemiological studies in humans:
 - adequacy of medical records and diagnoses

- statistical significance of positive results
- reliability of data on degree of exposure to the suspected carcinogen and to any other material which could affect results
- * the degree to which animal results can be extrapolated to human risk from occupational exposure, and where appropriate, review of of comparative metabolism

The contractor will attempt to develop a semi-quantitative scale, upon which each chemical will be ranked according to several independent, relevant factors. The weighted sum of the rankings may then establish an order of chemicals. The factors to be ranked may include, but may not necessarily be limited to, the following:

- * qualitative and quantitative presence (when available) of the toxic material in the workplace, data to be drawn from several sources mentioned in contractor's proposal
- * degree of confidence to be placed in results of studies, e.g. has the study been duplicated?"

Thus OSHA has instructed its contractor to develop the very criteria which are necessary to evaluation of the scientific data: potency, risk quantification, criteria for evaluating tests and human studies, priorities, etc.^{1/}

As a member of IRLG, OSHA is working on the preparation of criteria which would have a major impact on the substance and operation of the Proposed Regulation. Some clue to the type of criteria for the conduct and evaluation of animal data being considered by the IRLG is provided by the rule proposed by EPA

^{1/} Recommended procedures for chronic animal tests are set out in the National Cancer Institute's "Guidelines for Carcinogen Bioassay in Small Rodents," NCI Carcinogenesis Technical Report Series No. 1 (February 1976).

to establish guidelines and criteria for this purpose in connection with the Federal Insecticide, Fungicide and Rodenticide Act. 43 Fed. Reg. 37336 (August 22, 1978) (AIHC P.H.). ^{1/} These criteria govern acute, subchronic and chronic testing, including oncogenic, teratogenic and mutagenic testing. These same test criteria were made applicable "for the most part" to the Premanufacture Notification under Section 5 of the Toxic Substances Control Act, 15 U.S.C. § 2005. (Appendix I to Premanufacture Notification Draft Guidelines, September 1978, BNA Chemical Regulation Reporter, at 1118-1119 (September 22, 1978).)

The Work Plan of the IRLG and the Clement contract demonstrate that OSHA recognizes the need to establish criteria and standards as part of the Proposed Regulation. Until that is accomplished, the Proposed Regulation is an open-ended assertion of regulatory authority with none of the required criteria or standards to govern that authority so as to avoid unpredictable and inconsistent action by the agency.

AIHC clearly recognized this deficiency in the Proposed Regulation, and the AIHC Alternative sets out criteria for the conduct and evaluation of animal experiments and human studies and for the identification and evaluation of those data. ^{2/} The

^{1/} Drafts of the EPA proposed guidelines were published on June 25, 1975 (40 Fed. Reg. 76802), Ex. 150.

^{2/} See also the discussion of criteria in "The Design Criteria and Application of Dose Response Relationships to Interpretation of Carcinogenic Bioassay," Morris F. Cranmer, Ph.D. (1978) (Ex. 37).

lack of such criteria in the Proposed Regulation renders it unreasonable and invalid.

THE PROPOSED REGULATION MANDATING A STANDARD OF
NO EXPOSURE IF THERE ARE "SUITABLE SUBSTITUTES"
IS INVALID, AND SHOULD BE ABANDONED BY OSHA

Section 1990.112(b) of the Proposed Regulation provides
in part:

"When it is determined by the Secretary that there are suitable substitutes for certain uses or classes of uses that are less hazardous to humans, on the basis of best available evidence, the proposal shall permit no occupational exposure for such uses or classes of uses." 42 Fed. Reg. 54185.

A. The Terms Used In The Proposed Regulation Are Impermissibly
Vague

Nowhere in the Proposed Regulation or in the Preamble are there any criteria for determining what constitutes a "substitute," nor are there any criteria for measuring "suitability" of a substance as a substitute. OSHA has not consulted NIOSH regarding the criteria for determining a "suitable substitute". (Tr. 3056-3057.) Mr. Wrenn candidly admitted that OSHA had not moved beyond the conceptual stage in developing factors for determining what is a "suitable substitute". (Tr. 117-118.) Nor was Mr. Wrenn able to identify a witness other than himself who would testify directly regarding the issues of substitution and suitability. (Tr. 49-50.) A request for OSHA to produce such a witness was made during the course of the hearing (Tr. 3056-3059), however, no such witness appeared in the proceedings.

A number of witnesses addressed the complexity of the decision to substitute products. As AIHC witnesses pointed out, "[s]ubstitution . . . would be dramatically costly and disruptive if forced where no technological alternative now exists." (Tr. 3823.) The Shell Oil Company commissioned Charles H. Kline to assess the economic impact of both a price increase as a result of controls imposed on an industry and the consequences of a ban by a no exposure standard upon a finding that a "suitable substitute" exists^{1/} with respect to three basic petro-chemicals: ethylene oxide, benzene, and vinyl chloride. The huge irreversible shifts in the economy from such a price change or ban underline the great economic significance of this issue. (Tr. 5547-5550.)

Foster D. Snell, in its economic analysis of the impact of the Proposed Regulation on the producer and user industries prepared at the request of AIHC, studied the effect of substitution with respect to certain uses of two substances: ethylene oxide and perchlorethylene. As the perchlorethylene instance illustrates, the complexity and cost are great.^{2/} The ethylene oxide case raises issues as to the suitability of the substitute, with the added complexity of proprietary control over the tech-

^{1/} Charles H. Kline & Co., Inc., "An Assessment of the Economic Impact of OSHA's Proposal For the Identification, Classification and Regulation of Toxic Substances Posing a Potential Carcinogenic Risk to Ethylene Oxide, Benzene and Vinyl Chloride" (April 11, 1978).

^{2/} See also id. at 215-230.

nology for use of a substitute for one use (ethylene glycol).^{1/}

A major factor in the competitive process is commercial pressure to find new and better materials. The substitutes for existing substances used in the manufacturing process have already been examined and the most useful and cost effective substances selected. (Tr. 4020-4021.) Substitution by OSHA mandate will require use of less desirable materials. (Tr. 7045-7049, 7751, 7756-7757, 7842, 7847, 7913-7915, 8348-8349, 8381-8383, 8405.) OSHA has provided no clue as to how it proposes to measure substitutability in terms of the efficiency of the substitute process or in terms of equivalency of product.

On the record we are left completely in the dark regarding how economic factors figure in the decision. What if the proposed substitute costs two, three, fifteen or twenty times more? At what level is it economically suitable? What role do energy requirements play in the determination? What expenditure for process modification will be considered reasonable? What steps does OSHA propose to take if the substitute product or process is proprietary? Does OSHA believe it has authority to require compulsory licensing of proprietary or patented products or processes?

Similarly, the record is blank as to the criteria

^{1/} AIHC Economics Panel Tr. 4024; Snell Report at 260. See also Kline Report at 23-24 cited supra, at 69 n. 1. See Statements of Dry Cleaning Industry Council, International Fabricare Institute, Neighborhood Cleaner's Association Association and Cleaning and Laundry Association Executives.

for technological substitutability, although that is what OSHA "primarily had in mind." (Tr. 38-39.) What if a whole process must be scrapped to use the substitute? Is a substance technologically suitable if the product produced using the substitute lacks important qualities of the original product? How will OSHA weigh the impact on users of the product by reason of the new and different qualities? If the product is an intermediate for downstream users, how will OSHA weight the impact of the changes in the product on downstream users?

If the substance is manufactured from different raw materials, what analysis will OSHA make of the raw material supply and availability? How will OSHA assess the environmental impact of increased production of the raw materials? What will be the conclusion if the raw materials are in whole or in principal part imported, thus creating a reliance on foreign sources?

Similarly, OSHA has provided no clue as to the method or criteria it will use to determine that the substitute is less hazardous than the original substance. What form of risk analysis does OSHA propose to use in such a determination? What are the elements which will demonstrate the less hazardous character of the substitute? What difference in hazard is significant? Will OSHA assess the hazard associated with the original substance subject to controls with the hazard from use of the substitute, or will the assessment be made on the assumption that the original material is unregulated? What if the substitute requires controls; how will the comparative cost of

controls be assessed?

We believe it is clear that the terms used in the Proposed Regulation are impermissibly vague and OSHA's failure to define the terms or to offer any witness who could define the terms or the criteria to be applied leaves the proposal without any support in the record. See EPA Intra-agency Memorandum from Walter Barber to Andrew Breidenbach, dated November 29, 1977 (API P.H.).

Moreover, the "no exposure" limit, which is required automatically when a "suitable substitute" exists, also fails to give due consideration to economic feasibility. The failure of the Proposed Regulation to provide for specific consideration of the economic costs in determining whether there is a suitable substitute is likely to affect not only the enterprise in whose workplace the substitution would be required, but also customers and suppliers of that enterprise. It is not only possible, but even probable, that the "suitable substitute" requirement will lead to unreasonable results. For example, even an extremely weak carcinogen can automatically fall in Category I if the definitional criteria are met. Such a substance may well have a substitute that is technically and economically adequate within the context of the industry manufacturing that substance and which is marginally less carcinogenic. Under the Proposed Regulation these facts apparently would automatically trigger the imposition of a "no exposure" limit, even if the marginal benefits to be attained were at the cost of devastating another industry which

supplied the substance in question.

B. The Proposed Requirement Of "No Exposure" If A "Suitable Substitute" Exists Or In Other Circumstances Is Tantamount To Banning A Substance And Is Beyond OSHA's Authority

The term "no exposure" is undefined. Does OSHA intend "no exposure" as measured by today's standard industry monitoring equipment or does OSHA intend to use the most sensitive testing devices to determine no exposure? Moreover, "no exposure" is a moving target. (Koppers Co. Tr. 7780-7781.) In the recent past measuring to one part in a million was difficult. Today measurements to parts per billion are feasible and OSHA has imposed a standard of parts per billion (DBCP). Tomorrow we may be able routinely to measure parts per trillion or parts per quadrillion. If a plant is engineered and achieves control at parts per billion, a test sensitive to a part per million would register "no exposure". That plant, however, is faced with violation of the standard as a sufficiently sensitive test is devised. As a practical matter therefore, a "no exposure" limit is in effect a ban on the product. Indeed, Dr. Holaday stated that it is not possible to eliminate all exposure even in a completely enclosed system. (Tr. 2626.)

OSHA proposes to use the no exposure limit when it finds that there is a "suitable substitute". In addition, Mr. Wrenn said the Proposed Regulation did not preclude the imposition of a "no exposure" limit even when there are no suitable substitutes. (Tr. 114.) Mr. Wrenn acknowledged that OSHA has

prepared no criteria as to when the no exposure limit would be imposed when there are no substitutes. (Tr. 114.)

Thus OSHA is proposing a regulation which purports to grant to it broad and undefined authority to ban substances on a finding that a suitable substitute exists or when OSHA makes the judgment on the basis of undisclosed and undefined criteria that a substance should be banned even if there are no substitutes. OSHA has no authority under the Act to impose such a ban.

OSHA's powers to prevent worker exposure to a substance by closing down a plant are carefully defined in Sections 9 and 13 of the Act, 29 U.S.C. §§ 658, 662. Section 9 provides for citations for violation of a standard, rule or order. Section 13 establishes a carefully defined procedure under which the Secretary may seek an injunction against imminent dangers "which could reasonably be expected to cause death or serious physical harm. . . ." The injunction may

"prohibit the employment or presence of any individual in locations or under conditions where such imminent danger exists, except individuals whose presence is necessary to avoid, correct, or remove such imminent danger or to maintain the capacity of a continuous process operation to resume normal operations without a complete cessation of operations, or where a cessation of operations is necessary, to permit such to be accomplished in a safe and orderly manner." 29 U.S.C. § 662(a).

No authority to issue a "no exposure" ban on a substance can be found in these provisions. The legislative history confirms that these provisions were adopted to define

the limits of OSHA's authority to ban exposure to a substance. One of the major issues considered during the debates on the bill was the extent of authority, if any, the Secretary should have as an administrative matter to order a plant closing. The Conference Report rejected a grant of administrative authority to ban exposure by ordering a shutdown.^{1/} Thus the provisions of Sections 9 and 13 are the only authority under the Act to ban exposure to a substance. Usery v. Whirlpool Corp., 416 F. Supp. 30, 34 (N.D. Ohio 1976).

A ban on a substance by a "no exposure" standard is clearly not a "feasible" means of implementing the Act. Congress' intent in passing the Act was to protect employees, but not by putting their employers out of business or completely eliminating hazardous occupations. AFL-CIO v. Brennan, 530 F.2d 109, 120-121 (3d Cir. 1975); AFL-CIO v. Hodges, 499 F.2d 467, 477-478 (D.C. Cir. 1974).

Similarly, Section 3(8) of the Act, 29 U.S.C. § 652(8), requires that any standard or provision of a standard must be "reasonably necessary or appropriate" to provide a safe workplace. There is nothing in the record to support a conclusion that OSHA's attempt to assert authority to ban a substance is

^{1/} The difference between the House bill, which insisted on judicial proceedings to ban exposure, and the Senate bill, which favored a grant of administrative authority, was resolved in Conference in favor of the House position. H.R. REP. No. 1765, 91st Cong., 2d Sess. 401 (1970) in Legislative History of the Occupational Safety and Health Act of 1970 [hereinafter cited as "Legislative History"].

"reasonably necessary or appropriate." The Benzene decision clearly sets out the meaning of reasonable necessity in the Act. Affirming the construction given the same term, "reasonably necessary", found in the Consumer Product Safety Act (see Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Commission, 569 F.2d 831 (5th Cir. 1978); D.D. Bean & Sons Co. v. Consumer Product Safety Commission, 574 F.2d 643 (1st Cir. 1978)), the Court stated:

"Before it regulates, the agency must show that a hazard exists and that its regulation will reduce the risk from the hazard, for 'no [occupational safety and health] standard would be expected to impose added costs or inconvenience . . . unless there is reasonable assurance that the frequency or severity of injuries or illnesses will be reduced.' 569 F.2d at 839. More importantly for today's case, Aqua Slide also requires the agency to assess the expected benefits in light of the burdens to be imposed by the standard. Although the agency does not have to conduct an elaborate cost-benefit analysis, 569 F.2d at 840, it does have to determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard. 569 F.2d at 842." ____ F.2d 90-91.

OSHA has conspicuously failed to make any cost assessment justifying the "suitable substitute" provision and indeed has not indicated that cost would be a factor. To the extent that OSHA's conceptual thinking has been revealed, OSHA was thinking solely of technological substitutability. (Wrenn Tr. 38-39.) For this additional reason the "suitable substitute" provisions are unauthorized under the statute.

In the absence of an explicit grant of authority to ban substances, such a power cannot be created in OSHA by implication. Statutes allegedly authorizing administrative agencies to utilize the drastic remedy of banning substances must be strictly construed, and there is no freedom to add to the language of the statute as written by Congress. 62 Cases of Jam v. United States, 340 U.S. 593 (1951); United States v. Lexington Mill & Elevator Co., 232 U.S. 399 (1914). The Act is a detailed piece of legislation, and the presumption should be that Congress defined the limits of OSHA's authority in the express terms of the statute.^{1/}

This rule of strict construction is clearly demonstrated in 62 Cases of Jam v. U.S., supra, where the Supreme Court ruled that the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., did not "implicitly prohibit" the marketing of a product labelled as "imitation jam", as the government had contended when it seized the product. The Court stated that its

"problem is to construe what Congress has written. It is for us to ascertain -- neither to delete nor to distort. . . . In our anxiety

^{1/} The Report of the Comptroller General to Congress dated June 16, 1976, entitled "Federal Efforts to Protect the Public from Cancer-Causing Chemicals are Not Very Effective", concluded

"OSHA sets and enforces occupational safety and health standards, which pertain to a wide variety of areas, such as farm vehicles and a chemical worker's exposure to a carcinogen. OSHA cannot ban production or use of a hazardous chemical but can protect a worker from exposure to them."
Ch. 2, at 8.

to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." Id. at 596, 599-600.

Similarly, in United States v. Lexington Mill & Elevator Co., supra, the Court ruled that the government lacked the power to condemn sacks of flour admittedly containing poisonous substances, since it had not been proved, as required by statute, that these substances rendered the flour "injurious to health". The Court stated that

"where a law is expressed in plain and unambiguous terms, whether those terms are general or limited, the legislature should be intended to mean what they have plainly expressed, and consequently no room is left for construction. . . . [I]f Congress had intended to enact the statute in [a particular] form, it would have done so by choice of apt words to express that intent." Id. at 410.

Similarly, if Congress had intended that OSHA have the authority to ban substances, it would have said so expressly in the statute. Where Congress intended to vest in an administrative agency the authority to ban substances, it has indicated and effectuated that intention by explicitly granting the power to do so. See, e.g., the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.; the Federal Hazardous Substances Act, 15 U.S.C. § 1261 et seq.; the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135 et seq.; the Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.; and the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. It is thus clear that where Congress intended to grant the authority to ban substances, it knew

how to do so using explicit terms. No such explicit grant is contained in the Occupational Safety and Health Act.

Comparison with the recently enacted Toxic Substances Control Act is particularly instructive. That statute expressly grants the Environmental Protection Agency the authority to ban toxic substances upon a finding, following a carefully specified administrative procedure, that the substance poses an unreasonable risk of injury to the health or environment. The legislative history of that statute indicates that Congress assumed OSHA had no such authority. See H.R. Rep. No. 94-1341, 94th Cong., 2d Sess. 2, 6, 32-40 (1976); 122 Cong. Rec. E 5585 (October 1, 1976).

C. The Toxic Substances Control Act Makes The OSHA Substitute Provision Unworkable

As Mr. Dominguez stated "the whole question of substitution is now an entirely different issue than it was historically" due to passage of the Toxic Substances Control Act. (Tr. 4063.) When the inventory of existing substances is published later this year pursuant to that Act, significant new substances and significant new uses of existing substances will be subject to pre-market notification and screening under Section 5 of the Act, 15 U.S.C. § 2605. Thus before a manufacturer could use a substitute, the substitute substance could be subject to the constraints of Section 5 pre-market notification. Review of the pre-market notification will require 90 to 180 days. Thus it will be virtually impossible to determine within the six-

month period OSHA has allowed for the rulemaking whether the substitute OSHA has identified can in fact be used.

To identify and appraise the economics, technology, comparative risk and environmental impact of using a substitute is a time consuming process. If, in addition, the substitute must be subject to pilot tests, and downstream users are allotted time to appraise the product, the process is certain to take longer than the six months allotted for setting individual standards under this proposal. See, e.g., Refractories Tr. 6399-6400. The substitute provisions are therefore unrealistic and the process of nominating substitutes so fore-shortened as to be arbitrary on its face.

D. A Grant Of Authority To Ban Without Guiding Standards Would Be An Unconstitutional Delegation Of Legislative Authority

Even if it were assumed arguendo that OSHA does have the authority to ban substances under the Act, the manner in which such authority has been granted to the agency by Congress would constitute an unconstitutional delegation of legislative policy-making functions. A delegation of legislative authority is unconstitutional in the absence of standards to guide the delegatee's actions, Yakus v. U.S., 321 U.S. 414, 425-26 (1944), and in no circumstances is Congress permitted to abdicate the task of determining the policy of the law. See id. at 424; Panama Refining Co. v. Ryan, 293 U.S. 388, 421 (1935); Alexander v. Thompson, 313 F. Supp. 1389, 1395 (C.D. Cal. 1970). The Proposed Regulation allows OSHA, rather than Congress, to formu-

late difficult policy choices by authorizing the banning of substances without reference to whether the benefits of the ban are outweighed by the costs and the detriment that will be done to the economy. As such, the power to ban in these circumstances constitutes an unconstitutional delegation of legislative authority to OSHA. Cf., Stearns Electric Paste Co. v. EPA, 461 F.2d 293, 308-309 (7th Cir. 1972).

Conclusion

The AIHC Alternative would avoid all of these legal difficulties. Unlike the OSHA proposal, the AIHC Alternative would not call for OSHA to decide whether substitutes are available for a chemical being regulated as a carcinogen. (Tr. 3614-3615.) Nor would the Alternative impose a zero-exposure limit (tantamount to a ban of the substance) where substitutes are thought to be available. The AIHC Alternative would rely upon the incentives to industry of cost efficiency and health factors to provide replacements for materials discovered to be carcinogenic. See AIHC Alternative at 43-45. As Dr. Selikoff eloquently urged, the matter of substitutes should be left to the market place. (Tr. 1739-1740.)

VI

OSHA HAS FAILED TO COMPLY WITH THE NATIONAL ENVIRONMENTAL POLICY ACT

Introduction

OSHA has violated the provisions of Section 102(2)(C) of the National Environmental Policy Act ("NEPA"), 42 U.S.C. § 4321 et seq., by failing to prepare and circulate for comment a detailed and comprehensive draft environmental impact statement ("EIS"), by failing to publish and circulate such a draft prior to the first significant point of agency decision, and by making irretrievable commitments of resources to the Proposed Regulation prior to issuance of an adequate draft or final EIS.

Pending full and adequate compliance with its NEPA obligations, OSHA should not promulgate its final regulations. OSHA's failure to comply with NEPA has deprived interested parties and other Federal agencies of the opportunity to submit the critical commentary and objective data which OSHA is required to consider prior to taking any action.

Section 102(2)(C) of NEPA requires OSHA to issue not only a final but also a draft statement assessing in detail the environmental consequences of its proposed action. See Cedar-Riverside Environmental Defense Fund v. Mills, 422 F. Supp. 294, 323 (D. Minn. 1976). Full and adequate compliance with NEPA at the draft stage is a prerequisite to an agency's implementation of the NEPA mandate at the final stage, since adequate

weight cannot be given to environmental factors when data appear in the final EIS without being subject to the critical evaluation that occurs through public scrutiny at the draft stage. Appalachian Mountain Club v. Brinegar, 394 F. Supp. 105, 121-122 (D. N.H. 1975); see Realty Income Trust v. Eckerd, 564 F.2d 447, 453-454 (D.C. Cir. 1977); Jones v. District of Columbia Redevelopment Land Agency, 499 F.2d 502, 511 (D.C. Cir. 1974), cert. denied, 423 U.S. 937; Atchison, Topeka & Santa Fe Railroad Co. v. Callaway, 431 F. Supp. 722, 728 (D. D.C. 1977); Maine Central Railroad Co. v. ICC, 410 F. Supp. 653, 656 (D. D.C. 1975).

In purported compliance with its obligation to issue a detailed draft EIS, OSHA has included in the Preamble to its Proposed Regulation a two-page discussion entitled "Environmental and Economic Impact Assessment." 42 Fed. Reg. at 54180-54182. The agency styles this discussion, along with the rest of the proposal, as its draft EIS. This draft purports to set out the agency's complete thinking on the environmental impact of a regulation which will directly impact, by the agency's own admission, several hundred substances. This draft, however, does not contain the detailed comprehensive and objective analysis of environmental factors required by Section 102(2)(C) of NEPA, OSHA's own regulations, and the CEQ Guidelines.

OSHA's recent release of Clement's tentative categorization of substances on the NIOSH List of Suspect Carcinogens underscores the need for a comprehensive EIS. This new infor-

mation which OSHA should have had in its possession at a very early point in its decision-making process should assist OSHA considerably in more precisely quantifying the environmental impact of its proposal which it has heretofore stated was so difficult to quantify.

The same reasons which lead OSHA to change its original position that a regulatory analysis of the Proposed Regulation under Executive Order 12044 was not required (see supra, at 6-7) demonstrate that OSHA's decision to prepare an Environmental Impact Statement only in individual substance rulemaking is invalid. In the letter to ORC giving the reasons why a regulatory analysis was required, OMB stated:

"As Dr. Bingham has noted, it is difficult to conduct meaningful analyses for a generic standard when specific definitions have not been published. However, when generic standards will, upon promulgation preempt later regulatory decisions, then the economic effect of significant regulatory alternatives may never be analyzed." (AIHC P.H.)

In the memo to the Assistant Secretary, Messrs. Morris and Wrenn stated that the regulatory analysis being prepared would examine "realistic alternative approaches." Thus unless a comprehensive EIS is prepared now, the Agency will never consider, and the public will never have an opportunity to comment on the environmental impact under NEPA in later regulatory decisions on issues which are preempted by the generic standard, nor on the "realistic alternative approaches" to be discussed in the forthcoming regulatory analysis.

A. OSHA Has Failed To Prepare A Detailed And Comprehensive Statement

OSHA has totally failed to measure up to the rigorous standards of Section 102(2)(C) of NEPA. Its draft EIS is couched in conclusory language and its vague generalizations are often unsupported by objective data. In no sense can the draft be considered a "detailed" inquiry into the analysis of the environmental impact of the Proposed Regulation, and OSHA has therefore violated its duty to comply with NEPA "to the fullest extent possible."

The provisions of Section 102(2)(C) establish "a strict standard of compliance." Calvert Cliffs' Coordinating Committee, Inc. v. U.S. Atomic Energy Comm'n, 449 F.2d 1109, 1112 (D.C. Cir. 1971). Nothing less than a comprehensive and objective treatment of environmental issues by the responsible agency will suffice. Environmental Defense Fund, Inc. v. Corps. of Engineers, 348 F. Supp. 916, 927 (N.D. Miss. 1972), aff'd, 492 F.2d 1123 (5th Cir. 1974). A detailed statement serves three important purposes: (1) It permits a court to ascertain whether the agency has made a good faith effort to take into account the values NEPA seeks to safeguard, and to that end the EIS must explicate fully its course of inquiry, its analysis, and its reasoning; (2) It serves as an environmental full disclosure law; and (3) Perhaps most crucial, it "helps insure the integrity of the process of decision by precluding stubborn problems or serious criticisms from being swept under the rug." Sierra Club v. Morton, 510 F.2d 813, 820 (5th Cir. 1975); State of Alabama ex rel. Baxley v. Corps. of

Engineers, 411 F. Supp. 1261, 1267 (N.D. Ala. 1976).

The draft EIS issued by OSHA is neither a comprehensive nor an objective treatment of the environmental consequences of its Proposed Regulation. Rather, OSHA's EIS contains just the sort of superficial consideration of environmental factors that NEPA was meant to preclude. It fails to serve the three important purposes which the courts have interpreted NEPA as demanding.

OSHA's failure to comply with its obligation to file a "detailed" draft EIS manifests itself in a number of areas. The statement omits a description of the present baseline workplace environment, fails to substantiate the alleged beneficial environmental impact of the Proposed Regulation on that workplace environment, and inadequately discusses the secondary environmental consequences of the proposed action. The interrelationships and cumulative environmental impacts of the Proposed Regulation and other related Federal projects are not adequately analyzed, nor is the relationship between local short term uses of the environment and the maintenance and enhancement of long term productivity. Moreover, OSHA's discussion of alternatives to its proposed action is woefully deficient. Some of these points are discussed in greater detail below.

Scope. In July 1977, OSHA entered into a contract with Clement to screen and categorize the substances in the NIOSH suspect carcinogen subfile. The draft EIS, however, fails to mention or list the suspect chemicals being evaluated by OSHA and its

contractor for regulation under the proposal. It fails to discuss the alternative chemicals which are or may be used to substitute for the chemicals foreclosed from use by the regulations, or the environmental consequences of using these alternative chemicals.

Baseline. OSHA's draft EIS contains no description of the baseline workplace environment. There are no data or analyses, for example, of the number of employees exposed to the substances to be regulated, or of current conditions and practices in workplaces which might be covered by the regulation. Without an analysis of existing conditions such as these, there is no basis for evaluating the alleged beneficial environmental impact of the proposed generic standards.

Environmental Impacts and Benefits. OSHA's analysis of the potential environmental impact of its proposal and the potential benefits falls far short of NEPA's requirements.

The draft EIS is replete with examples of OSHA's uncertainty as to its ability to substantiate the beneficial environmental impact of its proposed generic standard. The primary impact of the Proposed Regulation is "expected to impact on the workplace by reducing worker exposure to Category I and Category II toxic substances." 42 Fed. Reg. 54182 (emphasis added). OSHA declares that "[t]he specifics of potential impacts, expected as a result of the promulgation of [the Proposed Regulation] cannot . . . be foreseen and is somewhat speculative." 42 Fed. Reg. 54182. The best that OSHA can offer is an "overview" giving "a

general idea of some of the types of impacts which may result." Id. The requirement that an EIS be detailed places a heavy burden on the responsible agency to gather and include in the EIS enough information to show that compliance has been genuine, not perfunctory. Brooks v. Volpe, 350 F. Supp. 268, 276 (W.D. Wash. 1972), aff'd, 487 F.2d 1344 (1973). OSHA's reliance on conclusions and assumptions without reference to supporting objective data prevents it from meeting that burden.

Adverse Impacts and Irretrievable Commitments.

OSHA's failure to discuss in detail the adverse environmental consequences of its proposal, including irreversible and irretrievable commitments made, is another serious deficiency in the EIS. Among the significant adverse impacts of the proposal on the physical environment which have not been adequately examined are the following:

(a) unnecessary use or depletion of energy resources by OSHA's (1) requirement to reduce workplace exposure limits to the lowest level feasible without regard to what is an adequate level and without regard to the cost of such controls and (2) mandated preference for energy-intensive engineering controls as the method for complying with permissible workplace exposure limits even though less energy intensive personal protection and administrative controls may accomplish the same end result; and

(b) air, water, solid waste and land use impacts likely as a result of the proposal's provisions (1) to ban substances where there are "suitable" less hazardous alternative substances and (2) to require reduction of exposures to the lowest level feasible without regard to economic cost or effects on international trade.

OSHA does purport to address the issue of possible energy resources depletion. Its conclusions, however, are not only vague, conclusory, and unsupported by objective data, but also contradictory. OSHA states in the draft EIS that its proposal "might result in an insignificant increase in energy consumption." 42 Fed. Reg. 54182. It does not provide any support for this assertion. Later in the draft, however, OSHA admits that potential impacts upon energy "cannot readily be quantified." Id.

The treatment in the draft EIS of the potential adverse impact on air, water, solid waste, and land use is also inadequate and unilluminating. OSHA admits that various engineering and hygienic controls "may result in increased contamination of water and increased sludge production, representing a potential negative impact on both water quality and the amount of solid waste." Dust collection methods, for example, "could impact water quality, solid waste and land use categories." 42 Fed. Reg. 54182. OSHA also admits, however, that it has little data which quantify these potential impacts." Id. Without such data, the balancing of beneficial and adverse environmental effects which NEPA demands prior to agency decision cannot take place.

Secondary Impacts. The inadequacy of the draft is further reflected in OSHA's failure to discuss in detail the secondary environmental consequences of its proposal. Among the matters which should have been considered in detail was the possibility of plant redundancies and dislocations caused by a ban or very

restrictive limits on a chemical, especially in circumstances where no alternatives are practically available, with attendant secondary environmental impacts in local communities. OSHA states only that the potential impact of its Proposed Regulation upon "human resources . . . cannot readily be quantified." 42 Fed. Reg. 54182. Besides these possible domestic unemployment effects, the draft EIS should certainly have discussed the probable impairment of the international balance of payments position due to the standards. There is no indication that this factor was considered at all. OSHA should also have addressed more adequately the impact of its Proposed Regulation upon medical research and on care and industrial hygiene resources. The draft EIS confines its discussion of this issue to the conclusory assertion that "[t]he exposure levels and compliance methods chosen should have no effect on the amount of monitoring and medical surveillance required." Id.

Alternatives. OSHA has said that its forthcoming regulatory analysis will "examine realistic alternative approaches for regulating these hazards" as well as "alternative criteria for the categorization of substances within the generic standard." The draft EIS contains only the most cursory discussion of possible alternatives to the proposed regulatory action and the environmental impacts of such alternatives. OSHA, however, is required to consider these matters as thoroughly at the draft as at the final stage. Natural Resources Defense Council, Inc. v. Nuclear Regulatory Commission, 539 F.2d 824, 842 (2d Cir. 1976); Natural Resources Defense Council, Inc. v. Hughes, 437 F. Supp. 981

(D. D.C. 1977). This requirement has not been satisfied. OSHA's statement omits altogether discussion of such crucial alternatives as the "no action" alternative, without which no EIS can be considered complete. Monroe County Conservation Council, Inc. v. Volpe, 472 F.2d 693, 698 (2d Cir. 1972). Even the discussion of those alternatives which are included is largely vague and uninformative, indicative of OSHA's failure to comply with the obligations of Section 102(2)(C) "to the fullest extent possible." OSHA states, for example, that the choice of alternative levels of exposure compliance is expected "to have impact in some way" on every category of the external environment. Such statements are neither supported by scientific data nor adequately explained. In no sense is OSHA's discussion of alternatives an adequate compliance with NEPA's requirement of a thorough consideration of alternative regulatory approaches and their environmental impacts.

Interrelationships With Other Federal Agency Actions.

OSHA's failure to adequately discuss the interrelationships and cumulative environmental impacts of the Proposed Regulation and other Federal activities is also violative of NEPA.

As was made clear by Messrs. Wrenn, Byington, Kennedy, and Jellinek, OSHA and other Federal agencies have embarked on a coordinated program to deal with toxic substances, including carcinogenic substances. The forums for these programs have been principally the IRLG and the Toxic Substances Strategy Committee where there is little or no opportunity for public participation. The deliberations of these bodies are intimately in-

tertwined with the OSHA regulatory program and accordingly merit full discussion in the EIS. AIHC believes it is incumbent on the IRLG to prepare an EIS before agreeing on the criteria, standards, etc. to be developed under the IRLG work plans. In any event, OSHA should prepare such an EIS with reference to this Proposed Regulation and those decisions being made in the IRLG context.

B. OSHA Has Violated NEPA's Mandate For Early Consideration Of Environmental Issues

OSHA's failure to publish and circulate an adequate draft EIS for comment prior to the first significant point of decision is also violative of NEPA. Contrary to the requirements of NEPA and the CEQ Guidelines, 40 C.F.R. § 1500.7(a), OSHA waited until a number of significant decisions had already been made before publishing its draft EIS. An EIS is meant "to serve as the means of assessing the environmental impact of proposed agency actions, rather than as a justification for decisions already made." Id. OSHA had begun work on the generic proposal in January 1976. (Tr. 164.) In January 1977, OSHA publicly circulated and made available to NACOSH for comment a proposal essentially identical to that published in the Federal Register. The purported EIS was not, however, released until October 1977. The course of action taken by OSHA undermines the intent of NEPA because it deprives government agencies and the public of a meaningful opportunity to comment and lends an irreversible momentum to the Proposed Regulation before an analy-

sis of environmental factors is ever undertaken. See Jones v. District of Columbia Redevelopment Land Agency, 499 F.2d 502, 511 (D.C. Cir. 1974), cert. denied, 423 U.S. 937 (1975); Natural Resources Defense Council, Inc. v. Hughes, 437 F. Supp. 981, 991 (D. D.C. 1977); Atchison, Topeka & Santa Fe Railroad Co. v. Callaway, 431 F. Supp. 722, 728 (D. D.C. 1977).

C. OSHA Has Failed To Assess Adequately The Generic Issues

Since this rulemaking purports to resolve certain critical issues and to foreclose their later consideration, it takes on added significance. To imply as OSHA does that it is "unable" (Wrenn S. 6) to make such an analysis now because the potential impact is difficult to analyze and to suggest therefore that it is better to wait until subsequent rulemakings on individual substances to make such analyses is akin to closing the barn door after the animals have fled, a fact which OSHA has acknowledged in its post-hearing agreement to prepare a regulatory analysis under Executive Order 12044.

There is a long line of judicial precedent which supports the need for a thorough NEPA analysis at the outset of a generic or programatic government action which will result in a series of environmental impacts. See, e.g., Scientists Institute for Public Information v. AEC, 481 F.2d 1079, 1088 (D.C. Cir. 1973); Jones v. Lynn, 477 F.2d 995 (1st Cir. 1973); see also Natural Resources Defense Council Inc. v. Nuclear Regulatory Committee, 539 F.2d 824, 839 (2d Cir. 1976).

D. OSHA Has Made And Continues To Make Irretrievable Commitments To The Proposed Regulation

OSHA has also violated and is continuing to violate NEPA by making irretrievable commitments of resources to the Proposed Regulation prior to the issuance of an adequate final EIS. The agency has, for example, already begun implementing the Proposed Regulation by relying upon it in the formulation of standards for particular substances. The economic feasibility studies for acrylonitrile and DBCP were prepared by OSHA contractors under instructions from OSHA to treat the generic standards as applicable. This course of action is clearly impermissible, for it prevents an EIS from serving as an input to the decision-making process before the final decision has been made by the agency.^{1/} A full environmental impact analysis must occur prior to an agency's commitment to a project. Inman Park Restoration, Inc. v. Urban Mass Transportation, 414 F. Supp. 99, 119 (N.D. Ga. 1975). Reliance by OSHA upon the Proposed Regulation prior to issuance of an adequate final EIS is improper because such activity involves irretrievable commitments of resources which serve to tip the balance away from environmental concerns and to prejudice the final agency decision. Subsequent broad-scale assessment of alternatives is also foreclosed. See Natural

^{1/} In addition, OSHA seems to be moving forward on record-keeping rules in a separate proceeding without consideration of evidence developed in these proceedings and, of course, without NEPA compliance. See 43 Fed. Reg. 31329, 31371 (July 21, 1978).

Resources Defense Council, Inc. v. U.S. Nuclear Regulatory Commission, 539 F.2d 824, 843-844 (2d Cir. 1976); Realty Income Trust v. Eckerd, 564 F.2d 447, 455 (D.C. Cir. 1977).

Conclusion

Section 102(2)(C) of NEPA requires that prior to the implementation of the Proposed Regulation in any manner, a full, comprehensive and adequate consideration of the probable environmental consequences of agency action be made and set forth in a detailed draft and final EIS. To date, OSHA has failed to undertake such a comprehensive analysis. A two-page analysis of a proposal of this importance on its face violates NEPA.

In order to insure that the interest in informed decision-making is preserved and that the agency's NEPA obligations have been fully complied with, OSHA should not issue final regulations and should prevent further commitment of resources thereto until an adequate NEPA analysis has been made.

VII

OSHA HAS FAILED TO MEET ITS LEGAL OBLIGATIONS TO ASSESS THE POTENTIAL ECONOMIC IMPACT OF THE PROPOSED REGULATION AND ALTERNATIVES THERETO

Introduction

OSHA has a legally-binding obligation to consider the economic impact of all aspects of this regulation and alternatives thereto. This obligation is triggered in this rulemaking, not, as OSHA suggests, in subsequent rulemakings on individual substances when the important issues will already have been decided. If economic analysis is to be a useful decision-making tool, as mandated by the Congress and the President, it must be utilized in this rulemaking. Studies submitted by Foster D. Snell and others demonstrate that such studies are possible and can meaningfully be done. Indeed, Appendix A to the Snell Report sets out a methodology which OSHA might utilize for such a study. Further, these studies demonstrate that the costs associated with the proposal are likely to be very substantial.

AIHC and others have urged OSHA to prepare an economic analysis of the Proposed Regulation since its first public release in January 1977. Only now, nearly three years after OSHA began working on the proposal and long after the hearing has closed, has OSHA agreed to undertake an economic analysis.

In response to a letter from Organization Resource Counselors ("ORC") dated June 14, 1978, requesting the Office of Management and Budget ("OMB"), the agency responsible for imple-

mentation of the President's Regulatory Analysis Program, to use its good offices to require OSHA to prepare a regulatory analysis of its proposal, OMB, in a letter dated July 25, 1978, advised that OSHA has "agreed that a regulatory analysis will be done for the generic standards and that [OMB] will continue to work with [OSHA] on the design of the analysis." (AIHC P.H.) In its letter OMB recognized, as AIHC and others have, that "when generic standards, will, upon promulgation, preempt later regulatory decisions, then the economic effects of significant regulatory alternatives may never be analyzed" if they are not analyzed in the generic proceedings.

OSHA has not released an outline or detailed description of the analysis being undertaken. In the memorandum which Messrs. Morris and Wrenn sent to the Administrator, there is some indication of the kind of analysis OSHA is making. (AIHC P.H.) As part of its analysis of "realistic alternative approaches," OSHA plans to use quantitative data from economic impact analyses of substances already regulated by OSHA. In the analysis OSHA will also "set forth for review the parameters which are included in a determination of feasibility." The review was to have been completed by October 1, 1978, but has not yet been made public.

AIHC welcomes OSHA's agreement to undertake a regulatory analysis. It is our hope that the analysis will have the objectives and content outlined by the President's Regulatory Analysis Review Group ("RARG"). In the analysis of the proposed acrylonitrile standard, the RARG described the analysis in

these terms:

"But simply knowing that the lower the permissible exposure level (PEL), the lower the risk of cancer, is not information enough upon which to base a standard unless it is intended to eliminate immediately all risks regardless of the consequences. Although as a long range goal this may describe the intent of the OSH Act, as an operational procedure it is empty, since in order to eliminate all risks forthwith, industry would have to shut down. Just as there is no absolute 'safe' level, there is no absolute 'feasible' level.

Thus decisions must be made by regulators as to how far it makes sense to us as a society to go and how fast. To use the criterion that we should reduce risk to the point just before the industry would be forced to shut down is illogical since the goal of the OSH Act is to protect workers, not industries. The proper procedure should be to promulgate regulations that provide greater gains to society than burdens." (AIHC P.H.)

We urge that a thorough airing of all of the economic aspects of this proposal and alternatives thereto with sufficient, meaningful opportunity for public notice and comment be had prior to final agency action.

A. The Legal Basis For Economic Analysis Is Clear

There are several independent legal bases upon which required analysis of economic impact rests. Each emphasizes the need for the use of such analyses as a tool at an early stage in the decision-making process.

1. The Occupational Safety and Health Act

The principal statutory bases for the Proposed Regulation are Sections 3(8), 6(b)(5) and 6(b)(7) of the Act. 42 Fed.

Reg. 54153-54154, 54183. These sections require OSHA to promulgate "reasonably necessary", "feasible", and "appropriate" standards or regulations. An integral element embodied in these concepts, as recognized by OSHA, the courts, and Congress, is an economic impact analysis. See Tr. 3796; American Iron & Steel Institute v. OSHA, 6 OSHC 1451 (3rd Cir.); Turner Co. v. Secretary of Labor, 561 F.2d 82 (7th Cir. 1977); AFL-CIO v. Brennan, 530 F.2d 109 (3rd Cir. 1975); Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467 (D.C. Cir. 1974); Florida Peach Growers Ass'n v. Department of Labor, 485 F.2d 120 (5th Cir. 1974); Aqua Slide 'N' Dive Corporation v. Consumer Product Safety Commission, 569 F.2d 831, 840, 845 (5th Cir. 1978); D.D. Bean & Co. v. Consumer Product Safety Commission, 574 F.2d 643 (1st Cir. 1978); Legislative History at 147, 148, 197, 464, 471-472.

The Court in Turner, adopting a decision of the Occupational Safety and Health Review Commission, underlined the importance of economic considerations in determining feasibility and emphasized that in determining economic feasibility both costs and benefits must be weighed. The Court held:

"It was, therefore, after thorough consideration of the relevant legislative history that the Commission formulated the standard which we presently adopt:

'* * * we conclude that the standard should be interpreted to require those engineering and administrative controls which are economically as well as technically feasible. Controls may be economically feasible even though they are expensive and increase production costs. See Arkansas-Best Freight Systems, Inc., 529 F.2d 649, 653 [3 OSHC 1910] (8th Cir. Jan. 29,

1976); Industrial Union Department, AFL-CIO v. Hodgson, supra [162 U.S.App.D.C. 311,] 499 F.2d [467] at 477. But they will not be required without regard to the costs which must be incurred and the benefits they will achieve. In determining whether controls are economically feasible, all the relevant cost and benefit factors must be weighed.' (Id.)" 561 F.2d at 85.

The Benzene decision demonstrates the basic importance of OSHA's determination of both costs and benefits in reaching the conclusion that a regulation is "reasonably necessary". OSHA must be able to show both costs and benefits, for without these findings OSHA cannot demonstrate the reasonableness of the cost in relation to the benefits. The court underlined the importance of both determinations when it said:

"OSHA's failure to provide an estimate of expected benefits for reducing the permissible exposure limit, supported by substantial evidence, makes it impossible to assess the reasonableness of the relationship between expected costs and benefits. This failure means that the required support is lacking to show reasonable necessity for the standard promulgated." __ F.2d at 93.

2. The National Environmental Policy Act

As discussed in the preceding section of this brief, NEPA and implementing CEQ guidelines and OSHA regulations require that a detailed environmental impact statement be prepared for major federal actions significantly affecting the quality of the human environment. Such statements must examine costs and benefits and consider economic impacts of contemplated government action. See, e.g., Chelsea Neighborhood Ass'n v. Postal Service,

516 F.2d 378, 386-387 (2d Cir. 1975); Sierra Club v. Morton, 510 F.2d 813, 827 (5th Cir. 1975); Calvert Cliffs' Coordinating Comm. v. AEC, 449 F.2d 1109, 113 (D.C. Cir. 1971); Texas Comm. on Natural Resources v. Bergland, 433 F. Supp. 1235, 1252 (D. Tex. 1977); Citizens Against Toxic Sprays, Inc. v. Bergland, 428 F. Supp. 903, 934-935 (D. Or. 1977).

CEQ's most recently proposed NEPA implementation regulations summarize NEPA's requirements as follows:

"When an environmental impact statement is prepared and economic or social and natural or physical environmental effects are inter-related, then the environmental impact statement will discuss all of these effects on the human environment." 43 Fed. Reg. 25229, 25245 (June 9, 1978).

3. Executive Order No. 11821 (Inflationary or Economic Impact Statements)

Executive Order No. 11821, 39 Fed. Reg. 41501 (November 20, 1974), as amended by Executive Order No. 11949, 42 Fed. Reg. 1017 (January 5, 1977), and as implemented by OMB (Circular No. A-107) and agency directives, including a directive of the Secretary of Labor, Secretarial Order No. 15-75, 40 Fed. Reg. 54484 (November 24, 1975), required "Inflationary" or "Economic" Impact Statements for "major" proposed regulatory actions.^{1/}

^{1/} The Executive Order, as implemented, defined "major" actions as those which would result in (1) a net increase in costs to consumers, businesses, federal, state or local governments of \$100 million or more; or \$10 million or more for any industry or level of government (certain specified productivity parameters were required to be considered in making such cost analyses); (2) energy demand increases of

(Footnote continued on p. 102)

Executive Order No. 11821 was in effect at the time the OSHA proposal was first published.

4. Executive Order No. 12044 (Regulatory Analysis)

Executive Order No. 12044 (43 Fed. Reg. 12660 (March 24, 1978)) requires "Regulatory Analyses" for significant proposed regulatory activities.^{1/} To be included within the scope of this order are all pending regulatory proceedings for which inflationary or economic impact statements have not been issued pursuant to Executive Order No. 11821 as amended. Section 3, 43 Fed. Reg. at 12663. "Closely related sets of regulations" are required by the Executive Order "to be considered together." Section 6, 43 Fed. Reg. at 12664. The Executive Order has recently been implemented by proposed Department of Labor regulations.^{2/} 43 Fed. Reg. 22915 (May 26, 1978).

(Footnote continued from p. 101)

25,000 barrels of oil per day or its equivalent; (3) reduction of the national supply of critical materials by 3 percent or more; (4) reduction of labor demand by 0.2 percent at the national level or 10,000 workers at the industry, state or local level; or (5) substantial (a) limitations on market entry, (b) market concentrations, or (c) potential for monopoly in a line of commerce.

1/ Pursuant to this Executive Order, a proposed action is to be considered "significant" where the action will result in an annual effect on the economy of \$100 million or more or a major increase in costs or prices for individual industries, levels of government or geographic regions. Section 3(a)(1), 43 Fed. Reg. at 12663.

2/ The proposed regulations require an analysis where the regulation is likely to result in: (1) an increased cost of \$100 million or more in any one year for the

(Footnote continued on p. 103)

We quoted earlier from the comments filed by the President's Regulatory Analysis Review Group on the proposed acrylonitrile standard. More recently on September 5, 1978 the Council on Wage and Price Stability ("CWPS") in comments on EPA's proposed drinking water standard described the reason for, and the contents of, a regulatory analysis under Executive Order 12044 in words directly applicable here:

"Because the resources available for health-related programs are limited, it is important that those resources be allocated in a way that maximizes the benefits (in terms of lives saved or cases of illness or injury avoided). This in turn requires that the incremental cost per case avoided be at least approximately equated for different regulations or different adopted standards. To ignore this fact is to allow more deaths than necessary for a given expenditure on health-related programs. It is therefore incumbent upon EPA to support its proposed regulations with careful risk-assessment and cost-benefit analyses, employing the best estimates available regarding uncertain variables, parameters, and relationships.

There is a considerable amount of uncertainty about both the costs and the benefits of these alternatives, but it makes little sense to act on uncertain evidence by imposing costly regulations on local communities while, at the same time, eschewing cost/benefit analyses because of this uncertainty." (At 1-2, AIHC P.H. (emphasis in original).)

(Footnote continued from p. 102)

nation, (2) a \$50 million or more increase in costs or total revenues in any one year for a specific segment of the economy, (3) a direct dislocation of 10,000 jobs, or (4) a substantial limitation on competition, marketing, market information or an increase in concentration in a market doing \$100 million of business a year or more. 43 Fed. Reg. at 22918.

B. An Economic Analysis Will Be Meaningful And Is Feasible

While it may be difficult to cost or precisely quantify all aspects of the Proposed Regulation, the preliminary economic analysis of the generic proposal made by Foster D. Snell, Inc., a division of Booz, Allen & Hamilton, Inc., for AIHC demonstrates that a meaningful analysis can be made. While the Snell Report was principally a "scoping" effort prepared under severe time constraints, it points the way for a full analysis. Appendix A to the Snell Report sets out a suggested methodology OSHA might use for a comprehensive analysis which Snell believes is both feasible and meaningful.

Moreover, the tentative categorization of substances on the NIOSH List of Suspect Carcinogens by OSHA's contractor, Clement Associates, released July 14, 1978, should greatly facilitate such analysis by removing some of the uncertainty associated with which substances will fall into which categories. The release of this document makes even clearer the need for an economic analysis.

While the application of the Proposed Regulation, as any regulation, will obviously be uncertain, this should not be an excuse to avoid an economic analysis. The use of alternate regulatory scenarios and case studies, standard economic analysis tools frequently utilized by OSHA itself, can overcome much of the uncertainty. Only through such analyses can optimal cost-effective regulation be assured. Such analysis will permit better understanding of how various aspects of the pro-

posal and alternatives thereto might impact costs. The CWPS in its comments on EPA's drinking water standard quoted above underlines the mistake of an agency's acting on uncertain evidence by imposing a costly regulation and at the same time failing to make a cost/benefit analysis because of the uncertainty. OSHA should not make the same mistake here.

C. The Potential Economic Impact Of The Proposed Regulation Is Significant

Studies by Snell and other participants in these proceedings demonstrate the substantial potential impact of the OSHA proposal, particularly when viewed in the context of the broader costs of compliance with a wide variety of government regulations of this sort. These substantial costs which are, in effect, costs to the entire nation (AIHC Economic Panel Tr. 3802-3803, 3825-3835), impose an obligation on OSHA to take a very close look at the economic costs of the Proposed Regulation and the alternatives thereto.

1. The Snell Report

The Snell Report is an effort, within the limited time^{1/} and resources available, to roughly estimate some of the potential compliance and other costs associated with the OSHA pro-

^{1/} The Proposed Regulation was published October 4, 1977. AIHC was formed and Snell retained by the end of October. Written comments were originally due by December 8, 1977. Although two extensions of time were thereafter granted by OSHA, those extensions were not granted in a way which allowed sufficient time to substantively change the scope or direction of the Snell Report. (Tr. 3810.)

pos^{1/}al. The Report was not commissioned with a view toward balancing lives against dollars or assessing risks against benefits, but rather toward examining how best to use society's limited resources, how best to render a "meticulous accounting". (Dr. Zeckhauser Tr. 4352, 4410).

It was, and is, AIHC's view that the Snell Report is useful in pointing out that the costs associated with the OSHA proposal are substantial, that certain aspects of the proposal might be particularly costly and that there may be ways to achieve similar goals more economically. The main conclusion of the Snell Report lies not in the costs developed themselves, but rather the inescapable fact that the costs are likely to be substantial and the Proposed Regulation and alternatives thereto therefore merit careful economic analysis by OSHA.

Snell examined the costs of compliance for three regulatory scenarios with alternate mandated control levels. The direct compliance costs, estimated by Snell were as follows:

Direct Compliance Costs (\$ Billion, 1977)

<u>Scenario</u>	<u>Capital Cost 10 ppm to 1 ppm</u>	<u>Annual Cost 10 ppm to 1 ppm</u>
Low scenario (38 high volume substances)	9-23	6-11
Medium scenario (1,870 substances)	17-47	10-20
High scenario (2,415 substances)	30-88	18-36

(Snell Report at 3.)

^{1/} Exhibit 66 briefly summarizes Snell's methodology and conclusions.

Snell found that smaller businesses and user industries were those most likely to bear the brunt of the economic burden. Snell Report at 494-495. This view was shared by numerous other participants in the hearing. See, e.g., Chamber of Commerce Tr. 8345-8349; PMA Tr. 7041-7051. Snell also concluded that certain features of the Proposed Regulation were particularly costly. These included monitoring, medical surveillance, OSHA's mandated preference for engineering controls, the absence of an exemption for mixtures or of an action level and the substitution requirements. (Tr. 3795, 3804.)

In addition to the compliance costs noted above, Snell also concluded that there would be other potential macroeconomic effects, including reduced labor and capital productivity, increased operating costs making U.S. firms less competitive with their foreign counterparts^{1/} and increased market concentrations with particularly adverse effects for small businesses. Snell estimated that the Proposed Regulation has the potential to add in excess of one percent to the annual rate of inflation.

