TO: Distribution

FROM: T. G. Grumbles
DATE: February 22, 1990

Interoffice Communication

VISTA

SUBJ: OSHA FINAL STANDARD ON OCCUPATIONAL EXPOSURES TO HAZARDOUS CHEMICALS IN LABORATORIES

The final standard was promulgated on January 31. It is effective on May 1 of this year, with a final compliance date of January 31, 1991.

The basic concept of the standard is the development and implementation of a Chemical Hygiene Plan (CHP). The CHP must include the necessary work work practices, procedures, and policies to ensure that employees are protected from hazardous chemicals in their work area. The CHP content is specifically defined in terms of general areas, such as establishing standard operating procedures, but the standard allows a large measure of flexibility in compliance methods.

Applicability of the standard to Vista's laboratories is unclear to me at this time. Much discussion of the applicability of the standard and a relatively elaborate definition of applicability is found in the preamble and standard. The preamble states most manufacturing quality control laboratories probably aren't covered (P. 3312), but it seems our labs probably meet the definition of "laboratory use of hazardous chemicals" (P. 3328) which would cause us to be covered. I will review this with Legal and advise on applicability as well as give you more analysis of the standard in the near future.

For now, I've enclosed a copy of the preamble and standard. The standard begins on Page 3327.

T. G. Grumbles

dlj

Attachment

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H-150]

RIN 1218-AA00

Occupational Exposures to Hazardous Chemicals in Laboratories

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule.

SUMMARY: By this Notice, the Occupational Safety and Health Administration (OSHA) hereby promulgates a final rule for occupational exposures to hazardous chemicals in laboratories.

The basis for this standard is a determination by the Assistant Secretary, after careful review of the complete rulemaking record, that laboratories typically differ from industrial operations in their use and handling of hazardous chemicals and that a different approach than that found in OSHA's substance specific health standards is warranted to protect workers.

The final standard applies to all laboratories that use hazardous chemicals in accordance with the definition of laboratory use and laboratory scale provided in the standard. Generally, where this standard applies it supersedes the provisions of all other standards in 29 CFR part 1910, subpart Z, except in specific instances identified by this standard. For laboratories covered by this standard, the obligation to maintain employee exposures at or below the permissible exposure limits (PELs) specified in 29 CFR, part 1910, subpart Z is retained. However, the manner in which this obligation is achieved will be determined by each employer through the formulation and implementation of a Chemical Hygiene Plan (CHP). The CHP must include the necessary work practices, procedures and policies to ensure that employees are protected from all potentially hazardous chemicals in use in their work area. Hazardous chemicals as defined by the final standard include not only chemicals regulated in 29 CFR part 1910, subpart Z, but also any chemical meeting the definition of hazardous chemical with respect to health hazards as defined in OSHA's Hazard Communication Standard, 29 CFR 1910.1200(c).

Among other requirements, the final standard provides for employee training and information, medical consultation and examinations, hazard identification, respirator use and recordkeeping. To the extent possible, the standard allows a large measure of flexibility in compliance methods.

DATES: *Effective Date:* This final standard published today shall become effective on May 1, 1990.

Compliance Date: Employers shall have completed an appropriate Chemical Hygiene Plan and commenced carrying out its provisions by January 31, 1991.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), the Agency designates for receipt of petitions for review of the standard, the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S-4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue NW., Room N3649, Washington, DC 20210; Telephone: (202) 523-8151.

SUPPLEMENTARY INFORMATION:

Information Collection Requirements

On March 31, 1983, the Office of Management and Budget (OMB) published a new 5 CFR part 1320, implementing the information collection provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* (48 FR 13666). Part 1320, which became effective on April 30, 1983 and was revised on May 10, 1988 (52 FR 16618), sets forth procedures for agencies to follow in obtaining OMB clearance for information collection requirements. The sections of this final standard on occupational exposures to hazardous chemicals in laboratories which may create recordkeeping requirements are paragraphs (d) Employee Exposure Determination; (e) Chemical Hygiene Plan; (f) Employee Information and Training; (g) Medical Consultations and Medical Examinations; (h) Hazard Identification; and (j) Recordkeeping.

In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA has submitted the information collection requirements for this final standard to OMB for review and has been granted approval of those provisions through 10/31/92. The OMB Control Number is 1218-0131.

Concurrent with granting approval of the information collection requirements for the proposed standard, OMB attached remarks which it requested the Agency to address when submitting the final rule for review. These remarks are reproduced below, followed by the Agency's response.

Each element of the chemical hygiene plan § 1910.1450(d)(2)(i) through (d)(x), shall be completely justified. This justification shall include a summary of the comments in the public rulemaking record on each element. Second, the final paperwork package shall include an estimate of the burden hours associated with § 1910.134, the respiratory protection program, which is referenced in § 1910.1450(e). Third, the agency shall arrive at a net change in burden by estimating the reduction in burden resulting from the exemption for laboratories from recordkeeping requirements in the general industry health standards. Fourth, the burden estimate of five minutes for exposure evaluations and three hours for development of chemical hygiene plans shall be supported by evidence from the record, or shall be revised accordingly. Fifth, the estimated current compliance rate of 56 percent for the chemical hygiene plan requirements shall be supported by evidence from the record, or shall be revised accordingly.

The Chemical Hygiene Plan has been redesignated as paragraph (e) in the final rule. OSHA believes that it has sufficient justification for the inclusion of each element of the Chemical Hygiene Plan including supporting comments from the public rulemaking record. In many cases, however, the comments addressed the appropriateness of the Chemical Hygiene in general terms rather than addressing individual elements. The discussion of the Chemical Hygiene Plan is presented in part VI of this preamble and includes summarization of comments in the record regarding specific elements of the Plan.

With respect to the burden hours associated with the respiratory program in § 1910.134, OSHA has assumed zero hours since the Laboratory Standard does not itself impose a requirement to use respirators. Paragraph (i) concerning the use of respirators is included to remind employers of the existing compliance obligation of the Respiratory Protection Standard which is found at 29 CFR 1910.134. Burden hours associated with respirator use are addressed in the Respiratory Protection Standard.

Laboratories are exempted in this final rule from the explicit requirements for recordkeeping prescribed in the substance specific General Industry Standards, except where a standard specifically includes laboratories. However, the Laboratory Standard includes in paragraph (d), requirements, under certain conditions, for complying with exposure monitoring of other standards. Similarly, medical

consultation and medical examinations provisions appear in paragraph (g).

Employers are required to establish and maintain for each employee accurate records of any exposure measurements and any medical consultations or examination results performed under this standard. Thus, OSHA's estimate of the burden hours associated with the recordkeeping requirements under the Laboratory Standard does not represent a reduction in burden as a result of exempting laboratories from the recordkeeping provisions of the General Industry Standards.

The burden estimate of five minutes for an exposure evaluation included in the proposed standard is no longer relevant since this requirement has been deleted in the final standard. The burden estimates associated with the development of chemical hygiene plans as presented in the proposed standard have been revised upward for small and medium size laboratories. The proposed standard estimated that 2, 5, and 8 hours, respectively, for small, medium and large laboratories would be required to develop chemical hygiene plans. Comments to the record (see e.g. Tr. 80 and Tr. 152) indicated that additional time might be required for chemical hygiene officers to acquaint themselves with proper chemical hygiene. OSHA believes that the additional time is reasonable, particularly for small and medium size laboratories. OSHA has therefore revised its estimate of the burden hours in connection with the development of chemical hygiene plans to eight hours for all laboratories, regardless of size.

OSHA estimates that approximately 67 percent of all laboratories that would be affected by the final standard are currently in compliance with the chemical hygiene plan requirements. This estimate is based on information generated in a survey of potentially affected laboratories conducted by Booz, Allen and Hamilton under contract to the Agency (Ex. 7–11). OSHA received no comments to indicate that the compliance rates for chemical hygiene plans for individual laboratory sectors that were presented in the Preliminary Regulatory Impact Assessment were not accurate estimates.

Public reporting burden for this collection of information is estimated to average, in the first year of compliance, 8 hours per laboratory, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Information Management, Department of Labor, Room N–1301, 200 Constitution Avenue NW., Washington, DC 20210; and to the Office of Management and Budget, Paperwork Reduction Project (1218–0131), Washington, DC 20503.

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I. Pertinent Legal Authority

Authority for issuance of this standard is found primarily in sections 6(b), 8(c), and 8(g)(2) of the OSH Act, 29 U.S.C. 655(b), 657(c), and 657(g)(2). Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. Section 3(8) of the Act, 29 U.S.C. 652(8), defines an occupational safety and health standard as:

> [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.

This standard is also issued pursuant to section 6(b)(8) of the Act. This section provides as follows:

> 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 Act than the national consensus standard.

For the most part, all of the subpart Z standards will be superseded for laboratories except as noted below. This standard better effectuates the purposes of the Act because it acknowledges the unique characteristics of the laboratory workplace and reflects a more reasonable approach to regulating toxic substances in the laboratory than the approach taken in the General Industry standards in 29 CFR part 1910, Subpart Z. Many of the standards in subpart Z were national consensus standards. This standard does not eliminate the requirement to maintain exposures below the applicable PELS and, therefore, does not reduce worker protection but provides greater flexibility in the methods of achieving it.

Authority to issue this standard is also found in section 8(c) of the Act. In general, this section empowers the Secretary to require employers to make, *keep, and preserve records regarding* activities related to the Act. Provisions of OSHA standards which require the making and maintenance of records of medical examinations and the like are issued pursuant to section 8(c) of the Act.