2. Other Studies

Hearing participants other than AIHC also offered evidence supporting the view that the OSHA proposal could have substantial economic impact.

In a study prepared for the Shell Oil Company, Charles H. Kline & Co., concluded that there could very well be significant

^{1/} See also Dr. Zeckhauser's comments on these points.
(Tr. 4326.)

economic impact associated with a price increase as a result of OSHA-imposed controls or a ban by a requirement of "no exposure" due to a finding that "suitable substitutes" were available. (Tr. 5549-5550.)

In a study done for the Refractories Institute, Arthur D. Little, Inc. concluded that a regulation for crystalline silica similar to the one proposed by OSHA for a Category I substance could have a far-reaching impact on the refractories industry. (Tr. 6433-6435.) See also comments of other hearing participants, e.g., Chamber of Commerce Tr. 8345-8349; National Association of Chemical Distributors Tr. 8421-8424; Crane Packing Company Tr. 7559-7561; National Manufacturers Association Tr. 7661-7668, 7674-7676; Society of American Wood Preservers, Inc. Tr. 7750-7757; Sun Chemical Company Tr. 7840-7841; Muskegon Chemical Company Tr. 7312-7313; Mallinckrodt, Inc. Tr. 7419-7421, 7433-7438.

3. The Broader Picture

The broader cumulative economic impact of the Proposed Regulation and similar proposals by other federal agencies make the need for a thorough analysis of this proposal even clearer.

Glenn Schweitzer of Cornell University and formerly Director of EPA's Office of Toxic Substances expressed serious reservations about, and submitted a report on, the cumulative impact of OSHA and other agency proposals on the growth of our economy and on innovation and technological advances. (Tr. 7108-7109, 7116-7119; Ex. 124.)

Studies by Edward Denison of the Brookings Institution

(Ex. 64) and Robert DeFina of Washington University (Ex. 65) also review the dramatic impact federal regulatory programs, including OSHA programs, have had on the economy. Denison concludes that by 1975 the output per unit input was 1.8 percent smaller than it would have been if business had operated under 1967 conditions. DeFina conservatively estimates the cost to the nation for job safety and health to be \$4.5 billion annually. (Ramey Tr. 8400-8402.)

In a recent memorandum dated June 26, 1978, to the President's Economic Policy Group, the Director of the CWPS states that regulations pending before OSHA and the Department of Transportation alone would require a total \$35 billion in capital costs. The Director cautions, however, that the economic costs may even be greater "because in several areas these decisions will set guidelines for future detailed regulations . . . [in such areas as] carcinogens, toxic substances, noise, air and water quality." The Director observes that "the estimated cost of proposed [OSHA] regulations suggests a cost impact in the future that approaches that for environmental improvement," the inflationary impact of which he notes EPA estimates at 0.4 to 0.8 percent annually. According to the Director, based on information from available studies, regulations by OSHA and other agencies "have contributed to about a 25 percent reduction in the rate of productivity growth within the private nonfarm economy."

These kinds of broader considerations add considerable urgency to the need for a thorough airing of the cost of the

Proposed Regulation and alternatives thereto.

D. Criticism Of The Snell Report Is Without Support

The Snell Report was criticized on several grounds, principally by OSHA's consultant, Southwest Econometrics, and by the AFL-CIO's consultant, Ruth Ruttenberg. A detailed commentary on these criticisms prepared by Foster D. Snell was filed as part of the AIHC post-hearing filing. The response by Snell to the post-hearing comments filed by Econometrics is being filed concurrently with this brief.

The first major criticism was that the underlying raw data were not made available. As pointed out by AIHC, it was not possible within the limited time available for submissions to the hearing record to collect meaningful data without a guarantee of confidentiality. (Tr. 3811.) Further, as noted by Snell, provisions for confidentiality are not unusual in studies of this kind. (Tr. 3811.) Indeed, the Bureau of the Census and the International Trade Commission follow similar confidentiality procedures in gathering their data. OSHA's solicitor argued that Wirtz v. Baldor Electric Co., 337 F.2d 518 (D.C. Cir. 1964), precluded OSHA reliance on studies for which the underlying data were not available. Whatever merit this decision may have in another context, it certainly is inappropriate here, for AIHC does not argue that the Snell estimates are hard numbers upon which regulatory decisions should be made, but rather that they are indicators of the need to take

a closer look.

The second principal objection to the Snell Report is that it fails to examine several other impacts of the Proposed Regulation, including the benefits of reduced medical care, expenses associated with reduced disease incidence and the differential economic impact of the AIHC Alternative.^{1/} (Tr. 5737.)

As pointed out by the AIHC Economics Panel, the Snell Report was only intended to be a "first step". AIHC and Snell both acknowledged the need to consider many of the additional factors suggested by its critics. Indeed, Appendix A to the Snell Report, which George Taylor of AFL-CIO said was an appropriate methodology for economic assessment (Tr. 5748-5759), set out a methodology for a complete study considering all the suggested factors. (Tr. 5747-5748.)

The third principal criticism directed at the Snell Report was that it was just industry "crying wolf". Vinyl chloride was again cited as the example of a regulation which industry, in a report prepared for it by Arthur D. Little, Inc.

^{1/} Snell and AIHC were also criticized for failing to analyze the potential cost impact of the AIHC Alternative. As was pointed out at the hearing, in addition to the problem of AIHC's own finite resources, it was not possible to examine the Alternative within the deadlines for filing in this proceeding since the Alternative was being developed in parallel with the Snell effort. In addition, as AIHC understands the law, it is OSHA's obligation, not AIHC's, to examine the impact of its Proposed Regulation and all reasonable alternatives thereto, including the AIHC Alternative. We might add in passing that almost three years have passed since work on the Proposed Regulation began without economic analysis of any sort by OSHA.

("ADL") (Ex. 69), said it could not live with and in fact did live with, according to some, very comfortably. Those who relied on the vinyl chloride "story", principally Ms. Ruttenberg and Dr. Epstein, however, obviously did not understand the assumptions built into the ADL analysis. (Tr. 5799-5800; 1250-53.) ADL surveyed the potential economic impact of a vinyl chloride regulation requiring no detectable exposure, which would shut down the industry. (Tr. 5800.) The regulation adopted by OSHA imposed a much more lenient permissible exposure limit of 1 ppm with a 5 ppm ceiling, not a no-detectable exposure limit. In fact, under questioning, Ms. Ruttenberg acknowledged she had not even read the ADL study upon which she so heavily relied. (Tr. 5799-5780.) It was obvious that she was confusing a study of the regulation prepared by Snell for OSHA (Snell's client) with the ADL study. Id.

Another example of "crying wolf" cited by Dr. Epstein was industry's compliance estimates for the Toxic Substances Control Act ("TSCA"). In his testimony, Dr. Epstein, however, mistakenly quotes Snell as estimating costs of \$12 billion. In fact, Snell estimated costs would range from \$360 million to \$1.3 billion depending on various assumptions and scenarios. Further, Dr. Epstein confuses EPA's budget for TSCA with the cost of TSCA compliance to the nation. (Epstein S. 72.) While on the issue of "track" records, it may be useful to examine EPA's own record on this issue. EPA originally estimated the costs of TSCA to the economy to be \$40 million which was

raised to \$45 million; EPA later raised the estimate to \$80 million, and then to \$140 million. In 1975 EPA estimated an TSCA annual operations budget of \$10 million. EPA now is discussing an annual TSCA budget of \$50 million.

To further put the allegations of industry overestimates and "crying wolf" into perspective, it may be helpful to examine the Snell data more closely. Snell estimated a compliance cost of \$1.1 billion for regulating the manufacture (as distinguished from downstream use) of 1,870 substances to 1 ppm. The MIT retrospective vinyl chloride study upon which Ms. Ruttenberg so heavily relied (Ex. 70) estimated the cost of compliance with vinyl chloride alone at \$350 million. This on its face certainly does not seem to be a case of industry crying wolf.

Finally, a number of methodological flaws were cited in the Snell Report which purportedly undermined it. Putting aside the fact that the stated significance of the Snell Report was not in the particular numbers set out therein but rather in illustrating the need to take a hard look at the OSHA proposal, it is clear that those criticizing the methodology did not adequately understand or take the time to understand the Report. For example, Ms. Ruttenberg criticized Snell for failing to take into account technological advances in the chemical industry which might result in cost savings. In fact, Snell had done so by relying heavily upon the data derived from its vinyl chloride case study, a substance for which significant technological control advances resulted in considerable economies.

Ms. Ruttenberg also criticized Snell for using an annual 10% employee turnover rate in its study. Ms. Ruttenberg argued, based on Department of Labor statistics, that the rate should have been only 1.8% annually. As pointed out in questioning, Ms. Ruttenberg mistakenly assumed her 1.8% figure was an annual one, when in fact it was a monthly figure. (Tr. 5801-5802.) Further, Ms. Ruttenberg criticized Snell for failing to take into account the purported cost savings of substitution. In fact, Snell did consider substitution cost savings and used substitution costs where applicable. See Snell Supplemental Statement at 12 (AIHC P.H.). Again in questioning, Ms. Ruttenberg's failure to study and understand this aspect of the Report was evident. (Tr. 5802-5806.) -

Despite the criticisms of the Snell Report, one fact remains unalterably correct: the OSHA proposal will have significant economic impacts, a fact which Southwest Econometrics, Inc. acknowledged. For this reason alone, the Proposed Regulation and alternatives thereto should be carefully analyzed from an economic perspective. Only through such analyses can societal resources be maximized.

Conclusion

Prior to publishing a final regulation in this rule-making, OSHA has an obligation to conduct a thorough economic analysis of the proposal and allow meaningful public comment on its analysis.

PART TWO

VIII

THE METHOD OF CLASSIFICATION AND THE CRITERIA FOR OSHA'S CATEGORY I ARE IMPERMISSIBLY VAGUE AND ARBITRARY

"Science deals in probabilities, and carcinogenesis bioassays give results that may fall anywhere on a continuous spectrum of probabilities, extending from 2 or 3% at the lowest to nearly 100% at the highest. Division of this spectrum into discrete categories may be necessary for regulatory processes, but is necessarily arbitrary from a scientific point of view. Thus the recommendations of a scientist would be to make the criteria for categorization flexible, and to apply as much scientific judgment to each case as is compatible with legal and regulatory requirements." (Dr. Rall S. 14.)

"The complexity of the problem dictates that the evaluation of the potential human hazards of a given agent must be individualized in terms of the chemical and metabolic aspect of that agent, its intended use(s), and data available at the time the decision must be made, and other factors pertinent to the case under consideration. Each case must be considered on its own and the criteria appropriate to one agent may not necessarily apply to another."^{1/}

"The judgment of carcinogenicity needs to be made by competent, experienced and objective professionals after analysis of all the relevant evidence. It goes without saying that this judgment should be objective and immune from conflicts of interest." (Dr. Saffiotti S. 7.)

"We believe that some flexibility is important to OSHA's categorization scheme both to avoid

^{1/} "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances; Report of the Subcommittee on Environmental Carcinogenesis, National Cancer Advisory Board," 58 J. Natl. Cancer Inst. 461 (Preamble Ex. 71) [hereinafter referred to as NCAB General Criteria].

unreasonable results and to separate clearly scientific from regulatory judgments. The greater the degree to which regulatory judgments flow from scientific judgments, the greater is the possibility that the scientific judgments could become biased. Conversely the more discretion the policy maker has to determine what regulatory action to take, the less likely is it that policy judgments will enter into scientific opinions." (EPA S. 4.)

"As a check on the reliability of the experiment and for the quantification of carcinogenicity, a positive test is generally not considered adequate unless the frequency of cancers is found to be dose dependent." 1/

Introduction

The regulation of carcinogens in the workplace involves two separate decisions. First, whether or not the substance is a carcinogenic risk to man. Second, whether or not regulatory action should be taken. These are separate and distinct decisions as a number of the OSHA and other witnesses recognized when they clearly separated their comments on scientific issues from matters of regulatory authority or policy. See, e.g., Upton Tr. 276-277, 297; Rall S. 2; Griesemer Tr. 894, 922; Lave Tr. 7013; EPA S. 4, quoted at the beginning of this section; and Meselson Tr. 1488. In this section of the brief, AIHC will address the issues relating to the determination that a substance presents a human cancer risk. In subsequent sections of the brief we will address the issues that relate to regulatory action.

1/ The National Academy of Sciences Report, "Contemporary Pest Control Practices and Prospects" NAS (1975), at 65 (attached to Dr. Kennedy's statement).

A. There Should Be An Independent Scientific Evaluation Of
The Data

The scientific evaluation process for both epidemiological studies and animal tests involves evaluation of the soundness of the design and conduct of the study and a determination as to whether the conclusions of the study are justified by the data. There are, of course, major differences in the evaluation of animal and human studies; a basic difference being that an animal study requires extrapolation across species to man while an epidemiological study does not.

AIHC believes that it is fair to say that OSHA witnesses agreed that the evaluation of human risk calls for exercise of scientific judgment by experts in several disciplines. Dr. Upton said "many experiments raise specific problems of interpretation. The resolution of these problems requires evaluation by experienced professionals in several disciplines and cannot be reduced to a formula." (Upton S. 12; see also Tr. 276-277, 292-293, 329-332.) Similarly, Dr. Rall said the evaluation process was one which demanded scientific judgment. (Tr. 358, 362.) In his prepared statement, Dr. Saffiotti (one of whose statements is quoted at the beginning of this section) referred to "judgment" fifteen times. (Saffiotti S. 6, 7, 13, 15, 16, 25, 27, 37, 38, 39, 41; see also Tr. 854, 896, 900; and see Dr. Griesemer Tr. 961, 971-974.) Most witnesses also agreed that the scientists making the judgment wanted all available facts. See, e.g., Schneiderman Tr. 818-819; AISI 4669, 4671; Rall Tr.

380, 417; NIOSH Tr. 2981-2982, 3075; see also Dr. Golberg Tr. 6488; Dr. First Tr. 6885; Dr. Kessler Tr. 6920; and Dr. Lave Tr. 6935. The weight to be given the data would be determined by the exercise of informed scientific judgment, not by any pre-judgment or prior administrative policy decision.

We addressed earlier in this brief (see supra, at 41-51) the legal question whether OSHA's "freezing" of science by its proposed policy determinations on scientific issues is valid under Section 6(b)(5) of the statute, 29 U.S.C. § 655(b)(5), which requires OSHA to consider the "best available evidence," including the "latest scientific data in the field," and whether OSHA's proposed process of amendment of the generic standard to accommodate new scientific information is valid or whether it denies due process. In this portion of the brief we are addressing the question whether foreclosing consideration of data bearing on the scientific evaluation of a substance is scientific.

1. The AIHC proposal for an Independent Scientific Data Evaluation and Classification Panel

OSHA's error stems in part from the intermixture of the scientific evaluation of the data on a substance with the separate issue as to what regulatory action should be taken. Each question is separate and distinct and the former should precede the latter.

The AIHC proposal for the creation of an independent, unbiased scientific Panel to evaluate the data and its relevance to man is a clear recognition of the fact that evaluation

of the data involves scientific rather than regulatory judgments.^{1/} AIHC proposes that the determination by the scientific Panel be final and binding on the regulator for three reasons: to bring the scientific evaluation to a speedy conclusion, to avoid intermixture of that evaluation with the regulatory determination, and at the same time to provide a basis for judicial review.

The second step in the process is a determination by the regulator of the nature of the hazard -- number of workers exposed and level of exposure -- and a determination as to what action, if any, is warranted based on the hazard evaluation.

AIHC agrees with EPA and Dr. Saffiotti in the statements quoted at the beginning of this section of the brief, that the scientific evaluation should be objective, unbiased and immune from conflicts of interest. For this reason, the selection process for membership in the independent scientific Data Evaluation and Classification Panel proposed by AIHC involves nomination by scientific institutes and associations, with selection of members of the Panel by the National Academy of Science. To assure objectivity, no member of the Panel would be employed by any other executive agency or independent regulatory agency during his term on the Panel, except in an academic, teaching or research capacity. The National Academy

^{1/} A description of the function and operation of the proposed scientific panel, together with a memorandum regarding authority to establish a panel is set out in Exhibit 62 (a copy of which is attached as Appendix C).

would be instructed to screen very carefully for conflicts of interest persons nominated for membership on the Panel who are employed by private industry. A proposed plan for the establishment and operation of the Panel is set out in Appendix C.

The idea of an independent panel is not new. The National Cancer Institute Ad Hoc Committee on Testing for Environmental Carcinogens in its report dated August 31, 1973, recommended the formation of a scientific panel to ensure reasonable standards for evaluation of tests and test results,

"in order to insure, insofar as possible, the validity of the experimental data and the interpretations placed upon them." (Ex. 14 at 4.)

Dr. Epstein also recommended an independent scientific panel, with functions considerably larger than those proposed by AIHC. (Epstein S. 103-105; see also NIOSH S. 7.)

AIHC believes its proposal is better suited to the function of scientific evaluation in this context than the proposals mentioned above. The AIHC proposal will assure consistent application of the best scientific judgment in the identification and evaluation of substances which pose a human carcinogenic risk from exposure in the workplace.^{1/}

^{1/} AIHC has suggested that an independent scientific panel of the stature and quality envisaged might also serve the other regulatory agencies: EPA, CPSC and FDA -- thus, assuring uniformity of scientific evaluation of the data for regulatory purposes. The establishment in the IRLG of a Toxic Substances Data Committee to identify and share data needed by the four regulatory agencies underscores the need for an agency such as the scientific Panel advocated by AIHC to serve as a source of reliable, uniform, scientific information and evaluation to the regulatory agencies. See Ex. 34, 43 Fed. Reg. 7186; Tr. 1418.

2. OSHA's intermixture of scientific and regulatory functions

OSHA's proposal to pre-determine scientific issues by policy decisions is based on a failure to recognize that scientific evaluation of data should be separate from societal decisions which are part of the regulatory process. ^{1/} The intertwinning of the two functions in one regulator creates problems of the kind recognized by EPA in its statement quoted at the beginning of this section. When the two separate processes are combined, the scientists are constrained and the regulator does not have the essential freedom to make the regulatory judgment on the basis of a separate unbiased scientific evaluation. (EPA Intra-Agency Memorandum from Roy Albert, Chairman, Carcinogen Assessment Group, to Andrew Breidenbach, dated November 25, 1977 (API P.H.).)

OSHA's confusion of the regulatory and scientific functions led OSHA to construct its Proposed Regulation on an artificial presumption/rebuttal process which is inconsistent with the process of scientific evaluation. As Dr. Griesemer said "[r]ebut is not a word in our vocabulary." (Tr. 941.)

Under the OSHA conception, positive results in animal tests create the presumption and the scientific evaluation follows as a rebuttal process. Dr. Rall's description of the scientific

^{1/} The IRLG Risk Assessment Work Plan carefully distinguishes the scientific problem on risk assessment from the policy decision as to the level of acceptable risk. See Ex. 34, 43 Fed. Reg. 7195.

evaluation process makes clear that a presumption/rebuttal model does not fit:

"The scientific decision as to whether a chemical has been shown to be carcinogenic in an animal species requires consideration of all aspects of the experiment, including not only the statistics of the number of tumors but also the pathological diagnoses, exposure regimens, health and nutrition of the animals, and many other factors. Once a chemical is established as a carcinogen in an animal species, there follows a presumption of risk to exposed humans, but the precise degree of risk depends on consideration of other factors, including routes of exposure, metabolic pathways, structure-activity relationships, etc. It is difficult to reduce these manifold considerations to a formula." (Dr. Rall S. 13.)

Positive results in animal studies before evaluation establish only that a potential for human risk exists. As both Dr. Upton and Dr. Rall made clear, it is only after the full scientific evaluation is made that a determination as to probable risk to man can be made.^{1/} In his testimony, Dr. Upton also referred to some of the factors which must be considered before

^{1/} The Subcommittee of the National Cancer Advisory Board described the scientific evaluation as follows:

"Quantitative extrapolation from animal studies for the purposes of evaluating human risks entails large uncertainties at the present time. Each case must be individually evaluated, taking into consideration such factors as adequacy of experimental design, statistical significance of the data, dose-response relations, duration of exposure, route of administration, metabolism (including species variations), host susceptibility, co-factors and other modifying factors, and the amount of the material to which humans will be exposed. The criteria for extrapolation may vary depending on the agent in question." NCAB General Criteria at 463.

a conclusion can be reached as to the risk to man:

- Dose response
- Ability of humans to detoxify, metabolize
or excrete the substance
- Mechanism of action and the way the substance
is handled in human tissue
- Adequacy of pathology
- Route of exposure
- Validity of test procedures (Tr. 322-325.)

See also Dr. Griesemer Tr. 936; Dr. Gross Tr. 8320.

OSHA's presumption/rebuttal procedure has turned the whole evaluation process upside down. Until the evaluation has shown that there is a human risk there is no basis for classification for regulatory purposes. OSHA's misunderstanding of the evaluation/extrapolation process is shown by its reluctance to add the fifth "rebuttal criteria": that for some scientific reason the results in animals "are not scientifically relevant to man." 42 Fed. Reg. 54171. When asked whether such evidence should be considered, Dr. Rall gave the unequivocal answer "always". (Tr. 364.) Dr. Saffiotti concurred. (Saffiotti S. 41.) See also NIOSH Tr. 3075; EPA Tr. 2366; and Dr. Gross Tr. 8315-8319.

The Proposed Regulation needs to be re-oriented. Evaluation must take place at the outset, not as an afterthought. Further, the relevant issue is human risk. Until such risk is established after scientific evaluation of all the evidence, there is no basis for regulatory action and categorization of substances. Only when the human risk is scientifically evaluated and presented to the regulator can the regulator assess hazard and reach the

appropriate regulatory conclusion.^{1/}

It is precisely for this reason that AIHC proposed the creation of the Scientific Data and Evaluation Panel. A substance would not be categorized under the AIHC proposal until the evaluation is complete.

B. The Criteria For OSHA Category I Are In Many Instances Arbitrary, Inflexible And Unwarranted

Both OSHA (Category I) and AIHC (AIHC Categories I and II) agree that a substance may be determined to present a carcinogenic risk to man on the basis of human epidemiology or mammalian animal data. There is agreement further that a substance which is a confirmed oncogen in two mammalian species should be subject to regulation as a probable human carcinogen. AIHC also agrees with OSHA that injection site sarcomas and chemical structure do not provide a basis for classifying a chemical.

These are major areas of agreement. There are, however, major areas of disagreement and, as we shall show, the record supports the AIHC Alternative as being the more scientifically sound. We shall discuss each of the areas of disagreement.

1. Human epidemiology

AIHC agrees with OSHA that positive epidemiology is

^{1/} If evaluation follows categorization, a great disservice is done. Not only is the product and the manufacture subject to increased burdens but the public may be unnecessarily alarmed. A serious due process issue arises if materials are categorized and stigmatized as a carcinogen before a reasonable opportunity to present evidence is afforded. (See discussion supra, at 48-51.)

the best evidence that a substance is a human carcinogen; indeed human experience is the only evidence that a material is a human carcinogen. (Dr. Van Raalte S. 12-22.) To underline the significance of this identification in man, AIHC proposed a separate category (AIHC Category I) which includes those substances identified by positive epidemiology as human carcinogens.

There are major differences, however, between OSHA and AIHC concerning the weight or importance of negative epidemiological studies.^{1/} In the Preamble OSHA details the difficulties associated with the design and conduct of epidemiological studies (42 Fed. Reg. 54155-156) and concludes that, as a "practical rather than a theoretical matter, positive animal data should supersede negative human data, in general, because of the inherent defects in such human studies, as pointed out above." Id. at 54161.

The record shows that OSHA for "practical" reasons is disregarding evidence which should be evaluated as a scientific matter with respect to any substance. Perhaps the clearest statement of the role of negative epidemiology is in the Report of the Subcommittee of the National Cancer Advisory Board entitled "General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances." In this very careful report subject to

^{1/} On September 11, 1978, as part of its post-hearing filing AIHC furnished to OSHA a copy of "Guidelines for Evaluation and Use of Occupational Epidemiologic Cancer Studies" prepared by AIHC. A copy of the guidelines is attached as Appendix D.

extensive peer review, the Committee concluded:

"Negative epidemiological data may not establish the safety of suspected materials. Negative data in a given agent obtained from extensive epidemiologic studies of sufficient duration are useful for indicating upper limits for the rate at which a specific type of exposure to that agent could affect the incidence and/or mortality of specific human cancers." NCAB General Criteria at 462.

Dr. Rall agreed with the NCAB as to the appropriate role for epidemiology. (Tr. 366.) Dr. Hoover and Dr. Bates also agreed that a valid negative study could identify the upper boundary of a potential hazard. (Tr. 794; Bates S. 11.) Dr. Berg urged OSHA not to reject a valid negative study. (Tr. 1679.) Dr. Epstein testified that negative studies should be weighed in the regulatory process. (Tr. 1462.) NIOSH testified flatly that "[a] negative epidemiological study should receive the same weight as a positive one but, in either case, this weight is a function of the scientific quality of the research. . . . It is obvious that if well designed and executed negative epidemiological studies are given little weight in scientific decision making, then no industry will conduct them." (NIOSH supplemental answer to OSHA question 5(3); see also Tr. 2954; Dr. Upton Tr. 317-318; AISI Tr. 4662; Dr. Gehring Tr. 4152; and Dr. Gross Tr. 8322; Dr. Robert Morgan written statement at 11 (AIHC P.H.).)

Dr. Morgan testified to a methodology for weighing negative and positive studies. (Tr. 3619-3622.) His statistical methods are set out in his paper. (AIHC P.H.) Thus OSHA has

available statistical methods for weighing positive and negative studies. Other witnesses set out alternative methods of evaluation of positive and negative studies. See, e.g., Hooker Chemical Tr. 4116-4140.

There are physiological and metabolic differences between rodents and man and substances which may be carcinogenic to animals may not be carcinogenic to man. There is evidence in the record that epidemiology can identify substances shown to be carcinogenic in animal tests which do not present a carcinogenic risk to man at the levels to which man is exposed. Dr. Clemmensen and Dr. McLean referred to phenobarbital (Tr. 3553-3556; 4804-4805). DDT^{1/} and saccharin were cited by Dr. Olson (Tr. 3226). Dr. Golberg referred to dinitrotoluene (Tr. 6511-6513), and DDT and aldrin/dieldrin were cited by Dr. Van Raalte (Tr. 3556-3558, Ex. 53) and Dr. Astolfi (S. at 3-5). Dr. Murray also referred to his extensive practical experience with a number of substances (S. 4).

Negative epidemiology can also serve to correct risk estimates based on positive animal data. Perhaps the best example in this record is ethylene dibromide where on the basis of an epidemiological study of 158 exposed workers, EPA was led to modify its risk assessment from exposure to that compound based on positive animal data. (Ex. 43, Tr. 2336; "Risk

^{1/} The NCI announced that its bioassay of DDT in Osborne-Mendel rats and B6C3F1 mice found no evidence of carcinogenicity. 43 Fed. Reg. 46585 (October 10, 1978).

Assessment for Ethylene Dibromide (EDB)," API P.H.) EPA also testified that negative epidemiological data are particularly useful where a positive animal study involves a route of exposure different from human exposure. (Tr. 2383.)

Another example in the record of the use of human epidemiology to adjust or correct a risk assessment based on animal data is the FDA risk assessment of aflatoxin in peanut butter. (Ex. 38.) The FDA relied on epidemiological data in reaching the conclusion that humans are biologically closer to aflatoxin resistant mice than the more aflatoxin susceptible rats. Id. at 3-4. The data were also used to calculate the potential health benefits from an additional reduction in aflatoxin level. Id.

The record does not support OSHA's administrative rejection of negative human studies. On the contrary, the record makes clear that such studies can have significant value.

2. Animal data -- an overview

Perhaps the most concise and clear statement regarding animal data was made by Dr. Rall. He testified:

"I believe that most scientists will be happy to see the introduction of something like Category II, recognizing that some experiments give inconclusive results and allowing us to escape from the dilemma of having to assign all chemicals into 'Yes' or 'No' categories. On the other hand, scientists always feel unhappy about the application of rigid criteria to complex questions. The scientific decision as to whether a chemical has been shown to be carcinogenic in an animal species requires consideration of all aspects of the experiment, including not only the statistics of the number of tumors but also the pathological diagnoses, exposure regimens, health and nutrition of the animals, and many other factors. Once a chemical is established as a carcinogen

in an animal species, there follows a presumption of risk to exposed humans, but the precise degree of risk depends on consideration of other factors, including routes of exposure, metabolic pathways, structure-activity relationships, etc. It is difficult to reduce these manifold considerations to a formula.

On the one hand, there are cases where a single well-conducted experiment giving clearly positive results should suffice to establish a chemical as a carcinogen and to justify stringent measures to reduce occupational exposure. On the other hand, there are cases where two or even three less conclusive positive results would still leave some doubt. The fact is that scientific experiments never give results that are 100% positive, nor 100% negative. Science deals in probabilities, and carcinogenesis bioassays give results that may fall anywhere on a continuous spectrum of probabilities, extending from 2 or 3% at the lowest to nearly 100% at the highest. Division of this spectrum into discrete categories may be necessary for regulatory purposes, but it is necessarily arbitrary from a scientific point of view. Thus the recommendation of a scientist would be to make the criteria for categorization flexible, and to apply as much scientific judgment to each case as is compatible with legal and regulatory requirements." (Rall S. 13-14.)

In addition, OSHA "recognizes that the results of a single study in a single species can be in error." 42 Fed. Reg. 54170. This is an acknowledgement of the more general principle cited by the National Academy of Science in the study "Drinking Water and Health"^{1/} [hereinafter referred to as "NAS Drinking Water Study"] where it noted:

"Any series of experiments will yield false-positive and false-negative results." NAS Drinking Water Study at 27.

^{1/} (NAS 1977). Appendix I to the prepared statement of Dr. Rall.

Dr. Furst discussed at length the problem arising because many tests performed in the past are invalid. Thus early positive tests on a number of substances are not reliable bases for regulatory decisions. (Tr. 6924-6926.)

Dr. Peto explained the statistical possibility that an erroneous positive result can be a matter of chance. (Tr. 2547-2550.) If the confidence level is 95% then there will be one positive study as a matter of chance in twenty studies of the same substance. (Peto S. 5.) See discussion infra, at 143, 163-164. Professor Zeckhauser made a similar explanation. (Tr. 4334.) See also Dr. Robert Morgan's written statement at 5 (AIHC P.H.). Dr. Greisemer did a calculation as to the probabilities of a false positive under conditions of the NCI bioassay, a calculation which has to be made for each study based on the conditions of that study. (Greisemer S. 8-10.)

Thus, the issue at the outset is the degree of certainty that a substance is an animal oncogen. The second question is the degree of certainty that the animal data may be validly extrapolated to man. Unfortunately, OSHA has not disclosed the criteria which it and the IRLG are considering for evaluating animal tests and thus a number of issues remain open and in doubt; they cannot be usefully commented on in this proceeding. It is clear, however, that OSHA should supplement or modify its criteria for Category I with respect to the following:

- maximum tolerated dose studies
- pharmacokinetics, metabolism and DNA repair

- statistical significance
- tumor prone species
- mouse data
- factors affecting test results
- positive/negative results
- single species or two species
- replication
- short term tests
- route of exposure

3. Maximum tolerated dose studies

The Proposed Regulation speaks of positive results in animal studies without any distinction between studies conducted at maximum tolerated dose ("MTD") or at levels more nearly similar to those to which humans are exposed.^{1/} This is a misuse of these animal data for regulatory purposes.

It is important to understand the very limited conclusion which NCI believes can be drawn from an MTD test. Dr.

1/ The NCI Guidelines for Carcinogen Bioassay in Small Rodents defines MTD as follows:

"The MTD should be the highest dose that causes no more than 10% weight decrement, as compared to the appropriate control groups, and does not produce mortality, clinical signs of toxicity, or pathological lesions (other than those that may be related to a neoplastic response) that would be predicted to shorten the animal's natural life span." (NCI Guidelines for Carcinogen Bioassay in Small Rodents, at 14-15, quoted in Dr. Saffiotti S. 9-10.)

The Guidelines limit the amount of a substance in a feeding trial to 5% of the diet. Id. at 18.

Upton explained that the NCI bioassay based on MTD is intended as a screening procedure to identify a substance with the potential to cause cancer, not as a test to measure the frequency of induced cancer at a particular level of exposure.^{1/} (Upton S. 11 Tr. 322; see also Bates Tr. 642-644.) Dr. Greisemer described the results of the program in the same way.^{2/} See also Tr. 4295-4296; Dr. Lijinsky S. 29. NCI's Clearinghouse has itself recognized that the "studies are a screen to provide a yes/no indication of carcinogenicity in animals."^{3/}

Dr. Upton and Dr. Rall both made clear that in order

^{1/} In earlier testimony, Dr. Upton described the NCI bioassay program to the House Interstate and Foreign Commerce Committee as follows:

"The NCI animal bioassay efforts from chemical carcinogens can merely detect the chemical's potential for causing cancer in humans. Its results cannot tell us whether a particular chemical will cause human cancer, but they may alert us to the presumptive risk, and thus serve as a basis for further studies of the chemical in question." (Tr. 322.)

^{2/} "The results of animal experiments conducted with the highest possible doses should not be used for quantitative risk assessments. By themselves, they provide little information about dose response and none that can be directly extrapolated to man. Such experiments, however, do provide a starting point for exploring dose response relationships in the experimental animals." (Dr. Griesemer S. 6; see also Tr. 958-959.)

^{3/} Report of the Clearinghouse on Environmental Carcinogens on the Review of the Bioassay Backlog and Data at 21 (May 1978) (emphasis added) [hereinafter referred to as "Report of the Clearinghouse"] (AIHC P.H.).

to evaluate the human risk additional data are needed.^{1/} (Tr. at 322-325, 487-488.) The NCI multidisciplinary evaluation process, which includes an independent review by the National Clearinghouse for Environmental Carcinogens, was described in detail by Dr. Griesemer. (Tr. 971-977). NIOSH similarly has a full multidisciplinary review of test data before reaching conclusions as to animal carcinogenicity and extrapolation to man. (Tr. 2884-2893, 2895-2898.)

Other witnesses indicated the particular weaknesses of the MTD test as an indication of human risk. Dr. Van Duuren expressed concern that only weight loss was considered by the NCI as a limiting parameter of MTD. He said

"an acceptable and more agreeable maximum tolerated dose is when the animals grow normally and healthy and gain weight normally unless they come down with a tumor." (Tr. 1808; see also Tr. 1814.)

^{1/} In an article by Dr. Rall entitled "Species Differences in Carcinogenic Testing," attached as Appendix E to Dr. Rall's testimony, Dr. Rall set out in tabular form the factors to be assessed as follows:

Table 1

Assessment of Environmental Chemicals for Carcinogenicity
Differences between Test Animals and Man

- I. Sensitivity of laboratory animals as compared to man
 - A. pharmacological differences
 - B. receptor differences
 - C. temporal differences
 - D. size differences
- II. Population differences
 - A. size
 - B. heterogeneity
 - C. selected nature of test population
- III. Environmental differences
 - A. nutritional
 - B. physical
 - C. chemical

He urged that a MTD be selected which did not damage organs or result in metabolic overloading. Dr. Gehring stressed the importance of the fact that repair mechanisms are overwhelmed at high doses. (Tr. 5034-5036, 5131-5132.) Similarly, Dr. McLean testified that large doses can alter metabolic pathways and injure tissues making it difficult to extrapolate from MTD doses. (Tr. 4845-5846.) Dr. Olson also emphasized that MTD can incapacitate or injure organ systems leading, for example, to renal damage as well as neoplastic lesions. (Tr. 3238.) Dr. Olson referred specifically to the MTD bioassay on trichloroethylene where there was evidence of renal and cardiac damage. (Tr. 3244.) Exhibit 83 is a statement by Dr. Bernard Oser, presented to the National Academy of Science committee evaluating saccharin, in which he refers to the organ damage which raised questions about the results of the experiments on saccharin. Similarly, Dr. Furst discussed the consequences of physical damage from an excessive dose. (Furst S. 7-9, Tr. 6931-6932, 6947-6948.)

Dr. Kotin stated that using high dose as an equivalent or substitute for large numbers of animals is "subject to very serious question," since the use of high doses may result in a series of chemical pathways resulting in the formation of end-products with contrasting biological effects. (Tr. 8615, 8716.) High doses, he added, interfere with DNA repair mechanisms as well as change metabolic pathways. (Tr. 8722-8723; see also Dr. Skalsky Tr. 7589-7590.)

Dr. Golberg testified in detail regarding the complexi-

ties of MTD testing. (Golberg S. 3-6, Tr. 6484-6491.) He pointed out the difficulties of choosing the correct MTD -- not too toxic or too low. Id. He called attention to the criteria of the Food Safety Council for selection of MTD:

- "1. Induces no overt toxicity, i.e., appreciable death of cells or organ dysfunction as determined by appropriate clinical, pathological, or biochemical methods.
 2. Induces no toxic manifestations which are predicted to shorten the lifespan of the animals except as the result of neoplastic development.
 3. In two generation studies, is not detrimental to conception rates, fetal or neonatal survival, or postnatal development.
 4. Does not retard weight gain during the sub-chronic test by greater than 10% as compared to control animals.
 5. Takes into consideration metabolic and pharmacokinetic data, and if dose-dependent qualitative or quantitative differences occur, at least one test dose should be set above the metabolic shift (provided the level(s) does not exceed the criteria listed above 1 through 4)."
- (Golberg S. 3-4.)

Thus, Dr. Golberg testified, if the MTD is not selected properly, massive nonspecific tissue damage can result. Id. at 4. This can lead to carcinogenic results by a "secondary mechanism" -- tissue damage. (Golberg S. 4-6, Tr. 6484-6491.) The questionable relevance of a positive result from secondary carcinogenesis was recognized, Dr. Golberg said, by the Food and Drug Administration in the case of selenium and by investigators in the case of anti-thyroid action of substances in rats which have no counterpart in man. (Golberg S. 5-6.)

The IRLG Risk Assessment Group also recognizes the phenomenon of secondary carcinogenesis as a result of stresses to physiological systems of the test animals to the point that the altered physiology itself leads to cancer. (Ex. 147.)

Despite these limitations on data from MTD experiments, the OSHA proposed categorization does not distinguish between MTD and lower dose experiments. This omission is not cured by the "rebuttal" criteria of Section 1910.111(a). If the route of exposure in the animal experiment was different from the route of exposure to man, it must be shown to be "grossly inappropriate", Section 1990.111(a)(2), a term undefined in the regulations. There is no definition of "suggestive" in Section 1910.111(a)(3) nor is there any indication as to how one could demonstrate the data are "totally inadequate" to establish conclusions under Section 1990.111(a)(4). Similarly, "some other reason" is not defined in subsection 5, Section 1990.111(a)(5).

To eliminate this ambiguity with respect to the MTD data, AIHC set out to establish criteria to identify these data and give them the meaning consistent with the NCI description. Thus experiments conducted at excessive doses are placed in Category III in the AIHC Alternative as substances for further testing which may be regulated in the meantime for acute or chronic toxicity other than carcinogenicity. This is substantially the same treatment as for substances OSHA classified in OSHA's Category II.

Criteria to identify excessive dose experiments have

been proposed by the American Conference of Government and Industrial Hygienists before this proceeding began. Since these were independently derived criteria, AIHC adopted them as guidelines for its Alternative. AIHC recognizes that such criteria can be refined to serve the purpose of identifying the MTD bioassay results so that on the basis of such tests substances would be classified in OSHA Category II and AIHC Category III.

4. Pharmacokinetics, Metabolism and DNA repair

The validity of animal tests as a basis for extrapolation to man depends on the similarity between the metabolism of man and the test species with respect to a particular substance. Despite similarities between mammalian species with respect to metabolic processes, -there are also differences. (Dr. Hart Tr. 3491-3492, 3499-3501; Dr. Kotin Tr. 4890-4891, 4908-4909, 8653-8654; Dr. Golberg Tr. 6498, 6511-6514; Dr. Yang Tr. 6799-6827; Dr. Rousch Tr. 4978-4979; Dr. Olson Tr. 3242-3241; Gross Tr. 8320).^{1/} As we have pointed out supra, at 121-123 and 128-131, many witnesses, including Dr. Rall and Dr. Upton, testified that a scientific evaluation of animal data to determine risk to man includes an appraisal of differences in metabolism and pharmacokinetics of the test animal and man. Dr. Albert

^{1/} A recent example of an instance in which an expert body took into account metabolic differences between species in assessing carcinogenicity is a 1978 report of a joint FAO/WHO committee on pesticide residues in food. (Ex. 53.) The committee concluded that aldrin and dieldrin were not carcinogens for man despite certain mouse data to the contrary. The committee discounted the mouse data on the basis of a thorough review of metabolic data. Id. at 11-12.

testified that EPA would evaluate metabolic data. (Tr. 2369.)

Much of the criticism of the relevance of metabolic differences between man and test animals turned on two points:

- 1) little is known about metabolism of substances, and uncertainties are great;
- 2) any delay to secure metabolic data would delay the regulatory processes unreasonably.

There is little doubt that the study of comparative metabolism is a science which has not yet developed to a level which allows careful interspecies analysis. On the other hand, experimenters like Dr. Hart and Dr. Yang make clear that the science of comparative metabolism has made great strides. (Dr. Hart Tr. 3481-3483; Dr. Yang Tr. 6799-6827.) Comparative metabolism provides results which are not only useful now when the data are available, but also holds enormous promise for the future if OSHA and other regulatory agencies recognize its value and encourage development of the data.

A number of witnesses addressed the subject of DNA repair, which is barely referred to by OSHA in the Preamble to the Proposed Regulation. DNA repair can be regarded as a phenomenon having a bearing on thresholds since DNA repair systematically and effectively can overcome deleterious effects of exposure to chemicals. (Dr. Hart S. 14-28, Tr. 3459-3462, 3477-3484; Dr. Skalsky Tr. 7584-7592.) Further, species differences in DNA repair capacity provide a number of insights as to man's ability to repair carcinogenic insults and acti-

vate compounds to their carcinogenic state.^{1/} Dr. Kotin referred to DNA repair as one of the areas in which the most important discoveries of recent years have been made. (Tr. 8752-8753.) In the present context, DNA repair is being discussed in the context of metabolic differences and similarities between animals and man.

Dr. Hart discussed and referred to the literature on the newly developing science of comparative studies of species differences in DNA repair. (Dr. Hart S. 14-28, Tr. 3459-3462, 3477-3482.) This work, like that of Dr. Yang, opens the door to the possibility of identifying the species whose metabolism is closest to man. The experimenter could use these data to select the species whose test results would be more relevant to man and the scientist could use the data in the risk evaluation with confidence. Indeed, Dr. Hart held out the prospect that test systems developed by this emerging science may enable scientists to identify, monitor and indeed quantify exposure of individuals to suspect substances. (Tr. 3473-3476, 3495-3496.)

AIHC joins with Dr. Hart in urging that OSHA encourage the development of data on metabolism and DNA repair. While these data serve a purpose now, their promise for the future is

^{1/} Dr. Hart noted that there was some emerging evidence to support the view that longer-lived species such as man are less able to electrophilically activate substances to their carcinogenic state and better able to repair carcinogenic insults than shorter-lived rodents. (Dr. Hart S. 28.)

great. Any refusal by OSHA, under the guise of administrative determination of scientific issues, which cuts off use of these data in individual substance proceedings can only be described as tragic.

There is an additional aspect of metabolism analysis which should also be noted. As we have pointed out supra, at 133-137, MTD testing may lead to metabolic overloading and organ damage. This in turn can lead to what Dr. Golberg and Dr. Skalsky referred to as "secondary" carcinogenesis. Thus, metabolic analysis can offer new interpretive tools which will enable the scientists to distinguish the "secondary" results whose relevance to human risk may be slight. See Dr. Gehring Tr. 5034-5035, 5186-5191.

Several witnesses have testified that the science of metabolic differences and pharmacokinetics have reached the stage in development where it is reasonable to include the data in mathematical extrapolation models. (Dr. Hoel Tr. 2145-2148; Dr. Peto Tr. 2538-2540; see also Dr. Skalsky Tr. 7590-7591, 7597-7599.)

AIHC does not suggest that OSHA require that metabolic data be available before a risk assessment is made based on animal data. However, in view of the developments in the science of comparative metabolism and the development of tests which promise relatively speedy metabolic comparisons (Dr. Hart Tr. 3473-3476, 3495-3496; Dr. Yang Tr. 6802-6807, 6811-6812; and Dr. Skalsky Tr. 7591-7602), OSHA should encourage the development and use of metabolic data

- (1) to select the test animals whose metabolism of a particular substance is extrapolatable to that in man;
- (2) to evaluate test results obtained when comparative metabolism data was not examined before selecting the test species or strains;
- (3) to evaluate test results for "secondary" carcinogenesis;
- (4) in the qualitative and quantitative risk assessment and in determining the permissible exposure limit.

Certainly it would be unreasonable for OSHA to exclude such comparative metabolic data from evaluation when such data are available.

5. Statistical significance

OSHA recognizes in the definition of "toxic substance" in Section 1990.102 that statistical significance is an important ingredient in the evaluation of animal and human data. However, that recognition is ambiguous in two respects and should be clarified.

In the Preamble to the Proposed Regulation, OSHA comments:

"5. Statistical significance. For an adequate demonstration of carcinogenicity of a substance in test animals, it is generally necessary that the increased incidence of neoplasms in one or more of the experimental groups should be evaluated statistically for significance (NCAB Report, p. 5; MRAK Commission Report, p. 465)." 42 Fed. Reg. 54162.

However, in the Proposed Regulation OSHA refers to statistical significance only with reference to decreased latency, and does not refer to statistical significance in connection with induc-

tion of tumors except by implication. The definition of "suggestive" in Section 1990.102 refers to results which are not statistically significant, thus implying that statistical significance is required for Category I purposes.

Moreover, as Dr. Saffiotti points out, the reference to statistical significance is ambiguous in that it fails to specify the value of the statistical significance required. (Saffiotti S. 25.) Dr. Saffiotti would solve the problem of this ambiguity by dropping rather than defining the term "statistically significant" and would rely on the much vaguer word "cause" as implying "adequate criteria". (Saffiotti S. 25-26, Tr. 908.) Rather than clarifying the meaning of the regulation, Dr. Saffiotti's proposal would introduce greater uncertainty and vagueness.

We believe it is clear from the record that "statistical significance" is an essential element in the evaluation of any animal or human study. Indeed one of the criteria of a valid study is that the results are statistically significant. See NCAB General Criteria at 463; Dr. Rogers Tr. 8565-8566. Thus, to leave out the evaluation criterion of statistical significance is "unscientific" in the sense that an essential part of the evaluation process is ignored.^{1/}

^{1/} Statistical significance is discussed in a memorandum from John Gart to Albert Kolbye dated July 11, 1978. (AIHC P.H.) See particularly the discussion therein of the Bonferroni correction factor. See also articles following the referenced memorandum in the AIHC post-hearing filing.

AIHC urges OSHA on the basis of this record to include statistical significance in its proposed criteria for the conduct and evaluation of animal and human studies. Whether or not a single common level of confidence should be selected in advance for all studies is controversial. Thus, NIOSH recommends that "statistically significant" be defined as "at the 95% confidence level" without any distinction as to the use to be made of an evaluation at that level of confidence. (NIOSH S. 5.) Dr. Peto, on the other hand, testified that significance levels of .05 (95% confidence level) should not be taken as strong evidence of carcinogenicity. (Tr. 2517.)

It is AIHC's view that it is not only important to retain the concept of statistical significance; it is also important to recognize that the level of statistical significance selected for a particular evaluation depends on the use to be made of the data. If the 95% level such as NIOSH recommended were to be selected by OSHA, OSHA should recognize three points relevant to that selection:

- (i) Since 1/20 of the tests may be random false positives under this confidence criterion (Dr. Peto Tr. 2548), confirmatory evidence becomes a matter of prime importance.
- (ii) There will be circumstances where a much higher level of confidence is required, as is discussed in a succeeding section of this brief. See infra, at 163-164.
- (iii) Different levels of statistical significance may be relevant in evaluating an experiment which produces rare tumors as distinguished from one which induces an increase in the tumors to which a tumor prone species is subject.

Dr. Upton made clear that statistical significance is not solely reliance on a bare arithmetic concept. We need to know also, he said, whether the controls behaved in accordance with the characteristics of the strain (Tr. 284); and the test results must be significant in light of the overall scientific evaluation of the test. Id. As Dr. Shimkin notes "[s]tatistics must make biological sense first and not be a mathematical exercise." (Report of the NCI Clearinghouse at 74, AIHC P.H.)

6. Tumor prone species

The record makes clear that one of the significant developments in cancer research has been the development of inbred strains of rodents. As several witnesses testified, these strains have been created to make the rodents more "sensitive" and hence better detectors of carcinogens. However, there have been consequences of this development which are not reflected in the Proposed Regulation.

The inbreeding has resulted in a varying but high degree of spontaneous tumor incidence. Dr. Jandl referred to the catalogues which enable the experimenter to select animals with particular spontaneous tumor rates. (Jandl Corrected S. 26-30.) He pointed out that inbred strains are not only less resistant to carcinogenesis (e.g., defects of DNA repair mechanisms, detoxifying mechanism, etc.) but, in addition, may be defective in their ability to excrete, to metabolize and may have other non-specific defects which increase their susceptibility to potentially injurious agents. Id. at 34-36. Dr. Van Duuren testi-

fied that he preferred random-bred animals with a low incidence of spontaneous tumors because results of inbred species, particularly the mouse, are difficult to interpret. (Tr. 1814-1815.)

We have pointed out above the need for OSHA to clarify what is meant by the term "statistical significance". With respect to the tumor prone strains, this becomes a matter of prime importance. Dr. Griesemer's testimony as to the statistical probabilities of a false positive in an NCI bioassay underlines the need for a separate calculation where conditions of the experiment are different from the NCI bioassay. Dr. Olson referred to the unexpected changes in the basal spontaneous tumor rate in the mouse, thus making a mouse experiment in such a strain difficult to interpret. (Tr. 3239; see also Dr. Crampton S. 5.) Nor can there be assurance that randomization will cure the defect. Since the qualities which lead to the change in the basal rate are not known, it is difficult to randomize for such a change. (Dr. Olson Tr. 3241-3245.) Dr. Furst testified that if the controls develop more spontaneous tumors than is "normal" for the particular strain, the experiment should be regarded as invalid.^{1/} (S. 22-23.)

^{1/} Thomas R. Fears, Robert E. Tarone, and Kenneth C. Chu, "False-Positive and False-Negative Rates for Carcinogenicity Screens" 37 Cancer Research, 1941-1945, 1941 (1977) (Attachment to Statement of Dr. Griesemer):

"The implementation of a number of chemical carcinogen screening programs has been accompanied

(Footnote continued on p. 146)

One of OSHA's witnesses, Dr. Robert Squire, gave consideration to the significance for classification purposes of whether the tumors induced were rare (i.e., tumors with spontaneous rates in controls of no more than 5%) or were an increase in spontaneous tumors. (Squire S. 27-28.) Dr. Squire concluded:

"The categories, as they are currently defined, are too restrictive and do not allow for consideration of all pertinent evidence. The determination of potential carcinogenicity must allow for some degree of judgment -- both in determining what data is relevant and in objectively evaluating that data. I fear that otherwise we may on occasion regulate on the basis of false positives and false negatives. I propose therefore that the categories be redefined to allow a greater role for scientific judgment in assessing the evidence." Id. at 27.

Based on these comments, Dr. Squire made suggestions for modification of the OSHA Category I criteria which would take into account the difference (in evaluation terms) of induction of rare

(Footnote continued from p. 145)

by the observation that some screens might have high false-positive error rates. With designs presently used at the National Cancer Institute and historical spontaneous tumor rates based upon control animals in previous experiments, we compute upper bounds on the false-positive error rates for several screening strategies. False-positive results are much less likely to occur at tissue sites with low spontaneous tumor rates; hence the site at which a significant tumor increase occurs is important. There is danger in relying solely upon the finding of statistical significance without incorporating biological knowledge and corroborative evidence such as the presence of a dose-response relationship or experimentally consistent results in different species or sexes. A report by the National Cancer Institute Carcinogenesis Program demonstrates these concepts." (Emphasis added.)

tumors as compared to an increase in spontaneous tumors. Id. at 27-28.

Dr. Dubin stated he would not use a strain with a 25% spontaneous tumor incidence. (Tr. 1188.)^{1/}

Nowhere in its classification system does OSHA take into account the consequences of the physical and genetic defects of the inbred strains of rodents.^{2/} If a scientific evaluation panel of the kind proposed by AIHC were adopted, these factors could be evaluated in the appropriate scientific atmosphere.

7. Mouse data

In addition to the problems presented by tests conducted on tumor prone species discussed above, there are special problems with reference to the mouse which deserve discussion.

Dr. Crampton and Dr. Grasso testified as to the extensive analysis they have made of published mouse data under the auspices of the British Industrial Biological Research Association. See Tr. 6557-6568, and publications listed in Ex. 138. Drs. Crampton and Grasso concluded that the mouse is a satisfac-

1/ For an interesting analysis of spontaneous tumor incidence in NCI bioassay animals, see letter from Thomas Cameron to Eric Schwartz dated September 13, 1978 and Report of the Clearinghouse at 84 (AIHC P.H.). Of particular interest is the comparatively high incidence of spontaneous tumors in mice at the lung (11.0) and the liver (19.7) and the comparative increase over time for these two sites. See also analysis of mammary pituitary and testes tumors for certain rat strains.

2/ The influence of environmental factors on incidence of tumors in inbred mice is discussed by Dr. Heston in a post-hearing statement. (Ex. 224-G.)

tory test animal if actual malignancy is induced by exposure to a chemical. Id. However, they have raised doubts as to the validity for extrapolation to man of four types of mouse tumors:

- (i) Lymphomas which are associated with a virus which is activated in a manner not found in man;
- (ii) Hepatomas to which the mouse is particularly prone and which can be induced by dietary changes and stress;
- (iii) Pulmonary adenomas which develop spontaneously because of genetic factors; and
- (iv) Mammary tumors which are associated with a virus not found in man. Id.

Similar objections as to mouse data were raised by Dr. Butler (Tr. 5384-5386, 5400-5401) and Dr. Vesselinovitch (Tr. 5391-5397). Dr. Butler offered as support for his views a monograph edited by himself and Dr. Paul Newberne of MIT on an international workshop called to address the problem of mouse hepatic neoplasia. Dr. Vesselinovitch offered into evidence a recent NAS analysis of data relating to the pesticides heptachlor and chlordane which validated a number of the views expressed by Dr. Crampton and Dr. Grasso with respect to the mouse. (Dr. Vesselinovitch Tr. 5390-5392.)

Two international peer groups meeting under the auspices of the International Agency for Research on Cancer ("IARC") have also recently had occasion to evaluate certain mouse data.

A reprint of an article which appeared in Cancer Research, April, 1978, entitled "Evaluation of the Carcinogenicity of Chemicals: A Review of the Monograph Program of the

International Agency for Research on Cancer (1971-1977)" by Dr. Tomatis and others was attached as an appendix to the statement of Dr. Tomatis filed in this proceeding. In that article Dr. Tomatis notes that the IARC Monograph program had been criticized for failing to assess human risk of exposure to carcinogens (id. at lines 350-362), and as a consequence an ad hoc working group was convened jointly by IARC and the World Health Organization in October 1977 "to update and revise the criteria on which carcinogenicity of chemicals to humans and/or experimental animals is assessed and on which the evaluation of the possible carcinogenic risks that they may represent for humans is made." Id. at lines 363-369. As a result of the deliberations of the committee, the changes made in the Preamble were described as follows:

"While it was recognized that no adequate criteria are presently available to interpret experimental data on carcinogenicity directly in terms of their carcinogenic potential to humans, it was also noted that extrapolation to a possible human risk can be reasonably approximated by utilizing data from appropriate animal tests. These data, however, may represent different degrees of evidence, this drawback being mainly due to our present insufficient knowledge of the mechanisms of carcinogenesis. Thus it was tentatively agreed that the carcinogenicity data may represent strong evidence of carcinogenicity when they indicate the unquestionable production of malignant neoplasms or 'weak evidence' when they solely indicate the appearance of neoplastic lesions such as lung adenomas or hepatomas in mice. In the presence of appropriate experimental carcinogenicity data and in the absence of adequate human data, it is reasonable to regard chemicals for which there is strong evidence of carcinogenicity as if they were carcinogenic to humans. Chemicals for which there is weak

evidence of carcinogenicity in experimental animals will, in general, require more experimental and epidemiological investigation." Id. at lines 381-402 (emphasis added).

A second ad hoc group was convened by the IARC earlier this year to review the work of the first ad hoc group. (Dr. Griesemer Tr. 926-927.) The revised criteria as they are to be published in IARC Monograph 17 appear in Exhibit 135. In this second peer review in a scientific rather than adversarial atmosphere, the criteria were discussed as follows:

"The term 'carcinogenic risk' in this IARC MONOGRAPH series is taken to mean the probability that exposure to the chemical will lead to cancer in humans.

Many chemicals induce both benign and malignant tumors; few instances are recorded in which only benign neoplasms are induced by chemicals that have been studied extensively. Benign tumors may represent a stage in the evolution of a malignant neoplasm or they may be 'end-points' which do not readily undergo transition to malignant neoplasms. If a substance is found to induce only benign neoplasms in experimental animals, the chemical should be suspected of being a carcinogen and requires further investigations.

* * *

In general, the evidence that a chemical produces tumors in experimental animals is of two degrees: (1) sufficient evidence of carcinogenicity is indicated by the production of malignant tumors; and (2) limited evidence of carcinogenicity reflects the qualitative and/or quantitative limitations of the experimental results.

* * *

In the present state of knowledge, it would be difficult to define a predictable relationship between the dose (mg/kg bw/day) of a parti-

cular chemical required to produce cancer in test animals and the dose which would produce a similar incidence of cancer in humans. The available data suggest, however, that such a relationship may exist, at least for certain classes of carcinogenic chemicals. Data that provide sufficient evidence of carcinogenicity in test animals may therefore be used in an approximate quantitative evaluation of the human risk at some given exposure level, provided that the nature of the chemical concerned and the physiological, pharmacological and toxicological differences between the test animals and humans are taken into account. However, no acceptable methods are currently available for quantifying the possible errors in such a procedure, whether it is used to generalize between species or to extrapolate from high to low doses. The methodology for such quantitative extrapolation to humans requires further development. (Ex. 135 at 15.)

* * *

Evidence for the carcinogenicity of some chemicals in experimental animals may be limited for two reasons. Firstly, experimental data may be restricted to such a point that it is not possible to determine a causal relationship between administration of a chemical and the development of a particular lesion in the animals. Secondly, there are certain neoplasms, including lung tumors and hepatomas in mice, which have been considered of lesser significance than neoplasms occurring at other sites for the purpose of evaluating the carcinogenic risk of chemicals to humans. Such tumors occur spontaneously in high incidence in these animals, and their malignancy is often difficult to establish. An evaluation of the significance of these tumors following administration of a chemical is the responsibility of the particular Working Group preparing the individual monograph, and it has not been possible to set down rigid guidelines; the relevance of these tumors must be determined by considerations which include experimental design and completeness of reporting.

Some chemicals for which there is limited evidence of carcinogenicity in animals have

also been studied in humans with, in general, inconclusive results. While such chemicals may indeed be carcinogenic to humans, more experimental and epidemiological investigation is required.

Hence, 'sufficient evidence' of carcinogenicity and 'limited evidence' of carcinogenicity do not indicate categories of chemicals; the inherent definitions of those terms indicate varying degrees of experimental evidence, which may change if and when new data on the chemicals become available. The main drawback to any rigid classification of chemicals with regard to their carcinogenic capacity is the as yet incomplete knowledge of the mechanism(s) of carcinogenesis." *Id.* at 21 (all footnotes omitted)(italics in original, double emphasis added).

Thus, two separate international peer review committees of the IARC have identified specifically as "weak" or "limited" evidence of carcinogenicity two of the mouse lesions whose weight and relevance Dr. Crampton and Dr. Grasso questioned. Both peer groups concluded that such lesions in the mouse were merely an indication that further investigation was required and not sufficient evidence for classification of a substance as a human carcinogen.^{1/}

We urge that on this record the Proposed Regulation should be amended to make clear that certain mouse data do not satisfy the criteria of OSHA Category I. Evaluation of these

^{1/} Another recent report raising questions about the relevance of mouse liver data is the report of the December 1977 meeting of a joint FAO/WHO expert committee. The committee concluded that, for the compound in question, "[c]ompared to other animal species, [the mouse] reacts rather anomalously and the mouse, therefore, may not be an appropriate model for man in this case." (Ex. 53 at 12.)

data is strictly a scientific matter. No policy decisions with respect to these data are warranted.

8. Factors affecting animal test results

In addition to the problems presented by tumor prone species, there are a number of other factors which can have a bearing on the outcome of an experiment. Dr. Furst testified that animal tests can be manipulated to give positive results. (Tr. 6932-6933, Furst S. 25; see also Dr. Roe S. 67, 74.) Dr. Furst spoke of inattention to diet and dietary deficiencies, to contamination of the test agent or diet,^{1/} to variations in the test agent, and hormonal stress, as factors which could influence the outcome of the study. Id; see also Dr. Kotin Tr. 4893-4894,

1/ The question of nitrosamine contamination in diet fed animals in NCI's bioassay program recently received considerable attention at an American Chemical Society (ACS) meeting. See W. Leary, "Nitrosamine, in Animal Feed May Affect Tests for Cancer", Washington Post September 13, 1978 (AIHC P.H.) The paper presented at that meeting concludes as follows:

"The highest NDMA level found was 52 ppb in the new National Institutes of Health open formula rat and mouse ration.

* * *

The presence of appreciable levels of so toxic an animal carcinogen as NDMA in the diets of laboratory animals which are being used for long-term carcinogenesis studies represents an awkward problem, particularly when possible cancer causing compounds are being tested at low levels. We recommend that the N-nitrosamine level of the control diet be reported in future carcinogenesis studies."

(Footnote continued on p. 154)

4911-4912. The bias may not be intentional but rather simply the result of error in design or conduct of the experiment.

Dr. Golberg testified that because of the complexities of selecting an MTD which does not produce tissue toxicity (other than carcinogenesis), tests are sometimes run with fluctuating dose levels. (Golberg S. 3, Tr. 6494-6495.) He cautions that evaluation of such test results should be examined with great care and preferably be redone with a valid protocol. Id.

Dr. Squire discussed the particular problems of hormone carcinogenesis and the possibility of experimental manipulation:

"Hormone carcinogenesis will be an issue of major concern under these proposed regulations. Hormones represent an unusual class of carcinogens and they require special regulatory attention. Hormones may not be carcinogens in the classical sense of being initiators; rather, they may act as promoters with dose-dependent, reversible cellular effects. Furthermore, in some cases, because of the fundamental differences between species in endocrine and reproductive physiology, test animal results may not be relevant to the human situation. The FDA Toxicology Advisory Committee on the Carcinogenic Risk of Antipsychotic Drugs (FDA 1977) concluded a discussion on the findings of mammary carcinogenesis in test animals with the following comments:

A. By using the rats and mice and manipulating variables associated with ovarian function and prolactin production, it is

(Footnote continued from p. 153)

D.H. Fine et al., "N-nitroso Compound Impurities in Consumer and Commercial Products", presented at the American Chemical Society Meeting September 11, 1978, at 2, 3 (AIHC P.H. (Supplemental 9/25/78)).

possible to design experiments that would demonstrate either a positive or negative carcinogenic effect or a protective effect against mammary tumor induction.

B. It is, therefore, inappropriate to consider the studies under review according to their design or whether mammary cancer was or was not induced.

C. There is, at present, insufficient evidence to extrapolate from mice and rats to humans with respect to the role of prolactin in human mammary carcinogenesis.

D. The rodent studies are not relevant to determination of the magnitude of human risk from mammary cancer.

E. The relevance to humans of rodents or other models requires additional pharmacological and physiological studies.

The present classifications require estrogenic substances to be Category I. I question whether estrogens used in drug formulations should be categorized and regulated in the same way as vinyl chloride, bis(chloromethyl)ether, and other confirmed occupational carcinogens."
(Dr. Squire S. 30-31.)

Dr. Roe and Dr. Olson discussed in some detail the impact of caloric intake on the cancer incidence in rodents. (Dr. Roe S. 31-41; Dr. Olson S. 16-19.) Differences in caloric intake significantly affected the incidence of tumors, with restrictions on caloric intake markedly reducing the tumors. Id. Dr. Roe referred particularly to a pathogen-free colony of random-bred Swiss mice established by Imperial Chemical Industries, Ltd. ("ICI") in England. The colony established in 1960 had a natural tumor incidence of 10%. Ten years later on the same diet and under the same conditions the spontaneous tumor incidence had risen to 80%. When an experiment was performed

in which the diet was reduced slightly in one group of test animals from 5.8 grams (ad libitum) to 5 grams per day, there was an 8 fold reduction in tumor incidence before the animals were 18 months of age in the animals on the restricted diet. (Dr. Roe S. 33-34.)

A subsequent life time experiment by ICI on both mice and rats indicated that dietary restriction extended the average life span of the animals. In addition, despite the fact that most of the difference in survival occurred after 18 months -- the period when tumors are most likely to arise -- the overall incidence of tumors in the animals on a restricted diet was significantly less. (Dr. Roe S. 35-39.)

Dr. Roe cautions against assuming that caloric intake alone was responsible. An animal on a restricted diet tends to consume its food quickly and be without food until the next ration. Ad libitum fed animals nibble throughout the day. As a result, the bacterial flora in the gut of the animals differ. In addition, the strain of looking at an empty food basket can induce a stress in the animals on restricted diet. (Dr. Roe S. 34.) Thus, unless close attention is paid to caloric intake by the experimenter, the results could be misleading.

Dr. Roe also points out that laboratory animals are left in an environment which results in unnatural hormonal status. (Dr. Roe S. 42.) Temperature, number of animals per cage, and lack of exercise have been shown to have an influence on the induction of tumors. Id.

Finally, we noted supra, at 148 that rodents are sensitive to viruses which are not oncogenic to man. Dr. Roe discusses at some length the prevalence of these tumor viruses in rodents. (Dr. Roe S. 62-65.)

Thus, depending on the level of confidence, the tumors induced in the treated animals as compared to the controls could be a matter of chance or diet. It could also be due to activation of a virus ^{1/} or to hormonal imbalance or other mechanisms not relevant to man.

Since OSHA has not disclosed the criteria it is considering with respect to the conduct and evaluation of animal tests, it is not possible to know whether OSHA will take into account the factors referred to above in evaluation of the test results. AIHC submits that any sound evaluation must take into account these factors which influence the outcome of animal studies. As Dr. Kennedy pointed out, no conclusions should be drawn from a poorly designed test. (Tr. 521-522.) For the same reasons it is imprudent to act on the basis of a single animal study without adequate confirmatory evidence. See discussion infra, at 162-166.

9. Positive/negative results

In the Preamble to the Proposed Regulation, OSHA discusses the relevance of negative and positive results in animal species. 42 Fed. Reg. 54161. OSHA concludes that positive

^{1/} See V. Riley et al, "The LDH virus: An Interfering Biological Contaminant," Science (AIHC P.H.).

results should generally supersede negative results because of the insensitivity of the animal studies. OSHA should re-examine this proposed administrative determination in light of the testimony in the record.

OSHA's statement as to positive and negative results is stated in terms of tests of equal soundness from an experimental point of view. Id. There is, however, a general recognition that tests are of varying quality and, as many witnesses pointed out (e.g., Dr. Griesemer Tr. 930; Dr. Furst Tr. 6924-6926, 7159-7160), the tests in the literature are recognized to be of very uneven quality. See discussion supra, at 128-131. Thus, OSHA's administrative determination is based on an assumption as to validity which is essentially unrealistic.

Indeed, as Dr. Golberg pointed out in his testimony, analysis of the results of tests under the NCI Bioassay program point to a wide variety in quality; even though these tests are more uniform than most, many are defective for a variety of reasons. (Ex. 113 at 3-5, Table II; Tr. 6487-6492.) He concluded:

"I know that changes have been made in an effort to correct some of these deficiencies. Nevertheless, the heritage of just this one program has provided a record of hundreds of tests whose results cannot be taken at their face value for automatic decisions on carcinogenic potential. For purposes of assessment of risk to man, the full data forthcoming from each test will need careful evaluation by appropriate experts who will consider them in the context of all the available information on the compound in question, not solely on the basis of

the test results forthcoming from the carcinogenesis bioassays." (Golberg S. 3.)

Thus, negative studies may raise questions as to the validity of positive results. (Kimbrough Tr. 1795-1796.) A careful analysis of negative and positive results may show that the studies are not inconsistent. (Dr. Hoel Tr. 2159-2160.) However, it is also possible that the positive result was random depending on the level of confidence required in the statistical analysis of the results (see supra, at 143), or that such a result may be an artifact of the design or conduct of the test (see supra, at 153-157). None of the witnesses were willing to exclude examination of negative data to provide administrative convenience. Indeed, Dr. Furst took the position that if a substance is positive in one species but negative in others, much less stringent regulation is warranted. (Tr. 6929-6930 S. 20; see also Dr. Roe S. 68.) In a paper filed as an exhibit to his written statement, Dr. Morgan discussed in detail the statistical analysis which can be used to determine the probability of carcinogenesis when there are numerous tests, some positive and some negative. (AIHC P.H.) See also "Guidelines for Evaluation and Use of Occupational Epidemiologic Cancer Studies" (AIHC P.H.), Appendix D hereto.

While as an administrative matter it may be convenient to reject negative results in the face of a positive test, the record demonstrates that any such conclusion is inconsistent with the scientific evaluation process.

10. Single species or two species

Generally it is AIHC's position that in a regulation

of this kind where interspecies extrapolation is made, it is sound to have as basic criteria for OSHA Category I and AIHC Category II the requirement that the substance be shown to be carcinogenic in two mammalian species. The basic uncertainties in animal data discussed in the preceding sections of this brief point to the conclusion that it would be unwise as a general matter to rely on a single test in a single species for a generic classification scheme.

There is an additional compelling reason for requiring tests in two species. As Dr. Saffiotti said, one cannot exclude the possibility that a carcinogenic response is species specific. (Tr. 857-858; see also Dr. Lamm Tr. 4598; Dr. Kotin Tr. 8679-8680.) Dr. Rall pointed out that a substance may affect one species but not another. (Tr. 486.) While such an event may be rare, there are numerous instances cited in the record where a substance is oncogenic to one species or strain, but not to another. The differences go both ways. Arsenic may be carcinogenic in man, but not in rodents. The reverse situation also has been shown. There has been no demonstration that DDT, aldrin/dieldrin or phenobarbital cause excess cancer in man. See discussion of negative epidemiology, supra, at 127.

Indeed, the possibilities of species differences are sufficiently real that the NCI bioassay calls for the screening test to be conducted in two species to reduce chances of a false negative. The same reasoning leads to the possibility that rodent data in one species gives a false signal of human risk

because of metabolic or other differences between man and the rodent. (Dr. Rall Tr. 391, 487-488; Dr. Meselson Tr. 1542; see supra, at 127, 137-141.) These differences between man and animal are not taken into account when testing to determine whether a substance is an animal carcinogen. (Dr. Griesemer Tr. 935.)

Differences between man and the rodent are particularly apparent when man is compared to the tumor prone rodent species, especially the mouse. A test with a sick, genetically defective animal subject to the unusual stresses of the test conditions raises particularly difficult problems of evaluation. Moreover, substances may be activating viruses in animals which are not oncogenic in man. See discussion, supra, at 148.

Finally, there are differences in sensitivity to substances between species and strains in a single species. (Dr. Peto Tr. 2674-2565; Dr. Kotin Tr. 8679-8680.) Both in extrapolating to man and particularly in quantifying the risk, a more reliable and accurate evaluation can be made if data from two species are available.

Since a regulatory decision in most cases is a \$100 million plus decision (Benzene \$500 million, Vinyl Chloride \$200 million plus), it is important that the agency act on the best information for making such a decision. The fact that a substance is not carcinogenic in one of two species is a signal that other differences in response may be found. Man may respond the way the animal in the negative test reacted.

AIHC is not suggesting that OSHA do nothing during the

period while a second test is being conducted, nor does AIHC suggest that OSHA await a comparative metabolic analysis before taking regulatory action when there are positive results in a single species. To the contrary, under AIHC Category III the agency might take action to lower exposure pending the development of more complete data.

The single test exception. During the hearings a number of witnesses suggested that OSHA was too conservative and should be willing to regulate a substance on the basis of a single positive animal test. Such statements usually referred to a "well conducted" or a "well designed and conducted" test and commonly the test was described as "clearly positive". E.g., Dr. Rall Tr. 386-387, 448; Dr. Bates Tr. 631. NIOSH testified that there may be an "exception" to the requirement that a test result be replicated when "highly significant results are obtained in an adequately conducted and biologically appropriate test." (Tr. 3030.)

Discussion of this proposed reliance on a single positive test can be assisted by reference to the statement of Dr.

Rall:

"The fact is that scientific experiments never give results that are 100% positive, nor 100% negative. Science deals in probabilities, and carcinogenesis bioassays give results that may fall anywhere on a continuous spectrum of probabilities, extending from 2 or 3% at the lowest to nearly 100% at the highest. Division of this spectrum into discrete categories may be necessary for regulatory purposes, but it is necessarily arbitrary from a scientific point of view. Thus the recommendation of a scientist

would be to make the criteria for categorization flexible, and to apply as much scientific judgment to each case as is comparable with legal and regulatory requirements." (Dr. Rall S. 13-14.)

He also said:

"On the one hand, there are cases where a single, well-conducted experiment giving clearly positive results should suffice to establish a chemical as a carcinogen and to justify stringent measures to reduce occupational exposure. On the other hand, there are cases where two or even three conclusive positive results would still leave some doubt."
Id.

Dr. Peto has probably the most complete comment on the problem of reliance on a single test. (Dr. Peto S. 13; Tr. 2548-2551.) He pointed out that in most experiments the separate incidence of tumors at different sites is independently documented and some of the many significance levels will be less than $p = 0.05$ by chance. In his testimony he elaborated on the random chance of a positive result when the confidence level is 0.05. In his statement he concluded:

"... for a single animal experiment to be convincing without such support, a P-value of well under 0.01 (perhaps even 0.001) should usually be required. Unless this policy of requiring rather extreme P-values is adopted, an unacceptably large number of misleading results will emerge by chance alone." (Dr. Peto S. 13) (emphasis added).

Thus, the reliance on a single positive test is highly qualified by those witnesses who addressed the subject.

Amplifying somewhat on Dr. Peto's argument, one might naively assume that a statistical finding of significance at the 5% level indicates that there is only one chance in 20 that the

data is "false positive". If, however, 10 or more criteria are applied to the same set of data, the probability that at least one criterion will appear to be statistically significant is no less certain than the toss of a coin. Should 20 criteria be applied, there is a high probability that at least one will be found statistically positive. The blind application of multiple criteria to the same set of data without recognition of this mathematical truth is bound to place OSHA in an untenable position. Using OSHA's own criterion of relying on a single positive test without reference to the total body of scientific knowledge of a given material, one can demonstrate that any substance is carcinogenic merely by repeating the same test frequently enough.

In addition to the statistical criterion suggested by Dr. Peto, AIHC believes that OSHA should press for comparative metabolic data when it is proposed that regulation be undertaken on the basis of a single animal study. See discussion supra, at 137-141. The AFL-CIO acknowledges the importance of these comparative metabolic data when it proposes that a substance be regulated upon a showing that it is metabolized in man into a metabolite which has been shown to be carcinogenic. (AFL-CIO S. 6.) The same reasoning leads to the conclusion that a showing of metabolic differences between man and the test animal are equally relevant and should be evaluated when such data are available. The fact that such data are being developed experimentally should encourage OSHA to press for such data, particularly when regulation on the basis of a single test is being considered.

However, AIHC believes that the issue of regulation on the basis of a single test may be largely an academic one. It is very unlikely that information other than a bare test result will not be available regarding the substance in question and that OSHA would have to decide whether to act on the basis of this test result alone. It is for this reason that AIHC has proposed that any regulatory action based on a single test should be outside the classification scheme and be handled as a regular administrative proceeding under Section 6 of the Act. OSHA would not be precluded from using an ETS in such a proceeding if there were a basis for the statutory findings. To include this probably highly unusual situation in the classification scheme would require separate treatment and separate criteria which would add complexities of interpretation.

It is AIHC's suggestion that the Proposed Regulation should not refer to the single test exception nor foreclose OSHA's beginning a regular administrative proceeding to establish standards in reliance on the results of a single animal study meeting the extraordinary criteria described above.

By definition, animal studies which do not meet the single test exception criteria discussed above have a lower confidence level and the results give a lower probability of risk to man.^{1/} In Dr. Rall's scale of probabilities, these tests

^{1/} The NCAB Subcommittee on Environmental Carcinogens states:

"The extrapolation of experimental carcinogenicity data to the human situation is strengthened by obtaining results in more than one species." NCAB General Criteria at 463.

fall in a range that does not approach the 100% level and range down to the 2-3% level. AIHC believes that it is both prudent policy and consistent with the scientific evidence in the record to require confirmation of such tests. AIHC urges adoption by OSHA of a positive test in a second species as the sounder basis for confirmation.

11. Replication

Section 1990.110(a)(3) of the Proposed Regulation provides that a substance shall be classified in Category I on the basis of a positive test in a single species "if those results have been replicated in another experiment." We have addressed in the previous section the reasons why we believe it is important for OSHA, except in rare cases, to require positive results in two species before classifying a substance in Category I. It is unsatisfactory to attempt to argue away the need for a two-species test by confirming "replication" of a positive test in a single species. Should OSHA, despite the soundness of the view to the contrary, decide to rely on a single species, OSHA should require at a minimum the confirmation of "replication". (NIOSH S. 5.)

However, a number of problems remain. As NIOSH points out, the meaning of replication as used in the regulation is not clear. Id. at 5-6. Does OSHA mean replication by the same researcher; with the same strain; at the same dose levels; in the same laboratory; with separate controls? NIOSH proposed:

"We would hope that where researchers have the option, such confirming experiments would be

performed in a different laboratory, perhaps using a different sex or strain of test animal, additional dose levels, or a different route of administration to provide for a more comprehensive and accurate measurement of the substance." Id. at 6.

Dr. Weinstein and Dr. Furst made similar recommendations (Tr. 2249-2250, 6928), as did Dr. Squire (Dr. Squire S. 29).

Dr. Squire stated:

"OSHA should make explicit what it means by the replication of a finding in a second experiment. I suggest that the second experiment be defined as one conducted at a different laboratory by a different investigator, or one conducted at a different time." (Squire S. 29.)

As NIOSH points out, "simple replication using the exact same study design may not be particularly definitive." (NIOSH S. 5-6; see also Dr. Crampton S. 8.) It is imperative that if OSHA decides, incorrectly AIHC believes, to rely on replication of a test as confirmatory evidence, OSHA should clarify the ambiguous term "replication". The protocol or study design should be clearly defined. AIHC urges that OSHA adopt the NIOSH recommendations and require replication in a separate laboratory with separate controls. AIHC also recommends that a different strain and additional dose levels be required. If the route of administration is not the same as the route of exposure of humans, the replication should use the same route of exposure as humans:

"To properly evaluate carcinogenicity the suspect agent should be administered to animals by the same route as humans are exposed, namely, via the lungs, gastrointestinal tract, dermally and in some cases intramuscularly, intradermally and subcutaneously." (NIOSH response to Q. 31.)

12. Short term tests

Section 1990.110(a)(4) of the Proposed Regulation provides that a substance will be classified in Category I on the basis of positive results in a single mammalian species "if those results are supported by short term tests." The term "short term tests" is defined in Section 1990.112 as follows:

"'Short-term tests' includes, but is not limited to, positive results in more than one of the following assays for: (1) the induction of DNA damage and repair ; (2) mutagenesis in bacteria, yeast, or Drosophila melanogaster; (3) mutagenesis in mammalian somatic cells; (4) mutagenesis in mammalian germinal cells; or (5) positive results in tests for neoplastic transformation of mammalian cells in culture."

Not adequate confirmatory evidence. The end result of most short term tests is mutagenicity, not carcinogenicity. Mutagenesis and carcinogenesis are not biological equivalents. (NIOSH Answer to Q. 28; Dr. Kotin Tr. 8703.) Dr. Griesemer pointed out that the end point of long term animal experiments is the induction of cancer and that cancer is discovered by methods used by a pathologist. (Tr. 981.) Thus, any use of short term tests in connection with the Proposed Regulation must depend on a relationship between the different end points achieved and the difference between carcinogenicity and mutagenicity.

In August 1977, the Chemical Industry Institute of Toxicology ("CIIT") conducted a workshop on "Strategies for Short-Term Testing for Mutagens/Carcinogens" at which more than 50 ex-

perts from academia, government and industry met to assess the status and usefulness of the principal short term tests and to produce a set of practical guidelines for dealing with the results of those assays. (Golberg Tr. 6527-6528; Golberg, Transcript of Proceedings.)

The meeting produced agreement on several points.

Dr. Golberg described the results of the workshop as follows:

"Our own efforts to date, coupled with familiarity with the work of others in this field, lead to the conclusion that short-term tests have potential value but require a great deal of further investigation and validation before they can be considered reliable indicators of carcinogenic or mutagenic potential. Moreover, it is fundamental that no single test of this sort can yet be relied upon exclusively to reach a conclusion regarding carcinogenesis/mutagenesis. A battery of tests should be used, but there is no general consensus of the components of the battery, nor are all the necessary, currently available tests adequately developed and validated for inclusion in such a battery." (Golberg S. 2.)

Dr. Golberg in summarizing the conclusions of the workshop, cautioned against such statements as: "The results of the test correlate 90 per cent with animal carcinogenicity studies." Such statements are misleading because the measure of correlation can be manipulated by judicious selection of the chemicals tested. (Tr. 6533-6534.)^{1/} The workshop cautioned

^{1/} Dr. Marvin Legator (University of Texas), a participant in the CIIT workshop, criticized generalized statements that a system was "validated":

"Legator: In the literature, although we often refer to the 90% figure, in terms of correlation

(Footnote continued on p. 170)

against commonly accepted deviations from defined procedures in the conduct of the tests. Id. Only one test, the Ames test, has published criteria for the conduct and evaluation of the test. (Tr. 1521-1522.) However, in the course of the CIIT workshop, Dr. Marvin Legator of the University of Texas outlined "some serious limitations" to the Ames test because of questions about the S9 (activator) portion of the test:

- "(1) Inability to standardize in vitro activation systems.
 - (a) Insufficient understanding of the relationship of enzymes to mutagenicity.
 - (b) Variability with the amount of S9 fraction used.
 - (c) Variability with chemical inducer of liver microsomal enzymes, administered beforehand to the animal.
- (2) Inability of in vitro systems to detect promutagens activated by means other than by liver microsomes."

(Footnote continued from p. 169)

between the Salmonella system, and known carcinogens, the truth of the matter is that one can find in the literature correlations ranging from 44% to 90+%. In our own analysis of these studies, we can, in part, attribute the variation in correlation either to the number of classes or number of compounds studied. The high correlations reported in the literature are probably not valid for one or more of the following reasons: (1) Failure to establish uniform and meaningful criteria for what is a carcinogen, (2) Failure to establish meaningful criteria for the response in the Salmonella system, (3) Failure to code samples, and (4) Using literature studies to derive correlations." (Proceedings II 27.)

In the same workshop, there was a report of the NCI validation process by Dr. Virginia Dunkel who is in charge of of the NCI validation program (Dr. Golberg Tr. 6531)):

"b. Status of NCI validation studies. While it is anticipated that many of the proposed assays will become useful short-term tests, it must be remembered that substantial work remains to define systems and correlate results for most of the assays. Dr. Dunkel described the correlation studies that are in progress by the NCI:

Dunkel: The in vitro carcinogenesis program is currently both developing and validating a series of microbial and mammalian cell systems. The microbial assays include (1) mutagenesis in Salmonella typhimurium strains and E. coli WP2; and (2) DNA repair in E. Coli and pol A+ and pol A- strains. The mammalian cell assays include mutagenesis in the L5178Y mouse lymphoma cell line at the thymidine dinase locus; (2) DNA repair in primary rat liver hepatocytes; and (3) transformation in systems using BALB/c 3T3 mouse cells, early passage Fischer rat embryo cells, Fischer rat embryo cells infected with Rauscher leukemia virus, hamster embryo cells either treated directly in cell culture or exposed to the chemical transplacentally and then placed in culture and liver and skin epithelial cells. As now structured approximately 90 compounds will be tested blind in all assays.

Cline: How long will it be before we know the results of the study?

Dunkel: It may be two years before we know the results of the blind studies." (Proceedings II-27-28.)

Dr. Ray discussed the standardization and validation process:

"c. The standardization and validation process. Dr. Ray expressed the concern of many that some tests could be brought to regulatory status before they were sufficiently characterized.

Ray: I'd like to make a few comments on the standardization and validation process. Currently, a

number of mutagenicity assays have been proposed for use in safety evaluation studies to evaluate chemicals already marketed, or being made ready for introduction into man's environment. However, many of these assays have not been validated to the extent where their sensitivity and reproducibility have been established. Further, even the most thoroughly studied procedures, such as the Ames test, have not been analyzed to the extent that positive and negative compounds can be identified routinely by rigorous tests of statistical significance. Also, there are many forms of these assays, depending upon the laboratory involved. Clearly, the time has come to establish procedural standards in the performance of each assay. Especially so, since regulatory agencies are now considering guidelines which may impose requirements for these tests. Criteria must be established which define the validation process itself, and statistical methods adopted which permit all test substances to be evaluated by the same set of rules. Unfortunately, some tests are being made ready for adoption before a critical analysis has been performed on the available literature data. Correlative studies are being quoted in which one or more components lack standards of performance. Because short-term mutagenic tests hold considerable promise for identifying both the mutagenic and carcinogenic potential of chemicals, it is mandatory that they be developed in a rigorous scientific manner. The good which can come from the application of these assays will be hampered considerably if the standardized validation process is not adopted soon. This process not only validates individual assays, but must involve inter-test results and a comparison to relevant human experience when available. When one considers the cost of programs which are being proposed for implementation using these assays, surely the critical analysis suggested here will, in the long run, save millions of dollars and prevent many useless debates over test utility and reliability. A program which includes critical analysis of existing data, establishment of standard procedures, identification of proper statistical models and which requires examination of a minimal number of chemicals of diverse chemical classes for validation purposes, should be implemented, I believe, at the international level. This program

should be so constructed as to engender participation and support from industrial, government and academic organizations, and have a broad base of information exchange." (Proceedings II 28-30 (emphasis added).)

In response to OSHA question 28 calling for a full scientific discussion of short term tests, NIOSH stated:

"For scientific purposes, justification of the use of short-term tests for the purpose of screening thousands of chemicals for their suspected carcinogenic activity and for the purpose of prioritizing these chemicals for long-term animal bioassay, appears to be adequate. However, the original intent for utilization of these tests was only for these two objectives and not for use of a confirmation test for long-term animal bioassay.

It is inappropriate at this time to attempt to substitute a short-term test for a long-term animal bioassay for at least two reasons:

- (1) Validation procedures are not complete and correlations between the test systems have not been adequately performed; and
- (2) The outcome of the short-term tests as compared to the long-term bioassay are not biological equivalents. In one case the end point is mutagenesis, in the other case, carcinogenesis. However, one (mutagenesis) may often cause the other (carcinogenesis)."

The Clearinghouse on Environmental Carcinogens adopted a resolution on October 31, 1977 describing the role of short term tests as follows:

"Notwithstanding the limitations imposed by the current state-of-the-art, there still appears to be an immediate, practical application for short-term assays. At present, microbial mutagenicity assays offer a rapid and inexpensive approach to acquire information useful in selecting and ranking chemicals for long-term carcinogen bioassay. The concomitant or sequential use of

DNA repair and mammalian cell transformation systems should enhance the selection process. Results from these short-term assays should eventually provide important information that may be useful in assisting in the evaluation of marginal data on carcinogenicity.

It is recognized that short-term assays are still in the process of evaluation. Further, it is acknowledged that short-term assay data, by themselves, are inadequate to define the carcinogenicity or lack of carcinogenicity of a given chemical. Still, it is the sense of the Clearinghouse on Environmental Carcinogens that short-term assays are sufficiently developed to provide information useful in the selection of chemicals for carcinogen bioassay and in their later evaluation. It, therefore, is recommended that the Carcinogenesis Testing Program take the necessary measures to integrate short-term assays into the chemical selection and experimental design processes in a manner consistent with the tone and tenor of this resolution." Clearinghouse Resolution at 2.

There was also general agreement that short term tests alone are not a sufficient basis at the present time for regulatory of a substance as a carcinogen. (Dr. Upton Tr. 289-290; Dr. Griesemer Tr. 946; Dr. Epstein Tr. 1412; Dr. Fishbein Tr. 1868; Dr. Brusick S. 16, Tr. 5011-5012; Dr. Lijinsky S. 25; Dr. Revson Tr. 4220; Dr. Skalsky Tr. 7592-7593; Dr. Lawrence Tr. 778-7779; Mr. Gibbons Tr. 7389-7390; Dr. Gottesman Tr. 7487.) EPA in its Interim Cancer Policy treats mutagenicity and in vitro cell transformation as only "suggestive evidence" of carcinogenicity. 41 Fed. Reg. 21404 (May 25, 1976). Similarly, the Subcommittee of the National Cancer Advisory Board concluded:

"At present none of the short term tests can be used to establish whether a compound will or will not be carcinogenic in humans or experimental animals. Positive results obtained in

these systems suggest extensive testing of the agency in long-term animal bioassays, especially if there are other reasons for testing." NCAB General Criteria at 463.

The same reasons which lead to the conclusion that short term tests alone are not a satisfactory basis for regulatory action, point to the conclusion that the tests should not be used as confirmatory evidence in the regulatory process. The tests are in various states of development with agreed criteria for conduct and evaluation of the tests only in the case of the Ames test. (Dr. Meselson Tr. 1471; Dr. McCann Tr. 1551-1552.) However, Dr. Golberg testified that the workshop last year concluded that even the Ames test was not sufficiently standardized. (Tr. 6550.) All of the tests are currently being validated. (Dr. Upton Tr. 289-290; Dr. Rall Tr. 369; IARC Ex. 135 at 26-27.)^{1/} The in vitro tests produce false positives and false negatives. (Dr. Bates Tr. 6455.) The mechanism of mutagenesis is believed

^{1/} Dr. Valcovic of NIEHS described the state of validation of such assays in an article entitled "Mutagenesis Testing Program", 20 Environmental Health Perspectives 253 (1977)(AIHC P.H.) as follows:

"Until recently, mutagenicity testing was done on preselected compounds in a manner in which the testing laboratories know the identity of the substances under test and the 'expected' results, i.e., positive for compounds selected because of their carcinogenicity and negative for food additives. There is no completed study in which substances were tested blind using a standardized protocol. Also, little attention has been placed on reproducibility and variability within and between laboratories. These aspects are currently under investigation in microbial systems by NCI but the results will not be available for 1-2 years."

to be related to the mechanism of carcinogenesis in the cases where the substance (or metabolite) bind to the DNA. However, there is still great uncertainty about the mechanism even when DNA damage is involved and about whether the same mechanism is involved in mutagenesis and carcinogenesis.

Dr. Greisemer concluded:

"I think it is premature to attempt to utilize short term data as a very large component of the decision making process. At present I do not find short term tests very useful." (Tr. 946.)

Dr. Epstein concluded that the Ames test should not be used for regulatory purposes. (Tr. 1412.)

The Commissioner of the Food and Drug Administration summarized in the decision banning chloroform the reasons why short term tests are not an appropriate basis for regulatory action:

"Regarding the reported findings of Uehleke in the 'Ames study,' which used a bacterial system, the Commissioner recognizes that rapid progress is being made in the development of mutagenicity test systems. He is aware of a number of reports indicating a mutagenicity-carcinogenicity correlation using these test systems. However, a number of 'false positives' as well as 'false negatives' have been observed in these test systems. Such tests using non-mammalian systems have not been validated for establishing correlations and are not considered an appropriate basis for regulatory action." 41 Fed. Reg. 26842, 26843 (June 29, 1976).

The conclusions of the International Agency for Research on Cancer are similar. (Ex. 135 at 26, 27.)

Criteria and need for battery. If in the future short term tests are sufficiently validated and a correlation between the test results and carcinogenesis is established, criteria should be set out and a full battery of tests should be required.

Dr. McCann recommended that a full battery of tests should be used. (Tr. 1562.) Dr. Fishbein recommended that substances should produce positive results in two types of tests before reliance can be placed on them: microbial and mammalian cell tests. (Tr. 1888.) Dr. Brusick also recommended that a battery of at least four tests would be necessary to reach a conclusion regarding genetic activity. (Dr. Brusick S. 15, Tr. 5014.) The CIIT workshop also recommended a battery of tests. (Workshop Proceedings II 3-4.) Dr. Furst testified that a single positive test was not enough. (Tr. 6932.) Dr. Squire recommended that at a minimum a battery of tests be used. (Dr. Squire S. 9.)

Dr. Rall urged OSHA to adopt criteria and guidelines for short term tests and recommended the "Guidelines" produced by the DHEW Committee to Coordinate Toxicology and Related Programs^{1/} as a source for those criteria and guidelines. (Tr. 368 369, 457-462; see also Dr. Saffiotti Tr. 943-945.) The evaluation criteria used by Litton Bionetics are set out in the contract forms for the various tests. (Ex. 136.)

^{1/} DHEW Committee to Coordinate Toxicology and Related Programs, "Guidelines for the Laboratory Use of Chemical Substances Posing a Potential Occupational Carcinogenic Risk" (August 1978) (AIHC P.H.).

Both Dr. Peto (Tr. 2593) and Dr. Brusick (S. 15, Tr. 5014) urged that, if OSHA is going to use results of short term tests, criteria of mutagenicity should be established. Otherwise experimenters will reach different conclusions from the same data and consistent results cannot be achieved. Criteria to evaluate inconsistent results in in vitro tests also need to be established. The Environmental Defense Fund also favored establishment of guidelines as criteria for short term tests. (Tr. 7348.)

The IARC similarly recommended a battery of tests and criteria for their use:

"The present state of knowledge does not permit the selection of a specific test(s) as the most appropriate for identifying potential carcinogenicity. Before the results of a particular test can be considered to be fully acceptable for predicting potential carcinogenicity, certain criteria should be met: (1) the test should have been validated with respect to known animal carcinogens and found to have a high capacity for discriminating between carcinogens and noncarcinogens, and (2) when possible, a structurally related carcinogen(s) and noncarcinogen(s) should have been tested simultaneously with the chemical in question. The results should have been reproduced in different laboratories, and a prediction of carcinogenicity should have been confirmed in additional test systems. Confidence in positive results is increased if a mechanism of action can be deduced and if appropriate dose-response data are available. For optimum usefulness, data on purity must be given.

* * *

An adequate assessment of the genetic activity of a chemical depends on data from a wide range of test systems. The monographs include, therefore, data not only from those already

mentioned, but also on the induction of point mutations in other systems, of structural and numerical chromosome aberrations, including dominant lethal effects, of mitotic recombination in fungi and of sister chromatid exchanges." (Ex. 135, at 27 (footnotes omitted).)

The CIIT workshop discussed supra, at 168 similarly recommended a battery of tests and urged that criteria be established for those tests.

As noted in the earlier section, we believe short term tests should be used only as screens for further testing and prioritization of future testing. When short term tests have been validated and shown to be accurate predictors of carcinogenesis:

1. The tests which can be used should be identified and supporting validation supplied.
2. The battery to be used should be specified.
3. Criteria for the tests and for evaluation of results should be established.
4. Replication of the tests should be required.
5. Before relying on short term test results, an evaluation by geneticists and toxicologists with experience in short term tests should be performed.

13. Route of exposure

The record is clear that route of exposure is an essential element to be considered in the extrapolation of human risk from animal data. (Dr. Upton Tr. 324-325; Dr. Rall Tr. 485; Dr. Kennedy Tr. 579-580; Dr. Griesemer S. 8, Tr. 957-958; Dr. Claus S. 40; Dr. Gross Tr. 8315-8317, 8323.) Perhaps the most complete statement regarding the significance of the

route of exposure in the evaluation of animal data and the extrapolation to human risk was by NIOSH:

"Another consideration in evaluating a predictive model for human carcinogens is the route of administration. Although the route of administration might not be important in determining whether or not an agent is carcinogenic for research purposes, it is important from a preventive health standpoint. To properly evaluate carcinogenicity, the suspect agents should be administered to animals by the same routes as humans are exposed, namely, via the lungs, gastrointestinal tract, dermally and subcutaneously. The latter conditions would apply, for example, to those agents such as metal fragments that might become embedded in skin or muscles. In industrial exposures to particulates, oral exposures are frequently as important as pulmonary exposures in as much as the particulates that are trapped in the upper respiratory tract are usually swallowed." (NIOSH first answer to Q. 31; see also answer to Q. 1(a).)

Many witnesses (Dr. Rall Tr. 485; Dr. Van Duuren S. 5; Dr. Claus S. 40) expressed serious reservations concerning the use of animal data except for qualitative purposes where the route of exposure of man is different from that in an animal experiment.^{1/} The importance of the same route of exposure for humans and in animal experiments was emphasized by the NAS:

"Before extrapolation is attempted, considerable attention must be given to the appropriateness of the experimental data. Bioassay procedures must be of high quality in order to avoid

^{1/} NIOSH points out the difficulties when the route of exposure used in an animal experiment is different from that by which man is exposed in the workplace. However, such a test may yield valid qualitative data. In evaluating human risk from a different method of exposure each case would have to be evaluated individually. (NIOSH first answer to Q. 6 and second answer to Q. 6(b)).

misleading risk estimates. Also oral administration of the carcinogen is necessary because we are concerned with estimating the risks associated with drinking water consumption." Id. at 48-49 (emphasis added).

The scientific reservations as to the risk assessment for man when the human route of exposure is different from that in animal experiments means that OSHA should be reluctant to regulate where the animal data are not relevant to the human route of exposure until there is, as Dr. Rall proposed, a risk assessment defining as precisely as possible the magnitude of the risks and defining the uncertainties in the estimate. (Tr. 456-457.)

C. OSHA Is Correct In Rejecting Structure Similarity And Physical Induction Such As Injection Site Sarcomas As Bases For Regulatory Action

1. Molecular structure or similarity

In the Preamble to the Proposed Regulation, OSHA sets out the reasons for concluding that structure similarity between known carcinogens and an untested substance does not provide a basis for regulating the untested substance as a carcinogen. 42 Fed. Reg. 54168. OSHA's conclusion is supported by the record. ^{1/}

While two witnesses thought that investigators with years of experience and research could arrive at a conclusion

^{1/} The issue is not whether structure similarity would be considered along with other data in evaluating a particular substance. Numerous witnesses listed structure as one factor to be included in the evaluation. The issue discussed here is whether structure similarity is a valid basis for classification.

that on the basis of structural similarity a compound is likely to be carcinogenic (Drs. Van Duuren and Fishbein Tr. 1825-1828), ^{1/} a number of witnesses testified that structure similarity is not a valid basis for classifying a substance as a carcinogen. E.g., Dr. Lijinsky Tr. 1048; Dr. Meselson Tr. 1526-1528; Dr. Weinstein S. 9; NIOSH answer to Q. 29; Dr. Hart Tr. 3467-3468; Dr. Furst S. 27-29, Tr. 6932, 6943; Dr. Holmberg S. 4.

In EPA's Interim Cancer Policy chemical structure is included in the risk assessment among "ancillary reasons which bear on judgments about carcinogenic potential." 41 Fed. Reg. 21404 (May 25, 1976). Others described structure similarity as useful for prioritization for further testing. (Dr. Rall Tr. 446; Dr. Weinstein Tr. 2273-2275; NIOSH answer to Q. 29.)

2. Injection site sarcomas and other instances where induction due to physical causes, e.g., implants, stones or calculi

In the Preamble, OSHA discusses the reasons why particular routes of exposure should not be considered applicable to man: injection site sarcomas and other instances where there is reason to believe the tumors that occurred may not be due to a specific effect of the compound, e.g., bladder implant. 42 Fed. Reg. 54164. We believe the record supports the conclusion that tumors induced by the physical damage at injection site or the physical action from an implant do not provide an adequate

^{1/} According to Dr. Fishbein "hundreds" of chemicals could be identified as probable carcinogens on the basis of structure similarity. (Tr. 1829.)

basis for extrapolating the risk to man. (NIOSH answer to Q. 6 (b); Dr. Rall Tr. 484; Dr. Furst Tr. 6925.) The same reasons should apply to other instances where the induction is from physical causes such as stones or calculi. (Dr. Rall Tr. 455; Dr. Roe S. 68; Dr. Grasso S. 3.) The same principles should lead to rejection of test results where the lesion is due to "secondary carcinogens" and organ damage, supra at 133-137.

Conclusion

It is apparent from this discussion that the scientific knowledge of carcinogenesis is far from complete; it is also apparent that significant advances in knowledge are being made almost daily. It behooves OSHA, therefore, to structure a regulation so that it acts always on the basis of the "latest available scientific data in the field." 29 U.S.C. § 655(b)(5).

It is apparent, moreover, that carcinogenesis is a complex area and that no simple or simplistic statement can serve as a satisfactory summary for regulatory purposes. Prior to the issuance of its Interim Cancer Policy, EPA published first 9, later 16, and later 17 "principles" of carcinogenesis drafted by Dr. Saffiotti. These "principles" were widely criticized and on November 10, 1975, the NCAB subcommittee discussed these "principles" which Dr. Saffiotti described as "a sort of personal and somewhat informal summary of state of the art of points that

had been previously debated and discussed in great detail."^{1/}

The NCAB subcommittee, after discussion, concluded that the "principles" were not "an adequate definition of a carcinogen for use by a regulatory agency for regulatory purposes."^{2/}

The 17 principles rejected by the NCAB subcommittee bear a striking resemblance to the "Policy Determinations" and "Concepts" on which OSHA relies in the Preamble. Appendix E of this brief is a tabular comparison of the "principles" and

^{1/} Proceedings National Cancer Advisory Board Subcommittee, November 10, 1975, at 23. (These proceedings were filed with NACOSH at the time the draft of this Proposed Regulation was being considered-by NACOSH.)

^{2/} A motion was made by Dr. Weinstein with references to the "principles" as follows:

"DR. WEINSTEIN: Is a motion in order?

DR. SHUBIK: Yes.

DR. WEINSTEIN: I would move that the draft by Dr. [Umberto] Saffiotti, titled 'Statements on Principles of Chemical Carcinogenesis in Relation to the Evaluation of Carcinogenic Hazards,' be considered as a useful background for discussions on the definition of a carcinogen, but that we do not feel that it is an adequate definition of a carcinogen for use by regulatory agencies for legislative purposes. This Committee should, therefore, consider de novo the problem of deriving a definition of carcinogen and that if necessary a subcommittee of this group, recruiting additional expertise, be appointed for this purpose.

DR. SHUBIK: Thank you. Do we have a second to that?

DR. NELSON: I second it.

DR. SHUBIK: All in favor?

(There was a chorus of "Ayes".) (Proceedings at 28.)

the "determinations" and "concepts". Two examples illustrate the similarity.

<u>Principle</u>	<u>Policy Determination or Concept</u>
12. "Since many benign tumors can develop into cancers, for the purposes of carcinogenicity testing there is no valid distinction between the induction of benign or malignant tumors and they should be considered synonymous."	OSHA "proposes to place as much weight on an experiment in which only benign tumors are observed, as upon experiments in which both malignant and benign tumors are induced." (42 Fed. Reg. at 54163-54164)
15. "There is no scientific basis for the existence of a "no effect" level for carcinogens. In principle no dose of a chemical carcinogen is too small to induce tumors in susceptible individuals."	"[A] no-effect or threshold level may theoretically exist for any specific carcinogen. As yet, however, there is no satisfactory scientific basis for determining such levels for any given population. Thus, as has been proposed any human exposure to a carcinogen . . . would be considered by OSHA to present a potential cancer risk as a policy matter." (42 Fed. Reg. at 54174)

Elizabeth Anderson, Executive Director of EPA's Carcinogen Assessment Group, in a recent speech traced the history of EPA's 17 principles. She explained that the agency had decided to establish a Cancer Review Group with a two-step approach to regulation, rejecting the 17 principles because "[s]uch a simplified approach received broad and general criticism by the scientific community, a substantial part of the private sector and the Congress."^{1/}

^{1/} E. Anderson, "Risk Assessments and Regulatory Approaches to Carcinogens", presented at the Symposium on Risk/Benefit Decisions and the Public Health Third FDA Office of Science Symposium, at 2 (February 15, 1978).

The reasons which lead to the rejection of the EPA principles as a basis for regulatory action are equally applicable to the "Policy Determinations" and "Concepts", which bear a striking similarity to the rejected "principles".^{1/}

AIHC submits that its Alternative minimizes the errors outlined above and offers a reasonable, workable basis for regulatory action based on the "latest available scientific data in the field."

^{1/} For the same reasons the "principles" proposed by NRDC (NRDC S. 18-19) which were patterned on the EPA principles do not provide an adequate basis for regulatory action.

IX

THE PROPOSED REGULATION WOULD IMPERMISSIBLY "FREEZE" THE PRESENT STATE OF RELEVANT SCIENCE BY FORECLOSING RECONSIDERATION OF THE VALIDITY OF THE CLASSIFICATION SYSTEM AND OTHER POLICY ISSUES IN RULEMAKINGS ON INDIVIDUAL SUBSTANCES, AND BY ERECTING UNREASONABLE BARRIERS TO OSHA'S OWN CONSIDERATION OF RELEVANT NEW SCIENTIFIC DEVELOPMENTS

"I feel that the criteria proposed by OSHA for classifying chemicals into Categories I, II and III are somewhat too rigid, and that the preamble introducing them does not adequately reflect the complexity of the processes involved in chemical carcinogenesis. . . . If regulations are to be rational, they should be firmly based on up-to-date scientific knowledge." (Dr. Farber S. 1-2.)

Section 6(b)(5) of the Act requires that OSHA formulate standards dealing with toxic materials or harmful physical agents "on the basis of the best available evidence," including "the latest available scientific data in the field." 29 U.S.C. § 655(b)(5). Despite this statutory mandate, OSHA proposes, once its generic standard is promulgated, to foreclose consideration of scientific and other evidence by preventing the introduction in subsequent individual rulemakings of evidence concerning the "validity of this classification system and most other policy determinations made in this proposal, including the procedural structure intended to be followed." 42 Fed. Reg. 54154. Such a "freezing" of scientific and other evidence as of the date of the promulgation of the generic standard is clearly improper and a violation of the Act.

Moreover, by foreclosing discussion of the underlying issues in subsequent Section 6(b) rulemakings, OSHA will deny to

affected parties their legal right under both the Administrative Procedure Act and the due process clause of the U.S. Constitution to comment upon these issues as they relate to specific toxic substances. This issue is discussed more fully in the portion of this brief dealing with OSHA's lack of authority to establish generic rules where an inflexible set of regulatory consequences automatically flow from the classification. See discussion supra, at 44-51.