The Secretary's authority to issue this standard is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary to "prescribe such rules and regulations as he may deem necessary to carry out [his] responsibilities under [the] Act," in this case as part of, or ancillary to, a section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

> Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651(b)(1));
>
> Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, and by creating an Occupational Safety and Health Review Commission for carrying out adjudicatory functions under the Act (29 U.S.C. 651 (b)(3));
>
> Building upon advances already made through employer and employee initiative for providing safe and healthful working conditions (29 U.S.C. 651(b)(4));

Providing for the development and promulgation of occupational safety and health standards (29 U.S.C. 651 (b)(9));

Providing for appropriate reporting procedures * * * which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem (29 U.S.C. 651 (b)(12));

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions * * * (29 U.S.C. 651(b)(6));

Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment (29 U.S.C. 651(b)(13)); and

Developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems (29 U.S.C. 651(b)(5)).

Because the laboratory standard is reasonably related to these statutory goal, the Secretary finds this standard necessary and appropriate to carry out his responsibilities under the Act.

II. Background and History of the Regulation

Since the early eighties, OSHA has been involved in efforts directed toward formulating a special regulatory approach to control occupational exposures to hazardous chemicals in laboratories.

Prior to the promulgation of this final rule, laboratories were subject to all provisions of OSHA's General Industry Standards codified in 29 CFR part 1910, subpart Z. However, interested parties involved in laboratory operations have for some time opposed this arrangement. Through their participation in rulemaking proceedings for certain OSHA health standards, various interest groups have indicated that the Agency's approach to standards development did not result in standards that were relevant to laboratories and were not focused on typical exposure conditions in laboratories. As a result they argued that laboratories were required to comply with provisions that were more appropriately designed for industrial workplaces.

Objections regarding the inappropriateness of applying OSHA's health standards to laboratory operations began to surface in 1973, when OSHA began rulemaking for 14 specified carcinogens (29 CFR 1910.1003–1910.1004, 1910.1006–1910.1016; one standard was subsequently vacated). The preamble to the standard regulating those substances noted the following objections from parties representing laboratories interests: Laboratories use very small amounts of the substances; laboratory work is done by, or under the direct supervision of, highly trained personnel; and in the absence of an exemption or other special consideration, the standard would obstruct important research, including cancer research (39 FR 3756, 3759, January 29, 1974).

While the final standard (39 FR at 3759) did include some provisions for the laboratory use of these substances (see, for example, 39 FR at 3787, 3790), these provisions were later vacated on procedural grounds. See *Synthetic Organic Chemical Manufacturers Association* v. *Brennan*, 503 F2d 1155, 1160 (CA 3, 1974), cert den. 420 U.S. 973 (1975), reh. den. 423 U.S. 886 (1975). See also *SOCMA* v. *Brennan*, 506 F2d 385,392 (CA 3, 1974, cert den. 423 U.S. 830 (1975).

Similar objections were raised by laboratories in response to OSHA's Cancer Policy (45 FR 5001, 5202, January 22, 1980). Again, OSHA considered the concerns expressed by the laboratory community. While laboratories were included under the scope of the Cancer Policy, OSHA reserved the right to revisit the issue and, if warranted, to waive or modify procedures related to laboratories regarding a specific potential occupational carcinogen. (See 45 FR at 5202).

Concerns regarding the impact of the Cancer Policy on laboratory operations prompted the formation of informal groups of laboratory experts to study the problem further. OSHA met with members of one such group, representing a cross section of various types of laboratory disciplines in government, industry and academia. OSHA also met with members of professional organizations representing clinical laboratories. Input received from these groups was carefully considered. As a result, OSHA decided that further investigation into the problems related to occupational exposure to toxic and hazardous substances in laboratories was warranted.

On April 14, 1981, OSHA published a Request for Comment and Information concerning health hazards of toxic substances in laboratories (46 FR 21785). This action was taken to gain further insight into the problems OSHA health standards might pose for laboratories. Interested parties were invited to submit comments, views and data concerning issues which OSHA needed to address in deciding whether a special laboratory policy was necessary. Some 200 comments were received in response to this Notice.

On July 24, 1986, on the basis of information received in response to the Request for Comments and other considerations, OSHA published a notice of proposed rulemaking (NPRM) entitled "Occupational Exposures to Toxic Substances in Laboratories" (51 FR 26660). OSHA received 129 comments in response to the NPRM.

The NPRM also invited requests for an informal public hearing. Two requests were received: United Steel Workers of America, (Ex. 8–38) and Standard Oil Company (Ex. 8–42).

A public hearing, conducted under OSHA's procedural regulations for rulemaking (29 CFR part 1911), was held from March 24–26, 1987 in Washington, DC. The hearing was presided over by Administrative Law Judge Glenn R. Lawrence. All participants who had filed appropriate Notices of Intent to Appear at the hearing were given the opportunity to present oral testimony and question other witnesses.

The 3-day hearing generated some 400 pages of testimony from a number of interested parties. The post-hearing comment period during which hearing participants were permitted to submit additional data to the record was originally scheduled to close on June 9, 1987. However, in response to a request for additional time by one of the participants (Ex. 37), Judge Lawrence extended the post-hearing period until July 30, 1987. Twenty submissions were received during this period.

The public record for the proposed rule was certified by Judge Lawrence on May 18, 1988. All materials submitted to the OSHA Docket Office, Docket No. H–150, either by OSHA or the public are contained in the record.

Copies of the official list of entries to the record and the exhibits are available from the OSHA Docket Office, Docket No. H–150 Room N–2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; Telephone: (202) 523–7894.

III. Significance of Risk

OSHA included a discussion of significant risk in the preamble to the proposed standard. In that discussion OSHA reviewed the relevance of the Supreme Court's Benzene Decision (*Industrial Union Department* v. *American Petroleum Institute*, 448 U.S. 607 (1980)) to the proposed standard.

In the Benzene decision, the Court said that section 3(8) of the Act applies to all permanent standards promulgated under the Act and requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment.

The "significant risk" determination constitutes a finding that, absent the change in practices mandated by the

standard, the workplaces in question would be "unsafe" in the sense that workers would be threatened with a significant risk of harm. Id. at 642. A significant risk finding, however, does not require mathematical precision or anything approaching scientific certainty if the "best available evidence" does not warrant that degree of proof. Id. at 655–656; 29 U.S.C. 655(b)(5). Rather, the Agency may base its finding largely on policy considerations and has considerable leeway with the kinds of assumptions it applies in interpreting the data supporting it. Id.

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the proposed standard, it must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer a material impairment of health * * * *" (section 6(b)(5) of the Act). The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility. *American Textile Manufacturers Institute, Inc.* v. *Donovan*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is "Id. at 509.

OSHA has begun to develop a systematic approach to significant risk determination. This approach was introduced in the publication of the significant risk determination for arsenic (48 FR 1864, January 14, 1983). OSHA identified, in the arsenic case, five factors that comprised the basis of a significant risk determination. Those factors were relevant to evaluating risks associated with specific substances. This standard, however, concerns risks in the laboratory workplace which could result from a large variety of substances or work conditions. Therefore, OSHA believes the methodology used in the arsenic risk determination may not be fully applicable for this standard.

This is a generic laboratory standard. Laboratories generally have many hazardous chemicals present to which exposures are intermittent rather than a few substances to which there are regular exposures. Therefore the appropriate consideration is whether a significant risk would be present in laboratories without good laboratory practices rather than development and consideration of risk assessments for hundreds of chemicals present, an exercise likely to be impossible to perform. OSHA's significant risk finding for this standard is based on the following factors: Epidemiological information relating to disease and mortality rates among chemists; evidence from other OSHA rulemaking proceedings which show significant risks for specific substances which are used in the laboratory workplace; the general recognition by the regulated community that safe work practices are necessary to prevent adverse health effects; case report information about adverse health effects resulting from exposures to substances commonly used in laboratories; and relevant policy considerations.

In the absence of safe work practices, exposure to hazardous chemicals in the laboratory presents a significant risk of material health impairment. None of the comments submitted to the record indicates that hazardous chemicals do not pose a risk to laboratory workers. If OSHA's health standards that now apply to laboratories were withdrawn it is clear that the risk would increase. OSHA's intent in this standard is to reduce significant risk by at least as much as current standards do, while regulating in a manner more appropriate to laboratories. Because the working conditions and exposures are of a different nature than those in general industry, the hazards should be regulated in a different way.

The fact that many laboratory employers have implemented some type of work practices to control employee exposure to hazardous chemicals in general and carcinogens in particular, indicates the recognition of a potentially unsafe work environment. Many corporations, academic institutions and government agencies have devised detailed guidelines for the handling of hazardous chemicals (see, for example, Exs. 3–2, 3–50, 3–77 and 7–1). In particular, they have given carcinogens and suspected carcinogens special treatment.

In the preamble to the proposed standard (51 FR at 26665), OSHA noted that several commenters who have active safety and health programs (see, for example, Exs. 3–79, 3–85, and 3–108) indicated that their records show the absence of risk in their laboratory operations. OSHA believes that these records really attest to the effectiveness of programs such as the Chemical Hygiene Plan required by this final rule in reducing the risks due to inherent hazards associated with laboratory work (see Exs. 3–29, 3–64, 3–145 and 3–174). In contrast, OSHA also notes the comments of organizations without similar safety and health programs (see Exs. 3–35, 3–36 and 3–133). These comments indicate that there may be significant risks associated with chemicals to which laboratory personnel are exposed.