It is particularly inappropriate to preclude consideration of newly available evidence or data in a field which is undergoing as rapid an evolutionary change as the study of the causes and mechanisms of cancer. The testimony of a number of witnesses explored the ongoing or expected development of major advances in carcinogenesis research and theory. ^{1/} See, e.g., Dr. Hart Tr. 3457-3458, 3468-3469; Dr. Snyder Tr. 4696-4697, 4734-4735; Dr. Yang Tr. 6799-6827; Dr. Rogers Tr. 8585; Dr. Kotin Tr. 8751-8753. Many of these witnesses testified that it would be improper, unwise, and indeed, arbitrary and capricious, for OSHA to ignore these developments by foreclosing consideration of the factual premises and policy grounds on which its generic standard is based; premises and policies

^{1/} In addition to those areas of research discussed earlier in the brief, one such area is immunotherapy research. See J. Kuahenbul and J. Remington, "Belligerent Blood Cell: Immunotherapy and Cancer," Human Nature 52 (January 1978) and W. Stockton, "A New Clue in the Cancer Mystery," The U.S. Times Magazine 18 (April 17, 1978) (AIHC P.H.).

which even if valid today could become obsolete in the very near future. See, e.g., Mr. Gideon Tr. 3050-3051; Mr. Dominguez Tr. 3924-3925; Mr. Janous Tr. 4114-4115; Mr. Woolrich Tr. 4231, 4296-4298; Dr. Synder Tr. 4683-4684. The need for consideration of all relevant evidence in the development of a rational approach to the regulation of carcinogens was constantly stressed during the course of the hearings, as was the need for providing a means by which the regulatory scheme can be modified to include new information as it becomes available. See, e.g., Dr. Hart Tr. 3469, 3484; Dr. Thorpe Tr. 4582; Dr. Swanson Tr. 4597-4598; Dr. Synder Tr. 4696-4698.) Glen Schweitzer admonished OSHA (Tr. 7112) to heed the words of caution issued by the court in Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976):

"By its nature, scientific evidence is cumulative: the more supporting . . . evidence available, the more likely the accuracy of the conclusion." 541 F. 2d at 38.

However, OSHA proposes not only to foreclose consideration of newly available evidence presented by employers subject to regulation in the individual rulemakings conducted pursuant to Section 6(b) of the Act; it also intends to erect formidable barriers to its own ability to take advantage of improvements or developments in relevant learning by preventing modification in proceedings on individual substances of the scientific principles administratively adopted in this generic rulemaking proceeding. Mr. Wrenn testified that the objective of the Proposed Regulation is to identify and establish generic policy

determinations. (See Wrenn S. 8, 9, 12 for examples of "generic" policy determinations.) When the policy considerations of a "generic" nature are made, no evidence contradicting those administrative conclusions would be admissible in individual substance rulemaking. Thus, for example, in a subsequent rulemaking strong evidence of a threshold would not be considered; the policy determination that there is no safe level would prevail. (Mr. Wrenn Tr. 148-149, 151.) EPA, on the other hand, testified that "we believe that opportunity should always be available for presentation of substantial genuine new evidence." (EPA S. 9, Tr. 2361.) In contrast, under the OSHA proposal such new evidence would only form the basis for a petition to amend the generic regulation, but until that amendment was made, the evidence would not be receivable despite its strength or validity. (Wrenn Tr. 148-151.)

This time-consuming and ponderous mechanism for incorporating into the regulatory standards newly available evidence or data concerning heretofore unresolved issues surely does not satisfy OSHA's obligation to premise its standards on "the best available" and "latest available" evidence in the field.

The AIHC proposal, on the other hand,

"proceeds on the basis that if a categorical approach is desirable and necessary to enable OSHA to deal effectively with potential carcinogens, there is still no statutory authority--or need--to preclude interested parties from presenting evidence, with respect to any particular chemical, to counter any conclusion of carcinogenic risk that might otherwise be

drawn on the basis of the general principles
on which the OSHA proposal intends to rely."
AIHC Alternative at 29.

AIHC's Alternative, unlike the Proposed Regulation, provides a mechanism by which all relevant evidence of new scientific developments will be considered in determining appropriate categorization and regulatory responses to particular substances. The Data Evaluation and Classification Panel recommended by AIHC could, from time to time, propose revisions of the categorization scheme or its criteria, in light of the latest scientific advancements, newly available information, or knowledge derived from experience with the categorization scheme. In addition, reasonable public notice of intent to make such changes would be provided, in accordance with the Administrative Procedure Act, as well as an opportunity for interested persons to comment on such changes. See AIHC Alternative at 60-61. Further, the AIHC Alternative would permit any interested party to petition the Panel for reclassification of a chemical on the basis of significant data or scientific learning not considered at the time of prior classification. See AIHC Alternative at 69-70. The absence of provisions such as these in OSHA's proposal will prevent the agency from complying with its statutory obligation to consider the "best available" and "latest available" scientific evidence.

X

CATEGORY IV SHOULD BE ELIMINATED BECAUSE OSHA LACKS
STATUTORY AUTHORITY TO CREATE IT AND BECAUSE IT IS
OTHERWISE UNWISE AND INAPPROPRIATE

The Proposed Regulation would require OSHA to publish a Category IV list of substances which meet its definition of toxic substance but which are "not found in the American workplace."

It is our view that OSHA lacks statutory authority to create such a list and that it would serve no useful purpose within the context of this rulemaking. Furthermore, the arbitrary inclusion of substances on such a list could unnecessarily inhibit technical innovation, cause unwarranted damage to foreign industry, establish a new non-tariff barrier to chemical trade and potentially affect adversely our relations with foreign countries.

This view was expressed by numerous participants in these proceedings (e.g., AIHC International Committee comments) including NIOSH, which stated in its written submission:

"We do not recommend a Category IV in this classification system since U.S. workers would not have the potential for exposure to these agents and hence they would fall beyond the regulatory responsibility of OSHA as we understand it. Should these substances enter the U.S. workplace, they would automatically become eligible for classification into Categories I, II or III."
(NIOSH S. 3.)

See also Environmental Defense Fund S. 10 recommending that Category IV be eliminated.

A. OSHA Lacks Statutory Authority To Establish Category IV

OSHA lacks any authority to classify or to regulate toxic substances which are not currently found in and may never enter American workplaces. The Act grants to OSHA the authority to assure safe and healthy working conditions only in the domestic workplace.

In enacting the Act, Congress declared its purpose to be "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C. § 651(b) (emphasis added). Section 4 of the Act states that it applies only with respect to employment performed in a State, the District of Columbia, and various U.S. territories and possessions. This statutory grant of authority does not extend to substances which have not yet entered the American workplace. Where Congress intended to vest an agency with such authority, it has expressed that intent in clear statutory language. Such is the case, for example, with the Toxic Substances Control Act ("TSCA"). 15 U.S.C. §§ 2601 et. seq. Absent explicit authorization in the Act to classify toxic substances which are not currently found in any American workplace, such authority cannot be implied in OSHA.

B. OSHA's Resources Could Be More Effectively Channeled

OSHA suggests that the listed foreign toxic substances may become subject to future regulation if they are introduced into American workplaces, and notes that OSHA intends to enter

into an agreement with EPA with respect to implementation of the TSCA so that if such substances are introduced into the American workplace OSHA will be able to develop an appropriate standard. 42 Fed. Reg. at 54169.

OSHA therefore apparently recognizes that TSCA is the appropriate vehicle for monitoring the introduction of potentially toxic substances into the American workplace. The provisions of Section 5 of TSCA, 15 U.S.C. § 2604, regarding premanufacturing and preimportation screening for new chemicals are adequate to enable EPA to monitor and obtain information concerning toxic substances before they are introduced into American workplaces. There is certainly no demonstrated need for OSHA to blacklist such substances before they have been subjected to the screening mechanism which Congress has established for that purpose.

To follow the course of action suggested by OSHA would be a poor allocation of precious resources that could better be channeled to regulate substances already found in the domestic workplace. To the extent that the purported purpose of this generic rulemaking is to make the regulatory process more efficient, the proposed Category IV provision does the opposite.

C. There Is A Strong Possibility That The Decision To Classify A Substance In Category IV Could Be Arbitrary And Without Due Process

OSHA states with regard to the listing of foreign toxic substances that "OSHA does not intend to review the evi-

dence concerning carcinogenicity at [the] time [of listing]." 42 Fed. Reg. 54169. OSHA thus proposes to add substances to this list simply on the basis of unevaluated studies, whether or not they are scientifically sound. Witness after witness at the hearing has cautioned that studies are often of very uneven quality ranging from worthless to exceptional. To use unevaluated studies for the intended purposes can lead to innumerable problems.

This is further complicated by the fact that the procedures OSHA contemplates utilizing will be "without the formality of rulemaking, per se." 42 Fed. Reg. 54173. Because the allegedly toxic substance will not be used in the United States at the time of classification, all of the regulatory activity could unfold without any substantive review of the evidence concerning carcinogenicity. As a result, there is a strong possibility that the decision to classify a substance in Category IV could be wholly arbitrary and without due process.

D. Listing A Substance In Category IV May Create Misconceptions With Many Unintended Adverse Effects

Blacklisting a substance may create misconceptions among the public and press which, even if mistaken, are difficult to correct. The public and press misunderstanding of the NIOSH List of Suspect Carcinogens is an example of how lists such as these can create problems. Condemnation of a chemical product by listing it will certainly adversely affect the U.S. market for that product and will deter both domestic and foreign

companies from engaging in further development of that product, often without justification for such actions. Such a classification will also discourage a foreign company from exporting the substance to the United States. Category IV classifications have the clear potential to cause considerable problems with foreign industry and governments. The likely foreign view would be that a U.S. government agency has seen fit to blacklist products not found in the United States, over which that agency has no jurisdiction or statutory mandate, without making a careful review of the evidence. Indeed, this may be viewed by some as a non-tariff trade barrier to exclude potentially competitive products from the American market.

Conclusion

Rather than create a Category IV list, the authority for which is non-existent, and the wisdom of which is doubtful, OSHA should enter into an agreement with EPA whereby EPA will inform OSHA of the introduction of substances which might meet its definition of toxic substances into the American workplace. When and if such a substance is introduced into the U.S. workplace, OSHA can take appropriate action.

PART THREE

XI

QUANTITATIVE RISK ASSESSMENT IS ESSENTIAL TO A DETERMINATION OF THE REASONABLE NECESSITY OF A REGULATION

"It [OSHA] contends the standard promises appreciable benefits at a cost which industry can absorb. This justification is deficient in one crucial way: substantial evidence does not support OSHA's conclusion that benefits are likely to be appreciable. Without an estimate of benefits supported by substantial evidence, OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag." 1/

"There is needed some simple measure of cost and benefit that would make widely different risk situations comparable so as to attempt to maintain, in different areas, roughly similar standards for spending government and industrial funds to save lives. Without such a standard, as economists will sense immediately, cancer-avoiding expenditures cannot be spent efficiently. And, in addition, the public will have the greatest difficulty distinguishing minimal risks from large ones." 2/

"The societal need must be balanced against the estimated risks to society, for this is the only way any rational decision may be made. With the plethora of synthetic organic chemicals in use today, it will be a major task to develop the data base to allow risk estimations. But it must be done, for how can society intelligently

1/ The Benzene decision, ___ F.2d at 91.

2/ Federation of American Scientists, "Public Interest Report," at 7, May 1976.

regulate chemicals which pose human benefits and human risks without having an estimate of the risk?" 1/ (Emphasis supplied.)

"We believe that a risk assessment using the best data and techniques available, is needed as part of an adequate regulatory analysis." 2/

In the Preamble to the Proposed Regulation OSHA discussed briefly the matter of quantification of risk. 42 Fed. Reg. 54167. In that discussion OSHA proposes that quantification of risk be applied, if at all, only at the point of determining the feasibility of the regulatory provision of a particular standard, not to risk as determined by the classification system. 3/ Id. OSHA concluded its brief discussion with a request for comments on the question of whether quantitative risk estimate should be made and, if so, the methods to be employed in the standard set-

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- 1/ Dr. David P. Rall, "The Role of Laboratory Animal Studies in Estimating Carcinogenic Risks for Man," at 12, November 30, 1977. Appendix B to Dr. Rall's statement.
- 2/ Regulatory Analysis Review Group, Council on Wage and Price Stability, Report on OSHA Proposed Permanent Standard on Acrylonitrile, at 4, May 22, 1978 (Ex. 45).
- 3/ It is important to note that the term "risk" is used in the Preamble with two different meanings: qualitative human risk and quantitative human risk. A full scientific evaluation of human and animal data must address a determination not only of qualitative but the methodology of quantitative risk assessment to man.

Under the OSHA proposal a substance will be classified in OSHA Category I prior to the scientific evaluation of the data, particularly animal data, to determine its relevance to human risk. Thus metabolic, physiological and other differences between man and the test animal is considered after classification. Under the AIHC Alternative, the qualitative risk and quantitative risk to man is assessed by the Data Evaluation and Classification Panel as part of the classification process.

ting process on a particular substance. Id.

A. Risk Assessment And Quantification Are Necessary Components Of Regulatory Decisions

The Benzene decision provides a clear answer to the question OSHA posed. OSHA must provide a reasonable estimate supported by evidence to demonstrate that "measureable benefits will result." ___ F.2d at 91. The court specifically rejected OSHA's speculation that the benefits "may be appreciable" based on the assumption that exposure to benzene was unsafe at any level and that lower levels would be safer than higher levels. The court recognized the logic of OSHA's speculation but held that

"[T]his finding and deduction, however does not yield the conclusion that measureable benefits will result. . . . Acqua Slide requires OSHA to estimate the extent of expected benefits in order to determine whether these benefits bear a reasonable relationship to the Standard's demonstrably high cost." ___ F.2d at 91-92.

Without a risk assessment there can be no determination of the measureable benefits, the indispensable predicate for regulatory action.

The record also provides a clear answer to the question OSHA posed: ^{1/} identification of the techniques for quantification

^{1/} We shall discuss in another section of the brief what factors other than risk estimations OSHA should take into account in determining the level of control (see infra,

(Footnote continued on p. 200)

of the risk is an essential element of the scientific evaluation and risk quantification should be used by OSHA in the hazard analysis and in the regulatory determination of the degree of control appropriate to a particular substance. ^{1/} Dr. Upton, Dr. Rall, Dr. Kennedy, the witnesses for EPA and numerous other witnesses urged OSHA to make a quantitative risk assessment. Dr. Van Duuren testified that there are scientific bases for making a risk assessment and agreed that such an assessment should be made by OSHA. (Tr. 1879-1880.) Dr. Albert has expressed the view that the failure to provide for risk quantification in the Proposed Regulation is a defect which "could in the long run seriously jeopardize the Federal regulatory effort against carcinogens." (EPA Intra-Agency Memo from Dr. Roy Albert to Andrew Breidenbach, dated November 25, 1977, (API P.H.).) The methodology of an assessment of relative risks was discussed by Dr. Wilson, Professor Zeckhauser and Professor Lave.

EPA and FDA routinely make risk assessments and examples of these quantitative risk assessments are in the record. (Ex. 38, API P.H.) Other exhibits discuss the principles of, and examples of, risk assessment. (Exs. 13, 43, 45, 78, 85). The

(Footnote continued from p. 199)

at 215); in this section of the brief we are addressing the issue of risk assessment and the elements and methods involved in such an assessment.

- 1/ A risk quantification is implied in the OSHA proposal to identify suitable substitutes; unless a comparative risk analysis were made, OSHA would have no way of knowing whether it was increasing or decreasing the risk from use of the substitute.

quantitative risk assessment methods used by the NAS/NRC are set out in considerable detail in the chapter entitled "Chemical Contaminants, Safety and Risk Assessment" in the NAS Drinking Water Study. See Dr. Rall S. Appendix I.

We believe it would be difficult to state more succinctly or persuasively the need, despite the uncertainties, for such quantitative risk assessment and hazard evaluation than was set forth in the Work Plan of the Risk Assessment Group of the IRLG of which Dr. Bingham is a member:

"1. Introduction - A common objective of the four agencies is the assessment of human health risks associated with chemicals, devices, consumer goods, etc. to which the population of the United States is exposed in a variety of ways. In general the goals of risk assessment are to characterize the types of health hazards that may result from such exposures and to quantify the expected risks. For the present, the Work Group intends only to treat the problems associated with health risks due to chemicals. It is in this area that the greatest commonality of purpose exists among the agencies. Moreover, it is the area in which the greatest confusion now exists, not only among the public, but also within the regulated industry. It is also the subject presenting one of the greatest opportunities for success-achievement of the broad objectives of the IRLG.

2. The Scientific Problem. - Characterizing and quantifying health risks are scientific tasks. The data necessary to accomplish such tasks derive from toxicity testing and/or epidemiological studies.

* * *

Because of serious gaps in scientific knowledge, there are often alternative and conflicting views of the risks associated with chemicals to which people can be exposed. The Risk Assessment Work Group will examine the available scientific tools used in such assessments and select for use by the four agencies those currently having the strongest

experimental and theoretical support. Unless selections of these types can be made and agreed upon, conflicting views of risk will continue to cloud regulatory decision-making.

3. Role of the Policy-Maker - Whether a particular type or level of risk may have to be accepted in certain circumstances is a policy decision, but this issue should not become entangled with the scientific problem of risk measurement.

* * *

4. Need for Uniform Procedures and Criteria - The public and the regulated industry are ill-served when the agencies assess risk in different ways. Policy decisions made by the four agencies on the degree of acceptable risk in different circumstances create substantial confusion (in part brought about by differences in legal mandate and interpretation) and this confusion should not be compounded by differences in approach to the scientific assessment of risk.

5. Task of the Work Group - An objective of the Work Group might be the development of systems to insure that the agencies routinely work together to conduct risk assessments on specific substances of mutual interest. However, the Work Group holds that such an objective is far less important than the broader one of developing and selecting general procedures and criteria for risk assessment that can be uniformly applied to all chemicals regulated by the agencies, including those substances for which only one agency is responsible.

Until the rules for risk assessment are clearly laid out and agreed upon, efforts to reach a consensus on the type and degree of risk associated with specific substances of mutual concern will in many instances be thwarted. Furthermore, in the absence of uniform criteria and procedures, the risks associated with chemicals that are the responsibility of only one agency will continue to be estimated in a different manner than those associated with chemicals regulated only by a second agency. This undesirable situation will not be remedied if the task of the Work Group is limited to the joint conduct of risk assessments on substances of mutual interest.

6. Output of the Work Group - Several projects are envisioned (Section IV). Out of each will come a document detailing a set of procedures and criteria that can be adopted by each agency as acceptable for assessing risk. After appropriate internal review, these documents will be jointly published in some form and will become part of the scientific operations of agencies.

* * *

Of the several types of health risk projects that could be undertaken by the Work Group, a project on cancer risk assessment presents the highest probability for relatively short-term, successful accomplishment. A good portion of the necessary background documentation and study has been done, and the remaining tasks of bringing together the necessary information and making selections among the available approaches to carcinogenesis risk assessment should prove relatively straightforward.

* * *

RA 1.3 - Procedures for Quantifying Carcinogenic Risk

Output: Procedures for treating available dose-response relationships to estimate risk at expected or known levels of human exposure.

Task - The subgroup will survey the risk estimation procedures currently in use by the agencies. Reasons for the use of specific procedures, including relevant legal matters, will be detailed.

An updated review and discussion of all current mathematical models will be undertaken, including consideration of time-to-tumor analyses as a preface to the final selection of a model(s). The final document will include procedures for combining data from several experiments, use of human data, and modifications based on metabolic and kinetic data." 43 Fed. Reg. 7195-7197 (February 17, 1978).

B. The Prevalence of Uncertainties Underlines The Need For Risk Quantification So Far As Possible

There can be no doubt that there are uncertainties associated with risk assessment, as virtually all witnesses

pointed out, but the record shows that the existence of uncertainties should not lead to the nihilistic conclusion that no risk assessment should be attempted. There are uncertainties associated with all scientific matters; as Dr. Rall emphasized, scientists are dealing in probabilities, not certainties. (Dr. Rall S. 14.) Dr. Wilson and Professor Lave urged that the existence of the uncertainties makes a risk quantification and hazard evaluation more urgent and necessary. (Dr. Wilson Tr. 3364-3372; Dr. Lave Tr. 7002.) To the extent that any elements in the risk assessment can be quantified, the elements which must be evaluated by judgment can be identified and the decision made easier. Id.

Underscoring these points, Dr. Lave emphasized strongly that a careful quantification of risk and benefits is the only rational way to speed up the administrative process. (Tr. 7000-7003.) It is only by this process that the issues can be sharply defined so that testimony at the hearings will be directed at the areas of uncertainty, thus speeding up the administrative determination. Id.

Sheldon Samuels (AFL-CIO) testified that risk analysis is improving in accuracy and indeed proposed a permit system for the most "virulent" carcinogens in OSHA Category I. (Tr. 7256-7257, 7270-7274, 7290, 7300.) Any such distinction between carcinogens must of necessity be based on a risk analysis, as Mr. Samuels recognized. (Tr. 7300.)

C. Animal Data May Be Used For Quantitative Risk Assessment

AIHC believes that the record shows that animal test results, properly done and evaluated can provide a valid basis on which to assess the risk to man. As Dr. Kennedy said:

"Animal tests may be used to predict within confidence limits human risks. The hypothesis is tested by going through the exercise of making some human risk predictions and then turning to human data and assessing whether the predictions are accurate." (Tr. 505.)

Dr. Rall discussed this problem and expressed the view:

"There is very good general correlation between the carcinogenic activity of chemicals in animals and that in humans."
(Dr. Rall S. 8.) 1/

After reviewing several studies in which comparisons were made between the response of animals and the response of humans to particular substances, including an NAS study entitled "Contemporary Pest Control Practices and Prospects," 2/ (Dr. Rall S. 8-11), Dr. Rall concludes:

"Weighing all this evidence, it appears that carcinogenic responses of animals can be used both qualitatively and quantitatively to predict carcinogenic risks in humans."
(Dr. Rall S. 10.)

Similarly, Dr. Upton described the information necessary in assessing the risk as including the relative potency of the

1/ In addition to the studies referred to by Dr. Rall, Dr. Meselson described his efforts to find correlation among in vitro results and the reaction of animals and man.
(Tr. 1492-1497.)

2/ Appendix H to Dr. Rall's testimony.

carcinogen and the mechanism of action of the carcinogen. (Tr. 267-268.) ^{1/} While there are uncertainties, he concluded - and recommended - that a quantitative risk assessment should be part of the regulatory decision on the level of control. (Tr. 268-269, 296-297; see also IARC Ex. 135, at 20.)

D. Interchangeability Of Carcinogens Has Not Been Demonstrated

Several witnesses raised objections to a risk assessment, arguing that carcinogens are interchangeable and all exposures are additive. Dr. Hoel and Dr. Peto acknowledged that the supposed interchangeability of carcinogens was merely an assumption. (Dr. Hoel Tr. 2133; Dr. Peto Tr. 2513, 2512.) The record clearly establishes that there are no experimental or human data supporting a general assumption that exposure to submanifestational doses of several carcinogens either simultaneously or sequentially is additive. ^{2/} (Dr. Stewart Tr. 620-621; Dr. Saffiotti Tr. 928-929; Dr. Greisemer Tr. 928-929.)

The record does demonstrate that both in animals and in human experience (smoking and asbestos and smoking and radon) there are instances of additive or synergistic action between carcinogens or between a carcinogen and a potentially carcinogenic substance. However, this is far from a demonstration that

^{1/} Dr. Bates said that quantification of risk included consideration of potency. (Tr. 608-610.)

^{2/} See also the discussion by Dr. Mantel on the lack of evidence for the interchangeability of carcinogens set out in a letter attached to the statement of Dr. Gross.

cancer is a "multifactorial disease", in the sense that some use the term, and that exposure in the workplace is additive to the cancer burden from exposure to environmental carcinogens from diet, lifestyle, etc. On the contrary, the record shows that in many instances substances are inhibitory and indeed that some carcinogenic substances inhibit other carcinogenic substances. (Dr. Kaufman S. 21; Dr. McLean Tr. 4824, 4825; Dr. Kotin Tr. 8691.) This inhibitory action of one carcinogen on another is the basis of many drugs used in chemotherapy. Exhibit 42 contains a discussion of inhibitors of carcinogens. Several witnesses testified to the inhibiting effects of Vitamin A and Vitamin C. E.g., Dr. Kaufman S. 20; Dr. Upton, Ex. 82 at 3.

Dr. Kennedy, describing the work of the Research Planning Work Group of the IRLG in testimony before Congress, said:

"The inadequacy of scientific information to support regulatory decisions, and the lack of enough capability to produce more, present major problems for FDA and other agencies that share in the regulation of toxic substances." (Ex. 34, Kennedy S. 1.)

He identified areas where little or no research was being supplied by the four agencies, including "methods to measure total exposure and body burdens of chemicals." Id. at 3. Attached as Appendix A to Dr. Kennedy's statement is a list of High Priority Research areas including

"2. Interaction of hazardous substances - develop and validate for regulatory use, rapid, effective tests to predict interactive effects between two or more hazardous chemical substances.

* * *

4. Methods to measure total exposure and body burden on chemicals. Develop and validate for regulatory use a systematic approach to the determination of total exposure and body burden for chemical substances." (Kennedy S., Appendix A at 1.)

Dr. Saffiotti said that NCI is beginning some experiments with the objective of demonstrating whether exposure to submanifestational doses of several carcinogens either simultaneously or sequentially is additive. (Tr. 928-929.) The NIOSH statement on this subject demonstrates that a supposed interchangeability of carcinogens cannot be the basis for regulatory decision. NIOSH stated:

"Present knowledge does not permit development of a consistent and rational basis for decisions on additive and synergistic effects. Complicating this problem is the question of promoting agents and co-carcinogens, widely and variously used terms without the same meanings to everyone.

Additive effects should be assumed when two agents cause cancer at the same site, especially when the two agents also have chemical similarities, such as PN's or aromatic amines. Synergistic effects should be assumed only when there are data or principles suggesting in the specific case that potentiation is likely. Similarly, co-carcinogenicity and promotion should not be assumed except in a specific case where there are data or principles that apply." (NIOSH first answer to Q. 10.)

The argument that risk assessment is undermined by a supposed interchangeability of carcinogens is without support in the record.

E. Epidemiology Can Greatly Assist In Making Risk Assessments

The value of epidemiology in identifying and quantifying

risk has been discussed supra and that discussion will not be repeated here. Epidemiology can be used to identify the human risk. Negative epidemiology is useful to indicate "upper limits for the rate at which a specific type of exposure to that agent affect the incidence and/or mortality of specific human cancers."^{1/} As NIOSH points out, by using epidemiological studies and animal data in a coordinated way, the "benefits of each can be maintained and many of the individual methodological weaknesses can be overcome." (NIOSH first answer to Q. 5(c).)

F. Methods Are Available For Extrapolating To Low Doses

A basic problem in risk assessment arises from the fact that animal studies are normally conducted at doses significantly higher than those to which man is exposed and it is necessary to extrapolate resultant animal data to quantify human risk at low levels of exposure. Chapter II of the NAS Drinking Water study contains a discussion of various mathematical models used for extrapolating risk at low doses. Dr. Hoel and Dr. Peto discussed the mathematical models and attached to their written statements articles discussing various models. Dr. Gross discussed the Mantel Bryan model and attached a statement by Dr. Cornfield discussing that model.

The record points to the conclusion that the methods of extrapolation are in a period of development. It would be

^{1/} NCAB General Criteria at 462.

inappropriate therefore to select a single method now; to the contrary, the scientists working on the extrapolation should be alert to use improvements and new developments as they occur. The complexities which seem to be presented in selecting the method with the best data fit and most appropriate for the mechanism of action of a particular substance underlines the importance of the Agency's calling for development of data at multiple dose levels and for the development of metabolic and pharmacokinetic data to facilitate the selection of, and the refinement of, extrapolation techniques. Both Dr. Hoel and Dr. Peto suggested that pharmacokinetic data should be incorporated into extrapolation models. (Dr. Hoel Tr. 2145-2148; Dr. Peto Tr. 2538-2540; see also Dr. Skalsky Tr. 7590-7591, 7597-7599.)

In the interim, it seems wise to use more than one model, as does EPA. (Tr. 2289-2290.) However, this puts the responsibility for identifying the best model or the best technique on the scientists, an additional reason in support of the Scientific Panel proposed by AIHC. This will help to avoid the tendency of a regulator to choose the most conservative model, however inappropriate scientists may believe such a model may be for a particular human exposure.

These extrapolation techniques must be designed to be used by the Agency in its hazard evaluation. Properly done, the scientific risk analysis is an integral part of the appraisal of regulatory alternatives which the agency must consider as part of its decision to regulate and to what level. Thus,

selection of the appropriate method of extrapolation is one of the most important parts of a quantitative risk assessment, a fact which underlines the importance of the creation of the Scientific Panel proposed by AIHC.

G. Time-To-Tumor Concepts Should Be Used In Making Risk Assessments

The definition of toxic substances in Section 1990.102 of the Proposed Regulation (42 Fed. Reg. 54184) includes substances exposure to which

"(2) in a statistically significant manner decreases the latency period between exposure and the onset of neoplasms in (i) humans or (ii) in one or more experimental species."

This is a recognition by OSHA that the latency period for a particular substance is a function of both time and dose. As Dr. Jones pointed out, with a sufficiently small dose the time to first tumor will exceed man's lifetime, thus producing an effective carcinogenic threshold. (Dr. Jones S. 2-3; see also McArdle Laboratory for Cancer Research Comment at 2). The extension of time-to-tumor if the dose is lowered is shown by the draft report of the NCTR "megamouse" study. (Ex. 36.) Figure 9 of that report shows that a 24 months exposure at three levels (150 ppm, 100 ppm, and 75 ppm) had induced bladder neoplasms; however, exposure at four lower levels (60 ppm, 45 ppm, 35 ppm, and 30 ppm) had produced no tumors. See also Kaufman S. 5; Ex. 46.

Dr. Hoel discussed this question and while he agreed that on a statistical basis the time to first tumor will increase with

decreasing dose in the multistage model, he argued that some risk will still exist. (Dr. Hoel S. 7.) However, this conclusion is the result of the use of linear through zero extrapolation, which Dr. Peto frankly acknowledges is based on an "assumption" that some "asymptotic effectiveness" exists so that there is risk at any dose. (Dr. Peto S. Part I.)

In light of these analyses it seems appropriate to approach the matter of time-to-tumor as an important part of the risk assessment. Dr. Hoel also acknowledges this point when he says that "the choice of time-to-tumor model can greatly change any estimated low dose effects." (Dr. Hoel S. 7.)

Further refinement of the data may demonstrate that Dr. Jones is correct: there is an effective threshold at the dose level when time-to-first-tumor exceeds man's lifetime.^{1/} It is important that the Proposed Regulation does not prevent presentation of such data when appropriately developed. In

^{1/} Zapp, J.A., "An Acceptable Level of Exposure," 38 Am. Ind. Hyg. Assoc. J., at 425-421, 430 (1977) (AIHC Bibliography):

"We know that there is a dose: disease effect for carcinogens, as there is a dose: effect relationship for other toxic manifestations. We see it in the laboratory. As the dose of carcinogen is increased, the proportion which does not get tumors is decreased. As we lower the dose, the proportion of the animals which get tumors is decreased. In the laboratory one can find a dose which does not produce any excess of tumors within the lifetime of the animals under test."

(Footnote continued on p. 213)

the interval, there is no doubt that evaluation of these data are an important part of the risk assessment. The risk may be overstated because of the "assumptions" made in the particular extrapolation method, but if the regulator recognizes the consequences of the assumption, a risk analysis which includes these data can make an important contribution in the administrative process.

Conclusion

The record strongly supports the need for a risk quantification by OSHA as an integral part of the regulatory process. The work of the IRLG in developing methods of risk assessment is a step in the right direction, but it is impossible to comment on these efforts since no public information is available.

Risk assessment is indispensable to a determination of the measureable benefits which various possible regulatory measures offer. It affords a reasonable basis for determining goals

(Footnote continued from p. 212)

Roe, F.J.C., "The Principles of Cancer Prevention," 19
Gazetta Sanitaria, at 51-62, 53, (1970)(AIHC Bibliography):

"In animal experiments the risk of cancer development increases with dose. With increase of dose the average induction time tends to approach a minimal, seemingly obligatory, period. When this point has been reached, further increase in dose is without effect on induction time. At the other end of the scale, however, reduction in exposure dose is associated with prolongation of the induction time until within the limits of a particular experiment, none of the exposed animals develop cancers before they die from other causes . . . We have demonstrated these dose response relationships in mice exposed just once at birth, to a potent chemical carcinogen."

for risk reduction by assessing the degree of risk presented in the workplace as contrasted with the degree of risk that we all face from chemicals (natural or man-made) in our everyday lives.

The big problem for risk assessment arises from selection of an appropriate model for extrapolating animal dose/response data to man. The most conservative approach is a strictly linear extrapolation, which some have asserted to be scientifically supportable in a limited number of cases but which frequently leads to totally impractical and inappropriate exposure levels for occupational, environmental, or personal care considerations. Broadly applied, this would place an unjustified and excessive inflationary burden on the American public through loss of or increased cost of products.

In many cases a linear model is not the best fit to experimental data and should therefore not be used for extrapolation purposes.^{1/} AIHC believes that other methods may be more applicable in many cases. In no event should an agency foreclose the use of the best tool available in this period of rapid scientific advances.

^{1/} See J. Totter, "Discussion of the Use Of Thresholds in Regulatory Processes" (AIHC P.H.).

UNDER THE STATUTE OSHA MUST DETERMINE NOT ONLY THE
FEASIBILITY OF A STANDARD BUT WHETHER BENEFITS COMPARED TO
COSTS DEMONSTRATE THE STANDARD IS REASONABLY NECESSARY

"Because resources are limited, eschewing explicit cost/benefit analyses can result in more deaths and or cases of disease or injury; the costs imposed by a certain regulation might save more lives or prevent more cases if spent in other ways." 1/

Introduction

One of the most important and controversial provisions of the Proposed Regulation is that which requires the lowest feasible levels of exposure to be achieved for all Category I substances. Section 1990.112(b), 42 Fed. Reg. 54173. This provision embodies a proposed policy determination which "will not be permitted to be changed in the subsequent substance-by-substance rulemakings." 42 Fed. Reg. 54173.

There are two bases for objection to the single lowest feasible criterion. First, OSHA has never clarified what it means by "feasible" but has promised to do so in the forthcoming Regulatory Analysis. More important, the Benzene decision demonstrates that OSHA has disregarded the criteria of Section 3(8) which require that standards be "reasonably necessary and appropriate." 29 U.S.C. § 652(8).

1/ Evaluation of EPA's new drinking water regulations by the Council on Wage and Price Stability: Ivy Broder, "Analysis of EPA Proposed Drinking Water Regulations," at 9-10, September 5, 1978 (AIHC P.H.).

We will not repeat here the discussion of the Benzene decision which establishes that OSHA must quantify the benefits as an essential part of the regulatory determination that the costs involved are "reasonably necessary". See supra, at 7. We will discuss in this section OSHA's failure to define feasibility in a manner compatible with the Act.

A. The Definition of Feasibility

Unfortunately OSHA has not released its Regulatory Analysis so that participants in this proceeding could comment on whatever definitions or criteria of feasibility OSHA derives. Indeed it is not possible in this brief to do more than point to the considerations which the courts and other agencies have indicated are an essential part of determining feasibility.

The President's Regulatory Analysis Review Group in its comments on the proposed acrylonitrile standard pointed out that "[j]ust as there is no absolute 'safe' level, there is no absolute 'feasible' level." (Ex. 45 at 5.) The process of determining what is the "feasible" level in a particular situation was described by the CWPS in its comments on EPA's proposed drinking water standard:

"Regulatory agencies, within their legal constraints, may exercise much flexibility in the choice of specific activities or substances to be regulated and the type of standards to employ. Many alternatives, which produce varying health-related and economic impacts, are possible. That is, there are different costs and benefits to be derived from different regulatory alternatives.

In order to ensure that the regulatory process is efficient, an agency needs to perform cost-benefit analyses for proposed regulations. The benefits to be derived from many social regulations can be stated in terms of lives saved or cases of a disease avoided. Many regulators are reluctant to translate those benefits into dollar terms. However, the efficiency of the regulatory process cannot be improved upon without putting a 'dollar value on life.'

One can, through a risk-assessment procedure, calculate the number of lives saved or cases of a disease avoided by various regulatory alternatives. In particular, calculating the cost per life saved for the least stringent alternative and for more stringent regulatory levels yields estimates of the incremental costs of imposing increasingly stringent standards. Efficiency requires that these incremental costs be equated across regulatory actions that save lives and/or prevent cases of disease or injury. Although the 'lumpiness' of design standards and other factors make it impossible to arrive at exact equality of these costs per case avoided, it is sensible to avoid letting these values be unreasonably disparate. Because resources are limited, eschewing explicit cost/benefit analyses can result in more deaths and/or cases of disease or injury; the costs imposed by a certain regulation might save more lives or prevent more cases if spent in other ways." (CWPS Comments supra, at 9-10, AIHC P.H.)

We believe the record clearly shows and the statute requires that the factors and methods outlined by the OMB should be considered in determining feasibility. Alternate methods of control should be analyzed from a technical and economic point of view. The incremental health benefits can be examined in the manner suggested by CWPS and a realistic determination made of feasibility in light of costs and benefits.

AIHC hopes that in its Regulatory Analysis OSHA will

realistically deal with those factors to be considered in determining feasibility. Since we cannot comment on OSHA's proposed definition or listing of factors, we shall in this section of the brief discuss briefly those elements which we believe should enter into a determination of an appropriate exposure level.

B. The Proposed Regulation Should Be Amended To Provide For Consideration of Economic Feasibility

Section 6(b) of the Act requires the Secretary of Labor to consider feasibility in promulgating standards pursuant to the Act. Mr. Wrenn in his prepared statement and in his testimony recognized that feasibility involves consideration of both technology and economics. (Wrenn S. 6, 11, Tr. 34.) In addition, Mr. Wrenn stated that the agency makes decisions on the basis of judgments as to cost effectiveness. (Tr. 35.) In the preamble to the acrylonitrile standard OSHA acknowledged the need to evaluate economic as well as technological feasibility. 43 Fed. Reg. 45762, at 45779-45789 (October 3, 1978).

Both the courts and the Occupational Safety and Health Review Commission have construed the feasibility criterion as requiring a balancing of costs and benefits. See discussion supra, at 98-100. Dr. Rall as well as other witnesses urged OSHA that in selecting a "feasible" level, health risks, resources costs, economic costs and benefits should be taken into account. (Tr. 364.)

It is significant in this connection that the AFL-CIO recognized that economic analysis plays a significant role in

the regulatory process. (Tr. 5816-5826.) Indeed the AFL-CIO recommended that OSHA's economic capability be enlarged to analyze costs in the regulatory context and urged the development of a "respected methodology for cost benefit analysis" by OSHA. (Ruttenberg S. 5-9.) Mr. George Taylor endorsed the utility of a cost/benefit analysis. (Tr. 5748-5749, 5832.) Speaking for the Steelworkers, Mr. Wright said that if there are to be economic studies the Steelworkers wanted them done "right". (Tr. 5822.)

Despite this background, the Preamble and the Proposed Regulation itself are silent as to how costs are to be weighed in the light of benefits. Given complete freedom an engineer can always spend more to decrease exposures further. But the incremental gains drop significantly-and costs rise exponentially as lower and lower levels are fixed. It is precisely this relationship between incremental gains and incremental costs which the Regulatory Analysis Review Group established by President Carter pursuant to Executive Order 12044 concluded was part of an "adequate regulatory analysis". (Ex. 45 at 4.)

Yet nowhere in the Preamble nor in the Proposed Regulation does OSHA indicate how economic considerations will be taken into account in setting standards. Until AIHC can review the Regulatory Analysis being prepared by OSHA it cannot know whether OSHA will clarify its position on this point. AIHC agrees with EPA in urging OSHA to set forth clearly in the Proposed Regulation how feasibility will be determined and what role cost and benefits will play in reaching that decision.

(EPA S. 5, 27-30.)

The Proposed Regulation would foreclose consideration in future standard-setting procedures of the most cost and health effective combination of engineering controls, work practices, personal protective devices and administrative controls. The inflexibility of OSHA's position is particularly obvious in the construction industry. The most effective combination of engineering controls, administrative controls and personal protective systems requires consideration of the special problems of the construction industry -- the transitory nature of the work, the high labor turnover, and the complexity of using engineering controls. See the discussion supra, at 40.

The same principles apply in protecting workers in a plant. It is for this reason that AIHC urged that OSHA set performance standards, and require each plant to prepare a plan detailing the reasons why each part of the plan was adopted. Attached as Appendix F are pages from the AIHC Alternative describing the nature of the plan and guidelines for the plan. The existence of the plan in no way excuses the plant from failure to meet the PEL. But it does permit a plant owner to take into account the special problems of his plant without requiring an inflexible approach to the method of control, thus giving real meaning to the term "feasible".

The OSHA policy decision that mandates engineering controls even if they will not achieve the desired level is not consistent with the requirement that OSHA take economic

feasibility into account.^{1/} While AIHC recognizes that engineering controls are the preferable means of control, to mandate such an inflexible policy for all future standard-setting procedures conflicts with the requirement that economic feasibility be considered in each area.

This conclusion is reinforced by consideration of Section 3(8) of the Act. A standard must be demonstrated to be not only feasible but "reasonably necessary." 29 U.S.C. § 652. The Benzene decision makes clear that if OSHA mandates control of exposure to the lowest feasible level without a careful balancing of benefits and economic considerations, OSHA is failing to make the determination of "reasonable cost" required by the Act in order to show that a standard is "reasonably necessary".

C. The Record Supports The Conclusion That Exposure Levels Should Be Established On The Basis Of Acceptable Risk

Much of the testimony in the record has been aimed at OSHA's rejection as a policy matter of the concept of "threshold"

^{1/} The AFL-CIO suggested that the model standard for Category I substances requires control of exposures in particular plants to lower than the specified PEL -- i.e., lowest possible limit -- when such control is possible. (AFL-CIO S. 13, Tr. 5710-5711.) The AFL-CIO recognized that a requirement for "all feasible engineering controls" even where the PEL is not exceeded presents a statutory problem. (Tr. 5710.) This may be a matter for collective bargaining, it is not a basis for regulatory action.

or "no-effect" levels for carcinogens.^{1/} Dr. Claus and Dr. Olson testified that a "threshold" can be demonstrated on the basis of the biomolecular phenomenon of the number of molecules of a substance necessary to interact with cells of the target organ. (Dr. Claus S. 22-39, Tr. 3508-3511; Dr. Olson S. 31-34.) Many others testified on the basis of the principles of biology and toxicology that "threshold" is a universal concept in nature and there is no reason to conclude that a threshold does not exist for carcinogens. See, e.g., Dr. Skalsky Tr. 7588-7589, 7630; Dr. Goldwater S. 4-8; Dr. Lu S. 9-10. Dr. Upton testified that the possibility of a threshold cannot be excluded. (Tr. 347.) Dr. Kotin stated that a no-effect level can be predicted quantitatively in a variety of animal models for a variety of organ or organ system targets. (Tr. 8646.) Others testified that while a "threshold" has not been experimentally demonstrated, should such a demonstration be made, it should be considered by the agency in evaluating the human risk from exposure to a substance and in fixing levels of control. E.g., Dr. Upton Tr. 272; NIOSH Tr. 3075; see also EPA S. 9. Indeed failure to consider such evidence would be contrary to the requirement in Section 6(b)(5) that OSHA consider the latest scientific data available.

^{1/} A number of OSHA witnesses recommended the lowest feasible level of exposure on the ground that carcinogens are interchangeable and that exposure to a carcinogen in the workplace is added to the existing "burden" and may put an individual over the threshold. As we have shown supra, at 206-208, this concept of interchangeability is an assumption for which there is no data.

The fact that scientific debate continues on this subject does not alter in any way the fact that the record shows that OSHA should reconsider the policy decision upon which the unvarying low-as-feasible determination was made. That chemical substances which will be classified in Category I will vary widely in potency is a conclusion which OSHA itself recognized (42 Fed. Reg. 54165) and which the record amply supports. Indeed, it is this wide variation which makes quantitative risk assessment an essential part of the regulatory process. See the discussion supra, at 197-203.

There is no way to achieve zero risk in the workplace short of banning substances, unless a threshold is recognized and not exceeded. Even assuming that OSHA cannot identify a threshold for exposure to a carcinogen, it can assess the risks involved and take that risk into account in determining what is a permissible level of exposure, recognizing that some level of risk may be associated with the exposure. But it makes no sense in advance of such a risk evaluation to mandate lowest feasible for all future individual substance rulemakings. ^{1/}

It requires no scientific evaluation to conclude that risks from exposure are different when a worker is exposed to

^{1/} Dr. Rall endorsed generally the principle set out in the NAS Drinking Water Study, attached as Appendix I to Dr. Rall's statement:

"4. Material should be assessed in terms of human risk rather than as 'safe' or 'unsafe'." (S. 8.)

aflatoxin or bischloromethyl ether on the one hand or to nickel dust on the other when, for example, a cashier handles coins in making change. It is equally clear that the level of control of exposure should be different in light of the differences in risk. E.g., Dr. Jellinek S. 5-6; see also Mr. Samuels Tr. 7259-7271, 7272; Dr. Rall Tr. 385-386.

The fact that such extremes exist suggests that a careful evaluation of level of control can utilize a risk assessment in determining an acceptable level of risk for different substances. This will be possible when a systematic method of risk assessment such as that recommended by EPA and FDA, and which hopefully the IRLG is in process of formulating, is made part of the regulatory process.

D. Costs And Benefits Must Be Considered In Regulatory Decision Making

Risk and hazard constitute half of the essential evaluation which should be made in the regulatory process. The Benzene decision makes clear the other essential considerations are cost and benefits. Nowhere in the Proposed Regulation does OSHA indicate how costs will be taken into account or what factors are part of a cost consideration.

There was resistance on the part of some witnesses to consider benefits at all. Others shied away from the analysis of benefits because of the complexities and difficulties of quantification. AIHC believes these objections are based on a mis-

conception of the evaluation which should be made.

Costs in this context mean health and resources flowing to or from different groups - workers, taxpayers, consumers and industry. (Zeckhauser Tr. 4321-4322; Dr. Lave Tr. 7003-7005.) What one may view as a benefit, the other views as a cost. It is for this reason that Dr. Ashford recommended that a risk/benefit analysis be made to identify what he called "trade-offs". (Tr. 2429.) Dr. Zeckhauser called this "a meticulous accounting". (Tr. 4352, 4410.)

The position of the AFL-CIO is instructive. In their testimony they urged that OSHA's economic capability be increased and that where economic analysis is called for under the regulations, the analysis should be done "right". (Tr. 5822.) George Taylor stated that a cost/benefit analysis of the kind outlined by Snell was an appropriate part of the regulatory process on particular substances. (Tr. 5748-5749, 5745, 5751.) Sheldon Samuels testified that cost/benefit analysis was at an early stage of development; while many items in the analysis could not be quantified, he agreed that the items which could be quantified should be quantified to assist the regulator. (Tr. 7283-7285.) As an alternative to cost/benefit analyses, Mr. Samuels discussed "necessary" and "unnecessary" risks, unnecessary risks being those encountered in producing socially unnecessary products. (Tr. 7286-7287.) However, Mr. Samuels recognized this was in effect a different name for a cost/benefit analysis. (Tr. 7287-7289.)

While OSHA can and should never lose sight of the fact that the objective of regulation is to protect worker health, it cannot escape consideration of the effects which its regulations have on the worker's job and on workers in other industries. Thus, as Dr. Wilson pointed out, if compliance with a regulation requires construction, OSHA should not lose sight of the historical fact that one worker loses his life for every \$36 million in construction. (Dr. Wilson S. 47-49, Tr. 3372.)

Dr. Rall made the same point in a different way when he said:

"Ultimately, however, the selection of a 'feasible' level depends on a judgment as to when the costs of control (which may include health risks and resource costs as well as economic costs) are justified by the magnitude of the carcinogenic risks posed by unregulated exposure."
(Dr. Rall S. 1-2.)

The fact that OSHA does not make such an overt analysis should not conceal the fact that OSHA is making the societal judgments without acknowledging that it is doing so. (Dr. Lave Tr. 7003-7004, 7011-7013.) If a cost/benefit evaluation is made, regulatory judgment would be made on the basis of the best facts available; on the other hand, if OSHA does not make such an analysis, the judgment is being made by OSHA in ignorance and without consideration of the societal costs and benefits.

The fact that such an analysis is difficult should not stand in the way of attempting the assessment. FDA makes such

analyses as a regular part of its regulatory function. Many of the analyses involve drugs where the same person is both the person at risk and the one who receives the benefits. But FDA also makes analyses of risks and benefits where the costs, risks and benefits involve different groups. A good example is the analysis which FDA recently made in regulating the amount of aflatoxin which will be permitted in peanut butter. (Ex. 38.) EPA regularly makes cost/benefit analyses at various levels of control under the Federal Insecticide Fungicide and Rodenticide Act and will make such analyses under the Toxic Substances Control Act. (Tr. 2357.)

Another example of a risk/cost assessment is that undertaken by the Nuclear Regulatory Commission. (Ex. 67.) As a part of its determination of the numerical guides for design objectives and limiting conditions for operation required to meet the criteria "as low as practicable", the Commission adopted a monetary value for reducing exposure of \$1000 per total-body man-rem. 40 Fed. Reg. 19439 (May 5, 1975.)

On the basis of the interim value of \$1000, the Commission has prepared evaluations of the cost/benefit analyses in support of nuclear power reactor applications. (Ex. 67.) This experience, evaluated in the light of applicable EPA environmental standards, lead the Commission to reconsider the need for further efforts to redefine the worth of reducing radiation exposure to

1/ In December 1975, the Commission changed the terminology "as low as practicable" to "as low as is reasonably achievable" to conform to the International Commission on Radiological Protection. 40 Fed. Reg. 58845 (December 19, 1975).

the general population. Id. The Commission cancelled the proposed rulemaking to review the interim value, stating:

"The cancellation of this rulemaking should not be interpreted as an abandonment by the Commission of the concept of a quantified cost-benefit analysis for defining as low as is reasonably achievable levels of radiation exposure. The Commission believes that the Appendix I rulemaking proceeding (Docket No. RM-50-2) and the subsequent experience with the Appendix I rule show that this concept has considerable merit and utility. In this regard, the Commission notes the opinions of the Advisory Committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences - National Research Council 6/ that:

Such analyses could facilitate rational and cost-effective safety and control procedures and the avoidance of health hazards and economic dislocation associated with excessive or inadequate expenditures in relation to risk. Health benefit/cost assessments, even though present data are incomplete, can provide some guidance to decision makers, direct attention to gaps in knowledge, indicate priorities for research, and stimulate the accumulation of needed data and analysis, and contribute to public understanding of the relevant issues and problems *** (page 6).

* * *

6/ National Academy of Sciences - National Research Council Advisory Committee on the Biological Effects of Ionizing Radiation. 'Considerations of Health Cost-Benefit Analysis for Activities Involving Ionizing Radiation Exposure and Alternatives.' Issued as EPA Report in EPA 520/4-77-03 (1977).

The reasons why the NRC found a risk/benefit analysis useful should be persuasive that a similar analysis should be

made by OSHA. Based on his experience in radiation, Dr. Upton said that the principle of "diminishing returns" is generally valid:

"In connection with radiation, it has been suggested that beyond a certain point, the costs to society involved in further reducing the dose and hence the presumptive risk may outweigh the costs associated with that hypothetical risk. So I think the principle that one may reach a point of diminishing returns is a valid principle. And I would suppose that a regulatory decision would weigh in arriving at the concept of feasibility all of the factors that have to go into a socially acceptable judgment." (Tr. 271; see also Tr. 283.)

As Dr. Wilson and Professor Lave pointed out, to the extent it is possible to quantify even partially the complex factors in a regulatory proceeding, the proceeding is facilitated because the number of factors which must be evaluated on judgment alone will be identified and their number reduced. (Dr. Wilson Tr. 3374; Professor Lave Tr. 7001-7002.) Indeed, as Professor Lave emphasized, making such a cost/benefit analysis is the best way to speed up the administrative process. (Tr. 7000-7002.)

The CWPC's comment on uncertainty in determining costs and benefits emphasizes the urgency of making the analysis:

"There is a considerable amount of uncertainty about both the costs and the benefits of these alternatives, but it makes little sense to act on uncertain evidence by imposing costly regulations on local communities while, at the same time, es-

chewing cost/benefit analyses because of this uncertainty." 1/

AIHC believes that the record strongly supports the conclusion that OSHA should undertake a cost/benefit analysis as part of the regulatory process to determine the level of control. This may not necessitate an elaborate formal cost/benefit analysis but it does mean that OSHA will have sufficiently identified the societal costs and benefits that it can more reasonably determine an acceptable level of risk - the reasonably necessary level - in setting particular standards. Section 3 B(1) of Executive Order 12044 requires that such an analysis be performed; it directs the agency to identify alternatives and assess their economic consequences. See discussion supra, at 102-103.

Some form of risk/benefit analysis is being developed by the IRLG. AIHC applauds this development in principle but cannot comment in greater detail because the recommendations of the IRLG are not available for comment. We do not know whether the proposals will or will not be reasonable and adequate.

E. The AIHC Alternative Provides A Reasonable Procedure For Identifying An Acceptable Level Of Risk

The AIHC Alternative spells out the procedure for determining the reasonably necessary and acceptable level of

1/ CWPS comments on EPA's proposed drinking water standard, September 5, 1978 (AIHC P.H.).

risk. ^{1/} An orderly method of risk quantification is set out and the analyses of the risks and societal costs and benefits of alternative methods or levels of control is described. Under the AIHC Alternative an orderly and logical sequence for administrative determination of an acceptable level of risk for both emergency temporary and permanent standards would be established. Costs and quantified benefits are examined as the court directed in the Benzene decision.

Emergency Temporary Standards ("ETS"). Under AIHC Category I (known human carcinogens) and Category II (confirmed animal oncogens) the initial step is a determination whether the facts justify an ETS. If an ETS is issued, the level of exposure is set based upon all the data available. If sufficient data are available to quantify risks and to perform the cost/benefit analysis, the acceptable level will be identified and the method of attaining it described. If sufficient data are not available for the necessary analysis, the temporary standard will specify a permissible exposure level which can be achieved through a practical combination of readily available engineering controls and personal protective equipment. The Interagency Testing Committee established under the Toxic Substances Control

^{1/} AIHC Alternative at 70-84, (Appendix G to this brief is a supplementary statement of the principles AIHC believes should be followed in a risk/benefit analysis).

Act would be notified of the desirability of further testing.^{1/}

Permanent Standard. Under AIHC Categories I and II the Alternative provides that where data are available to quantify risks, the acceptable exposure level will be set after evaluating the risks, costs and the benefits in the manner provided. Where data are not sufficient to quantify risks, a five-year "interim permanent" standard would be fixed upon the basis of the best data available. If data became available in the five year period, the "interim permanent" standard will be reviewed in light of the data and a permanent acceptable level fixed. If data do not become available, the permanent standard will be fixed at the lowest level economically and technologically feasible.

We believe that AIHC's proposal satisfies the statutory standard of feasibility in Section 6(b)(5), read in the light of the "reasonably necessary" criteria in Section 3(8).

F. A Risk/Benefit Analysis Is Required Under The National Environmental Policy Act

Finally, the statutory requirements of the Act must be considered in light of OSHA's obligations under the National Environmental Policy Act, 42 U.S.C. § 4321 et seq. (See supra,

^{1/} Both the temporary and permanent standards provide for exclusions of mixtures containing low concentrations of the substance and for an "action level". The mixture exclusion level and the action level would be determined based on the risk/cost/benefit analysis.

at 100 for a discussion of OSHA's obligations under that statute.) It is sufficient to note here that unless OSHA makes the risk/cost/benefit analysis of the kind discussed above, it will have neither the necessary basis upon which to weigh the broad environmental impact of alternative control levels in devising a particular standard, nor the data to analyze the resource commitment as required under Section 102 of NEPA, 42 U.S.C. § 4332.

Conclusion

Compliance with these statutory requirements cannot be made without a risk/cost/benefit analysis of the kind embodied in the AIHC Alternative. The fact that other agencies make such analyses demonstrates that while the analysis may have uncertainties and may indeed be complex, such analyses can be made and do contribute to rational decision making.

XIII

THE PROPOSED REGULATION UNLAWFULLY REQUIRES ISSUANCE OF EMERGENCY TEMPORARY STANDARDS WITHOUT APPRAISAL OF RISK

The Proposed Regulation would require, in every case of a Category I classification within its scheme, automatic issuance of an ETS. This requirement clearly contradicts the plain language of the statutory authorization for the issuance of an ETS, the Congressional intent behind the grant of authorization, and the court decisions construing this authorization.

Section 6(c)(1) of the Act, 29 U.S.C. § 655(c)(1), requires that prior to the issuance of an ETS the Secretary of Labor must make a determination that "employees are exposed to grave danger" from toxic and physically harmful substances, and that an ETS is "necessary to protect employees from such danger." The Proposed Regulation would not require these specific, prescribed factual findings to be made prior to the issuance of an ETS. In fact, no assessment of the degree or significance of carcinogenic risk posed by a particular substance is provided for, either in the classification process or subsequent thereto.

The proposed automatic issuance of an ETS for every Category I substance is contrary to the intent of Congress that the power to issue an ETS be used sparingly and only in unusual circumstances: "Congress considered that . . . emergency temporary standards should be considered an unusual response to exceptional circumstances."

Dry Color Manufacturers Ass'n v. Department of Labor, 486 F.2d 98, 105 n. 9a (3d Cir. 1973). In like fashion, the Court of Appeals for the Fifth Circuit has stated that "[the extraordinary powers] granted to the Secretary in Section 6(c) of the Act should be delicately exercised, and only in those emergency situations which require it." Florida Peach Growers Ass'n v. Department of Labor, 489 F.2d 120, 129-30 (5th Cir. 1974). See also Taylor Diving and Salvage Co. v. Department of Labor, 537 F.2d 819 (5th Cir. 1976).

OSHA's purported justification for the wholesale issuance of ETS is that any substance which has been shown to cause cancer in animals, ipso facto, presents a grave danger to humans. The courts, however, have not supported this contention when offered by OSHA in the past.

In Dry Color Manufacturers Ass'n, Inc. v. Department of Labor, supra, the United States Court of Appeals for the Third Circuit stated that, "[a]lthough the danger of cancer is surely 'grave,' Subsection 6(c)(1) of the Act requires a grave danger of exposure to substances 'determined to be toxic or physically harmful.'" Id. at 104. For a valid ETS to issue, there must be a showing of "more than some possibility that a substance may cause cancer in man." Id. The court then stated that the record before it failed to show "more than some possibility that DCB [3,3' Dichlorobenzidine] and EI [Ethyleneimine] may cause cancer in man," and that the "most that can be said is that DCB and EI pose a 'potential' cancer hazard to man," indicating that the record did not

support issuance of an ETS. Id. at 105 (emphasis added); ^{1/} see also Florida Peach Growers Ass'n v. Department of Labor, supra, at 131. The evidence then before the court included the reports of laboratory rodent experiments on DCB and EI which OSHA and NIOSH regarded as constituting clear evidence of carcinogenicity in two species, far more evidence than the OSHA proposal would require for an ETS.

In interpreting the requirements for issuance of an ETS, the court stressed the value Congress had intended that the normal rulemaking procedure would have, noting that it was clear that Congress

"considered that the ordinary process of rule-making would be that provided in subsection 6(b), dealing with permanent standards; emergency temporary standards should be considered an unusual response to exceptional circumstances. The courts should not permit temporary emergency standards to be used as a technique for avoiding the procedural safeguards of public comment and hearings required by subsection 6(b). Especially where the effects of a substance [on man] are in sharp dispute, the promulgation of standards under subsection 6(b) is preferable since the procedure for permanent standards is specifically designed to bring out the relevant facts." Dry Color Manufacturers Ass'n Inc. v. Department of Labor, supra, at 104 n. 9a.

Consistent with the statutory language, Congressional intent, and relevant court decisions, the AIHC Alternative would not require automatic issuance of an ETS. Instead, it calls for

^{1/} Having clearly indicated its views that an ETS would not generally be warranted on the basis of animal data alone the court set aside the ETS on another ground. Dry Color Manufacturers Ass'n Inc. v. Department of Labor, supra, at 104-105.

the exercise of informed judgment and discretion exercised on the basis of an evaluation of all the evidence of potential carcinogenic risks (e.g., carcinogenic potency as indicated by the epidemiologic data, animal experimental data, where available, such as dose-response relationships, metabolism, duration and amount of exposure, route of exposure) and an evaluation of actual hazards, (e.g., physical and chemical properties, degree of occupational exposure, likelihood of a carcinogenic event.)

In short, the AIHC Alternative fully complies with the statutory requirements. The Secretary will not only appraise the facts to determine if there is "grave danger," but also to determine, as the Act requires, whether an ETS "is necessary to protect employees from such danger." 29 U.S.C. § 655(c)(1). The Benzene decision underlines the need for specific findings of benefits before an ETS can be shown to be "necessary".

XIV

OSHA HAS A LEGAL AND MORAL OBLIGATION TO SET REGULATORY PRIORITIES

"The more we spend on safety, the less we have with which to fight poverty and disease or to spend on those goods and services which make life worth living, for ourselves and others. Whatever money we make available for safety we should spend in such a way that it produces the maximum benefit. There is nothing humanitarian in spending lavishly to reduce a particular hazard which has been brought to our attention and ignoring the others." 1/

In the Preamble to the Proposed Regulation OSHA discusses various procedures by which it can systematically classify and regulate the substances in the NIOSH list of "Suspected Carcinogens". 42 Fed. Reg. 54169. - Several proposals are discussed, including the possibility that the substances be taken in alphabetical order. This discussion must be considered in the perspective of Section 1990.103(a) of the Proposed Regulation, which would require the Secretary to initiate the regulatory process whenever information is presented by a public petition.

The issue of priorities was brought into sharp focus during the hearings on July 14, 1978. On that date OSHA released a preliminary list of chemicals classified according to the system in the Proposed Regulation. (Ex. 132.) The lists were pre-

1/ Kletz, T. A., "The Application of Hazard Analysis to Risks to the Public at Large," at 1. Presented at World Congress of Chemical Engineering, Amsterdam, July 1, 1976. AIHC Bibliography.

pared by Clement pursuant to contract. The NIOSH list was screened by Clement to identify commercial products on the NIOSH list. Two computer comparisons were made: one with the EPA tentative inventory of existing chemicals under the Toxic Substances Control Act; and the second with the International Trade Commission data on commercial organic chemicals. The chemicals on the NIOSH list identified as commercial were then screened by review of articles cited in the NIOSH list; review of the U.S. Public Health Service survey of chemicals tested for carcinogenesis; a check of the National Library of Medicine's Cancer Line data base; and review of the IARC monographs.

As a result of the screening process the chemicals were presumptively assigned to the OSHA categories as shown in the following table:

	List I (Based on EPA TSCA Candidate List)	List II (Based on USITC Data Base)
Category I	269	116
Category II	218	72
Category III	396	181

In a memorandum accompanying the press release, and in the press release itself, participants in the hearing were asked to propose a system of priorities for regulation of those substances and to explain the criteria they would use.

AIHC has responded to this request in a separate communication. (Appendix H to this brief.) In this section of

the brief, we address the more general question of priorities under a generic regulation such as that proposed by OSHA.

A. The Statute Requires OSHA To Establish Priorities

Section 6(g) of the Act directs the Secretary to establish priorities. 29 U.S.C. § 655(g). That section provides:

"(g) Priority for establishment of standards. In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health, Education and Welfare regarding the need for mandatory standards in determining the priority for establishing such standards."

Congress has specifically directed that OSHA "shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments" in determining the priority for establishing standards. 29 U.S.C. § 655(g). Clearly, Congress intended that OSHA first address those health problems presenting the greatest hazard to workers. A decision by OSHA to regulate substances in the random fashion suggested would constitute a flagrant denial of this intent.

Perhaps of greater practical significance, a failure to prioritize substances for regulation on the basis of the potential risk for human carcinogenicity and the degree and extent of employee exposure to the substances, could result in a serious

waste of OSHA's and industry's manpower and resources. Surely the state of scientific knowledge allows for this rational approach to regulation, as recognized by the FDA, EPA, and CPSC.

Donald Kennedy, U.S. Commissioner of Food and Drug, Food and Drug Administration, testified at the hearing that hazard assessment should be employed for setting agency regulatory priorities. Commissioner Kennedy described the factors considered in such an assessment as the relative carcinogenic potency of the substance, the number of workers exposed and the dosage of exposure. (Tr. 493-497, 514.)

EPA utilizes a similar system for setting regulatory priorities. The Assistant Administrator for Toxic Substances for the EPA, Steven Jellinek, testified that the agency prioritizes substances for regulation on the basis of an analysis of relative potencies and the number of persons exposed. (Tr. 2359, Jellinek S. 2.)

Finally, both the testimony of Chairman Byington in this hearing and the recently published Interim Statement of Policy and Procedure for Classifying, Evaluating, and Regulating Carcinogens in Consumer Products, 43 Fed. Reg. 25657 (June 13, 1978), demonstrates that the CPSC will utilize quantitative hazard assessment in establishing regulatory priorities, with the extent of exposure being a major consideration. (Tr. 2095, 2088-2089). The Interim Statement of Policy and Procedure specifically states that:

"In determining the order in which products containing classified substances will be evaluated by the staff, the Commission recognizes that it may need to set priorities among substances. Generally, priority will be based on the relative certainty of the evidence concerning the substance (i.e., the category to which it is assigned), the apparent potency of the substance, the extent of consumer exposure to products containing the substance, including the approximate number of products and the amount of the substance contained in each, and the potential for human uptake. This may lead in some cases to the allocation of resources to the investigation and possible regulation of high priority Category B or C substances rather than low priority Category A substances." 16 C.F.R. § 1040.31 (published at 43 Fed. Reg. 25664).

The past actions of OSHA demonstrate its concurrence in the approach of the FDA, EPA and CPSC. As discussed supra, at 65, in their contract OSHA has instructed Clement to develop criteria for, inter alia, potency and risk quantification for the purpose of "ranking" substances:

"The contractor will attempt to develop a semi-quantitative scale, upon which each chemical will be ranked according to several independent, relevant factors. The weighted sum of the rankings may then establish an order of chemicals."

Presumably, this ranking is to serve as the basis for prioritization of substances for regulation.

In addition, the affidavit executed by Grover Wrenn in Textile Workers Union of America v. Usery, Civil Action No. 75-2157 (D.D.C., filed March 1976) demonstrates that historically NIOSH has prepared criteria documents on a priority basis and that OSHA has set regulatory priorities "based on severity of

the hazard and extent of employee exposure" (Wrenn Affidavit at 2, 4). In fact, the Wrenn affidavit flatly states that it is a function of Mr. Wrenn's job to determine priorities. The affidavit specifies the factors involved in past prioritization:

"One major function of my job is determining priorities for health standards development. In making such determinations I consider among other things the type of hazard involved, its extent and severity, whether it is seasonal or continuous, whether it is already meaningfully regulated in whole or part, and the number of employees exposed. These factors must also be balanced against my manpower capabilities and those of the Solicitor's Office, since no employee will be protected if we undertake so many proceedings we cannot effectively complete any." Wrenn Affidavit at 10 (emphasis added).

Materials that are known or seriously alleged to be human carcinogens or highly potent animal carcinogens surely present a much more manageable number of substances for regulatory and compliance purposes than the "universe" described by the NIOSH subfile, and are very likely to account for the great majority of the potential occupational hazards being encountered in domestic workplaces. Regulating these substances first would enable greater benefits to be achieved, and ensure greater acceptance by those being regulated, in view of its manifest reasonableness.

B. OSHA Should Not Allow Persons Outside The Agency To Dictate Its Priorities

At any rate, OSHA should retain the flexibility to exercise informed judgment and to consider regulating first the

most potent human carcinogens to which the greatest number of employees are exposed. Regulating substances not currently on the NIOSH subfile of "suspect carcinogens" in the order that information is received by OSHA from any source would deprive OSHA of the ability to exercise judgment in establishing priorities for rulemaking. For example, under the OSHA proposal, the filing of a "citizen petition" could force OSHA to give equal priority to such seemingly unequal problems as selenium, an essential human nutrient, asphalt, and carbon tetrachloride, compared to bischloromethyl ether and aflatoxin. In addition to being irresponsible, allowing citizen petitions to force automatic regulatory responses would be a clear abdication by OSHA of its duty to set priorities in accordance with the guidelines set by Congress in Section 6(g) of the Act, 29 U.S.C. § 655(g).

EPA has testified that OSHA would lose control of its processes unless it established priorities and reserved discretion to decide not to regulate a particular substance. (Jellinek S. 6; EPA S. 20-22.) The CPSC Interim Statement of Policy and Procedures does not provide for "citizen petitions" which would trigger automatically the regulatory procedure, despite the close adherence of the Statement to OSHA's Proposed Regulation. In short, other federal agencies have recognized the inadvisability of placing their regulatory responsibilities in outside persons. We believe OSHA should do so also on both policy and statutory grounds.

C. OSHA Should Heed The Advice Of The Interagency Task Force On Priorities

The Interagency Task Force on Workplace Safety and Health has recommended that OSHA better utilize its limited standard-setting and enforcement resources and maximize worker protection by issuing criteria for determining which hazards will become the subject of proposals and of final standards:

"The new Administration has taken significant steps to make OSHA enforcement more rational, remove unnecessary paperwork and compliance burdens, and provide workers neglected health protection. The more the agency gears up to issue health standards, however, the more it will need a system for determining priorities to insure that maximum worker protection is obtained and that standards begun are completed in time. The universe of job safety hazards is relatively finite; chemical threats to health expand by hundreds of substances each year and are unlikely to be completely covered even through rulemaking aimed at generic chemicals or processes rather than single substances. The need to carefully select areas for which regulation will produce the greatest health and safety gains at the least cost to the government is clear. Lack of such a priority system leaves the agency vulnerable to pressures against as well as for particular standards. It has in the past delayed standards completion and demoralized both standard-setting and enforcement staff, who have found themselves flung from one project to the next on a crash-and-wait basis. It has in the past put the agency on the defensive with respect to NIOSH, which has a formal priority system and pursues it with some rigor, generating dozens of criteria documents to which OSHA has been forced to respond ad hoc. Perhaps more importantly, it hampers the long-range standards planning a priority system will provide.

This recommendation proposes that OSHA establish formal criteria for determining when particular hazards should trigger full-scale rulemaking, including:

- number of workers exposed
- extent of their exposure
- potential severity of resulting injuries and illnesses
- alternative means of controlling the hazard
- practical aspects of enforcing the standard
- costs to the government of developing and enforcing the standard.

The recommendation also proposes that based on these criteria, OSHA should develop a weighted numerical index for ranking hazards being considered for protective rulemaking; that it should publish an annual list of such candidates for public comment; that it should disclose the reasons for deciding which hazards to regulate; and that it should set up a separate office, building on current plans for an Office of Carcinogen Classification, to set, monitor, and revise resulting priorities.

Because of present deficiencies in available data, it is the systematic consideration of the listed criteria, rather than the numbers emerging from that consideration, which will probably prove most productive over the short run. It should also be emphasized that this recommendation will afford OSHA continued flexibility by enabling it more productively to select not only topics for rulemaking at the initial stage, but aspects of proposed standards to press to completion after rulemaking has begun. Finally, it should be noted that this recommendation merely proposes to systematize factors which OSHA has long used to make similar decisions on a more ad hoc basis. Making those criteria explicit offers a significant opportunity to better manage standards setting and efficiently comply with the President's recent order on improving government regulations." ("First Recommendation Report" August 1, 1978, at IV-24 - IV-25 (AIHC P.H.).)

PART FOUR

XV

THE PROPOSED REGULATION SHOULD PROVIDE THAT IN SETTING STANDARDS IN SUBSEQUENT RULEMAKINGS AN EXCLUSION FOR MIXTURES CONTAINING SMALL QUANTITIES OF A CARCINOGEN WILL BE MADE AND AN ACTION LEVEL WILL BE ESTABLISHED

The Proposed Regulation does not contain provisions on two subjects which would have a material impact on the cost of compliance with particular standards and yet would not impair worker health protection:

- (a) exclusion of mixtures which contain a small quantity of a carcinogen as a constituent or contaminant;
- (b) establishment of an action level below which a number of the requirements of the standards, particularly monitoring and medical surveillance, are significantly reduced.

The Proposed Regulation should be amended to provide that in setting individual substance standards an appropriate exclusion will be made for mixtures and an action level established.

A. A Mixture Exclusion And An Action Level Should Be Incorporated Into The Standards

Any conceptual difficulty which OSHA may have with a mixture exclusion and an action level stems from two administrative policy determinations which, as we have shown, should on the basis of the record be modified. These policy determinations are:

- (i) There is no safe exposure level and any exposure is associated with risk.

- (ii) Therefore, lowest feasible exposure is mandated in all cases.

When the concepts of risk analysis, and an evaluation of the reasonable necessity of controls following a risk/cost/benefit analysis of the kind described above replace the two inflexible policy determinations proposed by OSHA, the conceptual difficulties vanish.

An acceptable level of "contamination" of mixtures by a carcinogen can be established in the same way that an acceptable risk level of exposure is determined. The level will vary with the substance and the risks associated with the level of contamination. The same reasons that a mixture cut-off was set in the proceedings involving the fourteen carcinogens, and more recently in the standards for benzene and acrylonitrile, point to the conclusion that the Proposed Regulation should authorize such a mixture "cut-off" in individual substance standards.

There is no conceptual difficulty with an action level if the standard is set at a feasible, reasonably necessary level. When controls are engineered, they are generally engineered to achieve a level below the PEL. Otherwise the normal operation of a plant would lead to continued violations or changes in control methods as production and control efficiencies changed. Thus an action level is in reality a recognition of this engineering "fact".

B. A Mixture Exclusion And An Action Level Could Materially Reduce Cost And The Number Of Establishments Regulated

Since the proposed model standard provides that it is

applicable whenever a substance is "introduced" or is "present" in the workplace, (Section 1910.000(d)), the workplaces subject to the standard will include every workplace where a mixture containing any amount of the substance is opened or used. By fixing a mixture cut-off, the number of regulated workplaces will drop dramatically without in any way endangering employee health.

Similarly, the use of an action level makes it possible to reduce dramatically the cost of compliance since monitoring and medical surveillance, which make up a large part of the cost of compliance, will be reduced.

Snell testified that the mixture exclusion would have a material effect on costs of compliance and costs of enforcement. (Tr. 3837-3838, 3890; Snell Report at 520-521.) An action level would not adversely affect worker health since the worker exposure would be below the PEL. Without such exclusions for mixtures and an action level Snell estimated that the entire workforce of the United States could be covered by standards promulgated pursuant to the Proposed Regulation with costs of compliance "significantly higher" than those estimated in the Report. (Snell Report at 5, 520-521.) Further, it would eliminate from the standards requirements many persons with infrequent and minimal exposure who might otherwise be unintentionally and needlessly covered, such as delivery men, telephone repairmen and safety inspectors. See Air Products S. App. 9-10.

Conclusion

AIHC, SPI and a number of witnesses recommended that OSHA include the action level concept and mixture exclusion in the Proposed Regulation. See, e.g., NIOSH Tr. 3133-3136; Dr. Harris Tr. 3170-3171; Dr. Billings Tr. 2866-2867; Mr. Holaday Tr. 2321-2324. The AFL-CIO did not oppose the principle of an action level and indeed made proposals as to the level of an action level and as to monitoring. (AFL-CIO S. 17-18.) Absent such provisions all of the requirements of the standards arguably would apply even where only a single molecule is present. Indeed, amounts which are at the part per trillion level would be deemed "present" by Mr. Wrenn for purposes of the model standards. (Tr. 67-68.) The Proposed Regulation should be amended to provide that an appropriate mixture exclusion and action level may be set in rulemaking on individual substances.

THREE MATTERS SHOULD NOT FOR PRACTICAL AND LEGAL
REASONS BE PART OF THE PROPOSED REGULATION: (1) RATE
RETENTION, (2) A PERMIT SYSTEM OR (3) LIMITATIONS ON THE
USE OF COMPANY DOCTORS IN MEDICAL SURVEILLANCE

Three matters have been addressed by union representatives which should not be included in the Proposed Regulation: (1) rate retention; (2) the proposal first made by Mr. Samuels on July 18 that OSHA adopt a permit system for potent carcinogens; and (3) the suggestion first made by union representatives on July 14 that severe limitations be imposed on the use of company doctors in the medical surveillance programs.

(1) Mr. Wrenn said at the opening of the hearings that rate retention would be considered for this Proposed Regulation in a subsequent hearing after OSHA has evaluated the earnings retention hearings held last fall in the context of the proposed lead standard. (Tr. 9698; see 42 Fed. Reg. 46547 (September 16, 1977).)

(2) At the hearing on July 18, 1978 for the first time Mr. Samuels presented a permit program for "particularly virulent carcinogens". (Tr. 7256-7258, 7270-7273, 7290, 7300-7301.) This was a revival of a proposal made in 1973 in the proceedings involving the 14 carcinogens (Ex. 131.) and rejected by OSHA at that time. Mr. Samuels' proposal was in fact a modification of the earlier proposal but without details as to the modification.

(3) In their prepared statement the AFL-CIO urged that physical examinations be given by a doctor of the worker's choice.

(Notice No. 71, attachment at 15.) On July 14 and 15, union representatives greatly enlarged this proposal by the surprise suggestion that severe limitations be imposed on the use of company doctors in the medical surveillance programs. (UAW Tr. 5723-5724, 5778-5781, 5791-5795; Steelworkers Tr. 5993-5995, 6032, 6050; Teamsters Tr. 5842-5843.)

On practical and legal grounds, none of these proposals should be part of the Proposed Regulation.

A. Rate Retention Provisions Should Not Be Incorporated Into The Proposed Regulation

It has been suggested in these proceedings that OSHA adopt a provision which would require an employer to ensure no loss of employee wages, seniority or other benefits where that employer removes an employee because of a medical determination which indicates that further exposure to the substance in question would seriously increase the employee's health risk.

AIHC believes such a provision to be unwise and without legal foundation. We support Mr. Wrenn's suggestion that this issue be addressed in a subsequent rulemaking after OSHA has had an opportunity to consider its record on this matter in the earnings protection hearings held last fall in the context of the proposed lead standards. (Tr. 96-98; see 42 Fed. Reg. 46547 (September 16, 1977).)

Without belaboring the point, we should point out that the problem of rate retention is a complex one, varying from situation to situation and not readily amenable to uniform nationwide

solution. Further, we believe there is no sound evidence to support the proposition that there is a serious problem which requires such drastic measures.

Finally, and perhaps most importantly, we do not believe the Congress intended that OSHA venture into the area of economic protection but rather intended the agency to focus its efforts on providing a safe workplace. The explicit provisions of the Act, its legislative history, and other legislative efforts all clearly indicate that economic protection is an area beyond OSHA's statutory authority.

Section 27 of the Act, 29 U.S.C. § 676, recognizes the problems associated with employee economic security. However, rather than authorizing OSHA to deal with the inadequacies of available economic assistance, the Congress decided in that section that a national commission should be established to review and report on the adequacy of worker's compensation laws. The commission's report, published in 1972, has, in fact, led to many legislative amendments at both the state and federal levels. (See OSH Rep. (BNA - Cur. Dev.) 1448 [1976]; and Director, Office of Workmen's Compensation v. Boughman, 545 F.2d 210, 215 n.15 (D.C. Cir. 1976). See also Section 4(b)(4) of the Act, 29 U.S.C. § 653(b)(4).

In addition, the Congress has considered and continues to consider legislative matters pertaining to economic compensation for work-related injuries and diseases. See, e.g., OSHA Rep. (BNA - Cur. Dev. -- Workmen's Comp.): H.R. 8689, 95th Cong., 1st Sess. (1977) (asbestos) and H.R. 3480, 95th Cong., 1st Sess.

(1977) (cotton dust); BNA, supra, August 3, July 7 and March 17, 1977 at 313, 178-179 and 1311-12; H.R. 3630, 95th Cong. (hearings were held September 1978). Such matters are perceived by the Congress to be and are appropriately within the domain of the legislature, not OSHA.

The legislative history of the Act further demonstrates that Congress did not intend that OSHA become involved in economic protection. Indeed, an earlier bill approved by the House Committee on Education and Labor would have permitted a form of earnings protection. The bill as passed by both the House and Senate, however, contained no such provision. See Legislative History at 416, 842, 860, 985-86, 1008-1009 and 1089.

Where the Congress has intended that an agency step into the area of economic protection, it has clearly spoken out. For example, the Coal Mine Health & Safety Act, enacted a year prior to the Act, explicitly provides a federal directive on economic compensation for individual workers. See 30 U.S.C. § 901. Further, the Clean Air Act Amendments of 1977 explicitly include authorization for worker protection. See 42 U.S.C. § 7410(a)(6). The fact that no such provisions are contained in the OSH Act is highly significant.

B. The Permit System Has Been Insufficiently Considered In This Hearing And Is Not Authorized By Law

The suggestion was made in the course of these proceedings that OSHA should include in its Proposed Regulation

a system whereby an employer would be required to seek a use permit prior to any use in his workplace of a regulated carcinogen. Such a permit system would require the employer to be inspected and licensed by OSHA before employees are allowed to work in the area of exposure. Shutdown orders would be issued by OSHA to employers operating without a permit or to permit holders who fail inspection. In addition, permit applicants would have the burden of proving the absence of a safe or technologically feasible alternative to the regulated substance. (AFL-CIO Tr. 7256-7258; see also Dr. Wolfe Tr. 6353-6354).

AIHC strongly believes that the establishment of a use permit system is not only unwise, but is beyond the scope of OSHA's legal authority.

The primary rationale voiced in favor of a use permit system is that such a system is "the only way to ensure that zero level exposures will be implemented." (Dr. Wolfe Tr. 6353.) Indeed, pre-approval inspection as a means of ensuring that no exposure will result from the activity inherently raises the concept of zero tolerance. However, AIHC believes that it would be improper for OSHA to set uniformly a lowest feasible level of exposure, no less a zero exposure level. Imposition of any such single level of exposure would disregard the potency and risk of exposure to a particular substance. Therefore, AIHC supports, and the record demonstrates the propriety of the establishment of exposure levels on the basis of acceptable risk, after the risk/cost/benefit assessment, which must be an indispensable

part of OSHA's regulatory decisions, has been made.

Moreover, the establishment of a use permit system would clearly exceed OSHA's statutory authority. Nowhere in the statute is OSHA explicitly granted the power to impose a permit system on employers. OSHA's authority is limited under Section 6 of the Act, 29 U.S.C. § 655, to the promulgation of occupational safety and health standards, to be uniformly applied to places of employment as a means of protecting the safety and health of affected employees. Where such standards could not be met, Congress provided the Secretary with authority to grant variances from standards issued under the Act under specified circumstances. 29 U.S.C. §§ 655(b)(6) and (d).

It must be recognized that the authority to impose a permit system is equivalent to the authority to prevent a business from getting started, to close down an existing operation, or, at the very least, to ban production of a particular substance from an operation, simply by denying a permit or refusing to renew a permit. However, both the Act and its legislative history demonstrate that OSHA does not have and was never intended to have such authority. The section of this brief dealing with the "suitable substitute" provisions demonstrates OSHA's lack of authority to completely ban the production of substances. Similarly, the agency cannot order a particular plant to cease its operations. Rather, the statute contemplates that an employer shall conduct his business in accordance with duly promulgated standards in order to provide safe and healthful working condi-

tions for his employees. If, after an investigation (pursuant to Section 8 of the Act, 29 U.S.C. § 657), the Secretary determines that the employer is in violation of a standard, a citation may be issued (pursuant to Section 9, 29 U.S.C. § 658). The employer is provided with a "reasonable time" to correct the violation or fifteen days to contest the citation. 29 U.S.C. §§ 658, 659. The Act does not, however, provide for the cessation of operations during the time in which the employer seeks to correct the violation or contest the citation.

In fact, the legislative history of the Act indicates that when it was proposed that the Secretary be vested with the power to shut down an operation for up to 72 hours if he found that an "immiment danger" existed, such a suggestion was rejected. See 116 Cong. Rec. 38,379 (1970), U.S. Code Cong. & Admin. News, 91st Cong., 2d Sess., at 5236 (1970). Under Section 13 of the Act, the Secretary may seek a cessation of operations in the case of an "imminent danger", but such an order can only be issued by a United States District Court. See 29 U.S.C. § 662. OSHA itself has no direct authority to order a shutdown. Thus,

"[i]t is obvious that Congress considered the shut-down of an operation such a serious matter that nothing short of the judicial process with its full complement of due process protections was acceptable as a means of accomplishing it." Usery v. Whirlpool Corp., 416 F. Supp. 30, 34 (N.D. Ohio 1976).

A use permit system such as that proposed during these proceedings would vest in OSHA the very authority which Congress intended to be exercised, if at all, by the courts, and not by the agency.

Had Congress intended that OSHA have the power to issue permits ordering a cessation of operations (or a ban on production) it would have granted such authority expressly in the statute. In a number of other statutes, Congress has explicitly granted administrative agencies the authority to issue permits or licenses. These statutes include: the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.; the Federal Water Pollution Control Act, 33 U.S.C. § 1151 et seq.; and the Communications Act of 1934, 47 U.S.C. § 151 et seq. Absent such explicit authorization in the Act, the power to establish a use permit system cannot be implied in OSHA. The Supreme Court has clearly stated that "[w]hen Congress passes an Act empowering administrative agencies to carry on government activities, the power of those agencies is circumscribed by the authority granted." Stark v. Wickard, 321 U.S. 288, 309 (1944).

Finally, it should be noted that this issue was not raised in the OSHA proposal nor has it been adequately discussed in the proceedings to date. To move forward as suggested, presents, in addition to all the other problems outlined, serious questions of procedural due process.

C. The Proposal To Restrict Use Of Company Doctors In Medical Surveillance Programs Is Unsound For Practical And Legal Reasons And Without Support In The Record

In its prepared statement, the AFL-CIO proposed that physical exams be given by a doctor of the worker's choice. (AFL-CIO Notice No. 71, attachment at 15.) At the hearing,

however, union representatives proposed a surprising new and sweeping limitation on the use of company doctors in medical surveillance. (Tr. 5723-5724, 5778-5781, 5791-5795, 5842-5843, 5993-5995, 6032, 6050.) This proposal by the unions late in the hearings presents serious practical and legal problems.

A major underlying purpose of the medical surveillance program is to enable the company and the government to do prospective epidemiology. There is no way that this objective can be achieved unless full information regarding workers' health and exposure can be appropriately recorded. Indeed, this procedure may be the only effective way to identify susceptible individuals whose exposure would present significant problems. Thus, for example, if smoking increases the risk of lung cancer by orders of magnitude when the worker is exposed to asbestos, knowledge of smoking habits is the only way to protect the worker. See Dr. Lamm S. 4-5 (AIHC P.H.).

Some of the union representatives complained about the incompetence of company doctors. E.g., Tr. 5991-5993. This is not, however, a matter for general regulation. The reasonable way to deal with incompetence, if indeed it exists, is to enlist the State medical authorities and the medical societies and to make the medical program a matter of collective bargaining. Under some circumstances, moreover, incompetence in performing medical surveillance could be a basis for an OSHA enforcement proceeding. To use the isolated instances cited by the unions as a ground for sweeping condemnation of company medical sur-

veillance programs is totally unjustified.

Post-hearing filings by Dr. Alan A. McLean, President of the American Occupational Medical Association (Ex. 209), Dr. Harold R. Imbus, Medical Director of Burlington Industries, Dr. M. A. Johnson, Administrator Environmental Health Projects of the B. F. Goodrich Company, Dr. K. D. McMurrain, Medical Director of the Procter & Gamble Company, and Edward C. Dalglish, General Manager of Hughson Chemicals, provide cogent reasons why the union's belated proposal to restrict company doctors is unsound.

First, the very high worker participation in voluntary medical examination programs demonstrates that workers do not distrust or have concern about the position of company doctors.

Second, the quality of the medical surveillance would suffer because the majority of physicians lack training in occupational medicine. When there is an examination of workers at regular intervals by a trained company doctor, earlier detection of industrially caused disease is enhanced. When the examinations are done by one physician or several physicians in close communication, it is possible to arrive at useful conclusions which would not occur if examinations were not standard and records scattered. Thus, the observation that vinyl chloride is a human carcinogen was made by a doctor who noticed three cases of an unusual tumor. Had separate doctors seen the workers it is unlikely that the connection would have been made.

Third, unless medical records are assembled centrally,

it will be much more difficult to conduct the epidemiological studies which are an essential objective of medical surveillance programs.

These post-hearing filings also demonstrate the significant efforts that are being made to upgrade the standards of occupational medicine and the high level of ethics observed by company doctors. It would do workers a disservice were OSHA to take steps which would set back occupational medicine by promoting the dispersal of medical surveillance among untrained general physicians.

Finally, despite the post-hearing filings discussed above, there is a serious question of notice and due process. This proposal was made long after the hearing began and at a time when many company witnesses had already testified and had no opportunity to respond. Others had no notice of the union demand and thus no reasonable opportunity to comment.

Conclusion

For the foregoing practical and legal reasons, there should be no provision in the final regulation requiring rate retention, establishing a permit system or restricting company medical surveillance.

XVII

KEY WORDS IN THE PROPOSED REGULATION ARE IMPERMISSIBLY VAGUE

The Proposed Regulation is impermissibly vague in its failure to define a number of key terms. For example, OSHA's proposal provides no definition of the term "suitable substitutes" (Section 1990.112) or of the phrases "as low as feasible" (Section 1990.112) and "lowest feasible level" (Section 1990.160(c)). Other impermissibly vague aspects of the regulations include the lack of definition of "suggestive" (Section 1990.102), the "any other evidence" criterion (Section 1990.110), whether a substance has "unique" properties or uses (Section 1990.113(d)), and the rebuttal criteria of Section 1990.111(a), including the terms "grossly inappropriate" (Sections 1990.111(a)(2) and 1990.121(a)(2)), and "totally inadequate" (Sections 1990.111(a)(4) and 1990.121(a)(4)). The vagueness of these terms effectively deprives the public of a meaningful opportunity to comment on the Proposed Regulation. Moreover, the vagueness of these terms would render the Proposed Regulation invalid as a denial of due process.

A. Critical Terms In The Proposed Regulation Are Vague And Inadequately Defined

A number of critical terms in the Proposed Regulation have either been inadequately defined or not defined at all. For example, the regulations provide in Section 1990.112(b) that, upon a finding by the Secretary of Labor that there are "suitable

substitutes" for certain uses or classes of uses that are less hazardous to humans, no occupational exposure shall be permitted for such uses or classes of uses. However, nowhere in the Proposed Regulation or in the Preamble thereto are there any criteria for determining what constitutes a "substitute", nor are there criteria for measuring "suitability" of a substance as a substitute. Mr. Wrenn, candidly admitted that OSHA had not moved beyond the conceptual stage in developing factors for determining what is a "suitable substitute". (Tr. 121-122.)

Similarly, the other key terms in the Proposed Regulation referred to above suffer the same defect of vagueness and inadequate definition. The AIHC, on the other hand, provides a full and precise explanation for each of the critical terms and concepts included in its Alternative. For example, in place of the vaguely defined concept of "lowest feasible level", the AIHC recommends the determination of an "acceptable risk level" for each Category I and II substance, to be determined by a process of risk and benefit assessment fully described in the AIHC Alternative. See AIHC Alternative at 33-34, 78-84. This is the procedure approved by the Benzene decision.

B. Critical Terms In The Proposed Regulation Are So Vague As To Preclude Effective Public Comment On The Proposed Regulation

Section 4 of the Administrative Procedure Act, 5 U.S.C. § 553(b)(3), requires that prior to the promulgation of a final

rule, the agency must publish either the terms or the substance of the proposed rule or a description of the subject and issues involved. The courts have ruled that an agency's notice of proposed rulemaking must describe sufficiently the subject matter of the rulemaking so that informed comment and criticism can be offered by interested parties. See Portland Cement Association v. Ruckelshaus, 486 F.2d 375, 392-394 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974); Mobil Oil Corp. v. FPC, 483 F.2d 1238, 1249-1251 (D.C. Cir. 1973). The courts have not hesitated to invalidate final regulations where the agency did not give adequate notice of the subjects and issues involved and thereby deprived the public of an opportunity to submit effective and meaningful comments. See, e.g., Wagner Electric Corp. v. Volpe, 466 F.2d 1013, 1019-1020 (3d Cir. 1972); Natural Resources Defense Council v. SEC, 389 F. Supp. 689, 698-700 (D. D.C. 1974).

Without more detailed knowledge of the criteria which OSHA proposes to apply in determining what constitutes a "suitable substitute", "lowest feasible exposure" or "other evidence" convincing to the Secretary, or how the presumption that a substance should be classified as a Category I substance can be rebutted, it is impossible for manufacturers or users of potentially affected substances to offer meaningful comment on the impact of OSHA's proposed method of controlling Category I toxic substances. If, for example, the public were advised whether and how OSHA proposes to take into account such factors

as differences in cost and availability of supply in determining adequacy of substitutes, manufacturers and users could submit detailed factual and legal arguments and appropriate scientific and economic data for OSHA's consideration. Use of vague and insufficiently detailed criteria thus defeats the purpose of Section 4 of the Administrative Procedure Act, to provide for informed public participation in the rulemaking process and to enable the agency promulgating the rule "to educate itself before establishing rules and procedures which have a substantial impact on those regulated." Texaco v. FPC, 412 F.2d 740, 744 (3d Cir. 1969); see also Natural Resources Defense Council v. SEC, supra, at 699.

If the Proposed Regulation was adopted as a final regulation, manufacturers and users could be precluded from challenging the validity of the consequences of classification of a substance as a Category I toxic substance, including a ban on production if a "suitable substitute" exists. While the definition of "suitable substitute" and other vaguely-defined terms may be fleshed out on an ad hoc basis in a series of individual rulemakings, such rulemakings cannot afford industry in general an adequate opportunity for comment and hearing on OSHA's definition of these critical terms. The issues in these individual rulemakings will be limited to the principal question whether the substance was correctly classified as a Category I toxic substance and, secondarily, to various ancillary issues viewed in the context of the particular substance. Thus, there will be

little or no opportunity to comment on the more detailed criteria which OSHA will presumably adopt to give meaning to these vague and insufficient terms. Moreover, it is unlikely that parties not directly concerned with the substance at issue will be able to participate effectively, even though their interests may be vitally affected by the implicit or explicit development of precedent as to the meaning of key terms.

The courts have rejected agency attempts to circumvent the notice requirement of Section 4 of the Administrative Procedure Act where the agency has adopted ambiguous rules and evaded proper rulemaking procedures when the ambiguous rule later was clarified. In Saint Francis Memorial Hospital v. Weinberger, 413 F. Supp. 323 (N.D. Cal. 1976), the Department of Health, Education and Welfare ("HEW") adopted unclear rules on accounting for interest paid on certain construction loans and subsequently sought to "clarify" its rules, both retroactively and prospectively, without conducting a rulemaking. The court followed Pharmaceutical Manufacturers Ass'n v. Finch, 307 F. Supp. 858 (D. Del. 1970), in holding that a rulemaking was required because the clarification was not interpretative. The court observed in St. Francis that a rule is substantive and not interpretative where "there is such genuine ground for difference of opinion on the wisdom of the policy embodied in the rule as to make the hearing process a meaningful and important requirement." Saint Francis Memorial Hospital v. Weinberger, supra, at 329. The court rejected HEW's argument that its

"clarification" was not a substantive rule because, prior to its issuance, HEW's regulations were ambiguous:

"In essence, defendants' argument seems to be that because the Secretary created an ambiguity in the regulations he need not adhere to the proper rulemaking procedure when he clears up that ambiguity. Without reaching the issue of whether there was any ambiguity in the regulations as they existed at the time section 206 was promulgated, the court rejects this argument as fundamentally inconsistent with the purposes of the rule-making requirements of the Administrative Procedure Act. The Medicare Act conferred on the Secretary the authority and duty to promulgate regulations governing reimbursement of providers of medical services. He could not fulfill that duty by enacting ambiguous regulations through the proper procedure and then 'clarifying' them behind closed doors thereafter." Id. at 330.

Similarly, OSHA may not properly seek to insulate its proposed standards for regulation of Category I toxic substances from a rulemaking which provides for public comment on the merits of the proposed standards by subsequently adopting criteria which define "suitable substitute", and "lowest feasible occupational exposure", and other critical terms without effective opportunity for public participation.

C. If Adopted In The Form Proposed, These Vague Provisions
Of The Proposed Regulation Would Deprive Affected Parties
Of Due Process Of Law

By reason of the defects referred to above, the Proposed Regulation is so vague and indefinite as to allow the agency virtually unlimited discretion in severely limiting or even banning the manufacture and use of Category I toxic substances. The breadth of this discretion violates the constitutional require-

ment that administrative action be guided by regulations setting out standards which are sufficiently definite to confine agency discretion within predetermined bounds.^{1/} Without such standards, affected parties are deprived of due process of law, and meaningful judicial review of agency action is impossible.

In Environmental Defense Fund v. Ruckelshaus, 439 F.2d 584 (D.C. Cir. 1971), the court reviewed EPA's refusal to suspend the registration of DDT as a pesticide. The court noted that it had neither an evidentiary record, nor scientific expertise to aid its review of the agency's actions, but that it had "an obligation to ensure that the administrative standards conform to the legislative purpose, and that they are uniformly applied in individual cases." Id. at 596. The court remanded to EPA for an explanation and formulation of standards to guide agency discretion:

"Judicial review must operate to ensure that the administrative process itself will confine and control the exercise of discretion. Courts should require administrative officers to articulate the standards and principles that govern their discretionary decisions in as much detail as possible." Id. at 598.

See also Holmes v. New York City Housing Authority, 398 F.2d 262, 265 (2d Cir. 1968).

These decisions were followed in City of Santa Clara v. Kleppe, 418 F. Supp. 1243 (N.D. Cal. 1976), a case in which

^{1/} See generally Papachristou v. City of Jacksonville, 405 U.S. 156, 170 (1972); Kenneth Culp Davis, Administrative Law of the Seventies, supplementing Administrative Law Treatise, § 2.00 - § 2.04 (1976); Amalgamated Meat Cutters v. Connally, 337 F. Supp. 737, 758-759 (D. D.C. 1971).

the Bureau of Reclamation's decision withdrawing low-cost federal hydroelectric power from the City of Santa Clara was remanded for failure to provide procedural due process:

"Procedural due process has a function beyond that of encouraging enlightened, informed administrative decisions. Courts have with increasing frequency recognized that due process means that administrators must do what they can to structure and confine their discretionary powers through safeguards, standards, principles and rules . . . It is all the more imperative that courts require administrators to articulate the standards that guide their discretion where, in cases such as the one at bar, the court lacks the scientific expertise that would permit meaningful review." Id. at 1260-1261.

Similarly, regulation of carcinogens involves complex and highly technical determinations. If the Proposed Regulation is adopted in the form proposed, OSHA's vague and indefinite standards for controlling Category I toxic substances would encourage arbitrary and inconsistent determinations by OSHA. By the same token, the lack of content of many key terms in the Proposed Regulation would effectively prevent meaningful judicial review both of the Proposed Regulation itself and of subsequent regulatory actions taken pursuant thereto.

PART FIVE

XVIII

OSHA'S MODEL STANDARDS ARE UNLAWFUL AND INAPPROPRIATE

A. The Act Prohibits The Kind Of Inflexible Model Standards OSHA Has Proposed

In describing health standards that OSHA must promulgate, among the benchmarks used by the Congress were that standards be "appropriate", "reasonably necessary or appropriate", "feasible", and based on the "best available evidence". See 29 U.S.C. §§ 652 (8), 655(b)(5) and 655(b)(7). To establish rigid, inflexible model standards in this rulemaking without regard to their need or adequacy in the context of particular substances and workplaces flies in the face of OSHA's statutory mandate.

Any model standards should be in the nature of guidelines and should be sufficiently flexible to accommodate disparate properties, hazards and workplaces. There is a great danger in deciding these matters, a priori, in this rulemaking for all subsequent rulemakings. OSHA's professed need for expedition should be no bar to a considered analysis in subsequent rulemakings of language appropriate to the matter then at hand. Certainly OSHA can, as it has in the past, and as it has in the proposed model standards, draw heavily (and expeditiously) from language used in past standards. There is no need to lock the agency in, at this time or in the foreseeable future, to specific language in a model standard.

OSHA urges that there is sufficient flexibility in the model standards because it will consider in subsequent rulemakings the "unique properties or uses" of substances to determine whether the standards are "inappropriate" or "infeasible". (Section 1990.113(d), 43 Fed. Reg. 54173.) This position is not persuasive, however, for several reasons. First, none of these critical terms is defined so there is no way of knowing how OSHA will implement this provision. Second, in looking for exceptions to what should be required rather than looking to what should be required, OSHA is turning the statute on its head and proceeding in a most unscientific manner. In addition, while there may be an opportunity in a subsequent rulemaking to argue that a model standard is "inappropriate" or "infeasible" because of the "unique" properties of the substance, this, in practice, will put a very heavy burden on the proponent of such a proposition. Moreover, while there may be some opportunity to argue the merits of permanent model standards in subsequent rulemakings, this opportunity will be considerably more limited with respect to the model emergency temporary standard which will go into effect promptly after categorization. (Hygiene Panel Tr. 2693-2694.)

Thus, while OSHA argues that there is sufficient flexibility to accommodate future concerns, we do not agree. Even if the model standards are to be used only as guidelines, there is need for significant revisions.

Because AIHC believes a "fill-in-the-blank" approach is inappropriate, it has recommended in its Alternative to the

OSHA proposal that the basic principles applicable to model standards be elucidated in this rulemaking which would then be addressed in the context of particular risk/hazard combinations in subsequent rulemakings. AIHC Alternative at 50-52. See Appendix F to this brief.

NIOSH and others have also expressed concern about the inflexibility of the standards. In particular NIOSH recommended that OSHA seriously consider an approach to the model standards which would set out several alternate options within each subsection of the standard tailored to particular characteristics and properties of the substances to be regulated. See letter from Edward J. Baier to Docket Officer dated June 7, 1978. For example, there might be three alternate sections on personal protection from which OSHA could select the best-suited provision for a particular substance. This, as NIOSH notes, is an approach that OSHA and NIOSH have used in their joint Standards Completion Project. Unfortunately, the proposed model standards seem to proceed on the assumption that the substances to be regulated present similar hazards and risks and therefore require similar monitoring, medical surveillance and housekeeping. In fact, as discussed earlier, this is clearly not the case. Indeed as API very ably points out in its post-hearing comments, OSHA's previous standards for carcinogens have frequently varied from the rigid requirements embodied in the proposed model standard.

B. Because The Model Standards Will Be Applicable In Enforcement Actions, Their Meaning Must Be Clear

Because the model standards proposed in this rule-making may be the subject of compliance action by OSHA's field enforcement staff, the standards must, to the extent possible, be crystal clear both to the regulated and to the OSHA field staff. Any possible ambiguities, as noted by OSHA's industrial hygiene panel, should be clarified now to avoid future controversy and litigation. (Hygiene Panel Tr. 2620-2621, 2698-2699.) The purpose of many of the following comments on the model standards is to do just that.

C. The Model Standards Are In Need Of Revision

1. Scope and Application (Subsection (a))

The model standards should provide for an "action level" below which certain provisions of the standards, such as medical surveillance and monitoring, are not required and should provide a cutoff for mixtures containing small amounts of the regulated substance. In the absence of such provisions, all of the requirements of the standards arguably would apply even where only a single molecule of a regulated substance is present.

The regulations should also exempt laboratory, maritime, construction, and agricultural workplaces from its scope. These workplaces should be handled separately by OSHA. See discussion supra, at 37-41.

2. Definitions (Subsection (b))

In order to avoid ambiguity, certain terms used in the model standard are very much in need of definition. Among these are the terms "feasible", "suitable," "occupational exposure" (Wrenn Tr. 37-38, 67-68), "present" and "work area" (Hygiene Panel Tr. 2813-2815). Further, the definition of the term "emergency" is too broad. It should include only occurrences which result in massive releases. See Air Products S. App. 15-16.

3. Permissible Exposure Limit (Subsection (c))

a. General

The model standard provisions requiring lowest level feasible exposures or mandating substitution should be modified as noted earlier in this brief.

b. Dermal and Eye Exposure

As proposed, the model standards for Category I and II would require that the employer "assure that no employee is exposed to eye contact or skin contact" with the substance. Sections 1910.160(c)(2) and 1910.170(c)(2). Such a seemingly absolute prohibition is logically inconsistent with permitting finite airborne exposures in the workplace. (NIOSH Tr. 3140-3141.) Moreover, even protective clothing and equipment cannot eliminate all skin and eye contact. (Dr. Holaday S. 6-7, Tr. 2838-2839.) The provisions of the model standard are also at variance with the Preamble to the Proposed Regulation which states that the provision is directed only at "repeated" skin contact. 42 Fed. Reg. 54174.

The preferable approach to requiring what appears to be zero exposure is, as noted by NIOSH, to tailor the requirements to the hazard for eye and skin contact. Varying physical properties and hazards require varying regulatory responses. (NIOSH Tr. 2634.) Some substances may require substantial safeguards, others only minimal safeguards. (NIOSH Tr. 3138-3140; Dr. Murray S. 4-5.) The concept of the significance of the hazard presented should, according to NIOSH and Dr. Soule, be factored into this aspect of the regulation. (NIOSH Tr. 3140-3141; Soule Tr. 2813-2832.) A sensible approach suggested by NIOSH is to specify protective clothing which is designed to meet a particular goal rather than require an absolute prohibition (e.g., require protective clothing sufficient "to prevent prolonged or repeated contact"). See NIOSH submission on Standards Completion Project Decision Logic at 82.

Further, Dr. Holaday suggested OSHA's permanent standard should be clarified and explicitly state for substances to be regulated "why protective clothing is required and what exposures are sought to be avoided or reduced." (Dr. Holaday S. 6.)

c. Category II Substances

OSHA has invited comment on that aspect of its proposal which requires for Category II substances that permissible exposure limits be established or reduced where necessary to that level which protects against acute or chronic non-carcinogenic effects.

AIHC is of the view that in such situations (OSHA Category II, AIHC Category III), the substance should be referred to the Interagency Testing Committee ("ITC") for possible testing. Further, we believe OSHA should have the authority to issue a notice of proposed rulemaking to set the PEL at the present OSHA standard or establish a new or reduced PEL based on the acute or chronic non-carcinogenic effects of the substance.^{1/} AIHC Alternative at 85.