The preamble to the proposed standard cited five studies on the long-term effects of exposure to toxic substances in the laboratory (51 FR at 26665). A study by Li et al. (Ex. 7–3), "Cancer Mortality Among Chemists," was based on data from 3,637 members of the American Chemical Society who died between 1948 and 1967. Li found a significantly higher proportion of deaths from cancer among male chemists ages 20–64, and age 64 and older, as compared to professional men in general. Li stated: "Though not conclusive, [the study] raises the possibility that occupational exposure of chemists increases their risk of lymphoma and pancreatic cancer."

Robert Olin, of the Royal School of Technology, Stockholm, has done several studies of disease and morfality among Swedish chemists. In a 1976 study (Ex. 7–4), "Leukemia and Hodgkin's Disease Among Swedish Chemistry Graduates," he traced 517 graduates; 58 had died, 22 from cancer, which were nine more than expected. Six cancer deaths were due to malignant lymphomas or leukemias, a significant increase over the 1.7 deaths expected from this cause. Olin noted a somewhat lower than expected incidence of lung cancer. Olin tried to investigate the type and extent of chemical exposure in the cohort by asking a senior professor to distinguish between persons who had done any type of laboratory work ("chemists") and those who had not ("non-chemists"). All but one of the 22 cancer deaths occurred in the "chemist" group and Olin concluded: "[It] strongly suggests that the difference in the neoplasm death rates of the two groups is at least partly attributable to work in chemical laboratories."

Another study by Olin (Ex. 7–5), "The Hazards of a Chemical Laboratory Environment: A Study of the Mortality of Two Cohorts of Swedish Chemists," indicated a tendency toward a lower overall death among chemists, but a higher mortality rate due to tumors. An increase in mortality due to leukemia, malignant lymphomas or urogenital tumors and possibly brain tumors was observed. Olin stated: "It is probable that employment in a chemical laboratory, and particularly in organic chemistry, is associated to some extent with the increase." A follow-up study by Olin published in 1980 revealed similar findings. (Ex. 7–6).

A study by Sheila K. Hoar (Ex. 7–7), "A Retrospective Cohort Study of Mortality and Cancer Incidence Among Chemists," was based on data from employees of the DuPont Company from 1964–1977. This study indicated that male chemists experienced a lower overall mortality rate than other salaried employees at DuPont. Chemists appeared to have a higher risk of death from malignancies of the colon, cerebrovascular disease and a higher incidence of melanoma and prostate cancer than non-chemists. Chemists, however, had a lower rate of lung cancer than non-chemists. Hoar noted that anticipated excesses of certain types of cancer shown in other studies were not observed "possibly because of the use of absolute mortality rates [rather than proportional rates], inadequate length of follow-up, exposure to hazardous chemicals by the referent group, or restriction of case identification to active employees."

The Hoar study indicated, in general, less of a risk associated with working in laboratories than did the other studies. The Hoar study further pointed out that if the results of the other studies, expressed as proportional rates, were adjusted to show standardized mortality rates, apparent differences would be smaller but still present. Another explanation for the difference could be that DuPont followed better laboratory practices than did the laboratories covered by the first three studies.

OSHA believes, based on the known existence of hazardous substances in laboratories, the probability of risk associated with the results of the foregoing studies, and evidence from other OSHA rulemaking proceedings, that there is sufficient evidence of significant risk of material health impairment to workers not protected by an appropriate standard to justify this standard under the OSH Act.

Although OSHA does not believe it is necessary to demonstrate significant risk on a substance by substance basis, it is useful to focus on some of the substances currently regulated by OSHA for which a significant risk determination has been or could be made. The fact that many laboratory workers are exposed to these substances supports the general significant risk showing for laboratories. In the benzene decision, the Supreme Court noted that: "In other proceedings, the Agency has had a good deal of data from animal experiments on which it could base a conclusion on the significance of risk." 448 U.S. at 657, n. 64. The Court then referred to findings in the rulemaking record for vinyl chloride, and bis chloromethyl ether. An extension of the Court's reasoning indicates that findings for some of the other substances regulated in the 1974 carcinogen standard also form a sufficient basis for a significant risk determination. For example, benzidine was demonstrated to be a carcinogen in experimental animals and, by virtue of epidemiologic investigations, carcinogenic in humans. Epidemiological studies conducted by Melick *et al.* and Koss *et al.* have established the potential of 4-aminodiphenyl to induce bladder cancer in humans.

Recent studies on ethylene oxide indicate significant risk at levels as low as 1 part per million parts of air over a working lifetime. (Final standard for Ethylene Oxide, (49 FR 25734, June 22, 1984).) OSHA has determined that a significant risk of material health impairment exists in the event of overexposure to many of the specific substances it regulates. The fact that many of these substances are also used in laboratories provides a potential for significant risk to laboratory workers.

The preamble to the proposed standard also included case reports as evidence of hazardous chemical exposures in laboratories (51 FR at 26666). In particular, it cited the results of a 1979 survey pertaining to xylene exposures among members of the California Association of Cytotechnologists. (CC) (Ex. 3–41). The problems noted among the 70 respondents to the survey included inadequate ventilation (59%); lack of an exhaust system (22.6%); and lack of inspection of the exhaust system (43%). The comment submitted by the CAC also included an article by Roberta N. Hipolito which documents five case studies of xylene poisoning in laboratory workers. A xylene study of 71 workers in 15 laboratories indicated that there were 170 health complaints among the group. In addition, 45.5% felt that they had experienced significant exposures to xylene and 14% considered changing jobs due to xylene exposure.

Health hazard evaluations conducted by the National Institute for Occupational Safety and Health (NIOSH) present further evidence of the risk associated with hazardous chemicals in laboratory operations. NIOSH was requested on several occasions to evaluate employee exposures to xylene, formaldehyde, chloroform, toluene and methyl methacrylate in histology, cytology and surgical pathology laboratories following employee complaints of respiratory and behavioral problems. The result of these investigations showed that, in some instances, a health hazard did exist to employees exposed to certain of these substances. Major contributors to the hazardous conditions included ineffective exhaust ventilation and poor work practices (Ex. 7–8).

An article in International Laboratory cites examples of injury from hazardous chemical exposure in the laboratory which range from dermatitis to fatal pulmonary edema. The author, a research chemist with the Centers for Disease Control, U.S. Department of Health and Human Services, explains that these examples demonstrate at least three important points:

> First, exposure to toxic agents in the laboratory can have severe consequences, including death; second, these injuries can occur in any type of laboratory where toxic chemicals are handled; and third and most important, most all of the injuries are preventable. If these people had had the proper equipment, if they had been using the proper techniques and if they had had adequate knowledge, these exposures probably would not have occurred. (Ex. 7–9).

During the public hearing on the proposed laboratory standard, Dr. Jay Young, a chemical safety consultant specializing in laboratory safety, cited several examples of risks confronting laboratory workers. Dr. Young's examples were gleaned from the Manufacturing Chemists' Association (MCA) compilation of case histories of accidents or near-accidents occurring in the chemical industry, including those occurring in laboratories. The MCA case histories were based on incidents voluntarily reported by member companies between 1951 and 1977. In presenting particular accident case histories, Dr. Young also stated that provisions prescribed in the proposed standard would have prevented such incidents. For example, regarding MCA Accident Case History No. 238, Dr. Young stated:

> A control laboratory analyst was exposed to hydrogen cyanide, an extremely toxic gas, because there was no provision in her operating procedures to protect [against] such exposure. Fortunately, in this instance she recovered after a short hospital stay. Clearly, a [Chemical Hygiene Plan] conforming to the [proposed standard] would have established standard operating procedures that would have mandated the use of engineering controls to prevent a near-fatal exposure. (Tr. 66.)

Dr. Young also presented MCA Accident Case History No. 34:

> A carbon monoxide cylinder ruptured causing the death of the laboratory worker who was either connecting or disconnecting the cylinder to a gas line. Probably, the rupture was caused by contamination of high pressure carbon monoxide with air. A CHP

with provisions for suitable chemical safety instruction would have prevented this incident. (Tr. 65.)

Additional evidence supporting the significant risk argument was noted in the testimony of Diane Factor of the AFL–CIO. According to Ms. Factor, her first encounter with health hazards in the laboratory came when she was a chemistry student and part-time laboratory assistant. Ms. Factor said, "As I sat in the stockroom of the laboratory during quiet hours, I would read toxicology texts and was surprised to learn that several of the substances we routinely handled in the lab were extremely toxic." Ms. Factor said that she became particularly interested in the potential exposure to mercury, because of the tendency of beginning chemistry students to break thermometers. The visible evidence of the presence of mercury in areas of the laboratory prompted her to bring the problem to the attention of one of her professors who, subsequently, conducted instrumental monitoring which showed high levels of mercury vapors in the laboratory classrooms and stockroom. Because of her concern for a safe laboratory environment, Ms. Factor said that she was assigned to clean up the labs. As she testified, "In that process, I discovered a laundry list of problems—improper storage of chemicals, as explosive as picric acid, leaking drums, incompatible storage, lab hoods that did not function, incorrect disposal of solvents and metal and friable asbestos." As she stated further: "The correction of these problems was expensive and time consuming but was accepted by the supervision of the department because they realized that I had uncovered a virtual time bomb." (Tr. 460–461).