4. Exposure Monitoring (Subsection (e))

a. Representative Monitoring

The model standards require representative employee monitoring. The Preamble makes clear that any form of monitoring which is "representative" is permissible. 42 Fed. Reg. 54175. This would include both biological monitoring and area sampling. It may include sampling one employee or many for several hours or for a full 8-hour shift. The model standard is, however, susceptible to a different interpretation; particularly Section 1910.160(e)(3)(ii), which requires in the case of exposures exceeding the PEL limit that the employer repeat monitoring for "each

^{1/} We do not subscribe to the AFL-CIO suggestion that a substance remain in Category II for no more than three years. We believe no arbitrary time limit should be set but rather that the ITC should determine the relative urgency and need for testing the substance in question. Given the limited testing resources available in the nation, it would not be possible to test within three years the large number of substances which might fall into Category II, a number which Clement has estimated to be as high as 218.

such employee monthly." Some have taken this to mean that biological sampling of each exposed employee is necessary, a clearly unnecessary allocation of manpower and resources.^{1/} See Reynolds Metals Co. S. 2-3. The standard should make clear that the "representative" which is used only in Section 1910.160(e)(1)(i) is intended to be applicable throughout subsection (e) and that biological monitoring and area sampling are permitted forms of monitoring. Further, it should be made clear that what is "representative" may vary considerably depending on the properties of the substance and the nature of the workplace and the exposure.

b. Initial Monitoring

Where the regulated substance is "present", the model standard requires initial monitoring. While this may be a generally sensible provision, an exception to this requirement should be made where exposure is not reasonably foreseeable as in the case of materials locked into products in such a way that their release is not likely. See, e.g., Johns-Manville S., Exhibit A at 4, on fibers locked into asbestos products. The standard should permit the use of an initial "determination" in the place of initial "monitoring" in such situations, as well as in other appropriate situations. See NIOSH/OSHA Standards

^{1/} If, for example, an employer has fifty employees who perform the same job, and industrial hygiene monitoring has confirmed that in the group of employees all have approximately the same type and level of exposure, the employer should be permitted to comply with the standard by monitoring three or four employees on a monthly basis.

Completion Project, 40 Fed. Reg. 20201, 20203 (May 8, 1975).

c. Additional Monitoring

The model standards require additional monitoring whenever there has been a production, process, control or personnel change which may result in new or additional exposure. Section 1910.160(e)(4). This provision is susceptible to an overly broad interpretation requiring additional monitoring when there is any change in production, process or control, however minor. The intent of the provision would appear to be to reach only matters of significance and, accordingly, AIHC suggests that the word "significant" be added before the word "exposure".

OSHA should not lose sight of the fact that our national industrial hygiene and analytical resources are limited and that these resources should not be overburdened with unnecessary chores. (Hygiene Panel Tr. 2827-2828.)

d. Employee Notification

The Act requires that notice be given only to those employees exposed in excess of the PEL, not to those exposed below the PEL. 29 U.S.C. § 657(c)(3). The model standard should be revised accordingly.

Rather than requiring written individual employee notification in all situations, the standards should permit other reasonable means of notification, such as posting.

An unintended but, we believe, serious possible ramification of the burdensome requirement for employee notification proposed by OSHA is that employers may be discouraged from using

automatic monitoring devices because minor deviations may more frequently trigger onerous notification requirements.

5. Methods of Compliance (Subsection (g))

The OSHA proposal requires the use of engineering controls or work practices to reduce exposures to the extent feasible. Further, the proposal requires the use of engineering controls even when they will not reduce exposures below the PEL.

While AIHC subscribes to the view that in many situations engineering controls are the best means of compliance, the model standard should be flexible enough to permit other effective means of control where appropriate. For example, it may be that relatively simple and inexpensive protective clothing may as adequately serve OSHA's goals as expensive engineering equipment where the hazard is skin contact. See Dr. Murray S. 4; API Alternative Panel Tr. 4539-4541.

Further, if engineering controls will, in any event, have to be supplemented by other means of control in order to achieve compliance, it makes little sense from a health or economic perspective to require installation of expensive engineering controls which cannot do the job anyway. (API Alternative Panel Tr. 4540-4543.) In its economic study, Snell concludes that the mandated preference for engineering controls is one of the single most costly aspects of the OSHA proposal. See Snell Report at 496, 503, 519.

The President's Regulatory Analysis Review Group expressed similar reservations to OSHA's mandated preference for

engineering controls in its analysis of OSHA's acrylonitrile proposal. (Ex. 45 at 21-24). The Group urged consideration be given to wider use of non-engineering controls, where appropriate, to achieve the desired end.

Finally, if respirators and protective clothing are relegated to the subsidiary role envisioned by OSHA there will be little, if any, incentive for industry to develop better respirators and protective clothing, a most unfortunate development.

We concur in the recommendation of the Environmental Defense Fund that for OSHA Category II substances OSHA should require only a practical combination of administrative, work practice and readily available and economical engineering controls. (EDF Tr. 7328-7330.) Since Category II is essentially a transitory stage, it makes little sense to require installation of expensive engineering controls for substances which are likely to be reclassified shortly as Category I or III.

6. Respiratory protection (Subsection (h))

As noted in the preceding section, AIHC is of the view that means other than engineering controls or work practices, including respiratory protection, may be appropriate in certain limited circumstances.

While AIHC and other industry participants do not believe that regular 8-hour per day use of respirators is generally a sound approach to control (Tr. 3820, 4516), there may be situations where brief exposures occur regularly or irregularly

for which respirator usage seems appropriate but which nonetheless do not appear to fall strictly within OSHA's limited exceptions for respirator use. For example, a brief exposure of a few minutes duration, a couple of days a week, for an employee entering a production room from a quality control room where there are engineering controls would seem to be a situation in which it makes more sense to use a respirator than to install very expensive engineering controls. (Mr. Douglas Tr. 2776.)

There is a need for maintaining flexibility concerning the use of respirators. NIOSH suggested an approach for respirator use similar to that in the Standards Completion Project, which permitted respirator use for one hour per week (see, e.g., 40 Fed. Reg. 20201, 20211 (May 8, 1975)) over and above the exemptions OSHA has already suggested in this proposal. (NIOSH Tr. 3145-3146.) We believe such an approach would be a useful starting point.

7. Emergency situations (Subsection (i))

Subsection (i)(2)(i) requires the installation of alarms to alert employees to emergencies. This provision should be sufficiently flexible to permit means of alerting employees to hazards other than by sound alarms.

8. Protective clothing and equipment (Subsection (j))

OSHA's proposed model standard is susceptible to the construction that whenever eye or skin contact "may occur" protective clothing is necessary.

This provision of the model standard should be clarified to assure that such equipment is required only where there is a reasonable likelihood of significant exposure which may affect the worker's health. (NIOSH Tr. 3141, 3143.)

Dr. Holaday recommended use of protective clothing to protect against the "demonstrated risk of skin cancer, or even where the risk is subject to debate, where employees are subjected to repeated insults to the liquid form of Category I substances presenting the possibility of skin absorption." (Dr. Holaday S. 5-6.) He did not recommend protective clothing wherever any contact "may occur" with a Category I substance. Indeed, he noted some of the difficulties of extended usage of such clothing. (Dr. Holaday Tr. 2839.)

9. Housekeeping (Subsection (k))

a. Surfaces

OSHA's proposal requires that all surfaces be maintained "free of accumulations". It is, as OSHA's own witnesses recognized, of course, not possible to keep surfaces absolutely free of contaminants where finite airborne exposures are permitted. (Hygiene Panel Tr. 2626.)

Among the options the Hygiene Panel suggested should be considered were that a quantitative parameter or a "visibility" criterion be used as benchmarks where appropriate. (Hygiene Panel Tr. 2627-2629, 2633, 2695, 2809-2810.) Even OSHA's recent cotton dust and inorganic arsenic standards require only that

surfaces be maintained as free "as practicable" of accumulations. See 29 C.F.R. § 1910.1018(k)(1) and 29 C.F.R. § 1910.1046a(c)(1)(i); 43 Fed. Reg. 19583, 19627 (May 5, 1978); 43 Fed. Reg. 27349, 27434 (June 23, 1978). By requiring adequate decontamination procedures, AIHC believes OSHA should be able to obtain the same workplace objective without the attendant difficulties associated with the words "free of accumulations".

b. Vacuum

The standards appear to require separate portable vacuums for each regulated substance. This is an unnecessary burden for employers who may have many regulated substances in their workplace. The burden would be particularly heavy on laboratories and batch operations. Absent a showing of hazard associated with the use of the same vacuum for multiple substances, we see no need for such a restrictive requirement. (Nat. Constructors Ass'n., Ex. 125 at 10-11.)

c. Waste Disposal

The model standards require waste from regulated substances to be disposed of in sealed bags or closed containers. While this again is generally sensible, where such wastes, because of their characteristics, e.g., having been incorporated in another substance, are not likely to present a hazard, disposal in this manner seems unnecessary. (Johns-Manville S., Ex. A at 89.) Further, disposal of large equipment in sealed bags is an obvious impossibility. Adequate decontamination procedures should be allowed as a substitute. See Air Products S. App. 13.

10. Hygiene facilities and practices (Subsection (m))

The standards require employers to provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply whenever food and beverages are consumed in the "workplace". The term "workplace" is not defined. If it is defined to mean anywhere in the entire place of employment, a severe hardship may occur. See Polyurethane Manuf. Ass'n S. 12. The requirement for showers should be tailored to the needs of the workplace in such a way that the showers requirement could be less onerous if one is, for example, dealing with volatile substances. See, e.g., Benzene Standard, 43 Fed. Reg. 5954 (February 10, 1978).

The model standards also require employers to "assure" that employees wash their hands and face prior to eating. Apart from providing training, education, facilities and opportunity for use of facilities, it is not reasonably possible for employers to "assure" that employees wash their hands or face. If the word "assure" means the foregoing, then it should be so defined. If it means more, we think serious questions of personal freedom and physical compulsion are raised. The use of the word "assure" in this section (and in other sections) of the model standards should be deleted and the word "require" substituted therefore with an appropriate definition to exclude compulsion. See Johns-Manville S., Ex. A at 9.

11. Medical surveillance (Subsection (n))

The need for an action level is particularly evident in

this subsection which would require medical surveillance where there is any exposure whatsoever even for guards or delivery personnel who might enter a facility only a few times a year. (Hygiene Panel Tr. 2833-2835; Johns-Manville S., Ex. A at 9-10.) Such an approach to regulation would be an extremely wasteful allocation of the limited medical resources available to our nation.

The model standards do not appear to require medical exams at specified periodic intervals. AIHC endorses the need to retain this flexibility and the need for tailoring the frequency and nature of periodic exams to the substance and workplace in question. To set an arbitrary limit makes little sense since many medical procedures themselves involve inherent risks. (Dr. Lynch S. 3.)

The standards also require that a medical exam be made available to an employee who has not had an exam within six months of the termination of his employment. Such examinations do not seem to be a useful expenditure of limited medical resources particularly where periodic exams are required. The matter should be left in the sound discretion of the employer who will take into account his medical surveillance program and the medical surveillance needs for the particular substance in question. This is not a matter which should be dealt with "across the board" in a regulation. (Johns-Manville S., Ex. A at 11.)

In addition, the standards require the employee's physician to state whether the employee has "any detected medical

condition which would place [him] at an increased risk of material impairment" from exposure to the substance. Such a requirement is an unreasonable one to place on a physician, particularly in times such as these when malpractice plays such a significant role in a physician's professional life. The standards provide no guidance whatsoever to the physician in making the Solomon-like determination as to what is an "increased risk of material impairment."

Finally, the standards prohibit physicians from disclosing to employers findings or diagnoses unrelated to occupational exposure discovered in the course of medical examinations. This provision should make clear that a physician may advise the appropriate supervisor of the employee (e.g., plant manager) of restrictions which should be placed on the employee's work activities, if any, for medical reasons without disclosing the medical reasons therefore. To do otherwise would deny the employer information essential to maintaining a safe workplace. See Reynolds Metal S. at 5.

12. Signs and labels (Subsection (p))

For reasons set forth infra, at 291, AIHC believes OSHA does not have authority to promulgate the proposed standards dealing with labeling.

The record includes no evidence to support the use of the legend which OSHA proposes for its signs and labels. When OSHA's industrial hygiene panel and the NIOSH panel were queried

on this issue, neither were able to offer any evidence in support of the OSHA position. (Hygiene Panel Tr. 2699-2715; NIOSH Tr. 3052-3053.) Indeed, they were totally unfamiliar with the extensive literature on the subject cited by counsel for the Polyurethane Manufacturers Association. (Tr. 2699-2715.) Although counsel for PMA requested that OSHA present the evidence upon which it relied on this issue, OSHA failed to do so. (Hygiene Panel Tr. 2731-2732.)

As Dr. Chapanis noted, a sign with the legend "cancer" merely creates fear in employees and does not provide those employees with any understanding of the nature of the hazard to which they are exposed. (Dr. Chapanis Tr. 7076.) Dr. Chapanis was particularly critical of OSHA's failure to provide a positive instruction about what to do in the presence of the hazard. (Dr. Chapanis Tr. 7073-7077, 7084, 7090-7091.)

13. Recordkeeping (Subsection (g))

The model standards evidence no thought with respect to what OSHA intends to do with the voluminous records it has asked to be kept and no forethought as to what purpose these records will serve. Further, there is no evidence of any effort to attempt to minimize paperwork burdens by coordinating these requirements with other federal agency requirements. Dr. Berg noted critically that the time to plan the analyses of data is before collection begins, not after masses of material are accumulated. (S. 25.) He recommended that outside expertise be used in the design

of a minimally effective system to determine which administratively desirable goals are feasible, as well as to help determine how best to achieve feasible goals. Id. at 26.^{1/} We wholeheartedly endorse this concept.

The ever-increasing paperwork burden has been the subject of much discussion by the Federal Commission on Paperwork, the President in Executive Order No. 12044 (published at 43 Fed. Reg. 12660, 12668 (March 24, 1978)) and others. Johns-Manville suggested that pilot recordkeeping programs be inaugurated to insure efficient, meaningful data compilation. See Johns-Manville S., Ex. A at 13-15. Some such system would appear to be necessary to insure that the right data are being collected in the right way. NIOSH's response to a question about whether it has made any effort to study the voluminous records collected to date for carcinogens is most illuminating. In response to a question as to what kind of analysis and study has taken place to date with respect to the records accumulated by NIOSH on the 14 carcinogens, the Director stated that no studies have taken place but that they have been "looked at a couple of times." (NIOSH Tr. 3144-3145.)

Much to our consternation, at the very time this rule-making is going forward OSHA has decided to publish yet another rule and proposed rule dealing with the question of medical and

^{1/} Testimony was presented by Diamond Shamrock on an innovative system they were well on the way to developing which they had offered to share with OSHA. (Tr. 7742-7749.)

exposure recordkeeping and access thereto.^{1/} It is not clear whether this newly proposed regulation "preempts" the issues on this matter so that they will be resolved in another forum. In view of the strange double method of addressing the issue of these records and access thereto, we will make only a brief comment despite the importance of the matter. Medical records contain much private information and access to them should not be given to anyone without the individual's consent. There is no doubt that these records are covered by the right to privacy. DuPont v. Finklea, CCH, OSHD, 1978 ¶ 22398 (S.D. W. Va. 1970). To protect that privacy, access should be given only to another licensed physician and confined to information supplied by the employee himself, as distinguished from third parties. If OSHA or NIOSH are to have access, it must be subject to the safeguards the court imposed in the DuPont case.

Exposure records present a different but equally important problem. These records frequently contain confidential trade material. To allow unlimited access to exposure records without restriction on disclosure, use or sale of confidential trade material raises very serious problems. While it may be reasonable to provide exposure information to an employee, that disclosure must be made under circumstances which prevent disclosure of confidential information. Similarly, there must be carefully designated regulations to prevent dis-

^{1/} 43 Fed. Reg. 31329, 31371 (July 21, 1978).

closure of any such secrets which may get into the hands of OSHA or NIOSH.

In view of the unusual procedure adopted by OSHA whereby two overlapping rules are being proposed on the same subject, we believe OSHA should consolidate the records so that comments filed in Docket NO. H-112 are considered also in this proceeding. To eliminate the confusion as to which rule is being considered by OSHA and which docket should be selected for filing comments, we urge that the only reasonable course is for OSHA to consider the comments in Docket No. H-112 as applicable in this proceeding.

A decision on the scope and nature of OSHA's authority to have access to, or to grant NIOSH access to, medical records is expected soon in General Motors v. Finklea, Civil No. C-3-77-339 (S.D. Ohio). That decision should clarify the statutory issue. In the meantime, OSHA should eliminate the overlapping proceedings.

D. Several Provisions Of The Model ETS Are Not Authorized By The Statute

Several provisions of the model ETS standard are not authorized by the Act. Among these are those dealing with labels, training and extensive monitoring and medical surveillance. As API correctly points out in its post-hearing comments, the Congress did not intend for such provisions to become a part of the short-lived, limited purpose ETS envisioned by it.

XIX

THE LABELING PROVISIONS OF THE MODEL
STANDARDS ARE NOT AUTHORIZED BY LAW

OSHA's proposed model standards for Category I and Category II substances require that employers affix precautionary labels to containers of such substances and of products containing such substances, and that the labels remain affixed when the substances or products containing such substances are "sold, distributed, or otherwise leave the employer's workplace." Sections 1990.150(p)(3), 1990.160(p)(3) and 1990.170(p)(3). Because the scope of OSHA's authority is limited to the issuance of standards designed to protect an employer's own employees while in the employer's own workplace, these proposed labeling provisions are beyond OSHA's jurisdiction.

The language of the Act demonstrates that OSHA's authority is limited to the regulation of workplaces, not products. Section 4(a) provides that the Act "shall apply with respect to employment performed in a workplace" 29 U.S.C. § 653(a) (emphasis added). Section 2 declares the Congressional purpose to assure "safe and healthful working conditions" by encouraging employers and employees to reduce "occupational safety and health hazards at their places of employment." 29 U.S.C. § 651(1) (emphasis added). Similarly, Section 5(a), the "general duty clause", requires that each employer

" . . . shall furnish to each of his
employees employment and a place of
employment which are free from recog-

nized hazards that are causing or are likely to cause death or serious physical harm to his employees." 29 U.S.C. § 654 (a)(1) (emphasis added).

Thus, OSHA's regulatory mandate is limited to the workplace itself, and does not extend to products once they have left the workplace.

More specifically, it is clear that Section 6(b)(7) of the Act, which sets forth OSHA's only authority to promulgate standards requiring labeling, was intended to provide for signs, notices, and other forms of warning (collectively referred to as "labels") in the workplace for the benefit of employees working with substances in that workplace. Section 6(b)(7) was not meant to confer any labeling authority upon OSHA outside of those workplaces. Where Congress intended to grant to administrative agencies such broad and general labeling authority, it has, in other statutes, explicitly granted that authority. Absent such explicit authorization in Section 6(b)(7), the power to require labeling outside the workplace cannot be implied.

Section 6(b)(7) provides that:

"[a]ny standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed . . . "

29 U.S.C. § 655(b)(7).

The statute does not explicitly grant to OSHA the authority to require the affixing of labels to substances once they have left the employer's workplace (i.e., the place of manufacture or use)

or to require labeling as a means of protecting anyone other than one's own employees. Rather, the reference to the protection of employees clearly indicates that OSHA's standards can require labels only in the employer's workplace for the benefit of his employees working with a substance in that workplace.

The limited scope of OSHA's labeling authority is also demonstrated by the legislative history of Section 6(b)(7). The Conference Report on the Act, after summarizing the provision of the Senate bill that had required labels for employee protection, states:

"The House amendment similarly required the posting of labels and warnings to apprise employees of the existence of hazards and of the suggested methods of avoiding or alleviating them." Legislative History at 1188 (emphasis added).

The quoted language indicates Congress' intention that OSHA require those types of labels and warnings that could be "posted". By their very nature, such labels are limited to an employer's workplace. Similarly, other references in the legislative history indicate Congress' concern that employers apprise their employees of hazards. See, e.g., Legislative History at 431, 1004. There are no references to imposition of labeling requirements for the benefit of "other persons".

Section 6(b)(7) also authorizes OSHA to promulgate standards prescribing suitable protective equipment and control or technological procedures, appropriate requirements for the monitoring or measuring of employee exposure, and the type

and frequency of medical examinations or other tests to be made available by the employer to employees. These protective measures are clearly intended to be provided by an employer for his own employees as a safeguard against hazards in the plant of manufacture or use. Absent clear Congressional indication to the contrary, the provision authorizing OSHA to require labeling is similarly limited in scope.

That OSHA has no authority to require an employer to affix labels to substances once outside the workplace as a means of protecting employees other than his own is also indicated by the variance provisions of the Act. Section 6(b)(6)(A) provides that an employer may obtain a temporary variance from a standard only if he shows that "he is taking all available steps to safeguard his employees against the hazards covered by the standard." 29 U.S.C.A. § 655(b)(6)(A). In addition, the employer must notify "his employees" of the application, so they can petition the Secretary for a hearing. 29 U.S.C.A. § 655(b)(6)(B). Section 6(d) provides for the issuance of a permanent variance to an employer demonstrating that

"the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard." 29 U.S.C. § 655(d) (emphasis added).

Congress would not have allowed an employer to obtain a variance by showing that his employees would be protected if it had in-

tended OSHA's standards to require employers to protect other people's employees as well.

In a number of other statutes, Congress has explicitly granted administrative agencies general labeling authority, encompassing the power to require labeling of products distributed in interstate commerce. These statutes include: Consumer Product Safety Act, 15 U.S.C. § 2051 et seq.; Toxic Substances Control Act, 15 U.S.C. § 2601 et seq.; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.; Federal Hazardous Substances Act, 15 U.S.C. § 1261 et seq.; Poison Prevention Packaging Act, 15 U.S.C. § 1471 et seq.; and Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 135 et seq. Absent such explicit authorization in the Occupational Safety and Health Act, such broad and general labeling authority cannot be implied in OSHA. As the Supreme Court stated in Stark v. Wickard, 321 U.S. 288, 309 (1944): "When Congress passes an Act empowering administrative agencies to carry on governmental activities, the power of those agencies is circumscribed by the authority granted." See also Zuber v. Allen, 396 U.S. 168 (1969); Exxon Corp. v. Train, 554 F. 2d 1310 (5th Cir. 1977); Textile and Apparel Group v. F.T.C., 410 F. 2d 1052 (D.C. Cir. 1969); State Highway Commission of Missouri v. Volpe, 479 F. 2d 1099 (8th Cir. 1973); National Association of Regulatory Utility Commissioners v. F.C.C., 533 F. 2d 601 (D.C. Cir. 1976).

The Benzene decision, relying principally on cases dealing with multi-employer construction worksite cases, con-

cluded that if OSHA can validly require the affixing of labels to benzene and benzene products, OSHA can forbid the removal of those labels from the containers which leave the workplace. This is a far cry from a finding of a general labeling authority in OSHA. Moreover, the court made clear that OSHA must make a valid finding of quantifiable benefits to the workers in the employer's workplace from a labeling requirement and relate those benefits to the costs or detriments in order to show the requirement is reasonably necessary. A second similar cost benefit analysis is necessary to determine whether OSHA can reasonably require the employer not to remove the labels when the containers leave the workplace.

Thus, under the standards of the Benzene decision, it would be unreasonable to require labels on mixtures containing small amounts of the regulated substance in the absence of the requisite finding of measureable benefits with a reasonable relation to cost. Even when it is reasonable to require labeling of containers in the workplace, it may be unreasonable to prohibit removal when the containers leave the workplace if, for example, the labels "have such deleterious effects on sales that it affects the reasonable necessity for this feature of the regulation." Benzene decision, ___ F.2d at 99.

The Benzene decision provides no basis for arguing that OSHA has general labeling authority. That case deals only with removal of labels which OSHA has validly found are reasonably necessary for the particular workplace.

Conclusion

The OSHA Proposed Regulation is substantively and procedurally defective. OSHA is just now making the Regulatory Analysis of the Proposed Regulation. AIHC believes that OSHA should also conclude that an Environmental Impact Statement should be prepared. The results of the IRLG Work Group in areas relevant to the Proposed Regulation will become available in the near future. AIHC believes that in view of these developments, OSHA should withdraw the Proposed Regulation and repropose a regulation modified to correct the deficiencies in the Proposed Regulation. The AIHC Alternative provides a reasonable guide for a reproposed regulation. At a minimum, OSHA must provide an adequate opportunity to comment on the new developments before publishing a final regulation.

Respectfully submitted,

Robert C. Barnard
Eric Schwartz
Price O. Gielen
Robert L. Glicksman

Attorneys for the American
Industrial Health Council

Of Counsel:

Cleary, Gottlieb, Steen & Hamilton
1250 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 223-2151

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A P P E N D I C E S

Appendix A - Statutes Involved

Section 3(8) (29 U.S.C. §652(8))

The term "occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

Section 6 (29 U.S.C. §655)

Standards

Promulgation by Secretary of national consensus standards and established Federal standards; time for promulgation; conflicting standards

(a) Without regard to chapter 5 of Title 5 or to the other subsections of this section, the Secretary shall, as soon as practicable during the period beginning with the effective date of this chapter and ending two years after such date, by rule promulgate as an occupational safety or health standard any national consensus standard, and any established Federal standard, unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees. In the event of conflict among any such standards, the Secretary shall promulgate the standard which assures the greatest protection of the safety or health of the affected employees.

Procedure for promulgation, modification, or revocation of standards

(b) The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

(1) Whenever the Secretary, upon the basis of information submitted to him in writing by an interested person, a representative of any organization of employers or employees, a nationally recognized standards-producing organization, the Secretary of Health, Education, and Welfare, the National Institute for Occupational Safety and Health, or a State or political subdivision, or on the basis of information developed by the Secretary or otherwise available to him, determines that a rule should be promulgated in order to serve the objectives of this chapter, the

Section 6 (29 U.S.C. §655)

Secretary may request the recommendations of an advisory committee appointed under section 656 of this title. The Secretary shall provide such an advisory committee with any proposals of his own or of the Secretary of Health, Education, and Welfare, together with all pertinent factual information developed by the Secretary or the Secretary of Health, Education, and Welfare, or otherwise available, including the results of research, demonstrations, and experiments. An advisory committee shall submit to the Secretary its recommendations regarding the rule to be promulgated within ninety days from the date of its appointment or within such longer or shorter period as may be prescribed by the Secretary, but in no event for a period which is longer than two hundred and seventy days.

(2) The Secretary shall publish a proposed rule promulgating, modifying, or revoking an occupational safety or health standard in the Federal Register and shall afford interested persons a period of thirty days after publication to submit written data or comments. Where an advisory committee is appointed and the Secretary determines that a rule should be issued, he shall publish the proposed rule within sixty days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission.

(3) On or before the last day of the period provided for the submission of written data or comments under paragraph (2), any interested person may file with the Secretary written objections to the proposed rule, stating the grounds therefor and requesting a public hearing on such objections. Within thirty days after the last day for filing such objections, the Secretary shall publish in the Federal Register a notice specifying the occupational safety or health standard to which objections have been filed and a hearing requested, and specifying a time and place for such hearing.

(4) Within sixty days after the expiration of the period provided for the submission of written data or comments under paragraph (2), or within sixty days after the completion of any hearing held under paragraph (3), the Secretary shall issue a rule promulgating, modifying, or revoking an occupational safety or health standard or make a determination that a rule should not be issued. Such a rule may contain a provision delaying its effective date for such period (not in excess of ninety days) as the Secretary determines may be necessary to insure that affected employers and employees will be informed of the existence of the standard and of its terms and that employers affected are given an opportunity to familiarize themselves and their employees with the existence of the requirements of the standard.

Section 6 (29 U.S.C. §655)

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

(6)(A) Any employer may apply to the Secretary for a temporary order granting a variance from a standard or any provision thereof promulgated under this section. Such temporary order shall be granted only if the employer files an application which meets the requirements of clause (B) and establishes that (i) he is unable to comply with a standard by its effective date because of unavailability of professional or technical personnel or of materials and equipment needed to come into compliance with the standard or because necessary construction or alteration of facilities cannot be completed by the effective date, (ii) he is taking all available steps to safeguard his employees against the hazards covered by the standard, and (iii) he has an effective program for coming into compliance with the standard as quickly as practicable. Any temporary order issued under this paragraph shall prescribe the practices, means, methods, operations, and processes which the employer must adopt and use while the order is in effect and state in detail his program for coming into compliance with the standard. Such a temporary order may be granted only after notice to employees and an opportunity for a hearing: *Provided*, That the Secretary may issue one interim order to be effective until a decision is made on the basis of the hearing. No temporary order may be in effect for longer than the period needed by the employer to achieve compliance with the standard or one year, whichever is shorter, except that such an order may be renewed not more than twice (I) so long as the requirements of this paragraph are met and (II) if an application for renewal is filed at least 90 days prior to the expiration date of the order. No interim renewal of an order may remain in effect for longer than 180 days.

Section 6 (29 U.S.C. §655)

(B) An application for a temporary order under this paragraph (6) shall contain:

(i) a specification of the standard or portion thereof from which the employer seeks a variance,

(ii) a representation by the employer, supported by representations from qualified persons having firsthand knowledge of the facts represented, that he is unable to comply with the standard or portion thereof and a detailed statement of the reasons therefor,

(iii) a statement of the steps he has taken and will take (with specific dates) to protect employees against the hazard covered by the standard,

(iv) a statement of when he expects to be able to comply with the standard and what steps he has taken and what steps he will take (with dates specified) to come into compliance with the standard, and

(v) a certification that he has informed his employees of the application by giving a copy thereof to their authorized representative, posting a statement giving a summary of the application and specifying where a copy may be examined at the place or places where notices to employees are normally posted, and by other appropriate means.

A description of how employees have been informed shall be contained in the certification. The information to employees shall also inform them of their right to petition the Secretary for a hearing.

(C) The Secretary is authorized to grant a variance from any standard or portion thereof whenever he determines, or the Secretary of Health, Education, and Welfare certifies, that such variance is necessary to permit an employer to participate in an experiment approved by him or the Secretary of Health, Education, and Welfare designed to demonstrate or validate new and improved techniques to safeguard the health or safety of workers.

(7) Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees. In addition, where appropriate, any such standard shall pre-

Section 6 (29 U.S.C. §655)

scribe the type and frequency of medical examinations or other tests which shall be made available, by the employer or at his cost, to employees exposed to such hazards in order to most effectively determine whether the health of such employees is adversely affected by such exposure. In the event such medical examinations are in the nature of research, as determined by the Secretary of Health, Education, and Welfare, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician. The Secretary, in consultation with the Secretary of Health, Education, and Welfare, may by rule promulgated pursuant to section 553 of Title 5, make appropriate modifications in the foregoing requirements relating to the use of labels or other forms of warning, monitoring or measuring, and medical examinations, as may be warranted by experience, information, or medical or technological developments acquired subsequent to the promulgation of the relevant standard.

(8) Whenever a rule promulgated by the Secretary differs substantially from an existing national consensus standard, the Secretary shall, at the same time, publish in the Federal Register a statement of the reasons why the rule as adopted will better effectuate the purposes of this chapter than the national consensus standard.

Emergency temporary standards

(c)(1) The Secretary shall provide, without regard to the requirements of chapter 5 of Title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.

(2) Such standard shall be effective until superseded by a standard promulgated in accordance with the procedures prescribed in paragraph (3) of this subsection.

(3) Upon publication of such standard in the Federal Register the Secretary shall commence a proceeding in accordance with subsection (b) of this section, and the standard as published shall also serve as a proposed rule for the proceeding. The Secretary shall promulgate a standard under this paragraph no later than six months after publication of the emergency standard as provided in paragraph (2) of this subsection.

Variances from standards; procedure

(d) Any affected employer may apply to the Secretary for a rule or order for a variance from a standard promulgated under this

Section 6 (29 U.S.C. §655)

section. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. The Secretary shall issue such rule or order if he determines on the record, after opportunity for an inspection where appropriate and a hearing, that the proponent of the variance has demonstrated by a preponderance of the evidence that the conditions, practices, means, methods, operations, or processes used or proposed to be used by an employer will provide employment and places of employment to his employees which are as safe and healthful as those which would prevail if he complied with the standard. The rule or order so issued shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize to the extent they differ from the standard in question. Such a rule or order may be modified or revoked upon application by an employer, employees, or by the Secretary on his own motion, in the manner prescribed for its issuance under this subsection at any time after six months from its issuance.

**Statement of reasons for Secretary's determinations;
publication in Federal Register**

(e) Whenever the Secretary promulgates any standard, makes any rule, order, or decision, grants any exemption or extension of time, or compromises, mitigates, or settles any penalty assessed under this chapter, he shall include a statement of the reasons for such action, which shall be published in the Federal Register.

Judicial review

✓(f) Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such standard. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The filing of such petition shall not, unless otherwise ordered by the court, operate as a stay of the standard. The determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole.

Priority for establishment of standards

(g) In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments. The Secretary shall also give due regard to the recommendations of the Secretary of Health, Education, and Welfare regarding the need for mandatory standards in determining the priority for establishing such standards.

Pub.L. 91-596, § 6, Dec. 29, 1970, 84 Stat. 1593.

Section 7 (29 U.S.C. §656)

Administration

National Advisory Committee on Occupational Safety and Health; establishment; membership; appointment; Chairman; functions; meetings; compensation; secretarial and clerical personnel

(a)(1) There is hereby established a National Advisory Committee on Occupational Safety and Health consisting of twelve members appointed by the Secretary, four of whom are to be designated by the Secretary of Health, Education, and Welfare, without regard to the provisions of Title 5 governing appointments in the competitive service, and composed of representatives of management, labor, occupational safety and occupational health professions, and of the public. The Secretary shall designate one of the public members as Chairman. The members shall be selected upon the basis of their experience and competence in the field of occupational safety and health.

(2) The Committee shall advise, consult with, and make recommendations to the Secretary and the Secretary of Health, Education, and Welfare on matters relating to the administration of this chapter. The Committee shall hold no fewer than two meetings during each calendar year. All meetings of the Committee shall be open to the public and a transcript shall be kept and made available for public inspection.

(3) The members of the Committee shall be compensated in accordance with the provisions of section 3109 of Title 5.

(4) The Secretary shall furnish to the Committee an executive secretary and such secretarial, clerical, and other services as are deemed necessary to the conduct of its business.

Advisory committees; appointment; duties; membership; compensation; reimbursement to member's employer; meetings; availability of records; conflict of interest

(b) An advisory committee may be appointed by the Secretary to assist him in his standard-setting functions under section 655 of this title. Each such committee shall consist of not more than fifteen members and shall include as a member one or more designees of the Secretary of Health, Education, and Welfare, and shall include among its members an equal number of persons qualified by experience and affiliation to present the viewpoint of the employers involved, and of persons similarly qualified to present the viewpoint of the workers involved, as well as one or more representatives of health and safety agencies of the States. An advisory committee may also include such other persons as the Secretary may appoint who are qualified by knowledge and experience to make a useful contribution to the work of such committee, including one or more representatives of professional organizations of technicians or professionals specializing in occupational safety or health, and one or more representatives of nationally recognized standards-producing organizations, but the number of persons so appointed to any

Section 7 (29 U.S.C. §656)

such advisory committee shall not exceed the number appointed to such committee as representatives of Federal and State agencies. Persons appointed to advisory committees from private life shall be compensated in the same manner as consultants or experts under section 3109 of Title 5. The Secretary shall pay to any State which is the employer of a member of such a committee who is a representative of the health or safety agency of that State, reimbursement sufficient to cover the actual cost to the State resulting from such representative's membership on such committee. Any meeting of such committee shall be open to the public and an accurate record shall be kept and made available to the public. No member of such committee (other than representatives of employers and employees) shall have an economic interest in any proposed rule.

Use of services, facilities, and personnel of Federal, State, and local agencies; reimbursement; employment of experts and consultants or organizations; renewal of contracts; compensation; travel expenses

(c) In carrying out his responsibilities under this chapter, the Secretary is authorized to—

(1) use, with the consent of any Federal agency, the services, facilities, and personnel of such agency, with or without reimbursement, and with the consent of any State or political subdivision thereof, accept and use the services, facilities, and personnel of any agency of such State or subdivision with reimbursement; and

(2) employ experts and consultants or organizations thereof as authorized by section 3109 of Title 5, except that contracts for such employment may be renewed annually; compensate individuals so employed at rates not in excess of the rate specified at the time of service for grade GS-18 under section 5332 of Title 5, including traveltime, and allow them while away from their homes or regular places of business, travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of Title 5 for persons in the Government service employed intermittently, while so employed.

Pub.L. 91-596, § 7, Dec. 29, 1970, 84 Stat. 1597.

Section 8(c) (29 U.S.C. §657(c))

Maintenance, preservation, and availability of records; issuance of regulations; scope of records; periodic inspections by employer; posting of notices by employer; notification of employee of corrective action

(c)(1) Each employer shall make, keep and preserve, and make available to the Secretary or the Secretary of Health, Education, and Welfare, such records regarding his activities relating to this chapter as the Secretary, in cooperation with the Secretary of Health, Education, and Welfare, may prescribe by regulation as necessary

Section 8(c) (29 U.S.C. §657(c))

or appropriate for the enforcement of this chapter or for developing information regarding the causes and prevention of occupational accidents and illnesses. In order to carry out the provisions of this paragraph such regulations may include provisions requiring employers to conduct periodic inspections. The Secretary shall also issue regulations requiring that employers, through posting of notices or other appropriate means, keep their employees informed of their protections and obligations under this chapter, including the provisions of applicable standards.

(2) The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries requiring only first aid treatment and which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.

(3) The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 655 of this title. Such regulations shall provide employees or their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Such regulations shall also make appropriate provision for each employee or former employee to have access to such records as will indicate his own exposure to toxic materials or harmful physical agents. Each employer shall promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents in concentrations or at levels which exceed those prescribed by an applicable occupational safety and health standard promulgated under section 655 of this title, and shall inform any employee who is being thus exposed of the corrective action being taken.

Section 8(g) (29 U.S.C. §657(g))

**Compilation, analysis, and publication of reports and information;
rules and regulations**

(g)(1) The Secretary and Secretary of Health, Education, and Welfare are authorized to compile, analyze, and publish, either in summary or detailed form, all reports or information obtained under this section.

Section 8(g) (29 U.S.C. §657(g))

(2) The Secretary and the Secretary of Health, Education, and Welfare shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this chapter, including rules and regulations dealing with the inspection of an employer's establishment.

Pub.L. 91-596, § 8, Dec. 29, 1970, 84 Stat. 1598.

Section 9 (29 U.S.C. §658)

Citations

**Authority to issue; grounds; contents; notice in lieu of citation
for de minimis violations**

(a) If, upon inspection or investigation, the Secretary or his authorized representative believes that an employer has violated a requirement of section 654 of this title, of any standard, rule or order promulgated pursuant to section 655 of this title, or of any regulations prescribed pursuant to this chapter, he shall with reasonable promptness issue a citation to the employer. Each citation shall be in writing and shall describe with particularity the nature of the violation, including a reference to the provision of the chapter, standard, rule, regulation, or order alleged to have been violated. In addition, the citation shall fix a reasonable time for the abatement of the violation. The Secretary may prescribe procedures for the issuance of a notice in lieu of a citation with respect to de minimis violations which have no direct or immediate relationship to safety or health.

Posting

(b) Each citation issued under this section, or a copy or copies thereof, shall be prominently posted, as prescribed in regulations issued by the Secretary, at or near each place a violation referred to in the citation occurred.

Time for issuance

(c) No citation may be issued under this section after the expiration of six months following the occurrence of any violation.

Pub.L. 91-596, § 9, Dec. 29, 1970, 84 Stat. 1601.

Section 13 (29 U.S.C. §662)

Injunction proceedings

Petition by Secretary to restrain imminent dangers; scope of order

(a) The United States district courts shall have jurisdiction, upon petition of the Secretary, to restrain any conditions or practices in any place of employment which are such that a danger exists which could reasonably be expected to cause death or serious physical harm immediately or before the imminence of such danger can be eliminated through the enforcement procedures otherwise provided by this chapter. Any order issued under this section may require such steps to be taken as may be necessary to avoid, correct, or remove such imminent danger and prohibit the employment or presence of any individual in locations or under conditions where such imminent danger exists, except individuals whose presence is necessary to avoid, correct, or remove such imminent danger or to maintain the capacity of a continuous process operation to resume normal operations without a complete cessation of operations, or where a cessation of operations is necessary, to permit such to be accomplished in a safe and orderly manner.

Appropriate injunctive relief or temporary restraining order pending outcome of enforcement proceeding; applicability of rule 65 of Federal Rules of Civil Procedure

(b) Upon the filing of any such petition the district court shall have jurisdiction to grant such injunctive relief or temporary restraining order pending the outcome of an enforcement proceeding pursuant to this chapter. The proceeding shall be as provided by Rule 65 of the Federal Rules, Civil Procedure, except that no temporary restraining order issued without notice shall be effective for a period longer than five days.

Notification of affected employees and employers by Inspector of danger and of recommendation to Secretary to seek relief

(c) Whenever and as soon as an inspector concludes that conditions or practices described in subsection (a) of this section exist in any place of employment, he shall inform the affected employees and employers of the danger and that he is recommending to the Secretary that relief be sought.

Failure of Secretary to seek relief; writ of mandamus

(d) If the Secretary arbitrarily or capriciously fails to seek relief under this section, any employee who may be injured by reason of such failure, or the representative of such employees, might bring an action against the Secretary in the United States district court for the district in which the imminent danger is alleged to exist or the employer has its principal office, or for the District of Columbia, for a writ of mandamus to compel the Secretary to seek such an order and for such further relief as may be appropriate.

Pub.L. 91-596, § 13, Dec. 29, 1970, 84 Stat. 1605.

Section 20 (29 U.S.C. §669)

Research and related activities

Authority of Secretary of Health, Education, and Welfare to conduct research, experiments, and demonstrations, develop plans, establish criteria, promulgate regulations, authorize programs, and publish results and industrywide studies; consultations

(a)(1) The Secretary of Health, Education, and Welfare, after consultation with the Secretary and with other appropriate Federal departments or agencies, shall conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health, including studies of psychological factors involved, and relating to innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

(2) The Secretary of Health, Education, and Welfare shall from time to time consult with the Secretary in order to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling the Secretary to meet his responsibility for the formulation of safety and health standards under this chapter; and the Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments and any other information available to him, shall develop and publish at least annually such criteria as will effectuate the purposes of this chapter.

(3) The Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments, and any other information available to him, shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience.

(4) The Secretary of Health, Education, and Welfare shall also conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health, which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of this chapter. The Secretary of Health, Education, and Welfare shall also conduct research into the motivational and behavioral factors relating to the field of occupational safety and health.

(5) The Secretary of Health, Education, and Welfare, in order to comply with his responsibilities under paragraph (2), and in order to develop needed information regarding potentially toxic substances or harmful physical agents, may prescribe regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which the Secretary of Health, Education, and Welfare reasonably believes may endanger

Section 20 (29 U.S.C. §669)

the health or safety of employees. The Secretary of Health, Education, and Welfare also is authorized to establish such programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the susceptibility of employees to such illnesses. Nothing in this or any other provision of this chapter shall be deemed to authorize or require medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others. Upon the request of any employer who is required to measure and record exposure of employees to substances or physical agents as provided under this subsection, the Secretary of Health, Education, and Welfare shall furnish full financial or other assistance to such employer for the purpose of defraying any additional expense incurred by him in carrying out the measuring and recording as provided in this subsection.

(6) The Secretary of Health, Education, and Welfare shall publish within six months of December 29, 1970, and thereafter as needed but at least annually a list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur. He shall determine following a written request by any employer or authorized representative of employees, specifying with reasonable particularity the grounds on which the request is made, whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found; and shall submit such determination both to employers and affected employees as soon as possible. If the Secretary of Health, Education, and Welfare determines that any substance is potentially toxic at the concentrations in which it is used or found in a place of employment, and such substance is not covered by an occupational safety or health standard promulgated under section 655 of this title, the Secretary of Health, Education, and Welfare shall immediately submit such determination to the Secretary, together with all pertinent criteria.

(7) Within two years of December 29, 1970, and annually thereafter the Secretary of Health, Education, and Welfare shall conduct and publish industrywide studies of the effect of chronic or low-level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in aging adults.

Authority of Secretary of Health, Education, and Welfare to make inspections and question employers and employees

(b) The Secretary of Health, Education, and Welfare is authorized to make inspections and question employers and employees as provided in section 657 of this title in order to carry out his functions and responsibilities under this section.

Section 20 (29 U.S.C. §669)

Contracting authority of Secretary of Labor; cooperation between Secretary of Labor and Secretary of Health, Education, and Welfare

(c) The Secretary is authorized to enter into contracts, agreements, or other arrangements with appropriate public agencies or private organizations for the purpose of conducting studies relating to his responsibilities under this chapter. In carrying out his responsibilities under this subsection, the Secretary shall cooperate with the Secretary of Health, Education, and Welfare in order to avoid any duplication of efforts under this section.

Dissemination of information to interested parties

(d) Information obtained by the Secretary and the Secretary of Health, Education, and Welfare under this section shall be disseminated by the Secretary to employers and employees and organizations thereof.

Delegation of functions of Secretary of Health, Education, and Welfare to Director of National Institute for Occupational Safety and Health

(e) The functions of the Secretary of Health, Education, and Welfare under this chapter shall, to the extent feasible, be delegated to the Director of the National Institute for Occupational Safety and Health established by section 671 of this title.

Pub.L. 91-596, § 20, Dec. 29, 1970, 84 Stat. 1610.

AMERICAN PET. INSTITUTE v. OCCUPATIONAL SAFETY

80

The AMERICAN PETROLEUM
INSTITUTE et al., Petitioners,

The Manufacturing Chemists Association and the Chemical Specialties
Manufacturers Association, Interveners,

v.

OCCUPATIONAL SAFETY AND
HEALTH ADMINISTRATION
et al., Respondents,

Industrial Union Department,
AFL-CIO, Intervenor.

Nos. 78-1253, 78-1257, 78-1486, 78-1676,
78-1677, 78-1707 and 78-1745.

United States Court of Appeals,
Fifth Circuit.

Oct. 5, 1978.

Producers of benzene filed petition for review of a new health standard promulgated by the Occupational Safety and Health Administration limiting occupational exposure to benzene. The Court of Appeals, Charles Clark, Circuit Judge, held that: (1) regulation requiring employers to assure that no employee is exposed to airborne concentration of benzene in excess of one part benzene per million parts of air averaged over an eight-hour day would be set aside, in absence of substantial evidence indicating that measurable benefits to be achieved by the reduction of permissible exposure to benzene bore a reasonable relationship to the one-half billion dollar cost of such regulation for affected industries; (2) regulation requiring employers to assure that no employee is exposed to dermal contact with liquid benzene would be set aside, since such

regulation was based upon dated, inconclusive data, and unrefuted evidence revealed the existence of modern experimental methods which could provide accurate information on factual issues which were unresolved by past studies, and (3) Administration had authority to prohibit employer from removing warning labels from containers of benzene and benzene products when those containers leave his work place.

Petition for review granted.

1. Labor Relations ⇌ 27

In reviewing regulations promulgated by the Occupational Safety and Health Administration, substantial evidence standard is applicable with respect to factual findings subject to evidentiary development; legislative-like policy judgments, though not so susceptible to verification or refutation by record, must nevertheless be scrutinized on judicial review for consideration as to whether such judgments are consistent with statutory language and purpose and within decision-making power of Secretary of Labor within limits imposed by Congress. Occupational Safety and Health Act of 1970, § 6(f), 29 U.S.C.A. § 655(f).

2. Labor Relations ⇌ 27

The Occupational Safety and Health Act of 1970 imposes on the Occupational Safety and Health Administration the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful work places; if standard does not fit in that definition, it is not one that the Administration is authorized to enact. Occupational Safety and Health Act of 1970, § 3(8), 29 U.S.C.A. § 652(8).

3. Labor Relations ⇌ 27

The Occupational Safety and Health Act does not give the Occupational Safe-

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ty and Health Administration unbridled discretion to adopt standards designed to create absolutely risk-free work places regardless of cost, but rather, the Act requires standards to be feasible, and contains a number of pragmatic limitations in the form of specific kinds of information the Administration must consider in enacting standards dealing with toxic materials; the conditions and other requirements imposed by standards dealing with toxic materials must be reasonably necessary or appropriate to provide safe or healthful employment and places of employment. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

4. Labor Relations ⇌ 27

Before it regulates, the Occupational Safety and Health Administration must show that hazard exists and that its regulation will reduce the risk from the hazard, and the Administration must also assess expected benefits in light of burdens to be imposed by standard; although the Administration does not have to conduct an elaborate cost-benefit analysis, it does have to determine whether benefits expected from standard bear a reasonable relationship to costs imposed by standard. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

5. Labor Relations ⇌ 27

Occupational Safety and Health Administration's regulation requiring employers to assure that no employee is exposed to airborne concentration of benzene in excess of one part benzene per million parts of air averaged over an eight-hour day would be set aside, in absence of substantial evidence indicating that measurable benefits to be achieved by the reduction of permissible exposure to benzene bore a reasonable relationship to the one-half billion dollar

cost of such regulation for affected industries. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

6. Labor Relations ⇌ 27

Judicial review of Occupational Safety and Health Administration regulations must be of the reasoning process of the Administration at the time it promulgated the standards based on the record before it. Occupational Safety and Health Act of 1970, § 6(f), 29 U.S.C.A. § 655(f).

7. Labor Relations ⇌ 27

When available evidence before Occupational Safety and Health Administration is of equivalent quality and is conflicting, a finding in accordance with one view or the other should be considered to be supported by substantial evidence. Occupational Safety and Health Act of 1970, § 6(f), 29 U.S.C.A. § 655(f).

8. Labor Relations ⇌ 27

Occupational Safety and Health Administration's regulation requiring employers to assure that no employee is exposed to dermal contact with liquid benzene would be set aside, since such regulation was based upon dated, inconclusive data, and unrefuted evidence revealed the existence of modern experimental methods which could provide accurate information on factual issues which were unresolved by past studies. Occupational Safety and Health Act of 1970, §§ 3(8), 6(b)(5), 29 U.S.C.A. §§ 652(8), 655(b)(5).

9. Labor Relations ⇌ 27

Occupational Safety and Health Administration had authority to prohibit employer from removing warning labels from containers of benzene and benzene products when those containers leave his

work place, in view of purpose of Occupational Safety and Health Act to protect every worker in nation, the express and broad statutory authorization for Administration to prescribe warning labels, and in view of fact that presence of benzene in product is often a concealed hazard; Administration's authority to require labeling of products containing benzene was not preempted by the Consumer Products Safety Commission which had promulgated regulations under the Federal Hazardous Substances Act. Occupational Safety and Health Act of 1970, §§ 4(b)(1), 6(b)(7), 29 U.S.C.A. §§ 653(b)(1), 655(b)(7); Federal Hazardous Substances Act, § 2 et seq., 15 U.S.C.A. § 1261 et seq.

On Petitions for Review of an Order of the Occupational Safety and Health Administration.

Before COLEMAN, CLARK, and TJOFLAT, Circuit Judges.

1. The petitioning or intervening producers of benzene and benzene-containing products are the American Petroleum Institute on behalf of itself and member companies; the American Iron and Steel Institute on behalf of itself and member companies; the Independent Petroleum Association of America on behalf of itself and member companies; and the Manufacturing Chemists Association on behalf of itself and member companies. The petitioning or intervening users of benzene and benzene-containing products are the Rubber Manufacturers Association on behalf of itself and member companies; the Armstrong Rubber Company and Uniroyal, Inc.; E. I. du Pont de Nemours and Company; and the Chemical Specialties Manufacturers Association on behalf of itself and member companies. The grouping of the petitioners into the producer or user category was made in order to coordinate the briefing and arguing of this case, and this opinion will continue to refer to those categories.

CHARLES CLARK, Circuit Judge:

This case presents consolidated petitions for review¹ of a new health standard limiting occupational exposure to benzene² promulgated by the Occupational Safety and Health Administration of the Department of Labor (OSHA), pursuant to the Occupational Safety and Health Act, 29 U.S.C.A. § 651 et seq. (1975) (the Act). The basis for the standard is OSHA's determination that benzene is a carcinogen for which there is no known safe level of exposure. Briefly, the standard requires employers to assure that no employee is exposed to an airborne concentration of benzene in excess of one part benzene per million parts of air (1 ppm) averaged over an eight-hour day;³ it requires employers to assure that no employee is exposed to dermal contact with liquid benzene;⁴ and it requires employers to assure that caution labels are affixed to all containers of products containing benzene and that the labels remain affixed when the product leaves the employer's workplace.⁵ In addition, the standard impos-

2. The standard, to be codified at 29 C.F.R. § 1910.1028, and OSHA's statement of reasons in support of the standard are published at 43 Fed.Reg. 5918-70 (1978).

3. The ceiling limit is 5 ppm as averaged over any fifteen minute period.

4. OSHA promulgated an amended standard the day before oral argument of this case which exempted from the scope of the standard all work operations where the only exposure to liquid benzene or its vapors is from liquid mixtures containing 0.5 percent (0.1 percent after June 27, 1981) or less of benzene by volume. 43 Fed.Reg. 27,962-71 (1978). The original standard's absolute prohibition of dermal contact with any liquid containing any amount of benzene is therefore no longer in existence. The effect of this amendment on the issues in this case will be discussed *infra*.

5. Not only does the scope of the amended standard affect the labeling requirement, but

es numerous compliance requirements for "each place of employment where benzene is produced, reacted, released, packaged, repackaged, stored, transported, handled, or used," with certain exceptions. These requirements include initial and continual exposure monitoring, engineering and work practice controls to reduce and maintain exposure below the permissible level, respiratory protection to prevent excessive exposure in limited situations, protective clothing and equipment to prevent dermal contact with liquid benzene, initial and continual medical surveillance, employee training programs, and retention of records regarding exposure monitoring and medical surveillance.

The petitioning producers and users of benzene and benzene-containing products principally attack the reduction of the permissible exposure limit to 1 ppm,⁶ the prohibition of dermal contact with liquids containing benzene, and the labeling requirements for such liquids. The petitioners also attack several of the ancillary provisions of the standard, including its broad scope, the monitoring and medical surveillance requirements, and the specification of mandatory engineering and work practice controls.

I.