Ms. Factor, an industrial hygienist, was also previously employed by CAL OSHA as a field inspector for five years, during which time she had many opportunities to inspect various types of laboratories. Ms. Factor also related some of her experiences in inspecting laboratories during her employment at CAL OSHA which included the lack of properly functioning hoods and make-shift laboratories without any ventilation (Tr. 462).

Dr. Daniel Teitelbaum, Director of Medical Toxicology at Denver Clinic Medical Centers also testified regarding the inherent risks associated with laboratory work. He stated:

> In my view there are common risks and responsibilities in laboratories, no matter what their mission. The common risks arise from the need to carry out exacting and frequently dangerous procedures at the cutting edge of the laboratory discipline. The common responsibility requires that the best possible working conditions and safest possible environment is provided in which to carry out the analytical and experimental procedure. Only in this fashion can we assure that the laboratory scientist is not harmed by his or her work. (Tr. 48.)

In addition to the risk posed by exposure to individual hazardous chemicals in the laboratory, workers are often exposed to a mixture of hazardous substances which may produce a variety of toxic reactions. In particular, such reactions may be additive or synergistic. This situation was recognized by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1963 when it adopted its formula to compute exposure to chemical mixtures. OSHA incorporated this formula into its air contaminants standard, 29 CFR 1910.1000(d)(2)(i) in 1971.

Because such mixed exposures may be more common in laboratories than in most other workplaces (see, for example, Exs. 3–27, 3–29, 3–107), possible synergistic effects could pose a greater risk to laboratory workers than the risk posed to workers exposed to the same substances singly.

Based on the factors discussed above, OSHA feels that exposure to hazardous chemicals in laboratories poses a significant risk of material health impairment, in the absence of the safe work practices and other provisions of this standard. Therefore, the provisions of this standard are reasonably necessary to reduce or eliminate that significant risk.

OSHA solicited comment on the arguments it presented regarding risk determination in the proposed standard. Two comments were received.

Thomas Evans, Director of Safety and Environmental Health for Monsanto (Ex. 8–36) concurred with OSHA's position that risk determinations in laboratories must consider the nature of the laboratory work and reflect the variety of materials and operations associated with a typical laboratory.

Standard Oil presented an opposing view:

> With respect to the bases for the significant risk finding, Standard Oil believes that (a) the referenced disease and mortality rate studies are non-conclusive, (b) the mere presence of an OSHA regulated chemical substance in the laboratory should not be used to designate or imply an unsafe workplace and (c) safe work practices are both needed and used to control employee exposure to chemical substances, but it is inappropriate for OSHA to use this as a basis for their finding of significant risk.
>
> With regard to case reports of adverse health effects, there is absolutely no demonstration that the proposed requirements would have been necessary to avoid such effects. Compliance with the general industry standards should be sufficient so that any residual risk is insignificant * * * (8–42).

In the case of this latter submission, OSHA believes that the commenter did not fully consider the guidance indicated in the benzene decision for establishing a finding of significant risk.

In accordance with the Court's ruling, OSHA feels that it has in fact presented the "best available evidence" of the risks associated with laboratory operations. As the Standard Oil comment pointed out, the studies cited in the preamble to the proposed standard on long term health effects of exposure to toxic substances in laboratories (Ex. 7–3 through Ex. 7–7) were not conclusive. However, OSHA believes that the result of the studies indicate that the increase in mortality rates among chemists is partially attributable to work in chemical laboratories.

OSHA agrees with the Standard Oil comment insofar as it states that the mere presence of an OSHA regulated substance in a laboratory should not designate it as an unsafe workplace. The point intended (at 51 FR 26665) was that laboratories commonly use OSHA-regulated substances for many of which a finding of significant risk has been clearly established. The use of such substances in the laboratory, in the absence of protective measures, including those required by OSHA's current standards, increases the risk of material health impairment.

OSHA's objective in this standard is to reduce the significant risk by at least as much as do its current health standards but in a manner which is more appropriate and cost effective for laboratories. Laboratory operations involve a greater variety of potential hazards than do most workplaces. Hence, effective employee protection requires precautions and work practices not usually found in other work environments.

Since OSHA's health standards are designed primarily to control exposures to a single substance that is used constantly and usually in large quantities, they do not adequately address the risk associated with the use of multiple hazardous substances as is typically the case in the laboratory workplace. Because of the multiple chemicals used by laboratories, OSHA is unable to develop a traditional type of quantitative risk assessment. However, OSHA believes that anecdotal information such as that cited in the preamble to the proposed standard demonstrates that hazardous situations,

and thus potentially significant risks, can exist in laboratories. In many of these cases, OSHA believes that the need for employee protection such as that afforded by the final laboratory standard is clearly evident.

OSHA therefore concludes that a significant risk exists in laboratories that do not implement work practices and procedures which are at least as effective as those prescribed by this final laboratory standard.

IV. Summary of the Regulatory Impact Assessment, Regulatory Flexibility Assessment, and Environmental Impact Assessment

Executive Order 12291 (46 FR 13197; February 19, 1981) requires that a regulatory analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. In addition, the Regulatory Flexibility Act of 1980 (Pub. L. 96-353, 93 Stat. 1164 (5 U.S.C. 601 *et seq.*)) requires the Occupational Safety and Health Administration (OSHA) to determine whether a new regulation will have a significant economic impact on a substantial number of small entities.

Consistent with these requirements, OSHA has prepared a Regulatory Impact and Regulatory Flexibility Assessment for the standard to control occupational exposures to hazardous chemicals in laboratories. This assessment includes a profile of the universe to be covered by the standard, an estimate of the costs of compliance with both the existing health standards applicable to laboratories and this standard, assessment of the economic and technological feasibility of the new standard, and an estimate of the potential benefits expected to accrue to laboratory employees.

The Secretary has determined that this action would not be a "major rule" as defined by section 1(b) of Executive Order 12291 as it will not have an annual effect on the economy of $100 million or more, cause major increases in costs or prices, or have any other significant adverse effects. OSHA has also determined that this action will not have a significant adverse impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

Summary of Industry Profile and Costs

The rulemaking record indicates that the Laboatory Standard could potentially affect 934,000 employees in 34,214 laboratories. Laboratories that would fall within the scope of this standard can be classified generally as industrial, clinical, and academic. Within these major categories, subcategories have been established for the purpose of determining potential impacts. In this industrial sector, there are approximately 10,000 captive research and development (R&D) and testing labs, and 2,500 independent labs in the industrial category. Of the clinical labs, there are about 7,100 in hospitals, and 7,600 independent labs. In the academic sector, there are about 1,200 labs in private post secondary schools, 5,600 in private secondary schools, and 214 in private professional schools.

OSHA has examined the annualized costs (in 1987 dollars) of compliance for the Laboratory Standard, and for comparison, the costs that would exist if laboratories remained covered under the General Industry health standards. These costs were estimated for all affected laboratory categories and were calculated from a baseline of current compliance levels. These estimates are displayed in Tables I and II. Costs are broken out for each lab sector and by the standard's provisions, such as the development of Chemical Hygiene Plans, employee training, personal monitoring, medical surveillance, and protective clothing.

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TABLE I

ANNUAL COST OF COMPLIANCE WITH GENERAL INDUSTRY STANDARDS ($)

Lab Type	Written Plans	Training	Personal Monitoring	Hood Monitoring & Maintenance	Medical Surveillance	Closed Containers	Respirators	Record-Keeping	Change Rooms Showers Lunch Rooms	Hazard Signs	TOTAL
INDUSTRIAL											
Indep. Test	30,350	75,100	287,675	633,525	360,000	1,525	42,825	42,425	720,950	26,300	2,220,675
Captive R&D	107,900	0	2,627,500	0	770,000	0	107,100	194,500	3,304,400	226,600	7,338,000
CLINICAL											
Hospital	86,194	0	584,117	0	0	17,324	167,278	27,619	0	80,443	962,973
Ind. Practice	92,264	0	396,416	1,348,164	204,288	18,544	162,716	18,848	1,917,784	61,484	4,220,508
ACADEMIC											
Post Secondary	16,992	1,122,396	386,256	1,710,504	514,800	3,216	57,816	149,316	0	24,756	3,986,052
Secondary	75,544	446,208	184,128	1,419,096	616,000	34,160	239,792	19,824	0	18,144	3,052,896
Professional	2,598	443,500	298,753	0	86,285	2,925	64,151	419,397	0	24,764	1,342,373
TOTAL	411,842	2,087,204	4,764,845	5,111,289	2,551,373	77,694	841,676	871,929	5,943,134	462,491	23,123,477
% of total	1.8%	9.0%	20.6%	22.1%	11.0%	0.3%	3.6%	3.8%	25.7%	2.0%	100.0%

Source: Booz, Allen & Hamilton; U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis

TABLE II

ANNUAL COST OF COMPLIANCE WITH LABORATORY STANDARD ($)

Lab Type	Medical Surveillance	Chemical Hygiene Plans	Training Programs	Hood Monitoring & Maintenance	Recordkeeping	Designated Area	Personal Monitoring	TOTAL
INDUSTRIAL								
Indep. Test	270,000	53,947	303,910	633,520	9,440	23,377	199,755	1,493,949
Captive R&D	2,250,000	43,157	0	0	94,400	151,050	1,658,625	4,197,232
CLINICAL								
Hospital	0	61,283	0	0	29,491	71,497	405,620	567,891
Ind. Practice	383,040	65,599	0	1,348,134	20,088	54,666	275,278	2,146,805
ACADEMIC								
Post Secondary	364,500	20,715	750,542	1,710,507	10,195	24,761	219,478	3,100,698
Secondary	100,800	241,681	1,281,034	1,419,096	2,115	20,140	51,150	3,116,016
Professional	161,280	1,856	0	0	11,313	21,986	207,467	403,902
TOTAL	3,529,620	488,238	2,335,486	5,111,257	177,042	367,477	3,017,373	15,026,493
% of total	23.5%	3.2%	15.5%	34.0%	1.2%	2.4%	20.1%	100.0%

Source: Booz, Allen & Hamilton; U.S. Department of Labor, OSHA, Office of Regulatory Analysis

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OSHA estimates that the total annualized costs would be $23.1 million under the current General Industry Standards compared to $15.0 million for the Laboratory Standard. Such costs would not adversely affect the competitive status of the entities in any of the laboratory categories.

Summary of Benefits

The new standard differs from many OSHA health standards in that it does not establish new exposure limits, but sets other performance provisions designed to protect laboratory workers from potential hazards in their work environment. By permitting a greater degree of flexibility to laboratories in developing and implementing employee safety and health programs, OSHA expects benefits to result from increased worker awareness of potential risks, improved work practices, appropriate use of existing personal protective equipment and greater use of engineering controls. Given the flexibility to design and implement innovative measures to reduce employee exposure to hazardous substances, employers also will reap rewards in terms of lower insurance premiums, lower property damage costs, lower turnover costs, less absenteeism and, in general, increased productivity. Finally, the potential decrease in acute and chronic health problems will result in overall benefits to society through the associated reduction in medical and productivity costs.

A substantial amount of evidence in this record indicates that laboratory workers are at risk to serious and even life threatening occupational hazards. Several companies with good work practice programs, however, indicated that these hazards can be overcome through sound safety practices, and submitted evidence of the magnitude of the benefits to be attained from this standard [Ex. 3–16, Ex. 3–24, Ex. 3–197, Ex. 42]. These companies reported accident rates 30 to 80 percent below the industry average. OSHA estimates that the benefits resulting from this standard include reductions in non-lost workday cases, lost workday cases, chronic disabling illinesses, and chemical source workplace cancers. It is projected that implementation of the standards will result in at least a 10 percent reduction in chemical-related illnesses and injuries in laboratories. Although precise estimates of current chemically related injury and illness rates in laboratories are not available, OSHA estimates that the Laboratory Standard will prevent 235 of these non-lost workday cases, 82 lost workday cases, 60 chronic disabling illnesses, and 40 cancers annually. In addition, other benefits may be realized since improved work practices may prevent accidents or other incidents not directly attributable to a chemical source.

Technological Feasibility

OSHA has determined that the Laboratory Standard is technologically feasible. Its primary emphasis is on administrative controls necessary to protect workers from overexposure to hazardous substances in laboratories. Engineering controls such as fume hoods, vacuum systems and glove boxes, which are necessary to limit chemical exposures, are considered conventional technology in this industry. This technology is commonly known and currently can be found in nearly all laboratories.

Regulatory Flexibility Assessment

OSHA has attempted to evaluate the expected cost of compliance for small entities. However, since a majority of labs are captive of larger establishments and firms, it was not possible to determine the precise impact on all small entities. For those laboratories which are part of for-profit enterprises, the cost of the standard is estimated to be less than 0.03 percent of annual revenues.

The relatively small compliance costs associated with this standard are not expected to alter small firms investment plans, or be especially burdensome to small firms. Indeed, small firms will gain substantial cost savings as a result of the new exemption from general industry standards.

Environmental Impact Assessment

As required by the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), OSHA has reviewed the new standard and has determined that there will be no significant environmental impacts as a result of the action. The standard focuses on reducing worker risk by means of work practices and procedures and therefore is not anticipated to adversely affect ambient air quality, water quality, solid waste, or land or energy use.

V. Summary of Major Differences Between the Proposed and Final Standard

Certain provisions have been modified in the final standard to reflect comments submitted in response to the proposed standard. The following discussion summarizes the major changes.

The title of the final standard, "Occupational Exposures to Hazardous Chemicals in Laboratories" has been changed from "Occupational Exposures to Toxic Substances" as in the proposal. The reason for this change, discussed in greater detail later in this preamble, resulted from the persuasive comments which called for consistency, to the extent possible, between the final laboratory standard and OSHA's Hazard Communication Standard (HCS). Thus, the term hazardous chemical as used in HCS, and as it relates to the definition of health hazard, has been included in this final standard.

In the preamble to the proposed standard, OSHA proposed to exempt certain laboratories (dental, veterinary and group medical practices) from coverage by the standard. The final standard does not provide for categorical exemption, but instead requires that determination of whether the laboratory standard applies be made on the basis of the definition of "laboratory scale" and "laboratory use."

Under the proposal, the laboratory standard would have superseded all substance specific health standards with the exception of the permissible exposure limits in subpart Z. There are, however, instances where the final laboratory standard will not preempt the substance specific standard in any case. For example, the use of formaldehyde in histology, pathology and anatomy laboratories will remain under the Formaldehyde Standard (29 CFR 1910.1048) as directed by that standard. All other laboratory uses of formaldehyde will be covered by this final standard.

As in the proposed standard, the final standard requires employers to develop and implement a Chemical Hygiene Plan (CHP). The CHP sets forth work practices and procedures to protect employees from health hazards in that particular workplace. The final standard responds to the recognized need for consistency in terms used in OSHA standards and further clarifies when a CHP must be implemented.

The proposed standard required employers to include in the CHP, special measures for handling carcinogens.

This final rule, however, modifies the carcinogen definition and the obligatory action so that special provisions must be explicitly considered by the employer, but need only be implemented when the employer deems them appropriate on the basis of the specific conditions existing in his/her laboratory. Moreover, the term, "carcinogen" has been replaced by "select carcinogen" which covers a narrower range of substances (see discussion below, paragraph (b) of this preamble). In addition, because it

was pointed out in the record that other substances such as reproductive toxins and acutely toxic chemicals also pose severe hazards, the final standard also requires that the same special provisions as for select carcinogens be considered by the employer in the Chemical Hygiene Plan.

The proposed standard required that carcinogens be handled in a regulated area. The final standard provides for the handling of select carcinogens where appropriate in a "designated" area, a term which is less restrictive and more appropriate for laboratory operations than the regulated area as defined in other OSHA standards.

Training and information provisions of OSHA's Hazard Communication Standard have been incorporated in the final rule so as to include physical hazards in the employer's training program as well as provide explicit training on health hazards involved.

The medical coverage afforded employees by the final standard has been revised in accord with substantial comment received. Medical attention is provided by this standard under the following circumstances: (1) Whenever an employee develops signs or symptoms associated with exposure to a hazardous chemical; (2) in the event of an occurrence such as a leak, spill or explosion resulting in the likelihood of a significant exposure; or (3) whenever an action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring or medical surveillance requirements is routinely exceeded. In this case the medical provisions of the standard must be complied with until the exposures are reduced below the action level.

In addition, when there is reason to believe that an action level is routinely exceeded, monitoring must be utilized to determine if that is the case.

VI. Summary of Issues and Explanation of Provisions of the Final Standard

The rulemaking record on which this final standard is based overwhelmingly supports the approach taken by the Agency in its proposed standard (51 FR 26660) to control occupational exposures to toxic substances in laboratories. Of the 129 written comments submitted in response to the proposal, 57 addressed the need for a separate standard for laboratories. Approximately 91% (52) of these 57 comments supported the need for the standard and agreed with OSHA's approach. (See, for example, Exs. 8-1, 8-14, 8-19, 8-23, 8-25, 8-32, 8-40, 8-64, and 8-74.) General acceptance of the concept notwithstanding, there were objections, concerns and recommendations related to certain aspects of the proposed standard. Most of these issues were related to specific provisions and are detailed in the paragraph-by-paragraph explanation of the final standard presented below.

The comments, however, raised other issues that also warrant further discussion and explanation. One such issue is the perception that the proposed standard was duplicative in certain respects to OSHA's Hazard Communication Standard. See, for example, Exs. 8-52, 8-85, 8-88, and 8-114.

In considering the two standards, it is important to note the objectives of each. The Hazard Communication Standard is designed to ensure that employees are apprised of the hazards associated with chemicals in their workplace so that they may make informed judgments regarding the necessary precautions to protect themselves. The final laboratory standard, on the other hand, requires that employers develop a comprehensive plan to implement those practices that safety and health experts have accepted as effective in minimizing laboratory employee exposures to hazardous chemicals. These practices, if followed, obviate the need to comply with the specific provisions of OSHA's health standards except in certain instances. See the discussion of scope and application (paragraph a).

Paragraph (a), Scope and Application

Preemption by Other OSHA Health Standards

As in the proposal, the final rule provides that any substance specific standard can require coverage to remain under that standard rather than under the laboratory standard. The preemption issue was raised in the rulemaking proceedings for benzene and formaldehyde as well as in comments to the proposed laboratory standard.

Dr. Emmett Barkley of the National Institutes of Health stated:

> Clarification is required as to whether the laboratory standard should preempt a substance specific standard if the chemical in question is used in an ancillary process, and not directly a part of the research protocol itself (e.g. a test substance, reagent, intermediate product, etc.), even if the use of this material meets all of the criteria set forth in the definition of "laboratory use of toxic substances". (Ex. 8-58).