The Act authorizes the Secretary of Labor⁷ to promulgate occupational safety and health standards. 29 U.S.C.A. § 655. An "occupational safety and health standard" is defined as "a stan-

dard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment" 29 U.S.C.A. § 652(8). In promulgating standards dealing with toxic materials, such as benzene, the Secretary is required to

set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

29 U.S.C.A. § 655(b)(5). When necessary or appropriate, standards may prescribe labels or other forms of warning, protective equipment, control or technological procedures, exposure monitoring, and

the amended standard also exempts from the labeling requirement liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978.

6. Presently the permissible exposure limit for benzene is 10 ppm. 29 C.F.R. § 1910.1000 Table Z-2 (1977). This standard has been in existence since 1971.

7. This authority has been delegated to the Assistant Secretary of Labor for Occupational Safety and Health, the chief executive officer of OSHA. References to the Secretary and OSHA are used interchangeably in this opinion.

medical examinations. 29 U.S.C.A. § 655(b)(7).

[1] Judicial review of occupational safety and health standards is authorized by 29 U.S.C.A. § 655(f), and on review "[t]he determinations of the Secretary shall be conclusive if supported by substantial evidence in the record considered as a whole." Several courts, including this one, have pointed out the problems involved in attempting to apply the traditional substantial evidence test in assessing OSHA standards resulting from informal rulemaking. *E. g.*, *Associated Industries of New York State, Inc. v. United States Department of Labor*, 487 F.2d 342, 347-50 (2d Cir. 1973); *Florida Peach Growers Association, Inc. v. United States Department of Labor*, 489 F.2d 120, 127-29 (5th Cir. 1974); *Industrial Union Department, AFL-CIO v. Hodgson*, 162 U.S.App.D.C. 331, 336-340, 499 F.2d 467, 472-76 (1974); *Synthetic Organic Chemical Manufacturers Association v. Brennan*, 503 F.2d 1155, 1158-60 (3d Cir. 1974). The problem centers not on how to apply the test to factual findings subject to evidentiary development, but rather on how to review legislative-like policy judgments. With respect to the former, the substantial evidence standard provided in the statute clearly is applicable. *See, e. g.*, *Industrial Union Department, AFL-CIO v. Hodgson*, *supra*, 499 F.2d at 474; *American Iron & Steel Institute, et al. v. OSHA*, 577 F.2d 825, No. 76-2358 *et al.* (3d Cir., filed March 28, 1978). Policy choices, though not so susceptible to verification or refutation by the record, must be scrutinized nevertheless. *See Associated Industries*

of New York, Inc. v. United States Department of Labor, *supra*, 487 F.2d at 348. Although the courts have differed in their articulation of the standard of review of these policy judgments, they have required the Secretary's action to be consistent with the statutory language and purpose. *Synthetic Organic Chemical Manufacturers Association v. Brennan*, *supra*, 503 F.2d at 1159. As this court stated in assessing an emergency temporary standard in *Florida Peach Growers*, "it seems clear that even with the required substantial evidence test, our review basically must determine whether the Secretary carried out his essentially legislative task in a manner reasonable under the state of the record before him." 489 F.2d at 129. This includes, of course, a review of whether the Secretary exercised his decisionmaking power within the limits imposed by Congress.

II.

Benzene is a ubiquitous hydrocarbon compound (C_6H_6) that is manufactured for a wide variety of industrial uses.⁸ The petro-chemical and petroleum refining industries are responsible for 94 percent of the total domestic production of benzene, and the steel industry produces the remaining 6 percent primarily as a by-product of the coking process. The primary use of benzene is as a feedstock in the manufacture of other organic chemicals; it is also used in the manufacture of detergents, pesticides, solvents, and paint, and as a solvent and reactant in chemical laboratories. Industries currently using benzene include the

8. Although benzene does occur naturally in small quantities (a few parts per billion) in certain substances, including the ambient air, it is produced in substantial quantities by the petroleum and steel industries. The produc-

tion of benzene is rapidly expanding, and at present only eleven other chemicals and only one other hydrocarbon are produced in greater tonnage in the United States. *See* 43 Fed.Reg. 5918.

chemical, printing, lithograph, rubber cements, rubber fabricating,⁹ paint, varnish, stain removers, adhesives, and petroleum industries. Among the products that contain benzene are motor fuels such as gasoline, which contain up to 2 percent benzene.

Benzene has been recognized since 1900 as a toxic substance capable of producing acute and chronic nonmalignant effects in humans. When benzene vapors are inhaled, the benzene diffuses rapidly through the lungs and is quickly absorbed into the blood. Acute circulatory failure resulting in death within minutes often accompanies exposure to benzene concentrations as high as 20,000 ppm. Other acute effects of exposure to milder, though still high (250-500 ppm), concentrations of benzene include vertigo, nervous excitation, headache, nausea, and breathlessness. When exposure is stopped, rapid recovery from these symptoms usually occurs.

The most common nonmalignant effects of chronic exposure to low¹⁰ benzene concentration levels are a non-functioning bone marrow and deficiencies in the formed elements of the blood.¹¹ The degree of severity of such disorders ranges from mild and transient episodes to severe and fatal effects. Chromosomal aberrations have also been associated

with chronic benzene exposure, and dermatitis or other dermal infections can be caused by direct bodily contact with liquid benzene.

As a result of its toxicity, benzene's history has been one of regulation. In 1946, the American Conference of Governmental Industrial Hygienists recommended a threshold limit value for benzene exposure of 100 ppm. This value was reduced to 50 ppm in 1947, to 35 ppm in 1948, to 25 ppm in 1963, and to 10 ppm in 1974. The American National Standards Institute adopted a threshold limit value of 10 ppm in 1969, which OSHA adopted in 1971 without rulemaking under the authority of 29 U.S.C.A. § 655(a).¹² This standard, codified at 29 C.F.R. § 1910.1000 Table Z-2 (1977) and still in effect, was based on the nonmalignant toxic effects of benzene exposure and not on any possible leukemia hazard.

Widely scattered through the benzene literature are studies suggesting a link between benzene exposure and leukemia, a usually fatal cancer of the blood-forming organs. During the 1970's several additional studies reported a statistically significant increased risk of leukemia among workers occupationally exposed to high levels of benzene and concluded

9. According to the rubber companies, the manufacture of tires requires the use of petroleum solvents which generally contain small amounts of benzene.

10. These toxic effects were documented at exposure levels above 25-40 ppm, and a few studies showed nonmalignant blood abnormalities at levels below 25 ppm. 43 Fed.Reg. 5924-25.

11. A decline in the red blood cell count (anemia) results in a decreased capacity of the blood to carry oxygen to various parts of the body and is characterized by fatigue. A decline in the white blood cell count (leukopenia) reduces the capacity of the body to defend

against disease and is characterized by recurrent infections. A decline in the platelet count (thrombocytopenia) results in an impaired clotting of the blood and is characterized by bleeding tendencies.

12. 29 U.S.C.A. § 655(a) directed the Secretary, within two years after the effective date of the Act and without rulemaking, to promulgate as an occupational safety or health standard any national consensus standard that he determined would result in improved safety or health for employees. The purpose of this power was to make the Act effective immediately, and the power expired on April 28, 1973.

benzene was a leukemogen.¹³ As a result of this new evidence, OSHA began procedures which culminated with the present proposal, among other things, to reduce the permissible exposure level from 10 ppm to 1 ppm.

In January 1977 OSHA issued voluntary Guidelines for Control of Occupational Exposure to Benzene recommending exposure not to exceed an eight-hour time-weighted average of 1 ppm. An Emergency Temporary Standard for Occupational Exposure to Benzene also providing for a reduction in the permissible exposure limit to 1 ppm¹⁴ was issued in May 1977, but this standard never went into effect because of judicial challenges. The proposed permanent benzene standard, which was based on OSHA's determination that the available scientific evidence established that employee exposure to benzene presents a leukemia hazard and that exposure therefore should

be limited to the lowest feasible level, was published on May 27, 1977. This proposal provided for a reduction in the permissible exposure limit from 10 ppm to 1 ppm and established requirements relating to dermal and eye contact,¹⁵ exposure monitoring, medical surveillance, methods of compliance, labeling, and recordkeeping. Public hearings were held July 19 through August 10, 1977, at which 95 witnesses testified. In addition, numerous exhibits and documents were submitted to OSHA as part of the rulemaking record. The resulting permanent benzene standard was promulgated on February 3 and published on February 10, 1978, with a March 13, 1978 effective date.

III.

The American Petroleum Institute on behalf of itself and member companies

13. One such study was reported in 1975 by Dr. Enrico Vigliani. In 1963, Dr. Vigliani participated in a study of workers exposed to resins, inks, varnishes, and glues containing various amounts of benzene, and found a risk of leukemia among these workers twenty times greater than that for the general population. Toluene was substituted for benzene in 1964 in one of the industries studied, and the 1975 study showed no new cases of leukemia among workers in that industry.

A second study was reported in 1972 by Dr. Muzaffer Aksoy, a hematologist who testified at the rulemaking hearing. In this study Dr. Aksoy reported four leukemia deaths among Turkish shoemakers resulting from their exposure to benzene concentrations in excess of 150 ppm for periods ranging from six to fourteen years, and at the hearing he estimated that the incidence of leukemia among the population he studied was twice what would have been expected for the population as a whole. Dr. Aksoy also noted a decline in leukemia cases after other solvents were substituted for benzene.

The study most heavily relied upon by OSHA was one reported by Dr. Peter Infante of the National Institute for Occupational Safe-

ty and Health, a body created to conduct research and recommend occupational safety and health standards. See 29 U.S.C.A. §§ 669-71. Dr. Infante studied workers exposed to benzene in the production of Phofilm at Goodyear's Akron and St. Mary's plants between 1940 and 1949 and found among them a five-fold increased risk of dying of leukemia when compared to two control groups. No specific exposure level during the period covered by the study was established, but testimony at the hearing indicated that exposure was probably around 100 ppm during most of the period studied with occasional exposure levels as high as several hundred parts per million.

14. Both the Guidelines and the Emergency Temporary Standard exempted work operations where the only exposure to benzene was from liquids containing 1 percent or less of benzene by volume.

15. The proposed permanent statement also exempted work operations where the only exposure to benzene was from liquid mixtures containing 1 percent (0.1 percent after one year from the effective date of the standard) or less of benzene by volume.

filed petitions for review of the standard in this court on February 2 and February 3, 1978. The American Iron and Steel Institute, the Independent Petroleum Association of America, the Manufacturing Chemists Association, the Rubber Manufacturers Association, the Armstrong Rubber Company and Uniroyal, Inc., E. I. Du Pont de Nemours and Company, and the Chemical Specialties Manufacturers Association subsequently either intervened on behalf of the American Petroleum Institute or filed original petitions for review in other circuits that were transferred to this circuit and consolidated with the American Petroleum Institute case. In addition, the Industrial Union Department, AFL-CIO, intervened on behalf of OSHA in support of the standard.¹⁶

The petitioners filed motions for a stay of the standard pending review on March 10, 1978, and on March 13 a judge of this court issued a temporary stay of the standard pending a hearing before a three-judge panel. The issues concerning the stay were fully briefed by the parties on an expedited basis, and after hearing oral argument a panel of the court on April 18, 1978, ordered a stay of the standard to be continued pending disposition of the petitions for review.¹⁷

The principal argument of the petitioning producers of benzene and benzene-containing products is that substantial evidence and the best available evidence do not show that the reduction of the permissible exposure limit from 10 ppm to 1 ppm is reasonably necessary or appropriate to provide safe or healthful employment and places of employment. These petitioners also attack several of

the ancillary provisions of the standard, including its broad scope, the monitoring and medical surveillance requirements, and the specification of mandatory primary means of compliance, as not being supported by substantial evidence that they are reasonably necessary or appropriate to provide safe or healthful employment. The attack of the petitioning users of benzene and benzene-containing products is two-fold: (i) They contend that substantial evidence and the best available evidence do not show that the dermal contact prohibition is reasonably necessary or appropriate to provide safe or healthful employment, and that the dermal contact prohibition is not feasible; and (ii) they contend that substantial evidence does not show the labeling requirement to be reasonably necessary or appropriate to provide safe or healthful employment, that the labeling requirement is not feasible, and that the labeling requirement is beyond OSHA's jurisdiction. OSHA, in addition to arguing that substantial evidence, the best available evidence, feasibility considerations, and its statutory mandate to protect workers justify the standard in its entirety, contends that Congress imposed on it no substantive requirement to promulgate only standards that are reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

On June 21, 1978, the day before oral argument, OSHA promulgated an amended standard to exempt from the scope of the benzene standard work operations where the only exposure to benzene is from liquid mixtures containing

16. Although we speak generally in this opinion about the contentions of the petitioners and the contentions of OSHA, the Industrial Union Department was an active participant in this

case and offered considerable support to OSHA's position.

17. The issuance of a stay pending judicial review is authorized by 29 U.S.C.A. § 655(f)

0.5 percent (0.1 percent after June 28, 1981) or less of benzene by volume, and to exempt from the labeling requirements liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978. 43 Fed.Reg. 27,971 (1978). Although the proposed emergency temporary standard and the proposed permanent standard had exempted work operations where exposure to benzene resulted only from liquid mixtures containing 1 percent or less of benzene by volume,¹⁸ the permanent standard that was promulgated contained no such exemption. As a result, the permanent standard prohibited all dermal contact with liquids containing any amount of benzene and it imposed the labeling requirements on all such liquids. Several industry groups petitioned OSHA for a stay of the dermal contact prohibition and labeling requirements as they applied to liquids containing small amounts of benzene.¹⁹ OSHA subsequently granted a stay as to work operations where the sole exposure to benzene was from mixtures containing 0.1 percent or less of benzene and instituted a new rulemaking proceeding which resulted in the June 21, 1978 amendment.

The court called for supplemental briefing to address the effect of this amendment on the issues already briefed and argued. This briefing has been com-

pleted, and it appears that the major effect of the amendment is on the arguments regarding the feasibility of the dermal contact and labeling provisions. Since the considerations associated with the feasibility of those provisions have been significantly changed by the amendments, we do not address the merits of the feasibility arguments in this opinion.

IV.

OSHA justifies the reduction of the permissible exposure limit for benzene from 10 ppm to 1 ppm by coupling two factual findings, which it contends are supported by substantial evidence in the record, with a regulatory policy which OSHA contends is required by its mandate to protect workers. The factual findings are that benzene causes leukemia and that there presently exists no known safe level for benzene exposure. The regulatory policy is to limit employee exposure to carcinogens to the lowest feasible level.

The producer petitioners, in addition to attacking the factual finding that no known safe level for benzene exposure exists,²⁰ contend that OSHA has failed to meet a burden which the Act imposes of determining that the reduction of the permissible exposure limit from 10 ppm to 1 ppm is "reasonably necessary" to

18. As noted above, the exemption in the proposed permanent standard fell to 0.1 percent after the first year.

19. These petitioners, who generally were among the user petitioners in this case, sought relief on the grounds that OSHA failed to provide adequate notice that the final standard might contain no exemption for work operations where the only benzene exposure was from liquid mixtures containing small amounts of benzene, that the dermal contact prohibition was not based on the best available evidence, and that the dermal contact prohibition was not feasible. With respect to feasibility, the

rubber industry contended that the manufacture of tires was impossible without some dermal contact with solvents containing trace amounts of benzene.

20. This argument is based on the fact that all studies associating benzene and leukemia involve high benzene concentration levels, that a substantial body of the scientific community subscribes to the theory that safe threshold levels exist for exposure to carcinogens, and that empirical evidence shows that low-level exposure to benzene does not cause leukemia.

provide a safe workplace. In support of the latter contention, these petitioners point to this circuit's recent decision in *Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Commission*, 569 F.2d 831 (5th Cir. 1978), and assert that OSHA failed to assess benefits expected to be achieved by the standard in light of the expected costs of compliance. The petitioners argue that by defining an "occupational safety and health standard" as one requiring conditions "reasonably necessary" to provide safe or healthful places of employment, 29 U.S.C.A. § 652(8), Congress recognized that safety and health resources are not unlimited and required OSHA somewhere in its decisionmaking process to (1) attempt to determine the extent to which its standards will benefit workers, and (2) decide whether the projected benefits justify the costs of compliance with the standard. Only if all standards are subjected to such assessment, argue the petitioners, can OSHA assure maximum benefit from the finite amount industry can expend on safety and health and thus carry out Congress' overriding policy "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651(b). Since OSHA has not made a valid determination that reducing the permissible exposure level of benzene from 10 ppm to 1 ppm is reasonably necessary to protect workers from a risk of leukemia, the producers ask us to set that part of the standard aside.²¹

OSHA denies that the "reasonably necessary" language imposes any substantive obligation on it in promulgating standards. OSHA would distinguish *Aqua Slide*, which dealt with the Con-

sumer Product Safety Act, on the basis that the "reasonably necessary" language in that Act appeared as a part of the sections which dealt with the agency's process of setting standards, 15 U.S.C.A. §§ 2056(a), 2058(c)(2)(A), whereas the "reasonably necessary" counterpart in the act it administers appears only in the section which defines the type of standard it may promulgate.

[2] In authorizing the Consumer Product Safety Commission to promulgate safety standards, Congress provided that "[a]ny requirement of such a standard shall be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product." 15 U.S.C.A. § 2056(a). It also required the Consumer Product Safety Commission to make a specific finding that its rules were "reasonably necessary to eliminate or reduce an unreasonable risk of injury." 15 U.S.C.A. § 2058(c)(2)(A). Rather than following this format, the Occupational Safety and Health Act defines the occupational safety and health standard it authorizes as one "which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C.A. § 652(8). We decline to construe the precisely similar requirements of these two Acts differently or to read words out of the OSHA legislation. The Act imposes on OSHA the obligation to enact only standards that are reasonably necessary or appropriate to provide safe or healthful workplaces. If a standard does not fit in this definition, it is not one that OSHA is authorized to enact.

21. As a corollary, they ask us to set aside all other provisions designed to effectuate the 1 ppm permissible exposure limit.

OSHA next argues that even if the conditions required by occupational safety and health standards must be reasonably necessary to provide safe or healthful places of employment, the Act still imposes on OSHA no obligation to undertake a cost-benefit analysis with respect to the standards it promulgates. OSHA argues that 29 U.S.C.A. § 655(b)(5) defines when conditions imposed by a standard dealing with toxic materials are reasonably necessary. It urges that the emphasis of that section on making of a standard "which most adequately assures . . . that no employee will suffer material impairment of health . . . [from] regular exposure . . . for the period of his working life," overcomes any requirement to make a cost-benefit analysis. Nevertheless, OSHA contends that it did undertake economic analyses of both costs and benefits associated with the standard as required by *Aqua Slide*, and that after assessing those analyses it promulgated the standard.

[3] Although 29 U.S.C.A. § 655(b)(5) requires the goal of attaining the highest degree of health and safety protection for the employee, it does not give OSHA the unbridled discretion to adopt standards designed to create absolutely risk-free workplaces regardless of cost. To the contrary, that section requires standards to be feasible, and it contains a number of pragmatic limitations in the form of specific kinds of information OSHA must consider in enacting standards dealing with toxic materials. Those include "the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest available scientific data in the field," and "experience gained under this and other health and safety laws." Moreover, in

standards dealing with toxic materials, just as with all other occupational safety and health standards, the conditions and other requirements imposed by the standard must be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C.A. § 652(8).

[4] Since the purpose of the Act to protect workers from dangerous conditions of employment is parallel to the purpose of the Consumer Product Safety Act to protect consumers from dangerous products, we must be guided by *Aqua Slide* in determining whether OSHA has met its burden of showing that the benzene standard is reasonably necessary to protect workers from a leukemia hazard. There we said:

In evaluating the "reasonable necessity" for a standard, the Commission has a duty to take a hard look, not only at the nature and severity of the risk, but also at the potential the standard has for reducing the severity or frequency of the injury, and the effect the standard would have on the utility, cost or availability of the product. 569 F.2d at 844; see also *D. D. Bean & Sons v. Consumer Product Safety Commission*, 574 F.2d 643 (1st Cir. 1978). Before it regulates, the agency must show that a hazard exists and that its regulation will reduce the risk from the hazard, for "no [occupational safety and health] standard would be expected to impose added costs or inconvenience . . . unless there is reasonable assurance that the frequency or severity of injuries or illnesses will be reduced." 569 F.2d at 839. More importantly for today's case, *Aqua Slide* also requires the agency to assess the expected benefits in light of the burdens to be imposed by the standard. Although the agency does not have to conduct an elaborate cost-benefit

analysis, 569 F.2d at 840, it does have to determine whether the benefits expected from the standard bear a reasonable relationship to the costs imposed by the standard. 569 F.2d at 842.

[5] The only way to tell whether the relationship between the benefits and costs of the benzene standard is reasonable is to estimate the extent of the expected benefits and costs. See 569 F.2d at 843. OSHA did this with respect to costs by engaging a consulting firm to assess the expected compliance costs and economic feasibility of the proposed standard. 43 Fed.Reg. 5934-39. Based on this study and other evidence, OSHA estimated compliance costs for all affected industries to be \$187-205 million first year operating costs, \$266 million engineering control costs, and \$34 million recurring annual costs.²² OSHA determined these costs to be feasible since they would not threaten the financial welfare of the affected firms or the general economy. However, OSHA disclaimed any obligation to balance these costs against expected benefits. 43 Fed.Reg. 5940-41. Rather than attempting to measure the extent to which the leukemia hazard of benzene exposure would be reduced by lowering the permissible exposure limit from 10 ppm to 1 ppm, OSHA merely assumed that benefits from the reduction "may be appreciable." It based this assumption on a finding that benzene was unsafe at any level and its conclusion that exposures to lower levels of toxic materials would be safer than exposure to higher levels.

OSHA's fall-back position attempts to justify its standard as being reasonably necessary within the meaning of *Aqua*

Slide. It contends the standard promises appreciable benefits at a cost which industry can absorb. This justification is deficient in one crucial way: substantial evidence does not support OSHA's conclusion that benefits are likely to be appreciable. Without an estimate of benefits supported by substantial evidence, OSHA is unable to justify a finding that the benefits to be realized from the standard bear a reasonable relationship to its one-half billion dollar price tag.

OSHA's assumption that the standard is likely to result in benefits is not unsupported. The divided opinion in the scientific community over the existence or not of safe threshold levels of exposure to carcinogens provides substantial evidence which would support the finding that exposure to benzene at the present level of 10 ppm poses some leukemia risk. The general agreement in the scientific community that exposure to carcinogens at low levels is safer than exposure at higher levels permits the further factual deduction that reducing the permissible exposure limit from 10 ppm to 1 ppm will result in some benefit. This finding and deduction, however, does not yield the conclusion that measurable benefits will result, and OSHA is unable to point to any studies or projections supporting such a finding. As we noted in *Aqua Slide*, mere rationality is not equivalent to substantial evidence that conditions required by standards are reasonably necessary. 569 F.2d at 841. The lack of substantial evidence of discernable benefits is highlighted when one considers that OSHA is unable to point to any empirical evidence documenting a leukemia risk at 10 ppm

22. Although the petitioners do not seriously challenge OSHA's estimate of costs in this suit, they refer to the promulgation of this standard as a \$1 billion decision.

Neither OSHA's estimate nor the petitioners' estimate takes into account the effects of the amendment, which narrows the scope of the standard.

even though that has been the permissible exposure limit since 1971. OSHA's assertion that benefits from reducing the permissible exposure limit from 10 ppm to 1 ppm are likely to be appreciable, an assumption based only on inferences drawn from studies involving much higher exposure levels rather than on studies involving these levels or sound statistical projections from the high-level studies, does not satisfy the reasonably necessary requirement limiting OSHA's action. *Aqua Slide* requires OSHA to estimate the extent of expected benefits in order to determine whether those benefits bear a reasonable relationship to the standard's demonstrably high costs.

We are not persuaded by OSHA's argument that this standard should be upheld since the lack of knowledge concerning the effects of exposure to benzene at low levels makes an estimate of benefits expected from reducing the permissible exposure level impossible.²³ The statute requires all conditions imposed by a standard to be reasonably necessary to provide safe or healthful employment, and it requires decisions to be based on "the best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," "the latest scientific data in the field," and "experience gained under this

and other health and safety laws." By requiring the consideration of such kinds of information, Congress provided that OSHA regulate on the basis of knowledge rather than on the unknown. *But see Society of Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301, 1308 (2d Cir. 1975). Until OSHA can provide substantial evidence that the benefits to be achieved by reducing the permissible exposure limit from 10 ppm to 1 ppm bear a reasonable relationship to the costs imposed by the reduction, it cannot show that the standard is reasonably necessary to provide safe or healthful workplaces.

This does not mean that OSHA must wait until deaths occur as a result of exposure at levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. *See Florida Peach Growers Association, Inc. v. United States Department of Labor*, 489 F.2d 120, 132 (5th Cir. 1974). Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary. For example, when studies of the effects of human exposure to benzene at higher concentration levels in the past are sufficient to enable a dose-response curve²⁴ to be charted that can

23. Although OSHA asserts that risk quantification at low exposure levels and therefore estimates of expected benefits from the standard cannot presently be made, OSHA has provided us with a Preliminary Report on Population Risk to Ambient Benzene Exposures, recently released by the Environmental Protection Agency, which attempts to extrapolate from the results of the Infante study a determination of the risk of leukemia to the general population at the exposure level of 1 part per billion. In addition, the petitioners introduced at the rulemaking proceeding a preliminary risk assessment for occupational exposure to benzene at 10 ppm and 1 ppm based on the studies at higher exposure levels relied on by

OSHA. Finally, OSHA's economic consultant testified that it could perform a cost-effectiveness analysis for the benzene standard, an analysis which would have included some kind of risk quantification. Although OSHA's assertion that present knowledge is insufficient to construct a valid dose-response curve for benzene may be correct, the record reflects that preliminary assessments are now being made and that valid extrapolations will be possible as more is known about the effects of past exposure at higher levels.

24. A dose-response curve shows the relationship between different exposure levels and the risk of cancer associated with those exposure

reasonably be projected to the lower exposure levels, or when studies of the effects of animal exposure to benzene²⁵ are sufficient to make projections of the risks involved with exposure at low levels, then OSHA will be able to make rough but educated estimates of the extent of benefits expected from reducing the permissible exposure level from 10 ppm to 1 ppm. Until such estimates are possible, OSHA does not have sufficient information to determine that a standard such as the one under review which it can only say might protect some worker from a leukemia risk is reasonably necessary.

We will not attempt to reconcile our decision with the cases from other circuits which uphold other standards regulating exposure to carcinogens. See *Industrial Union Department, AFL-CIO v. Hodgson*, 162 U.S.App.D.C. 331, 499 F.2d 467 (1974) (asbestos dust standard); *Society of Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301 (2d Cir. 1975) (vinyl chloride standard); *American Iron & Steel Institute et al. v. OSHA*, 577 F.2d 825, No. 76-2358 et al. (3d Cir., filed March 28, 1978) (coke oven emission standard). Those opinions did not address what Congress meant by requiring the conditions imposed by standards to be reasonably necessary to provide safe or healthful places of employment. In this circuit, under our *Aqua Slide* decision, substantial evidence must support a finding that those conditions are reasonably necessary, a showing that OSHA has not made. In addition, those cases were decided on their own records. Without critical analysis of what was established

levels. Generally, exposure to higher levels carries with it a higher risk, and exposure to lower levels is accompanied by a reduced risk.

25. Although there have been attempts to demonstrate the development of leukemia in animals exposed to benzene, those attempts for

in those proceedings, we hold in today's case that Congress intended for OSHA to regulate on the basis of more knowledge and fewer assumptions than this record reflects.

OSHA's failure to provide an estimate of expected benefits for reducing the permissible exposure limit, supported by substantial evidence, makes it impossible to assess the reasonableness of the relationship between expected costs and benefits. This failure means that the required support is lacking to show reasonable necessity for the standard promulgated. Consequently, the reduction of the permissible exposure limit from 10 ppm to 1 ppm and all other parts of the standard geared to the 1 ppm level must be set aside.

V.

OSHA's prohibition of dermal contact with benzene is based on "OSHA's policy that, in dealing with a carcinogen, all potential routes of exposure (*i. e.*, inhalation, ingestion, and skin absorption) be limited to the extent feasible." 43 Fed. Reg. 5948. OSHA, while acknowledging that the record evidence on the effect of benzene on the skin is "extremely limited" and that the few studies in the area "are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative rate of absorption through damaged skin," 43 Fed. Reg. 5948-49, nevertheless decided to prohibit dermal contact with liquids containing benzene. In arriving at this decision OSHA relied on animal studies

the most part have been unsuccessful. Those studies do not even establish that benzene exposure causes leukemia, much less the degree of risk associated with various exposure levels. See 43 Fed. Reg. 5930-31, 5932.

and one human study suggesting that benzene is absorbed through intact skin, on the assumption that benzene would more readily be absorbed through damaged skin than undamaged skin, and on the belief that substances containing benzene are readily absorbed through the skin and act as vehicles for absorption of benzene.

[6] OSHA now seeks in part to justify this prohibition as an adjunct to the permissible exposure limit for airborne concentrations of benzene and because of a concern for dermatitis. To the extent that the dermal contact prohibition is an adjunct of the permissible exposure limit, it would have to be set aside along with the permissible exposure limit. The concern for dermatitis, on the other hand, appears to be a post hoc rationalization for the dermal contact prohibition since it was not a significant part of OSHA's reasoning process that led to this provision.²⁶ The requirements of this standard were based on the possible leukemia hazard associated with exposure to benzene, 43 Fed.Reg. 5918, 5948, and our review must be of the reasoning process of the agency at the time it promulgated the standard based on the record before it. *Dry Color Manufacturers' Association, Inc. v. Department of Labor*, 486 F.2d 98, 104 n.8 (3d Cir. 1973).

26. At one point in the statement of reasons for the benzene standard OSHA did state that "[o]ne purpose of the protective clothing and equipment requirement is to protect employees from dermatitis and burns." 43 Fed.Reg. 5953. The reason for this standard as a whole, however, and the primary reason for the absolute prohibition of dermal contact with benzene (to which the protective clothing and equipment provision is tied), is to protect workers from a suspected carcinogen. It is within the context of OSHA's policy of reducing exposure to carcinogens to the lowest fea-

The user petitioners contend that substantial evidence and the best available evidence do not support a finding that the dermal contact provisions are reasonably necessary to provide safe or healthful employment, and in addition they contend that the dermal contact prohibition is not feasible since it is impossible for certain industries to operate without some dermal contact with liquids containing small amounts of benzene. Since the amendment to the standard on June 21, 1978, significantly affects the feasibility issue, we will not address that issue in this opinion. We agree with the users, however, that OSHA has not shown the dermal contact prohibition to be reasonably necessary to protect workers from contracting benzene-related leukemia since readily available evidence of the kind Congress required OSHA to consider was neglected. The record therefore fails to support the finding that benzene is absorbed through the skin. Since entry to the body by dermal contact was not established, the record will not support a finding that the prohibition of all dermal contact with benzene will result in quantifiable benefits in terms of a reduced risk of leukemia justifying the costs of the provision. Thus reasonable necessity is lacking here too.

Studies of whether benzene is absorbed by the skin of animals, conducted in the first half of this century, are re-

sible level that we must review the dermal contact prohibition.

Dermal diseases can pose significant hazards in the workplace, and regulatory action following proceedings specifically focusing on such hazards may be appropriate. OSHA recently announced the formation of a standards advisory committee on cutaneous hazards to "identify the occupational exposures in industry which pose a hazard to the skin and/or the use of the skin as a portal of entry." 43 Fed.Reg. 10,647-48 (1978).

ferred to in this record during the course of expert testimony and as background material in later studies of whether benzene can be absorbed by human skin. Though these studies reached different conclusions, their relevance with respect to the issue of absorption of benzene by human skin has been questioned since there are important differences between the permeability of the skins of animals and humans. The studies concluding that benzene penetrates skin of certain animals have also been criticized since the possibility of benzene inhalation was not excluded and since there was no guarantee that the skin remained intact through the course of the experiment.

Between 1946 and 1961, experiments were conducted to determine whether human skin absorbed benzene. Although the first several of these studies conducted in the late 1940's and mid-1950's had negative results, one study published in 1961 found that some absorption had occurred and concluded that "the absorption of benzene throughout the skin must not be neglected." The record reveals problems in the interpretation of all of these studies, however. In particular, the 1961 study reporting positive results used a technique, compressing benzene-soaked cotton against the skin with a glass plate for prolonged periods, that is recognized today as an efficient way to drive molecules into the skin.

The oral testimony on the issue of skin absorption of benzene is very limited. Representatives of the National Institute of Occupational Safety and Health testified that they were of the opinion that benzene can be absorbed through the skin, and that absorption is more likely when the skin is damaged or when the benzene is contained in a solvent which itself is absorbed. Except for a passing reference to what appears to be the 1961

positive study, these witnesses did not attempt to support their opinions by reference to empirical data.

The one expert dermatologist who testified in depth on the issue of skin absorption of benzene, Dr. Howard Maibach of the University of California Medical Center, after summarizing and discussing critically the studies that have been conducted to date, concluded that "in 1977 it is extremely difficult, if not impossible, to balance all of the information that is available. Admittedly, the overwhelming majority of the observations suggest that benzene does not penetrate the skin. One observation suggests that it does." Dr. Maibach testified that he did not know whether benzene is absorbed through the skin; that he did not know whether benzene would be more readily absorbed through damaged skin than intact skin, although the assumption, unsupported by any data, is that it would be; and that he did not know whether benzene would be absorbed more readily if it is in another solvent.

[7] Were this the extent of the record on the issue of skin absorption, OSHA's finding that dermal contact with benzene poses a cancer risk could pass muster. When available evidence of equivalent quality is conflicting, a finding in accordance with one view or the other should be considered to be supported by substantial evidence. See *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488, 71 S.Ct. 456, 465, 95 L.Ed. 456 (1951). This record speaks further on the issue of skin absorption, however, and in light of OSHA's statutory command this additional evidence removes the support for OSHA's actions.

[8] Dr. Maibach, following his conclusion that the studies conducted to date were not definitive on the issue of

whether human skin absorbed benzene, stated:

Today we have a much simpler and a much more direct way of answering this . . . because now radioactive benzene is available, and one simply would apply radioactive benzene, some Carbon 14 benzene, to the skin of the arm of an appropriate animal that has permeability characteristics similar to the people in this room . . . and then would simply look for the radioactivity excreted into the urine, the feces and the breath.

This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would then tell us definitively, without argument, and efficiently, just how much of any benzene penetrates the skin.

Dr. Maibach testified that this experimental technique can answer a number of questions other than whether any benzene penetrates the skin, including demonstrating any differences in existence and extent of absorption of various parts of the body which may be exposed; whether benzene applied to the skin has the same toxic potential as benzene inhaled; whether multiple exposures result in correspondingly greater absorption than a single exposure; whether it is possible for one to protect himself by wearing protective clothing; whether and to what extent the amount of benzene absorbed through the skin is dependent upon benzene concentration; whether, because of its volatility, benzene splashed onto the skin evaporates more rapidly or goes through the skin more rapidly; and whether benzene is

absorbed more readily if it is in another solvent. Dr. Maibach testified that the experiment would be relatively short term in length (six to twelve weeks), that the techniques are straightforward and reliable, and that the experiment could be done by anybody having the analytic facilities available. This testimony about the availability and reliability of modern experimental techniques is unrefuted in the record.

OSHA's decision to regulate on the basis of dated, inconclusive data when modern experimental methods can quickly and efficiently provide reliable information contravenes the directive from Congress to promulgate standards on the basis of the "best available evidence," "research, demonstrations, experiments, and such other information as may be appropriate," and "the latest available scientific data in the field." 29 U.S.C.A. § 655(b)(5). This is not a case where there is testimony that additional sophisticated research could be attempted, but might not shed new light on a subject. To the contrary, unrefuted testimony reveals the existence of simple experimental techniques, tried and proved effective for over 100 organic compounds, that can provide accurate information on the factual issues OSHA admits are unresolved by the past studies.²⁷ When such factual information is so readily available, 29 U.S.C.A. § 655(b)(5) requires OSHA to acquire that information before promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe.

In light of unrefuted testimony on the ready availability of conclusive evidence

27. In their brief the petitioners represent that Dr. Maibach is now conducting one such study.

on the subject, OSHA's choice to rely on old and inconclusive evidence that there is a possibility of absorption of benzene through the skin which might cause cancer is in clear disregard of the congressional directive as to the kinds of evidence OSHA is required to consider. Therefore, the provision of the standard prohibiting dermal contact with liquid benzene cannot stand on the present record.

VI.

[9] The reduction of the permissible exposure limit and the prohibition of dermal contact are the provisions of the benzene standard to which all the standard's other requirements are tied. Since neither of these provisions can be upheld on the present record, it follows that the standard as a whole must be set aside.

Although we vacate the labeling provision in conjunction with the rest of the standard, this or some similar requirement is sure to be considered by OSHA on remand. Therefore, we address the user petitioners' jurisdictional attack on one aspect of that provision. The labeling provision generally requires the employer to assure that caution labels are affixed to all containers of benzene and benzene-containing products. In the aspect of the provision under attack, OSHA further requires each employer to "assure that the caution labels remain affixed when the benzene or products containing benzene are sold, distributed or otherwise leave the employer's workplace."

By requiring caution labels to remain affixed when benzene products leave an employer's workplace, OSHA intended to assure that all employees along the product's distribution chain are apprised of the hazardous nature of benzene expo-

sure. 43 Fed.Reg. 5960. It relied on the authority given to it by 29 U.S.C.A. § 655(b)(7) to require the use of warning labels in standards, and it concluded that this authority was not limited to requiring an employer to warn his own employees of the hazardous products he manufactures. Since the manufacturer of a product containing a toxic substance (and subsequent employers who have been informed of the hazard) is in the best position to know of the hazard and warn others down the distribution chain, OSHA concluded that the protective purposes of the Act would best be served by requiring the manufacturers to refrain from taking steps designed to withhold information concerning the dangers of the products from downstream workers.

The petitioners contend that the Act gives OSHA the jurisdiction to regulate workplaces, not products. They argue that OSHA here is claiming the authority to regulate finished products leaving the workplace, an authority that would transform what was intended to be a federal workplace safety code into a federal product safety code. The petitioners contend that Congress intended to place the responsibility for protecting each employee on his or her own employer, an allocation of responsibility that has proved workable in all but unusual circumstances such as the multiemployer construction worksite; and that, since all employers would be required to assure that benzene-containing products in their own workplaces are labeled, and the usual allocation of responsibility for labeling would be workable and effective.

Cases involving multiemployer construction worksites have recognized a duty on an employer to comply with OSHA standards in order to protect the employees of another employer. See *Brennan v. Occupational Safety &*

Health Review Commission and Underhill Construction Corp., 513 F.2d 1032 (2d Cir. 1975) (*Underhill*); *Marshall v. Knutson Construction Co.*, 566 F.2d 596 (8th Cir. 1977); *Beatty Equipment Leasing, Inc. v. Secretary of Labor*, 577 F.2d 534 (9th Cir. 1978). These cases involved citations for violations of 29 U.S.C.A. § 654(a), which imposes two duties on employers:

Each employer—

- (1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;
- (2) shall comply with occupational safety and health standards promulgated under this chapter.

In holding that the § 654(a)(2) duty could be violated even though the cited employer's employees were not shown to have been exposed to the hazard created by the violation, the *Underhill* court emphasized that the § 654(a)(2) duty, unlike the § 654(a)(1) duty, was "in no way limited to situations where a violation of a standard is linked to exposure of his employees to the hazard." 513 F.2d at 1038 (emphasis in original). In reaching its conclusion, the court relied on the broad remedial purpose of the Act and on the fact that the cited employer had created the hazard and maintained the area where it was located. In agreeing with this analysis, the *Beatty* court stated:

[This interpretation of the statute] facilitates the broad remedial purpose of the Act which Congress declared is "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651. As this court has stated, "Congress clearly intended to re-

quire employers to eliminate all foreseeable and preventable hazards." [citation omitted] We agree with the Commission that this policy can best be effectuated by placing the responsibility for hazards on those who create them.

577 F.2d at 537. The duty on one employer to comply with OSHA standards for the benefit of employees of another employer, however, has only been expressly recognized in the multiemployer construction worksite context.

In deciding whether an OSHA standard can require an employer to assure that a warning label remains affixed when a benzene-containing product leaves his workplace in order to protect downstream employees, we too must keep in mind the Act's overall purpose "to assure so far as possible every working man and woman in the Nation safe and healthful working conditions." 29 U.S.C.A. § 651(b). In this light the provision of the statute requiring OSHA to prescribe labeling of hazards is broad in scope:

Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed . . .

29 U.S.C.A. § 655(b)(7). Unlike some sections of the Act, this provision does not expressly limit the employer's obligation of informing employees of hazardous conditions to the employer's own employees.

The ability of downstream employers to protect their own employees is also an appropriate consideration in determining where the duty to warn should lie. Cf. *Anning-Johnson Co. v. Occupational*

Safety and Health Review Commission, 516 F.2d 1081, 1086-91 (7th Cir. 1975). This record reveals that the presence of benzene in a workplace is often a hidden hazard. Some industries refer to benzene under code or trade names, and many products containing benzene are sold only under trade names with no listing of contents. Under such circumstances it is apparent that the manufacturer of a benzene-containing product is in a far better position to warn downstream employees in operations using the benzene-containing product of the benzene hazard than is a downstream employer.

Considering the purpose of the Act to protect every working person in the nation, the express and broad statutory authorization for OSHA to prescribe warning labels in standards, and the fact that the presence of benzene in a product is often a concealed hazard, we agree with OSHA that it has the authority to prohibit an employer from removing the warning labels from containers of benzene and benzene products when those containers leave his workplace. This is not a situation where OSHA is imposing a heavy regulatory burden on an employer solely for the benefit of the employees of another. Rather, the regulation says no more than that an upstream employer may not take affirmative steps to withdraw from downstream employees a protection that he must furnish to his own employees. The obvious reluctance of the maker of a product to intimate or suggest to his consumers that his product is less than totally desirable

is understandable. Such a consideration may even be shown to have such deleterious effect on sales that it affects the reasonable necessity for this feature of the regulation. See, *Aqua Slide*, 569 F.2d at 840-43. In such a case, OSHA may choose to eliminate the requirement altogether. It may also choose to moderate the label's description to more precisely describe the nature or extent of the hazard.

Placing the responsibility to warn downstream employees of concealed hazards on those upstream employers who create the hazards and know of the hazards is consistent with the remedial purpose of the Act and is within OSHA's broad authority to prescribe warning labels. If on remand OSHA decides to promulgate a new benzene standard which includes warning labels, OSHA may require an employer in the chain of distribution of those products to assure that such warning labels remain affixed when the product leaves the employer's workplace, provided, of course, the labeling requirement as a whole is shown to be reasonably necessary to provide safe workplaces.

The user petitioners also contend that OSHA's authority to require labeling of products containing benzene has been preempted under 29 U.S.C.A. § 653(b)(1)²⁸ by the Consumer Product Safety Commission, which has promulgated regulations under the Federal Hazardous Substances Act, 15 U.S.C.A. § 1261 et seq.,²⁹ requiring the labeling of products containing benzene. See 16

28. 29 U.S.C.A. § 653(b)(1) states:

Nothing in this chapter shall apply to working conditions of employees with respect to which other Federal agencies . . . exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

29. The Consumer Product Safety Commission has authority to promulgate regulations under the Federal Hazardous Substances Act by virtue of 15 U.S.C.A. § 2079.

C.F.R. § 1500.14(a)(3), (b)(3) (1977). We reject this argument. The preemption provision was intended to avoid the "duplication that would result where another federal agency was also providing for the occupational safety of a class of workers." *Organized Migrants in Community Action, Inc. v. Brennan*, 172 U.S. App.D.C. 147, 153, 520 F.2d 1161, 1167 (1975). It applies only when the preempting regulation is "directed at a working condition," *Southern Pacific Transportation Co. v. User*, 539 F.2d 386, 391 (5th Cir. 1976), which the promulgating agency has authority to regulate. The Consumer Product Safety Commission's regulation is not designed to protect a class of workers and it is not directed at the working conditions of employees. Although an existing requirement for labeling under another act may affect the reasonable necessity for an OSHA requirement, 29 U.S.C.A. § 653(b)(1) does

not prohibit OSHA from requiring containers of benzene products to bear the warning labels authorized by 29 U.S.C.A. § 655(b)(7).

Conclusion

The petitions for review are granted. The reduction of the airborne permissible exposure limit from 10 ppm to 1 ppm is set aside since the present record does not show that such a reduction is reasonably necessary to provide safe or healthful employment. The dermal contact prohibition is set aside since this provision was not based on the best available evidence or the latest available scientific data in the field. The remaining provisions of the standard are also vacated since they are ancillary to the permissible exposure limit reduction and the dermal contact prohibition.

Appendix C - AIHC, A Proposal To Achieve A
Cohesive, National Cancer Policy,
Exhibit 62

A PROPOSAL TO ACHIEVE
A
COHESIVE, NATIONAL CANCER POLICY

Summary: The essence of AIHC's proposal for achieving a more cohesive, national cancer policy is to recognize that the determination of whether a material is carcinogenic or not, and its potency, involve scientific, rather than regulatory judgments. We believe these determinations should be made by a panel of eminent scientists selected by the National Academy of Science. This panel would be located somewhere in government (e.g., HEW, OSTP, etc.) to serve on a continuing basis with appointed members serving terms of two-to-four years. The panel would have its own staff. While not making a specific recommendation as to where the panel should be housed, AIHC believes that the panel should be located separate from the various agencies whose regulatory actions would be affected by the panel's determinations.

The panel's cancer determinations would be binding upon the various regulatory agencies, but these determinations would be limited to scientific issues and would not intrude upon the regulatory responsibilities of the individual agencies involved. We recognize that these regulatory responsibilities, quite properly, do differ from one agency to another.

American Industrial
Health Council
5/24/78

A PROPOSAL TO ACHIEVE

A

COHESIVE, NATIONAL CANCER POLICY

Data Evaluation and Classification Panel: Determinations of carcinogenicity and potency are scientific, not regulatory issues. These determinations should be made:

1. Outside of regulatory authorities, such as OSHA.
2. Based on the critical, scientific evaluation of all available data.
3. By a panel of appropriately qualified and experienced scientists.

The American Industrial Health Council (AIHC) proposes that a Data Evaluation and Classification Panel ("the Panel") should be established to ensure the scientific validation of the determinations and to promote efficiency, consistency, and accuracy in the regulatory process. At the outset, the Panel would serve OSHA's purposes, but AIHC intends that it would come to serve other regulatory agencies as well in determining whether a material is carcinogenic or not, and its potency. Ideally, new legislation would be the best method to create the Panel. It could, however, without awaiting legislation, be created by Executive Order issued pursuant to the Reorganization Act of 1977, 5 U.S.C. § 901 et seq. (See Attachment I).

The Panel's determination of carcinogenicity classification would be administratively final (subject to appropriate judicial review). OSHA (and other regulatory agencies) would then proceed to assess occupational health hazards, and other pertinent matters and define necessary controls or priorities for regulation based on the Panel's determination and the agency's hazard assessment.

The Panel would consist of nine members, representing a cross-section of expertise and experience in disciplines such as toxicology, pharmacokinetics, cancer research and therapy, epidemiology, and occupational medicine. Candidates would be proposed on the basis of scientific expertise and professional qualifications by relevant professional groups such as:

National Cancer Institute

The Society of Toxicology

American Chemical Society

American Academy of Occupational Medicine
American Academy of Veterinary Pathologists
American Occupational Medical Association
American Cancer Society
American Industrial Hygiene Association
American Academy of Industrial Hygiene

Panelists would be selected from the candidate list by the National Academy of Science to serve with staggered appointments for terms from two-to-four years. They would not serve on any other government panel, committee, or agency during their service on the Panel. The Panel would have a staff. The Panel and staff would be housed within HEW, OSTP, the NAS or, perhaps, some other organization agreeable to the Interagency Regulatory Liaison Group (IRLG). The Panel would be substantively independent of whatever organization in which it may be housed.

It is proposed that the Panel would apply the Classification Categories and criteria recommended by AIHC 1/, but could revise them from time to time, upon public notice and opportunity to be heard in accordance with the rulemaking provisions of the Administrative Procedure Act. The Panel would, in appropriate circumstances, classify, reclassify, and declassify chemical substances.

Categorization: The Panel shall determine whether to assign a chemical substance to one of the following categories: Known Human Carcinogen; Confirmed Animal Oncogen; and Substances for Further Testing. Such assignment shall be accomplished as soon as possible following receipt of information, by petition or otherwise, that the Panel judges warrants consideration of making an initial categorization or of changing an existing categorization.

In deciding the order in which to categorize various chemical substances, including those listed in the NIOSH subfile of suspect carcinogens, the Panel shall give priority to those alleged or appearing to be known human carcinogens or confirmed, potent animal carcinogens, and shall consider the total available literature and industrial history for the substance.

1/
AIHC Recommended Alternatives to OSHA's Generic Carcinogen Proposal, February 24, 1978 (pp. 60-85). OSHA Docket No. H-090.

It is suggested that the Panel shall use the criteria developed in AIHC's Recommended Alternatives to OSHA's Generic Carcinogen Policy proposal (pages 60-85), for categorizing chemical substances or other agents. The Panel may from time to time propose revisions of the categorization scheme or the criteria, in light of scientific advancements, additional information, or experience with the categorization scheme. Reasonable notice of intended changes and an opportunity to comment are to be afforded the public, in accordance with the Administrative Procedure Act.

Operating Procedures: Requests for an initial categorization or to change an existing categorization are to be submitted to OSHA, and OSHA will initially determine whether any proposal warrants further consideration. In having OSHA rather than the Panel make the initial determination of the merit of a submission, AIHC is concerned that the Panel not be overburdened with frivolous submissions.

If OSHA determines that data submitted warrants consideration of an initial categorization, it will publish notice of receipt of that data in the Federal Register together with a request for written comments or data bearing on the categorization. (OSHA can also initiate a Panel classification in the absence of a request.) After an adequate comment period, time would be allowed for responses to comments submitted by other persons, although on a more expedited schedule (perhaps like a briefing schedule). The Panel may also seek its own data from other government agencies, private and other public sources, etc.

With respect to the time periods allowed for submission of comments and for Panel decisions, AIHC is concerned that there be adequate time for valid scientific deliberation and felt it would be preferable that a fixed time limit not be prescribed. Rather, AIHC recommends that as much time as practicable be allowed in each instance with the intention that the Panel is to make its decision as expeditiously as possible, consistent with the urgency of the review, the quality of the data available, and as allowed by procedures developed to guide the Panel in its efforts to achieve scientifically sound, equitable determinations.

AIHC does not recommend that the Panel hold public hearings, because such hearings could impose additional time demands upon Panel members and potentially subject the Panel's determinations to undue influence. While not explicitly recommended, it is recognized that the Panel's meetings will, in all likelihood, be public, and procedures will have to be developed so the Panel's determinations have a public record (e.g., summary minutes), but AIHC recommends against transcribing Panel deliberations. The Panel should have the right to close certain meetings. However, AIHC believes that operating procedures for the Panel are

extremely important, both in making changes in criteria and in determining individual categorizations. The operations of NCI can serve as a possible model.

AIHC expresses strong concern for the confidentiality of information submitted to the Panel; however, AIHC recognizes that confidentiality of information may be limited by the provisions of the Freedom of Information Act, the Government in the Sunshine Act, and other statutes.

Status of Panel Recommendations: The Panel's categorization of a chemical substance would be administratively final, subject to appropriate judicial review. The Panel's determinations and the reasons therefor would be provided to OSHA and published in the Federal Register.

Future Panel Activity: AIHC recommends that the Panel initially make carcinogenicity determinations only with respect to OSHA. However, it believes that the Panel should be structured with a view towards having it at some future time make carcinogenicity determinations for other agencies (such as FDA, EPA, and CPSC) in order to promote consistency. (It is recognized the Panel will have a major role in structuring its own operating procedures. How the Panel operates in executing its responsibilities will depend to a great extent on the nature, background, and composition of its members.)

Location: AIHC does not recommend a particular organization for locating the Panel within government, believing this can be better decided by the Administration. However, the National Research Council has recommended the following:

"The decision to inform those in affected workplaces of the hazard of a chemical is not to be taken lightly, as it involves the commitment of substantial resources. For that reason we believe it essential that a single national source, such as DHEW, be charged with making the decision that workers are at risk. This source should be, to the extent possible, credible to both management and labor; therefore, it should not be involved in the regulatory process. But, it must not be so remote from the realities of the workplace that it cannot make an appropriate assessment of risk, or at least announce its decision in a form that can be translated to a specific occupational situation." 2/

2/

U.S. Department of Commerce: NTIS; PB-269-599
Informing Workers and Employers About Occupational Cancer
(Prepared for OSHA); NRC - 6/77.

It may be that the concept for coordinating regulatory action, now served by IRLG, should become institutionalized, in which case the Panel could become a part of the resulting structure. Again, the Administration is probably in a better position to decide than industry is to recommend whether the function could be better located in HEW, OSTP, NAS or the Domestic Council, etc.; but the concept of separating the Panel from the regulatory bodies needs to be continually emphasized.

Organization: For a panel of nine rotating members, a permanent staff of three doctoral level professionals (e.g., toxicologists, epidemiologists, etc.), one lawyer, and two professional support technical personnel (e.g., writers, researchers, etc.), along with appropriate clerical and secretarial support, would seem a reasonable estimate for an organization formed to aid the Panel in its determinations.

Considering salary, benefits, travel, supplies, and space, as well as some allowance for consulting fees and computer time, it is estimated that the total cost to the government for the Panel would be about two-million dollars per year.