NIOSH further stated:

> It is important to very clearly state in the final standard that compliance with this standard does not alleviate compliance with more specific standards promulgated by OSHA (e.g. ethylene oxide and its use for non-research purposes) (Ex. 8-23).

It has always been OSHA's intention that in the absence of a statement of preemption in a substance specific standard, the determination of whether the laboratory standard applies must be dependent on both "laboratory use" and "laboratory scale" criteria. Therefore, if these criteria are met, then this laboratory standard applies. The NIOSH comment specifically addressed ethylene oxide which is widely used as a sterilant. Since the ethylene oxide standard (29 CFR 1910.1047) did not expressly preclude its preemption by the laboratory standard, and even though used as a sterilant and not part of an experiment, the use of ethylene oxide in a laboratory will be covered by this standard, provided the use conforms to the "laboratory scale" and "laboratory use" definitions.

OSHA believes that adequate protection is provided by this standard in the case of ethylene oxide.

In the preamble to the benzene standard (29 CFR 1910.1028), OSHA discussed whether users of benzene in laboratories would be required to comply with the benzene standard or the laboratory standard (52 FR 34528). OSHA stated that it would give additional consideration to this issue in the context of the laboratory standard rulemaking. Three commenters to the proposed laboratory standard felt that the benzene standard should not be preempted by the laboratory standard. Air Products and Chemicals Inc. (Ex. 8-18) stated that, "When and if specific requirements regarding benzene are adopted for workplace exposure they should be added to an appropriate section of 1910 and not be buried in § 1910.1450." Exxon Company (Ex. 8-35) agreed, saying, "If exposure is such that it meets the criteria of the benzene standard, then those workers would be covered by the benzene standard." Miles Laboratories (Ex. 8-091), too, regarded coverage under the benzene standard to be most appropriate, stating, "Medical surveillance for specific chemicals of increased risk should probably be handled through the General Industry Standards." Several others disagreed (Exs. 8-19, 8-36, 8-65, 8-66, 8-107, 8-112, and 10-1), maintaining that no single substance should have special provisions. OSHA believes that under this final rule it has satisfied the real concerns of both sets of commenters.

Under the laboratory standard, routine exposure above an action level will require the same exposure monitoring and medical surveillance provisions as in the relevant substance specific standard, in this case benzene.

Therefore, by preempting the benzene standard, this laboratory standard is providing more appropriate coverage for laboratories while continuing to provide full protection consistent with employee health and safety.

When the formaldehyde standard (29 CFR 1910.1048) was promulgated in December, 1987, it stated (52 FR at 46246) that formaldehyde use in histology, pathology and human or animal anatomy laboratories will continue to be covered by the formaldehyde standard rather than the laboratory standard. The preamble further notes (52 FR at 46246) that formaldehyde exposures in other types of laboratories will be considered in the rulemaking for the laboratory standard. No comments were received in the record of the proposed laboratory standard regarding the specific coverage of formaldehyde. In the absence of any comments, OSHA sees no reason why laboratories, other than histology, pathology and anatomy laboratories, which use formaldehyde should not be covered by this laboratory standard.

OSHA believes that, with this laboratory standard in place, future rulemakings covering specific substances will have criteria by which to decide whether laboratories will more appropriately be covered by the standard being promulgated or the laboratory standard. It is not OSHA's intention to add requirements which do nothing to protect the health of workers. In order to further clarify the application of this standard, OSHA has added a new paragraph (a)(3) concerning scope and application. Paragraph (a)(3) states that this standard will not apply where the only laboratory use of a hazardous chemical provides no potential for employee exposure.

Facilities

At the time OSHA began work on this standard a major problem was that of trying to define a laboratory. There are many facilities which are referred to as "laboratories" but which clearly should remain covered by other OSHA standards and not by this one. It is important to consider the genesis of this rulemaking to clarify this issue. As the background discussion in section IV points out, the purpose of promulgating a laboratory standard was to provide a standard appropriate for situations in which small quantities of multiple chemicals would be used—each, for the most part, for a relatively brief time duration. In trying to address this situation in the proposal, OSHA developed definitions for "laboratory scale" and "laboratory use" so as to focus on the conditions of the workplace rather than on the word "laboratory" itself. It was felt that it would be impossible to consider and categorize every establishment, or even every type of establishment, that regarded itself as a laboratory without clarifying criteria, and that a suitable course was to establish coverage in terms of the "laboratory scale" and "laboratory use" definitions to determine on the basis of a facility's specific activities and circumstances of exposure whether it was more appropriate to require compliance with the provisions of this laboratory standard or the provisions of standards covering the specific substances involved. That is to say, each facility would be judged on whether it met the criteria for the definitions of "laboratory scale" and "laboratory use." However, in preparing the proposal, it was necessary to identify categories of laboratories for purposes of analysis. Among the categories considered were veterinary and dental laboratories and those associated with group medical practices. OSHA proposed to exempt these facilities from coverage under the laboratory standard based on information then available (see 51 FR at 26672). In addition to comments received pertaining to the proposed exemptions, comment was also received regarding, in particular, whether or not facilities such as quality control laboratories and certain pilot plants should be covered by this standard.

Exemption of any laboratories was opposed by Dr. Daniel Teitelbaum of the Denver Clinic (Tr. 45). Dr. Jay Young, chemical consultant (Tr. 72–73), Dr. W. Emmett Barkley of the National Institutes of Health (Tr. 114), Mr. Frank Grimes of the United Steel Workers (Tr. 284) and Dr. Gerald Hoeltge of the American Society of Clinical Pathologists/College of American Pathologists (Ex. 43). The basic position of all these commenters was that the degree of protection afforded to an employee should not depend upon an arbitrary classification of the particular laboratory. OSHA agrees with this argument in principle, but other comments brought out that there are other relevant factors. Marcia Brody representing the American Veterinary Medical Association (Ex. 41) pointed out that veterinary "laboratories" were not really laboratories in the intended sense of this standard—that only minute quantities of substances in commercially prepared kits are used and that, in most cases, no chemical reagents were used at all. Supporting these comments were those of Dr. Cleveland Brown, a practicing veterinarian (Tr. 270) who stated that most detailed work is sent out to the larger diagnostic laboratories. Nevertheless, Dr. Emmett Barkley (Tr. 118) testified that, in NIH veterinary laboratories, chemical solvents, anesthetic gases and medications and drugs which represent toxic hazards to employees are all used. It is apparent to OSHA that the term, "veterinary laboratory" includes a wide range of different scales of operations and that this variation must be recognized in determining where this standard applies.

Mr. Norman Steere of Norman V. Steere Associates, and Dr. Alan Todd of Stewart-Todd Associates, Inc. (Tr. 141–142) pointed out that a similar situation exists in medical laboratories, with potential exposure conditions varying significantly between various size group practices, large diagnostic laboratories and hospital laboratories. It therefore seems clear that grouping all such facilities under one designation would be inappropriate and that blanket exemptions for such designations, as proposed by OSHA, are consequently also inappropriate.

Considerable comment was also devoted to whether "pilot plant laboratories" and "quality control laboratories" should be covered by this standard or by other General Industry standards. (Exs. 8–23, 8–24, 8–25, 8–41, 8–44, 8–45, 8–46, 8–69, 8–73, 8–79, 8–92, 8–93, 8–96, 8–100, 8–107, 8–110, 10–6, Tr. 95–96, Tr. 253, Tr. 417–420, Tr. 435 and Tr. 440). Arguments were presented for both positions. However, once again, great variation exists from one to another such facility. It is important to remember that one of the reasons for this standard is to eliminate inappropriate requirements such as monitoring in workplaces which are characterized by conditions where very small quantities of frequently changing substances are used. But where the quantities are not small and where the substance in question is usually present, it is entirely appropriate to monitor and, in such cases, employee health and safety is better served by complying with the requirements of the appropriate OSHA substance specific standard.

The record amplifies the inherent difficulties in attempting to classify facilities on the basis of what label is placed on a particular "laboratory", i.e. "quality control", "group medical practice", "pilot plant," for example. Therefore, OSHA believes that judgments about specific categories cannot be made on the basis of the label placed on that category and that categorical exemptions as were made in the proposal are not appropriate.

In general, pilot plant operations are typically closely connected with production processes. Such operations would fall outside the scope of the standard because they fail to meet the "laboratory use" definition which precludes laboratory procedures that are part of a production process or in any way simulate a production process. However, the rulemaking record suggests that, in some cases, pilot plant operations are an integral part of a research function (see Tr. 453–454). For example, as pointed out by Mr. Ron Larson of Exxon Research and Engineering Company, the pilot unit may consist of several small bench operations which are combined for the purpose of evaluating a particular effect. The operations do not always proceed to production but may remain part of the research activity. In these instances, if the pilot plant operation meets all other criteria for laboratory use and laboratory scale, it would indeed be within the scope of the standard. Therefore, although most pilot plants would not likely meet the required criteria for coverage under the Laboratory Standard, there are some which do and thus a blanket exemption for pilot plants is inappropriate.

Similarly, most quality control laboratories are not expected to meet the qualification for coverage under the Laboratory Standard. Quality control laboratories are usually adjuncts of production operations which typically perform repetitive procedures for the purpose of assuring reliability of a product or a process. However, as with pilot plants, there will be exceptions, and where quality control laboratories meet the criteria of the definitions for "laboratory scale" and "laboratory use," they will be required to comply with this standard.

It is OSHA's position that the determination, in general, of what facilities are covered must be made specifically on the basis of the definitions of "laboratory scale" and "laboratory use". OSHA believes that these factors represent the appropriate criteria for describing the conditions and health hazards which make this regulatory action appropriate. Some commenters believed that these definitions should be amended so that their facilities would be covered. (Exs. 8–20, 8–46, 8–69, 8–73, and 8–118). Others felt the definitions should be amended so they would not be covered. (Exs. 8–42 and 8–44).

These comments in themselves give testimony to the fact that the criteria contained in the definitions are in most cases sufficiently clear to provide substantial guidance as to whether a facility is considered to be covered by this standard or whether it is covered by other health standards in subpart Z.

An additional issue that was raised in the comments and hearing concerned the need to implement a Chemical Hygiene Plan when exposures are always minimal and involve substances which are of moderate or low toxicity. (See Exs. 8–79, 8–93, 10–10 and Tr. 417–418). OSHA believes that, in such cases, the standard is appropriate and reasonable because of the flexibility of the Chemical Hygiene Plan requirement. Minimal exposures to chemicals of low toxicity will require a simpler Chemical Hygiene Plan because the standard, while requiring that specific considerations be addressed, leaves it to the employer to specify how. Therefore, the employer is able to address the required considerations in a manner appropriate to the substances and conditions in the specific laboratory.

Chemicals

Reference was made in the proposed standard to the term "toxic substance" for the purpose of demonstrating when the Chemical Hygiene Plan, which outlined work practices and procedures to be taken to protect employees, was to be implemented. The term "toxic substance" was defined as any substance in 29 CFR part 1910, subpart Z as well as substances determined to be carcinogens or potential carcinogens by IARC or NTP. However, once instituted, the work practices and procedures which the CHP specified were expected to be sufficient to provide protection from all toxic or hazardous substances regardless of whether they were included in the "floor" of toxic substances specified by the toxic substance definition. As noted in the preamble to the proposed standard, (see 51 FR 26671):

> * * * [T]he impact of the standard is potentially broad since most laboratories would handle at least one substance which falls under one of the two categories and would therefore be required to implement work practices which would serve as effective protection against substances not explicitly covered by the standard but which may be potentially hazardous.

In the final standard, the term "hazardous chemical" is used in lieu of "toxic substance." The reason for this action is explained in greater detail later in this discussion.

Early in the rulemaking activities for this standard, OSHA's information indicated some important factors to be considered in developing a standard for laboratories: (1) The implementation of carefully designed work practices and appropriate training are key to effective workers protection; (2) the diversity of laboratory operations would best be addressed by using a performance approach in which appropriate work practices and procedures are determined by the employer; and (3) compliance with good laboratory practices, accepted by safety and health experts as effective, would obviate the need to comply with specific requirements prescribed in OSHA's substance specific health standards for maintaining PELs.

Accordingly, on the basis of this information, OSHA proposed that employers develop a Chemical Hygiene Plan as a mechanism to provide employee protection regarding substances regulated by OSHA as well as other potentially hazardous chemicals used in the laboratory. However, considering the number of comments which expressed an opinion regarding which substances the standard should address, it became obvious that the intended purpose of the Chemical Hygiene Plan, outlined in the proposal, was not clearly conveyed.

Many commenters urged OSHA to expand the definition to include more substances, increasing employee protection from exposure to a greater number of harmful substances used in laboratories. Various suggestions were made on how OSHA should expand the scope of substances to be covered. Commenters (Exs. 8–15, 8–20, 8–22, 8–25 and 8–97) specifically recommended that the toxic substance definition at least include the ACGIH TLV list. For example, Kent R. Weber of J. T. Baker Chemical Company stated:

> The proposed rule uses OSHA PEL requirements to trigger the activation of this standard. Because the PEL's can only be updated by a lengthy rulemaking process, * * * ACGIH TLV's are a better and more up-to-date list of standards. Use of ACGIH limits provides workers with the benefit of more current information and is more sensitive to the dynamic process of science as hazard investigations are carried out. As the preamble to the proposed rule indicates, only violations of the OSHA PEL standards would result in a citation, so use of ACGIH TLV's should not pose a regulatory burden on labs. (Ex. 8–97).

A similar view regarding the limitation of the proposed toxic substance definition was presented in the testimony of Dr. Alan Todd, Director, Industrial Hygiene for Stewart-Todd Associates, Inc. and expert OSHA witness:

> We concur with adding * * * the professional, updated guidelines incorporated in the ACGIH TLV's * * * I suggest that

others, such as the AIHA, meaning the American Industrial Hygiene Association, Workplace Environmental Exposure Levels along with some of the NIOSH criteria, where there is no OSHA PEL, be incorporated by reference to supplement the PELs * * * (Tr. 91).

Other participants in the rulemaking proceedings suggested that the scope of substances covered by the laboratory standard should be consistent with that of the Hazard Communication Standard (§ 1910.1200). Testifying as an expert OSHA witness, Dr. Jay A. Young, a chemical consultant, offered the following recommendation:

* * * The substitution of the term "hazardous chemical" as defined in the hazard communication standard for the term "toxic substance" as defined by the proposal will substantially increase the effectiveness of the proposed rule in preventing exposures to substances that are toxic but not now included in subpart Z nor in the IARC or NIP carcinogen lists. There are only a few hundred chemicals that are toxic included in subpart Z and the carcinogen lists; there are thousands of other chemicals that are toxic and that are also used in laboratories and which should be included in the purview of the proposed rule. A few of these taken at random from a current laboratory supplier catalogue will illustrate my point. All of the following are toxic. None are included within the presently proposed rule * * * Hazardous chemicals such as vanadates; selected bismuth compounds; acetyl halides and derivatives; hydroxylamine hydrochloride; selected indium compounds, perchloric acid and selected derivatives; phosphorous oxychloride; phosphorous (III) and (V) halides; sulfurous acid; sulfuryl halides (in addition to the fluoride); selected tetramethyl ammonium derivatives * * *

To reduce the risk of harm in chemical laboratory work, chemicals such as the above should be included, just as they already are included under the hazard communication regulation (Tr. 70–71).

Consistency between HCS and the final laboratory standard in terms of substances covered was also recommended by Dr. Frank R. Ciofalo on behalf of Cal/OSHA:

The term "toxic substances for laboratories" will get confused with "hazardous substances" for HCS as well as the specific definition of "toxic" and "highly toxic" in HCS. Therefore, the exact terminology should be transported to the CHP." (Ex. 8–28).

Similarly, David Chawes, Senior Industrial Hygienist for the Ecova Corporation commented:

The definition of toxic substances proposed is at variance with the existing OSHA definition of toxic substances used in the Chemical Hazard Communication Standard. This variance is unacceptable, because many institutions and employers with laboratories have already adopted the Hazard Communication definition * * * To introduce a new definition of "toxic" * * * would be counter-productive and would result in employee and employer confusion. (Ex. 8–34).

Although the majority of participants supported the need to expand the scope of substances covered, there were, however, some commenters who opposed coverage beyond OSHA regulated substances. For example, the written submissions of Exxon Company U.S.A. (Ex. 8–35) and Monsanto (Ex. 8–36) shared the concern expressed by Hoffman-LaRoche who stated.

* * * [W]e believe that coverage by this standard should be limited to substances for which there is an OSHA PEL. There are several difficulties in including the ACGIH TLV standards; it would give them a pseudo-regulatory status; * * * we strongly urge that before ACGIH TLVs are even suggested as "guidelines," they be published as proposed additions to OSHA's list of PELs with an opportunity for comment (Hoffmann-La Roche Inc., Ex. 8–111).

In response to these latter comments, OSHA would like to reiterate the arguement it made in the preamble to the proposed standard regarding the appropriateness of including under the scope of the standard substances determined to be carcinogenic by IARC or NTP. As stated at (51 FR 26665):

OSHA determined in the Hazard Communication Standard that it was appropriate to require certain procedural provisions for substances for which OSHA had not set an exposure limit and that this type of provision was much lesser in scope than setting an exposure limit and that the appropriate legal analysis was the discussion by the Supreme Court of "backstop" provisions in *Industrial Union Dept.* v. *American Petroleum Institute.* (See the discussion at 48 FR 53296–9, 53321 and at 448 U.S. 697, 658.) * * *

OSHA believes that this reasoning is equally appropriate (inclusion of substances for which there is no PEL) for the purposes and intent of this standard.

This standard was designed expressly for laboratories to address the unique exposure conditions under which work is performed and to protect employees from adverse health effects that may result from their work in laboratories regardless of what toxic and hazardous substances are used. In contrast to those who argued that OSHA's authority with respect to the protection of laboratory workers should be restricted to OSHA regulated substances, OSHA believes that any standard of this nature which does not include consideration of all potentially hazardous chemicals would not be an appropriate solution to providing the desired level of employee protection. This standard sets no exposure limits or threshold limit values. However, because substances which are involved in laboratory use are acknowledged to produce adverse health effects which could result in significant risk, then certainly protective measures are appropriate.

Supporting the concept of an all inclusive standard, the Chemical Manufacturers Association (CMA) suggested that a standard which applied only to PEL substances would be less protective than one which applied to a broad range of hazardous substances whether regulated or not. As George Stout, representing CMA, concluded in his testimony:

The current PELs have little impact on the total exposure hazard of most laboratories. The overwhelming number of materials handled in laboratories have no PELs. Often the toxicity information is scanty or non-existent. A performance-oriented good laboratory practices approach helps reduce risk for both regulated and unregulated materials. (Tr. 251).