CLEARY, GOTTlieb, STEEN & HAMILTON

1250 CONNECTICUT AVENUE, N.W.

WASHINGTON, D.C. 20036

(202) 223-2151

CABLE: CLEARBOLAW WASHINGTON

TWX 7108220108

ROBERT C. BARNARD
FRED G. TURNAGE
R. MICHAEL DUNCAN
DONALD L. MORGAN
CHARLES G. MANAFFIE, JR.
J. EUGENE MARANS
DOUGLAS E. KRIEGER
KENNETH L. BACHMAN, JR.
CHARLES F. LETTOW
RICHARD W. KINGS
RESIDENT PARTNERS

MATTHEW HALE
WASHINGTON COUNSEL

SARA D. SCHOTLAND
ERIC SCHWARTZ
JOHN S. MAGNEY
HENRY J. PLOG, JR.
EDWARD G. MODELL
RICHARD R. GARDNER
LEE C. BUCHHEIT
JOHN W. WILNER, JR.
EUGENE M. GOOT
PRICE O. GIELEN
G. ANN HORN
ROBERT L. GLICKSMAN

GEORGE W. BALL
COUNSEL

NEW YORK OFFICE
ONE STATE STREET PLAZA
NEW YORK 10004

PARIS OFFICE
41, AVENUE DE FRIEDLAND
75008 PARIS, FRANCE

BRUSSELS OFFICE
RUE DE LA LOI 23, BTE 5
1040 BRUSSELS, BELGIUM

LONDON OFFICE
WINCHESTER HOUSE
77 LONDON WALL
LONDON EC2N 10A, ENGLAND

May 9, 1978

Dr. Elwood P. Blanchard
Chairman, Alternatives Committee
American Industrial Health Council
1075 Central Park Avenue
Scarsdale, New York 10583

Dear Dr. Blanchard:

This letter is in response to your request for our opinion on whether the process of executive branch re-organization could be utilized to transfer the authority to classify and categorize chemical substances with respect to carcinogenicity from those agencies which would otherwise exercise such functions to an independent panel of scientists located somewhere within the executive branch. While the panel would be headquartered within an existing governmental entity, it would be independent of regulatory bodies such as the Occupational Safety and Health Administration, the Consumer Product Safety Commission, the Environmental Protection Agency, and the Food and Drug Administration, and its determinations would be binding upon all such agencies.

On the basis of our research, we have concluded that those classification and categorization functions currently vested in a regulatory agency within the executive branch, such as OSHA, could be transferred to the panel, provided the panel were not established as a new "executive department or independent regulatory agency." We have also concluded that the President's authority under the Reorganization Act of 1977 (the "Act"), 5 U.S.C.A. § 901 et seq., includes the power to transfer functions vested in an independent regulatory agency such as the Consumer Product Safety Commission, provided the reorganization plan does not abolish that agency, transfer all its functions to another agency, or consolidate it with another independent regulatory agency.

C-7

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The President's power to reorganize the executive branch is derived from the Reorganization Act of 1977, 5 U.S.C.A. § 901 et seq. Section 903(a) of the Act authorizes the President, after investigation and whenever he finds it necessary, to carry out any of the policies enunciated in § 901(a), ^{1/} to prepare a reorganization plan. Such a plan may provide for:

1/ Section 901(a) provides:

Th Congress declares that it is the policy of the United States --

- (1) to promote the better execution of the laws, the more effective management of the executive branch and of its agencies and functions, and the expeditious administration of the public business;
- (2) to reduce expenditures and promote economy to the fullest extent consistent with the efficient operation of the Government;
- (3) to increase the efficiency of the operations of the Government to the fullest extent practicable;
- (4) to group, coordinate, and consolidate agencies and functions of the Government, as nearly as may be, according to major purposes;
- (5) to reduce the number of agencies by consolidating those having similar functions under a single head, and to abolish such agencies or functions thereof as may not be necessary for the efficient conduct of the Government; and
- (6) to eliminate overlapping and duplication of effort.

Centralization of all authority to classify and categorize chemical substances for carcinogenicity in the panel would arguably further a number of these policies, including the promotion of economy and efficiency, the coordination and consolidation of governmental functions according to major purpose, and the elimination of overlapping and duplication of effort.

(1) the transfer of the whole or a part of an agency, or of the whole or a part of the functions thereof, to the jurisdiction and control of another agency;

(2) the abolition of all or a part of the functions of an agency, except that no enforcement function or statutory program shall be abolished by the plan;

(3) the consolidation or coordination of the whole or part of an agency, or of the whole or a part of the functions thereof, with the whole or a part of another agency or the functions thereof;

(4) the consolidation or coordination of a part of an agency or the functions thereof with another part of the same agency or the functions thereof;

(5) the authorization of an officer to delegate any of his functions; or

(6) the abolition of the whole or a part of an agency which agency or part does not have, or on the taking effect of the reorganization plan will not have, any functions.^{2/}

Section 903(a) does not explicitly authorize the President to prepare a reorganization plan which creates a new entity such as the classification panel. The President can transfer the functions of an "agency"^{3/} to the jurisdiction and control of another agency, or consolidate and

^{2/} A reorganization plan becomes effective sixty calendar days of continuous Congressional session after the President transmits the plan to Congress, unless either house passes a resolution disapproving the plan within that time. Section 906(a).

^{3/} "Agency" is defined, for purposes of the Reorganization Act, as

- "(A) an executive agency or part thereof; and
- "(B) an office or officer in the executive branch".

§ 902(1). It appears that OSHA, CPSC, EPA, and FDA would all constitute "agencies" under the Act, and that their functions could therefore be transferred to the panel. The question of whether the Act authorizes the President to transfer functions vested in independent regulatory agencies such as CPSC is considered in more depth below. The National Academy of Sciences however, probably does not constitute an "agency", as is also discussed more fully below.

coordinate agencies and their functions with the whole or part of another agency or its functions. Whether such a transfer or consolidation can be made with respect to a new entity as well as an existing agency is not apparent on the face of the statute.

We believe, however, that the President's authority under § 903(a) does encompass the transfer of functions to a newly created entity such as the classification panel. The Act, in § 905(a)(1), clearly prohibits a reorganization plan from creating a new "executive department or independent regulatory agency." Since you do not propose that the panel be established in the form of a new "executive department or independent regulatory agency", but rather as an independent body housed within an existing department or agency,^{4/} the

4/ It should be noted that the National Academy of Sciences is probably not an "agency" for purposes of the Reorganization Act, and thus § 903(a)(1) would not authorize the transfer of agency functions to a subdivision of that corporate entity. This conclusion is based on Judge Sirica's opinion in Lombardo v. Handler, 397 F. Supp. 792 (D.D.C. 1975), affirmed, 546 F.2d 1043 (1976), cert. denied, 431 U.S. 932 (1977). The court held there that NAS was not an "agency" for purposes of either the Federal Advisory Committee Act ("FACA"), 5 U.S.C.A. App. I, or the Freedom of Information Act ("FOIA"), 5 U.S.C.A. § 552. Both statutes define the term "agency" broadly. Under the FACA, which incorporates the definition used in the Administrative Procedure Act, 5 U.S.C.A. § 551(1), an "agency" is "each authority of the Government of the United States, whether or not it is within or subject to review by another agency." Under the FOIA, an "agency" includes "any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency." 5 U.S.C.A. § 552(e). Despite the fact that NAS was established by Act of Congress, reports to Congress, is obligated to perform investigations for the departments of the federal government when requested, and is subject to limitation by Congress with respect to the amount of real estate it may acquire, the court held that it was not an agency for purposes of either the FACA (and thus, by extension, of the APA) or the FOIA. The Court found it significant that NAS' decisions were not binding on EPA (another reason why NAS appears to be an inappropriate place in which to locate the classification panel), that it does not exercise "substantial independent governmental authority", that it neither functioned under nor was created by Congress or the President, and that no significant government control of the corporation could be shown.

limitations of § 905(a)(1) would not seem to apply.^{5/}

The legislative history of the Act supports this analysis. Senator Ribicoff, one of the floor managers of S. 626, which was eventually enacted as the Reorganization Act, expressed the view that the legislative purpose was to grant broad reorganization authority to the President. He stated in floor debate that

"[b]y authorizing the President to propose plans to reorganize the government any way he deems best, the Act permits the President to change the way the government operates. He may transfer and consolidate any functions he wishes, or make any other changes in the government's organization short of abolishing the programs themselves."^{6/}

(123 Congressional Record S. 3438 (March 3, 1977) (Emphasis added).)

^{5/} It should be noted that the Reorganization Act contemplates that a private group such as the American Industrial Health Council may suggest a reorganization plan to the President, since § 901(c) provides that

[i]t is the intent of Congress that the President should provide appropriate means for broad citizen advice and participation in restructuring and reorganizing the executive branch.

^{6/} The House debate reflects the same sentiment. For example, Mr. Brooks responded affirmatively to the following question of Mr. Kazen:

"[Can] the President reorganize several agencies, either put them together or separate functions or do whatever he wants to, but reorganize various agencies at one time under one package that he would submit to the Congress?"

Id. at H. 2668. (Emphasis added).

More specifically, Senator Ribicoff also stated that:

"[u]nder the reorganization authority that would be renewed by this bill, the President may propose to create or eliminate agencies, and transfer functions between agencies. The Act specifically prohibits the use of the reorganization authority, however, to create or abolish cabinet-level departments of the government. For that, regular legislation will continue to be required." (Id. (emphasis added).)

Senator Muskie agreed that the bill "will give the President the authority to create or abolish agencies and to transfer functions between agencies unless one house of Congress disapproves within 60 days."^{7/} (Id. at S. 3445).

Thus, it would appear that the President has sufficient authority under the Act to vest classification and categorization functions with the independent panel, provided it is established as an executive agency or part thereof or as an office in the executive branch, but not as a new executive department or independent regulatory agency.

You have also asked us to consider whether the President's reorganization authority includes the power to transfer to the panel functions currently vested in independent regulatory agencies, such as the Consumer Product Safety Commission.^{8/} It is our conclusion that the President is

^{7/} Senator Percy, the other floor manager in the Senate, stated that reorganization plans "cannot create, abolish, or transfer an executive department or an independent regulatory agency," id. at S. 3440, but he did not say the President was prohibited from creating a body like the proposed classification panel at other than the cabinet level, as a division of another department or agency. Moreover, Senator Percy clearly stated that realignment of functions "within or among" agencies was permissible. Id.

^{8/} It is the opinion of the Office of Management and Budget that CPSC, but not EPA, is an "independent Federal regulatory agency," at least for purposes of the Federal Reports Act, 44 U.S.C.A. § 3502. See OMB Circular No. A-40 and Attachment A thereto (November 5, 1976).

authorized by the Act to transfer functions vested in an independent regulatory agency to another agency, provided the reorganization plan does not abolish the independent regulatory agency, transfer all its functions to another agency, or consolidate it with another independent regulatory agency.

As we have discussed above, the President is authorized by the Act to prepare a reorganization plan which provides for "the transfer of the whole or a part of an agency, or of the whole or a part of the functions thereof, to the jurisdiction and control of another agency." (§ 903(a)(1)). The term "agency" is defined to mean

- "(A) an Executive agency or part thereof; and
- "(B) an office or officer in the executive branch."

(§ 902(1)). Since an independent regulatory agency is an Executive agency,^{9/} the President is authorized by § 903(a)(1) to transfer the functions of such an agency to another agency.

The Act's express limitations on the President's power do not alter this conclusion. A reorganization plan may not provide for or have the effect of

"abolishing or transferring an...independent regulatory agency, or all the functions thereof, or consolidating two or more...independent regulatory agencies, or all the functions thereof." (§ 905(a)(1)).

However, this provision appears to prohibit only those reorganization plans which transfer all of the functions of an independent regulatory agency to another agency. The transfer of less than the totality of such functions would thus be appropriate.

This interpretation of the limiting provisions of § 905(a)(1) is confirmed by the discussion of that section contained in the House Report on the Act. (H. Rep. No. 95-105, Extension of Reorganization Authority of the President, 95th Congress, 1st Session (1977), hereinafter referred to as the "House Report"). The Act's treatment of independent regulatory

9/ Cf. Acron Investments, Inc. v. Federal Savings and Loan Insurance Co., 363 F.2d 236 (9th Cir.), cert. denied, 385 U.S. 970 (1966) (concluding that because FSLIC was subject to more than "custodial or incidental" congressional control, and was deemed by statute to be included within the Home Loan Bank Board, an "independent agency" and "an instrumentality of the United States", FSLIC was an "agency" for purposes of 28 U.S.C. § 1345, which establishes jurisdiction in federal district courts of all civil actions commenced by any "agency" of the U.S.)

agencies was explained as follows:

"Under the expired reorganization authority, independent regulatory agencies were treated as other agencies in the executive branch, and they were subject to reorganization in the same manner. The bill recognizes the unique status of independent regulatory agencies and their special relationship to the Congress by providing that the whole of independent regulatory agencies or all of their functions may not be abolished or transferred nor may two or more such agencies or all their functions be consolidated. This does not mean that such agencies are totally exempt from reorganization authority, but such authority is limited as described heretofore." (House Report, at 8 (emphasis added).)

Thus, the President can transfer functions currently vested in an independent regulatory agency, as long as the reorganization plan does not abolish that agency, divest it of all its functions, or consolidate it with another such agency.

The authority granted to the President under the Reorganization Act is, with some modifications, an extension of the same authority granted to previous presidents periodically since enactment of the Reorganization Act of 1949. Past use of reorganization authority may thus be an indication of the scope of power granted by the present Act. For example, in the Senate Report on the extension of reorganization authority enacted in 1971, a letter from OMB to the Senate is quoted, stating that among the significant uses the President had made of this power in the past was the creation of: a new Office of Telecommunications Policy in the executive office of the President through the transfer of certain functions from the Office of Emergency Preparedness; a new Domestic Council to deal with questions regarding the authority of OMB; a new separate Environmental Protection Agency bringing together key programs for setting environmental standards and abating pollution; and the National Oceanic and Atmospheric Administration in the Department of Commerce, assembling major programs for dealing with environmental problems. The letter further states that Congress allowed all these measures to become effective. (S. Rep. No. 920485 92d Cong., 1st Sess., reprinted in [1971] U.S. Code Cong. & Ad. News 2081, 2089-90).

One further point in favor of broadly construing the 1977 Act to allow the establishment of the classification panel is that if the Congress feels that the President has exceeded the scope of the authority delegated to him, it can reject the plan by passing a resolution of disapproval in either house.

Very truly yours,

CLEARY, GOTTlieb, STEEN & HAMILTON



AMERICAN INDUSTRIAL HEALTH COUNCIL

1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

September 11, 1978

GUIDELINES FOR EVALUATION AND USE OF OCCUPATIONAL EPIDEMIOLOGIC CANCER STUDIES

The evaluation of human data is becoming increasingly important in determining when and how to regulate exposure to suspected carcinogenic materials. As described in the AIHC Alternative proposal, epidemiologic studies are invaluable in determining the fact of human carcinogenicity and in assessing the actual risk under occupational exposure conditions.

The following guidelines are intended to describe major factors in assessing the strengths and limitations of epidemiologic studies, the use of which in turn will assure maximum and appropriate utilization of valid human data. The guidelines are not intended as a check list for accepting or rejecting a study. All data on human exposure to a substance should be considered in attempting to reach a judgment on the human health risks from occupational exposure. Although studies that satisfy all of these guidelines should receive greatest attention, studies that do not should receive attention commensurate with their strengths and weaknesses. There is no substitute for the evaluation of individual studies by highly qualified experts, such as the Data Evaluation and Classification Panel recommended in the AIHC Alternative.

These guidelines have two objectives:

1. To describe the major study design features and analytic methods necessary to allow for the evaluation

of the quality and results of an epidemiological investigation and/or report.

2. To describe appropriate use of epidemiologic studies in evaluating human risk from occupational exposure.

Part A includes the description of the major study features and analytic methods of a study. It also identifies the major factors in evaluating the results and interpretations of a specific study. It will be useful for OSHA in stimulating a dialogue with the investigators and for assuring the submission of a complete information package to the expert panel.

Part B indicates areas of concern for professional evaluations in determining the utility of a specific study in reaching a judgment on the likelihood of a significant health risk from a specific exposure. It stresses the need for examining the consistency of epidemiologic and biologic data and seeking explanations or investigations of apparent inconsistencies. The demonstration of a dose-effect relationship and the calculation of a human occupational exposure risk assessment assist judgmental determinations. Thus, OSHA can be provided with information and judgment essential to regulatory decision-making, particularly the need for and degree of control of specific substances.

PART A - Description, Analysis, and Evaluation of a Specific Study

I. Description of Study Features

An epidemiologic study needs to be adequately described so that the reviewer can understand which population was studied and with whom they were compared, what exposure was under investigation,

what health effect or outcome was evaluated, and how the study was carried out to assure validity and precision.

A. Population Characteristics

1. Study Population - The description of the study population should clearly indicate the criteria necessary for inclusion in the study cohort and the reasons for choosing those criteria. Methods used to assure that all individuals meeting those criteria are included and that only those individuals are included should be described, including demographic and other appropriate characteristics. Any deviations from these criteria should be clearly described, justified and interpreted in considering the actual conduct of the study.

2. Comparison Population - Ideally, the comparison population should differ from the study population only in that it lacks the exposure under consideration. Rarely is this the case. Internal comparison groups are generally preferable to external comparison groups. Consistent findings based on several comparison groups, including external comparison groups, usually strengthen the acceptance of the results.

3. Sampling Procedure and Sample Size - When all individuals satisfying the criteria of the study population are not included in the study, the method used to select the members who are studied should be described. The method used should assure that the group actually studied is representative of the study population. The size of the total study population and of the group actually studied should be indicated.

4. Observation Period - Dates of beginning and terminating of the observation period should be stated and should be similar for the study and comparison populations. The number of individuals observed and the person-years of observation (when appropriate) consistent with the latency period under consideration should be stated. The experience at different time periods during the period of observation (5 or 10 year periods, that are appropriate for the particular study) should be analyzed.

B. Exposure Characteristics

1. Occupational Exposure Under Study

The evidence or reason for identifying the study population as an exposed group should be clearly specified. Sufficient information on exposure characteristics should be presented to assure the reasonableness of this study population and comparison population to test the hypothesis. Environmental measurements or personal monitoring data greatly assist in defining the exposures. Methods and instruments used for measuring exposures should be described in detail. Division of the study population into groups of different levels of exposure is preferable so that analysis can examine for dose-effect relationships.

2. Confounding Variables

Each individual is exposed to more than the item being studied. Within the workplace, other exposures are present contemporarily and these other exposures may be different for the

various occupational groups. Different jobs within the same employment include different sets of exposures. Prior employment and subsequent employment often introduce other exposures. These other occupational exposures cannot always be documented but should be considered in the investigation. Every effort should be made to obtain information about them which may be verified.

Individual lifestyle habits affect one's exposures. Alcohol consumption and smoking histories, for instance, may greatly affect one's risk of developing certain types of cancers and other diseases. Analysis should consider the effects of each variable that may have an independent effect on the health outcome under consideration.

Confounding variables such as sex, age and race may be dealt with in the comparative analysis of the comparison group. Confounding variables, whether or not handled in the design or analysis, should be discussed in the interpretation.

C. Health Effect

The definition of a "case", or of an individual with the health effect under study, should be clearly indicated. It will be dependent upon the data source used. However, the same definition and data source should be used for both the study population and the comparison population. The classification of health effects should be the same for study and comparison populations. The methods used in making a diagnosis in each case in the study

and comparison groups should be described. Further investigations may determine the validity of diagnosis for each case.

D. Procedures

A full description of the procedures used in the conduct of the study will assist the judgment as to the study's validity and allow for its replication if necessary. Data sources should be identified, particularly those that are used to determine who is in the study population, the level of exposure, and the health outcome. Methods used to standardize the data collection and preparation should be determined before data collection and should be described, along with methods used to verify the data. Follow-up procedures and degree of completeness of follow-up for each subgroup should be indicated. The investigators responsible for the professional work should be identified.

E. Case Presentations

A case history should be given for each "case" in the study indicating demographic variables, exposure variables, confounding variables, and clinical variables. Sufficient details should be given to indicate both that each case satisfies the study criteria and that alternative exposures and etiologies do not explain the case's occurrence.

II. Analytic Method

The term analytic method is herein used to include all procedures and techniques by which data are handled, examined and

presented for the purpose of drawing conclusions or inferences. The analytic method should be presented clearly and in sufficient detail to enable the reader to fully understand the calculations and to accept, as appropriately applied, the procedures or techniques utilized. The following categories are suggested as a guideline for use in describing the analytic method employed in an epidemiologic investigation or report being critically evaluated.

A. Data Presentation

1. Summary data and their derivation supporting the major conclusions reached in the text should be adequately presented in tables, graphs, etc.
2. Data displays (graphs, tables, etc.) should be clearly defined and labeled.
3. Data presented should be internally consistent.

B. Data Analysis

A description of the rationale for the major analytic procedures used should be provided, either in the text or in noted references. These procedures may include:

1. Statistical methods used - rates, proportions, person-years, indices of association, and summary statistics such as, standardized mortality ratios, proportionate mortality ratios, relative risks, attributable risks, standardized morbidity ratios and confidence limits.
2. Significance tests employed - Chi-square, "t" test, etc.
3. Statement of the α and β error levels selected and the

minimum excess risk the study is designed to be able to detect.

4. Analytic methods - analysis of variance, regression, survivorship analysis, etc.
5. Methods for handling confounding variables - matching, adjustment (direct or indirect), stratification, etc.

III. Evaluation of Results and Their Interpretation

A. Hypothesis Testing - The author's conclusions and interpretations should be clearly stated. The hypothesis to be tested should be appropriate to the data base and the analytic method used. Additional hypothesis tested from the same data base should be indicated. The findings should be internally consistent and presented in sufficient detail to allow for judgment of the validity of the results. The description of the study population and comparison groups and their exposures should justify a reasonable conclusion that their significant difference is the result of their exposure to the item under consideration. The individual case histories should relate closely to the tested hypothesis. The reviewers should be able to determine whether the hypothesis the author is actually testing is the same as the hypothesis that was initially stated.

B. Limitations - All studies have limitations inherent in the type of data collected and the analytic methods used. Further limitations are introduced in the carrying out of the study because of the inability to collect all the desired data and

because of the difficulties of adjusting for confounding variables. The analytic method and data reduction may limit the testing of the desired hypothesis, assuming that the study has sufficient power (defined in D below) to test the hypothesis. The authors should frankly discuss the limitations of their own study.

C. Bias - Bias may be introduced in a study by the choice of the criteria that define the study population and observation period, the looseness of definition of the health effect evaluated, the procedural differences in counting health effects among the various risk groups to be compared, the care with which each aspect of the study is professionally carried out. It is of utmost importance that the criteria defining the study population and the observation period be established independent of knowledge of the characteristics of the individuals demonstrating the health effect and prior to the conduct of the study.

D. Power - The power of a study is dependent upon the size of each population, the frequency of the event being observed, as well as the difference in frequency of events among the various groups to be compared. The power of a study is the likelihood that it could observe a given frequency of an event or outcome at a given level of statistical significance. A typical power statement might be that, if the real frequency in the study population were twice that of the comparison population, the study would have had an 80% chance of observing a difference that is significant at the 0.05 level (two-tailed test).

Whether a study observes an excess or not, it should indicate the confidence limits of its result. These confidence limits will indicate the probable range of values which might exist for the real frequency (based on the observed frequency) and will indicate the probability that the real frequency will be within that range. A study is classically considered to be "positive" (show an effect) when the upper confidence limit of the frequency in the comparison population falls below the lower confidence limit of the frequency in the study population and this difference is not explained by the study's limitations, biases, or confounding variables.

PART B - Use of Epidemiologic Studies in
Evaluating Human Risk from Occupational Exposure

I. Judgment on Utility of Specific Study

Based on a review of the description of the study conducted and the analytic methods used and an evaluation of the study's results and interpretation, it may reasonably be concluded that a particular study has been well conducted and has demonstrated a rejection or acceptance of a specific hypothesis.

An additional judgment has to be made placing this study in the context of the results of other epidemiologic studies, biological knowledge (particularly concerning the health effect of this substance) and knowledge of use and exposures of the substance under consideration. Such professional judgments are necessary for determining the likelihood of a significant health risk for a specific exposure.

An individual study may or may not demonstrate that an increased risk of a specific health effect is statistically associated with a specific exposure. Additional studies may indicate the effect to be attributable to the exposure. Judgment on the causal and dose relationships of a substance depends upon the totality of epidemiologic, toxicologic, biologic, and industrial hygiene data. The utility of each specific study in assisting in that judgment must be determined.

II. Consistency with Other Epidemiologic Data - The conclusions based on published and unpublished reports and studies of human experience with the compound must be compared. Inconsistencies and contradictions must be identified and explained. "Positive" epidemiological studies can be used to estimate the magnitude of risk of a specific health outcome from a specific exposure. "Negative" epidemiological studies can be used to calculate an upper limit to the estimate of human risk. "Positive" and "negative" epidemiologic studies may be compatible, based on their exposure ranges and their sensitivities. A critical review of "positive" and "negative" studies may identify situations in which excess risk may be observed, situations in which excess risk is unlikely to be observed, and situations in which the evidentiary probability would indicate that either there is a small likelihood of the substance causing the health effect or that the substance is only weakly able to cause the health effect.

III. Biologic Consistency - A specific study may indicate a particular substance is associated with an excess frequency of a certain health effect. Before concluding that the excess frequency is attributable to that exposure or caused by that substance, it is necessary to develop additional information demonstrating the biological reasonableness of the hypothesis. Consistency with animal studies or other laboratory studies including human pathology must be considered and inconsistencies explained. Cases where human epidemiologic studies do not support the conclusions of laboratory studies, particularly of non-human animal studies, call for further evaluation of each study. The laboratory studies should be reproduced and extended. Additional epidemiologic studies should explore various human experiences with the substance. Differences in human and non-human animal responses to exposure may reflect differences in exposure dose or route or differences in metabolic handling or sensitivity, the further study or which may be necessary. Until such differences are resolved an estimate of human risk or at least an upper limit to the estimate of human risk can be calculated from the human epidemiologic data.

IV. Dose-Relationships - The totality of human and animal studies should be reviewed to determine the degree of relationship between the dose of the substance and the frequency of the observed health effect. A direct dose-effect relationship showing increased excess frequency of health effect with increasing dose of substance

would greatly strengthen the judgment that the substance is responsible for the excess health effect. Linear or curvilinear characteristics of the relationship should be evaluated. Additionally, review of the dose-effect relationship may indicate exposure levels at which an excess frequency of the health effect would be very unlikely.

Judgments have to be made as to when exposures may have effects whose significance may be theoretical, statistical, biological, or clinical.

V. Risk Assessment - The final determination of the health effect risk of occupational exposure to a given substance will depend upon:

(1) a determination that there is a specific increased risk of an identifiable health effect from exposure and that this risk increases with increased exposure level;

(2) an estimate of the magnitude of the health risk at specific exposure levels; and

(3) an estimate of the number of workers who would be occupationally exposed to the substance at different levels.

An estimate can be made of the magnitude of the total risk from occupational exposure and from exposures above certain levels. Thus, an estimate can be made of the magnitude of the benefits to be gained (reduction of risk) from establishing different levels of maximally permitted exposure. These potential benefits can be compared with the estimated feasibility and cost of their attainment.

Appendix E

EPA's Seventeen "Principles"*/

1. "Cancer is a major and increasing cause of death and morbidity in man. It imposes upon society an immense burden of death, suffering and economic loss."
2. "Cancer may be induced by many factors including exposure to chemicals."

*/ These principles are set out in a Motion To Take Official Notice of Certain Facts filed by EPA on June 27, 1975 in a proceeding to suspend the registrations of pesticides containing heptachlor and chlordane in In Re Velsicol Chemical Corporation, FIFRA Docket No. 336 et al. The principles are also set out in a slightly revised form in the EPA Administrator's Notice of Intent to Suspend the Registrations of Pesticides Containing Heptachlor and Chlordane, 41 Fed. Reg. 7552, 7554 (February 19, 1976).

"Policy Determinations" and "Concepts" on Which OSHA Relies in its Cancer Policy Proposals**/

"Cancer is a particularly dreaded and costly disease." (42 Fed. Reg. at 54149)

"The economic and social impacts of cancer in the United States are massive. . . ." (42 Fed. Reg. at 54150)

"[H]eart disease and cancer . . . now lead the nation's list of killers."

"Among the causes of cancer, those most prominent are believed to be traceable to environmental factors singularly or in conjunction with genetic or other substitutes."

* * * *

"The extent to which the observed incidence of cancers are attributable to man made chemicals cannot be estimated with any precision." (42 Fed. Reg. at 54150)

**/ 42 Fed. Reg. 54147 (October 4, 1977).

3. "Chemical carcinogenesis is characterized by a long latency period which in humans may be as long as 20, 30 or 40 years between exposure and the appearance of symptoms of the disease."
4. "Once a carcinogenic response has been triggered the development of cancer is irreversible."
5. "Given the long latency period of cancer and its irreversibility, in the case of a chemical for which there is widespread human exposure and thus no adequate control group it is virtually impossible to determine a carcinogenic effect by direct observation in man."
6. "The use of experiments with animals to test chemicals for carcinogenic hazard to humans is accepted by the scientific community and by public policy-making agencies in the United States."
7. "Mice and rats are preferred experimental animal species for carcinogenesis

"In man . . . the latent period of chemical carcinogens is often as long as a major portion of a lifetime . . . It has been found to be as long as 15, 20, 30 or more years in man. . . ." (42 Fed. Reg. at 54152)

"Following [initiation of a neoplastic change in a target cell], exposure to the carcinogen is no longer required to maintain the initial alteration that leads ultimately to a cancer cell, which is then capable of autonomous growth. Thus a single biological event produced by a very small number of molecules of the carcinogen may be sufficient to initiate the irreversible development of a tumor." (42 Fed. Reg. at 54152)

"The long latency period between exposure and symptoms [in man] and the irreversibility of the disease often makes it medically and scientifically impossible to identify carcinogens in the environment." (42 Fed. Reg. at 54156)

"The validity of using animal data as a qualitative indication of potential human effects has long been recognized by scientific advisory committees and other governmental bodies. . . ." (42 Fed. Reg. at 54157)

"OSHA relies in general only upon results found in testing of mammalian

testing because their relatively short lifespan permits lifetime testing covering the entire latency period of tumors within a reasonable time, and because the development of tumors in these species is well known."

8. "All chemicals known to cause cancer in man with one exception have been shown to cause cancer in animals, especially mice and rats."
9. "Pathological development of chemically induced tumors in experimental animals and in humans is very similar."
10. "Since the number of animals used in laboratory tests is extremely small when compared to the hundreds of millions of people who are involuntarily exposed to widespread chemical contaminants and since the variability of human response to chemical carcinogens is generally greater than that of laboratory animals, a positive oncogenic effect in any test animal is sufficient to characterize the chemical as posing a cancer risk to man and negative results in animal tests have only limited significance and should normally be superceded by positive results."

species. In that regard, the rat and mouse (and to a lesser extent the hamster) have traditionally been the species of choice for carcinogenicity testing. . . ." (42 Fed. Reg. at 54160)

"All chemical substances or mixtures that have been proven carcinogenic by direct observation in man have also been shown to be carcinogenic in experimental animals (with the possible exception of arsenic and benzene, still under experimental study)." (42 Fed. Reg. at 54146)

"The choice of the rat and mouse is not only dictated by considerations of convenience but because of their known susceptibility to agents known to be carcinogenic in humans as well as the similarity in mechanisms of tumor induction." (42 Fed. Reg. at 54160)

"[P]ositive results in tests with experimental animals . . . should generally supercede negative results, both because of the aforementioned insensitivity of laboratory bioassays conducted with limited number of animals, which may frequently lead to false negative results, and also because of interspecies differences in susceptibility." (42 Fed. Reg. at 54161)

11. "A carcinogenic substance is one which increases benign or malignant tumors or neoplasia in exposed animals; shortens the latency period between the exposure and the development of tumors or neoplasia; or which results in unusual tumors."

12. "Since many benign tumors can develop into cancers, for the purposes of carcinogenicity testing there is no valid distinction between the induction of benign or malignant tumors and they should be considered synonymous."

13. "Chemical carcinogenesis is a specific biological process which is induced by a relatively few classes of chemicals. Thus, it is not true that all chemicals induce cancer at sufficiently high doses."

"[A] toxic substance will be classified qualitatively as a 'potential occupational carcinogen' if . . . OSHA believes that it has been shown (a) to cause . . . an increased incidence of malignant or benign neoplasms . . . , or (b) . . . decreases the latency period between exposure and onset of neoplasm formation." (43 Fed. Reg. at 54169)

"A presumption exists that a toxic substance shall be classified by the Secretary as a 'Category I Toxic Substance' if . . . the Secretary finds that any other evidence is sufficient to convince him that the toxic substance should be classified as a Category I Toxic Substance." (43 Fed. Reg. at 54185)

"This basis is meant to include evidence, for example, of those substances that might possess a unique property, e.g., a substance that generates nonstatistically significant but extremely rare or unusual tumors. . . ." (43 Fed. Reg. at 54171)

OSHA "proposes to place as much weight on an experiment in which only benign tumors are observed, as upon experiments in which both malignant and benign tumors are induced." (42 Fed. Reg. at 54163-64)

"[T]here has been [a] tendency for some to suspect that all chemicals are capable of causing cancer if administered to experimental animals at sufficiently high doses. This claim appears to be based on the belief that carcinogenesis

is a non-specific kind of biological process associated with any substance under the right conditions, namely that test animals, bred for their sensitivity to carcinogens, when fed maximum tolerated doses of a substance for their lifetime become very ill and may be more susceptible to carcinogenic effects. However, there is evidence that renders this suspicion very unlikely to be true.

* * * *

[T]he available evidence provides strong indication indeed that not all chemicals are capable of causing cancer and that only a small number of the total is so capable." (43 Fed. Reg. at 54151)

"The testing of chemicals at constant high exposure levels, at or approaching the maximum tolerated dose level, is not inappropriate and is indeed required to overcome the statistically insensitivity of laboratory bioassays conducted with the limited number of animals that can be handled in practical laboratory conditions." (43 Fed. Reg. at 54161 [see also definition of "potential occupational carcinogen" as a substance which is oncogenic "at any level of exposure or dose" -- Proposal § 1990.102])

"[A] no-effect or threshold level may theoretically exist for any specific carcinogen. As yet, however, there is no satisfactory scientific basis for determining such levels for any given population. Thus, as has been proposed,

14. "High doses are administered in animal carcinogenicity tests because limited numbers of animals render the tests relatively insensitive to carcinogenic effects. Consequently, a substance which induces tumors at any dose level represents a warning signal of great significance."

15. "There is no scientific basis for the existence of a "no effect" level for carcinogens. In principle no dose of a chemical carcinogen is too small to induce tumors in susceptible individuals."

16. "Carcinogens are not specific to particular test species, nor are they specific to certain strains of test species."
17. "Most carcinogens are not organ specific. Thus, a carcinogen which induces liver tumors in mice might, for example, produce mammary tumors in rats and lung tumors in humans."

any human exposure to a carcinogen . . . would be considered by OSHA to present a potential cancer risk as a policy matter." (42 Fed. Reg. at 54174)

"[A] chemical that causes cancer in one animal species is likely to do so in most other species tested." (42 Fed. Reg. at 54157)

"There can be no presumption that the organ affected in animal experiments would be that at risk in man." (43 Fed. Reg. at 54162)

Appendix F - An Excerpt From The AIHC Alternative
Entitled "Health Program Management"

M. Health Program Management

The AIHC recognizes that there will be combinations of carcinogen classifications and risks/hazards that may differ for different chemicals - or will differ in each workplace for similar chemicals. In fact, the AIHC classification proposal, which contains 7 categories, when cross-referenced with only two risk/hazard levels will contain 14 different possible situations to be covered by a standard. For this reason the AIHC feels that the 2 or 3 model standards using a rigid format as proposed by OSHA are not appropriate. As an alternative we present basic principles which should be addressed in any standard, but which must be tailored to the classification - risk/hazard combinations which will be encountered in the workplace.

To ensure prompt and reasonable action to limit employee exposure to known or suspect carcinogens, and to ensure compliance with a permanent standard, each employer should prepare and implement a written plan. Because workplaces vary substantially in terms of how a substance is used, the number of employees present, the age of the plant, the duration, intensity, and frequency of exposure, and many other variables - it will often be appropriate for different employers to take different actions to reduce employee exposures to known or suspect carcinogens. A plan for compliance addresses the following item and delineates the actions to achieve the performance objectives stipulated therein. AIHC recommends that for each workplace the employer use the best practicable combination of engineering, administrative, and work practice controls, and personal protection.

Once regulatory action has been taken and OSHA has promulgated permissible exposure levels, OSHA should require employers to determine, for each workplace where a regulated substance is present, whether exposure levels higher than an action level are likely to be experienced. If the determination indicates the action level is likely to be exceeded, the employer should make measurements to confirm this estimate; if confirmed, he should prepare a plan which assures compliance with permissible exposure levels. A plan shall require use of engineering controls to the extent technically and economically feasible, augmented by administrative controls and personal protective equipment as appropriate. Where engineering controls are not incorporated, the plan must show why that action was not practicable or applicable and thus show that the action had been considered.

The plan should be made available upon request to any affected employee or his designated representative. It should be made available to an OSHA compliance officer upon request during his inspection. Compliance with such a plan would not excuse failure to comply with a permissible exposure level. The requirement to prepare a written plan would be in addition to the requirement to comply with a permissible exposure level.

The plan should include training potentially exposed employees to ensure that they are informed of the nature of the potential hazard. Restricting certain areas to authorized personnel may be necessary. The indiscriminate use of signs and the word "cancer" on signs designating each such area can be

counter-productive with respect to health and safety.

Any well-conceived plan would consider additional factors such as qualified personnel placement and training, house-keeping, medical monitoring, protective equipment, emergency procedures, and exposure records, along with the engineering controls, monitoring and administrative controls mentioned above.

For employees who are exposed above action levels, the employer should include in his plan a medical program prepared with the guidance of a trained physician. The employer must inform the physician of the nature and category of any substance, and of the evidence underlying the classification. Where specific effects of a substance have been identified, medical tests for those effects should be integrated with any general medical program already provided by an employer.

N. Special regulatory approaches to laboratories construction, agriculture and transportation

In general, regulations appropriate for the industrial workplace are not appropriate for laboratories, whether quality-control, pure research, or some admixture of both. OSHA's failure to distinguish between laboratory and non-laboratory workplaces is unreasonable. OSHA's proposed requirements for laboratory workplaces could lead to the unintended consequences of impeding important research on cancer and other serious health problems.

AIHC believes that special regulations for laboratories are appropriate. Probably a single work-practices oriented regulation for laboratories would be sufficient.

Appendix C - AIHC Alternative Supplement On Risk
Benefit Analysis

AIHC ALTERNATIVE SUPPLEMENT
RISK/BENEFIT ANALYSIS

AIHC accepts the appropriateness of the regulatory process to deal with the problem of cancer control. OSHA's generic control initiative articulates but one response to its perception of a cancer problem.

However, this proposal does not include adequate risk evaluation procedures. We agree that except in a very few instances where reliable human epidemiology is available, workplace cancer risk to humans must be assessed on the basis of available animal experiments.

The first step in any regulatory attempt to deal with workplace cancer risks must be to conduct a risk assessment on individual chemicals. An established risk assessment policy within OSHA (but applicable to other agencies as well) which demonstrates a sound scientific and regulatory approach is essential to reduce the incidence of challenge by litigation.

A risk assessment conducted on all chemicals that have been judged carcinogenic in test animals by the Evaluation and Classification Panel will permit prioritization of these chemicals by comparing relative risks of each. This comparison includes consideration of potency, numbers of workers exposed, and exposure levels. Regulatory efforts to reduce workplace cancer risks must begin with the higher priority risks and proceed systematically to the lower priority risks. Risk assessment will also permit government and industry to determine the extent to

which various possible regulatory measures can in fact reduce the risk. It will afford a reasonable basis for determining goals for risk reduction by assessing the degree of risk presented in the workplace as contrasted with the degree of risk that we all face from chemicals (natural or man-made) in our everyday lives.

The big problem for risk assessment arises from selection of an appropriate model for extrapolating animal dose/response data to man. The most conservative approach is a strictly linear extrapolation which some have asserted to be scientifically supportable in a limited number of cases but which frequently leads to totally impractical and inappropriate exposure levels for occupational, environmental, or personal care considerations. Broadly applied this would place an unjustified and excessive inflationary burden on the American public through loss of or increased cost of products.

In many cases a linear model is not the best fit to experimental data and should therefore not be used for extrapolation purposes. AIHC believes that different models may be more applicable in many cases. In no event should an agency foreclose the use of the best tool available in this developing period of scientific advances toward better understanding.

In the animal to man extrapolation process, consideration of equivalent dosages per body weight or surface area, fractions of food and water intake, appropriate multipliers for route of administration, and relating the length of exposure to life span for man and animal is in order.

Whenever confronted with a large group of chemicals classed as carcinogens, OSHA should be able to estimate a degree of risk for a broad range of chemicals rapidly and to publish an ordered listing of relative risks. This would provide industry and employees alike the opportunity to evaluate their particular situation at an early date to make the most effective use of resources in taking corrective actions.

Starting with the higher priority substances, OSHA and industry would then direct their efforts to exploration of all objective and subjective benefits and risk reduction methods for regulating any particular chemicals. These efforts would include a written statement by the agency of the magnitude of the risk, how it compares with other risks whether from chemicals or other sources in our society, the benefits from the chemical, and the incremental costs of various degrees of risk reduction.

Support for this logic process in regulatory matters concerned with human health is contained in several recently published deliberations of other government agencies. The Nuclear Regulatory Commission specifically embraced the concept of reasonably achievable health risk reductions on the basis of quantified cost-benefit analyses. (1) A further example is that contained in the Food and Drug Administration's risk assessment

1. "Low Level Radiation Exposure," Federal Register, 42 (101), 22253-22254, May 24, 1978.

for aflatoxins wherein epidemiologic data were combined with extrapolated animal data and benefit-cost analysis to arrive at an acceptable tolerance level for those toxic materials in food. (2) Finally, most recently the Council on Wage and Price Stability has published a review of OSHA's analysis of the proposed permanent standards for occupational exposure to acrylonitrile. (3) The Regulatory Analysis Review Group confirms the need for methodologies cited above as a critical element of the regulatory process for the reduction of health risks.

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2. "Assessment of Estimated Risk Resulting from Aflatoxins in Consumer Peanut Products and Other Food Commodities," Bureau of Foods, FDA, January 19, 1978.
 3. Letter from the Director of the Council on Wage and Price Stability to the Assistant Secretary of Labor, May 19, 1978, transmitting the report of the Regulatory Analysis Review Group on the "Proposed Standard for Occupational Exposure to Acrylonitrile - OSHA Docket No. H-108."



AMERICAN INDUSTRIAL HEALTH COUNCIL

1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

October 16, 1978

Mr. Grover Wrenn
Occupational Safety and Health Administration
Department of Labor
Third Street & Constitution Avenue, N. W.
Washington, D. C. 20210

Dear Mr. Wrenn:

On July 14, 1978 OSHA released a preliminary list of chemicals tentatively classified by Clement Associates, Inc. according to the system OSHA proposed on October 4, 1977 for regulating cancer-causing substances in the workplace. Simultaneously you asked each participant in the proceedings to submit to OSHA suggestions as to how to establish priorities for OSHA examination of the tentative list.

Attached is a memorandum prepared by the American Industrial Health Council in response to your request. You noted in your memorandum accompanying the list that the final regulation may contain different criteria than those in the regulation as initially proposed. AIHC believes strongly that the proposed regulation should be modified for the reasons to be stated in our Post Hearing Brief. However, in view of your request for comments before the final regulations are issued, we have undertaken as an exercise to outline the procedure based on the AIHC Alternative which AIHC believes is the most expeditious way to establish priorities. The steps outlined in the attached memorandum may be summarized as follows:

1. The Scientific Panel proposed by AIHC would be established.
2. OSHA would immediately start to gather information on the number of employees and levels of exposure to substances for which there are human epidemiological data or two or more positive animal studies.

Mr. Grover Wrenn

3. OSHA acting jointly with the Panel would screen the list of substances based on exposure data and a preliminary evaluation of the human and animal data in the literature to select for priority scientific evaluations those substances which it appears may present the greatest employee hazard.
4. As the Panel completes the evaluation and classification of the priority substances, OSHA will make a hazard evaluation to determine regulatory priorities.
5. On a continuing basis, OSHA and the Panel would re-evaluate the selected list of substances to identify the next and subsequent priorities.

Sincerely,



Elwood P. Blanchard

Enclosure

Proposed Procedure for Prioritizing
Substances on NIOSH List Tentatively
Classified in OSHA Category I by
Clement Associates

On July 14, 1978 OSHA released the results of a review by Clement Associates of the 1976 NIOSH subfile on suspect carcinogens. Based on a literature review, Clement tentatively assigned substances to the OSHA categories in the proposed regulations as shown in the following table:

	<u>List I</u> (based on EPA TSCA candidate list)	<u>List II</u> (based on U.S.I.T.C. data for organics and EPA list for inorganics)
Category I	269	116
Category II	218	72
Category III	396	181

The selection of substances from these lists for priority consideration by OSHA presents a number of complex problems. A prescreening method must be utilized to select for full scientific review those substances that present the highest carcinogenic risk and the highest relative hazard based on number of employees exposed, the exposure level and the relative potency of the substance. In this situation there will have to be an interaction between the scientists making the preliminary scientific review and those responsible for deter-

minations of regulatory action to assure that the selection is made for priority consideration of those substances presenting the greatest relative hazard.

The need for interaction between the scientific and regulatory appraisal stems from several considerations. NIOSH has stated in a memo published in the BNA Chemical Regulation Reporter that the list used by Clement may contain errors both as to substances now in the registry and as to substances deleted. Moreover the literature cited in the NIOSH list is not evaluated but is uncritically listed. In addition, the literature cited is biased in the sense that many negative studies are not published. The Clement screening process involved review of the literature but did not purport to be a full scientific evaluation. Clearly, steps will have to be taken to assure that the scientific evaluation is based on all available data. Moreover, the differences between List I and List II make it apparent that many substances on List I are of negligible commercial importance. Finally, the Clement list was based on the criteria in the proposed regulation which AIHC believes should be re-evaluated for the reasons stated in the AIHC Post Hearing Brief.

The purpose of this memo is to demonstrate how the AIHC Alternative offers a reasonable and expeditious means of establishing priorities for administrative review of substances tentatively classified by Clement in Category I.

Introduction

It is important also to point out that this memorandum is based on a clear distinction between (a) the scientific function of data evaluation and risk assessment and (b) the regulatory function of assessing hazard and determining what regulatory action, if any, is appropriate.

Assessment of risk in this context means: (i) evaluation of the data to determine whether the quality of the epidemiological study or animal test provides a valid data base for a determination that a human cancer risk is presented by exposure to the substance; and (ii) evaluation of the potency of the substance with respect to human risk. This latter function includes selection of appropriate extrapolation techniques and consideration of the relevant metabolic and pharmacokinetic data as available.

The regulatory function is to assess the hazard and determine the appropriate regulatory action. The "hazard" involves determination of the number of employees exposed, levels and types of exposure and the degree of potential danger to those employees. If regulatory action is warranted, the agency would proceed in the regulatory process to consider the factors involved in determining a reasonably necessary and feasible level of control.

Procedure

This memorandum assumes that OSHA has recognized the need for independent scientific evaluation by a Panel of dis-

tinguished scientists such as that proposed by AIHC. The fact that OSHA has used Clement in the preliminary evaluation of the NIOSH list is a recognition by OSHA of the need for a scientific evaluation. The Scientific Panel proposed by AIHC accomplishes the objective of speedy and scientifically valid evaluation of this large number of substances and assures that this evaluation will be accomplished on a scientific rather than adversarial basis. This provides assurance that substances posing the highest relative hazard will be selected for priority consideration.

1. AIHC urges that OSHA immediately take the first step in assuring reasonable prioritizing of these substances by requesting the President to establish the Scientific Panel so as to permit the process of selecting members to begin promptly. While the Panel is being appointed and getting ready to begin its functions, much necessary preparatory work by OSHA described below can be undertaken.

OSHA should request the cooperation of NIOSH and the National Library of Medicine in gathering copies of articles on all substances tentatively classified in Category I, II or III for use by the Panel. A procedure should also be established to provide all references on the substances as currently published.

2. Clement screened the 1976 NIOSH subfile of suspect carcinogens. The 1977 list is expected to be published shortly and, in any event, is available to OSHA on tape from

NIOSH. In order to do an orderly job on the NIOSH list, OSHA should immediately request NIOSH (or a contractor) to screen the substances added to the NIOSH list and to review the sub-file for substances deleted and for the additional information in the new literature references for substances in the 1976 list. The revised list of substances should be computer checked with EPA's revised inventory under TOSCA and with ITC data to identify the commercial substances. This revised list should be updated currently as additional information becomes available from NIOSH or other sources.

3. OSHA should begin immediately to gather information on employee exposure. Nearly 200 of the substances were identified by Clement as substances on which there were human epidemiological data (AIHC Category I) or which had been the subject of two or more positive animal studies (AIHC Category II). When the list is revised as described in (2) above, there may be other substances where the literature would tentatively appear to meet the criteria for AIHC Category I and AIHC Category II. We recommend that the OSHA efforts to collect employee exposure data concentrate on such substances.

4. There are four possible sources of information on employee exposure: The Department of Commerce, the International Trade Commission, NIOSH and the Environmental Protection Agency. These sources will have some, but probably incomplete, information as to the number of employees and levels and types of exposure for all the substances identified in (3) above. In

addition to employee exposure information, AIHC suggests that OSHA consider securing also to the extent available the names of producers and importers of the substances from these sources. AIHC recognizes that production volume has only a limited value in assessing employee exposure, but that data will be of assistance in identifying the insignificant products in the revised list. OSHA should also enlist the aid of trade associations in collecting these data.

5. Using the list of producers and importers referred to above, OSHA should begin a census of those companies requesting the following information:

(1) Number of employees exposed and the levels and types of exposure at the producer and importer establishments.

(2) Many producers may be able to give information on estimated employee exposure of down stream user plants. OSHA should also request cooperation of trade associations in gathering these data.

(3) NIOSH facilities may be available to collect the information.

6. Using the information collected on each substance OSHA should publish for comment the list of substances and the agency's best estimate of employee exposure. This list should not identify tentative classification since the data are unevaluated but should be identified as substances in which OSHA is

gathering data to determine if regulatory action is warranted. In order to avoid unwarranted stigma, we suggest this list be entitled "List of Substances To Be Evaluated For Carcinogenic Hazard Potential."

7. As soon as the Scientific Panel is selected, OSHA should furnish to the Panel the list of substances for which OSHA has gathered exposure data. The Panel should be requested to make a preliminary screening of the literature so as to determine validity of the scientific data and the potency of the substances for which there are valid data. Through an iterative process, OSHA and the Panel should jointly select in an orderly and sequential manner, those substances presenting the highest relative hazard considering number of employees exposed, nature and type of exposure, physical and chemical properties, exposure level and potency of the substance.

8. The list of substances selected for priority scientific evaluation should be published by the Panel for comment. The notice would request information and unpublished data on the substances. The Panel should request EPA to furnish non-confidential information in health and safety studies, relevant to carcinogenicity, which have been filed with EPA under Section 8 of TOSCA on commercialized chemicals. The Panel will also take such reasonable steps it deems appropriate to secure additional scientific data and scientific comment from the public during the evaluation process.

9. The Panel will complete the evaluation of the data as promptly as possible and prepare a qualitative risk assessment of carcinogenicity. When the Panel concludes that the data provide a valid basis for a qualitative evaluation of human risk, the Panel shall evaluate all of the elements necessary to prepare a quantitative risk assessment in such form as to enable OSHA to assess hazard at current levels of exposure, and at the PEL if one is established.

The evaluation shall be based on the weight of the scientific data and shall include evaluation of all epidemiological studies and animal data. In the risk assessment the Panel will identify the extrapolation techniques most compatible with the biological mechanism to the extent known. A reasoned statement of the grounds for identification of a particular extrapolation technique and any uncertainties associated with it will be reported. Metabolic and pharmacokinetic data should be considered in the extrapolation process to the extent available.

10. (a) Upon receipt of the Panel evaluation, OSHA will publish the list of substances and the evaluation and classification by the Panel. OSHA will also issue voluntary guidelines for all substances identified as presenting a significant human risk at occupational exposure levels. The guidelines would contemplate preparation by each producer or user of the substances of a site-specific plan for reducing employee exposure promptly by economic and readily available means which would include:

work practices
clean-up and housekeeping
determination of frequency and type of monitoring or other exposure determination
containment of leaks and open operations
provision for personnel protection and medical surveillance
notification and training of employees

This plan would be available to employees and to NIOSH or OSHA upon request.

(b) Immediately upon receipt of the evaluation from the Panel, OSHA will prepare a hazard analysis of the substances. Upon review of the hazard analysis, OSHA will determine regulatory priorities which will include a determination whether the guidelines have resulted in sufficient control, considering the employees' potential danger at then current levels of exposure. The evaluation of hazard for each substance would include a determination whether an Emergency Temporary Standard is justified and necessary under the statute. Where an ETS is not warranted under the statute, a standard setting procedure would be instituted in those cases where OSHA concludes regulation is necessary and appropriate.

11. During the time the Panel is reviewing the initial priority list, OSHA would continue to gather data on other substances on the list described in (3) above with particular attention to those substances which OSHA and the Panel agreed, based on preliminary screening by the Scientific Panel and available exposure data, indicate may present the highest relative hazard potential. As additional information becomes available, OSHA will consult the Panel to determine whether the new data changes

the relative priority for scientific evaluation.

12. When the scientific evaluation of the first priority substances is complete or nearing completion, OSHA in cooperation with the Panel will make a determination as to which substances should next be selected for scientific evaluation.