OSHA agrees with the arguments submitted to the record which suggested that where feasible there should be consistency in its standards so as to eliminate confusion with respect to compliance and ensure the greatest measure of employee protection. Such is the case with the final laboratory standard. Laboratories in the manufacturing sector, as well as other laboratories as a result of the expansion of scope of the Hazard Communication Standard (52 FR 31852, August 24, 1987), are covered by certain provisions of that standard. The term hazardous chemical, is used in the Hazard Communication Standard. To introduce a new term, "toxic substances," which lists fewer chemicals regarded as hazardous to laboratory workers could create confusion. (See, for example, Exs. 8–28 and 8–34).

In view of the comments submitted and the recognized need for consistency, OSHA has decided to incorporate the term hazardous chemical into this final standard. However, the use of this definition makes no change in the intent evinced in the preamble to the proposed standard. It should be recognized that, while appearing to enlarge the impact of the standard, this action will actually create little additional burden to employers. The intent has always been to mandate the implementation of an overall Chemical Hygiene Plan for the entire laboratory whenever any substance included in the scope of the standard was present. Therefore, any substance regulated by OSHA would automatically trigger the program for the laboratory as a whole. Since very few

laboratories will be free of all regulated substances, most laboratories would need to comply with this standard even if the scope were limited to such substances. The expansion of the scope to cover all "hazardous chemicals" ... should add few workplaces to those which will need to comply anyway. The addition of the term hazardous chemical will further clarify the fact that the laboratory employer must offer protection to all employees in all laboratory work situations.

Inclusion of Safety Hazards

In a related matter, OSHA requested comments and information on the appropriateness of developing a vertical standard for laboratories, covering both safety and health hazards. Some commenters (Exs. 8–20, 8–38, 8–70, 8–74, 8–75, 8–76, 8–108, 10–12 Tr. 47, Tr. 129, Tr. 285, and Tr. 294) recommended that OSHA include measures to protect laboratory workers from additional hazards such as biological, radiological and physical hazards such as fire and explosion. For example, the AFL–CIO stated:

> * * * Chemicals which pose health hazards may also pose fire and explosion hazards. Health hazards are not limited to toxic chemicals, but include biological agents and physical agents like radiation. Any standard designed to protect laboratory workers should not make artificial distinctions between toxic chemicals and other agents and between health hazards and safety hazards. Control measures should consider the laboratory environment as a whole and respond to all hazards present. The standard should be expanded to [provide] comprehensive coverage of toxic chemicals, biological and physical agents and both health and safety hazards. (Ex. 8–75).

Mr. Chain Robbins, manager of Health and Safety for International Technology Laboratories, emphasized the need to address physical hazards in this standard. Mr. Robbins stated:

> * * * It has been the experience in International Technology Laboratories that physical hazards have been those which have caused the most significant worker injuries * * * We believe that any laboratory standard for worker protection must include requirements for employers to address the physical hazards identification and controls necessary to prevent losses. (Ex. 8–74).

Norman Steere, consultant on laboratory safety, also urged OSHA to include biological and physical hazards under the standard. Mr. Steere stated:

> * * * I believe that the proposed standard should apply to all of the hazards encountered in laboratory workplaces, including physical and biological hazards * * * Although I am personally unaware of any deaths that have resulted from laboratory exposure to toxic chemicals, I do know of several deaths that have occurred from laboratory-acquired infections, and from laboratory fires or explosions, so I conclude that to omit the physical and biological hazards may be omitting a major portion of the problem (Tr. 129).

Dr. Alan Ducatman of MIT advised OSHA to complete the initiative that it had already begun and revise the standard to incorporate protective measures for other laboratory hazards at a later date. In response to a question regarding his position on whether OSHA should include biohazards under the proposed laboratory standard, Dr. Ducatman replied:

> I think it's so important that this proposal go through, that I would certainly be willing to see it go through without that. But, I would like to see, eventually, biohazards wrapped in. If not immediately, eventually, and that is because as our institutions become more technical, biology and chemistry are merging. In fact, biology, chemistry, and physics are merging. I think it is important that we try we get the most universal standard that we can.
>
> At this time, I don't think you have to do that. I think you should make it a future goal. (Tr. 183)

OSHA recognizes that laboratory employees may be exposed to potential hazards that are not addressed by this standard. However, since the initial emphasis for a separate laboratory standard was directed toward the inappropriateness of OHSA'S health standards for laboratory work, the record is not completely developed regarding other hazards facing laboratory personnel. While this standard exempts laboratories from most provisions of subpart Z, other subparts of 29 CFR 1910 which address physical hazards remain in effect for laboratories. For example, laboratories and other general industry employers must comply with subpart H which pertains to hazardous materials and includes regulations for compressed gases and flammable and combustible liquids and subpart G—Occupational Health and Environmental Control—which contains regulations for noise exposure and radiation.

Moreover, other comments indicated that OSHA's safety standards which cover physical hazards do not present the same type of compliance problems for laboratories as do its health standards. Such views expressed by Exs. 8–9, 8–18, 8–19, 8–36, 8–42 and 8–68 were similar to the following comment submitted by Eastman Kodak Company:

> We believe the rule, as proposed, should be limited to regulations of occupational exposures to toxic substances in laboratories and should not extend to cover other general laboratory safety issues which are currently addressed in other OSHA standards, such as flammability, corrosivity, and explosivity. Such hazards in laboratories are not significantly different from those in general industry, and attempts to incorporate protection against such hazards in this proposed rule would delay and complicate the development of appropriate Chemical Hygiene Plans. (8–118).

OSHA believes that the requirement for training on physical hazards, in conjunction with current safety regulations, should improve effective employee protection. Therefore, although the final laboratory standard does not dictate provisions for work practices to protect employees from potential physical hazards associated with chemicals used in their work areas, it does require that such physical hazards be addressed in the employer's training program. (See 29 CFR 1910.1450(f)(4)(B).)

Currently, OSHA has no regulations which specifically address biological hazards. However, the Agency has issued a proposed rule entitled "Occupational Exposure to Bloodborne Pathogens" (54 FR 23042, May 30, 1989). When the Agency promulgates a final standard on this subject, laboratory workers would be included under its coverage. Meanwhile, several guidelines are available which make recommendations pertaining to biosafety for laboratories. For example, the Centers for Disease Control and the National Institutes of Health have jointly published "Biosafety in Microbiological Laboratories." In addition, the National Committee for Clinical Laboratory Standards has recently issued a proposed guideline entitled "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood and Tissue."

Because of the aforementioned considerations, including the record evidence, OSHA believes that the focus of this final standard is appropriate and addresses the most critical areas of need with respect to laboratory worker protection.

Paragraph (b) Definitions

The proposed standard contained definitions to facilitate interpretation of its provisions and intent. Extensive explanation was provided in the preamble for those definitions which were unique to the proposed standard. In the final standard, certain definitions remain unchanged from the way they were proposed since there was little or no objection in the record regarding their content or purpose.

The following terms are defined identically in the proposed and final standard: "Assistant Secretary", "Chemical Hygiene Officer",

"emergency", "laboratory-type hood", and "protective laboratory practices and equipment." The explanation for certain of these terms is repeated in this discussion of definitions to assure that their original intent is clearly conveyed in the final standard.

The final standard retains the proposed definition for "Chemical Hygiene Officer." As defined, the "Chemical Hygiene Officer" is an employee who is designated by the employer, and who is qualified by training or experience, to provide technical guidance in the development and implementation of the employer's Chemical Hygiene Plan. Use of this term is not intended to place any limitations on the job title or position description which the designated individual shall hold within the employer's organization. Consequently, the term "Chemical Hygiene Officer" may apply to another job title provided that the designated employee is technically competent to fulfill the responsibilities of developing and administering the employer's Chemical Hygiene Plan.

As in the proposed standard, the term "laboratory" is broadly defined by intention in the final standard. The basis for this standard focuses on the conditions of chemical usage commonly found in laboratories and not on the particular classification or category of laboratory operations. Although certain categories of laboratories have been mentioned for purposes of preparing cost estimates, the determination of which laboratories are covered by this standard will be based on whether or not conditions of "laboratory use" and "laboratory scale" as defined in the standard exist in the particular workplace.

As a result of changes to the proposed standard, certain proposed definitions were deleted in the final standard because they were no longer relevant. "Closed system" and "exposure evaluation", for example, are neither referenced in the final standard nor included in the final standard's definitions.

In some cases definitions have been substituted for the proposed terms and in other cases definitions have been added or amended for clarification. For example, the term "hazardous chemical" substitutes for "toxic substance" defined in the proposed standard. The term "hazardous chemical" used in this final rule relies on the definition of "health hazard" found in the OSHA Hazard Communication Standard. As discussed in the scope and application section above, commenters urged OSHA to maintain consistency in terms between the Hazard Communication Standard and this final standard since laboratories are subject to both regulations. Therefore, in the final standard the Agency incorporates the term hazardous chemical which is defined as any substance which meets the definition of health hazard under the Hazard Communication Standard.

In a similar action, OSHA has substituted the term, "designated area" in the final standard for "regulated area" defined in the proposed standard. "Regulated area" is a term that is used in most of OSHA's substance specific health standards. Typically, it refers to an actual demarcation that is established in the work area to minimize and restrict the number of employees exposed. Also, under the 13 carcinogen standards, specific procedures such as showers and attendance lists were required for those working in regulated areas. Commenters objected to the proposal's requirement that work with carcinogens be performed in regulated areas, perhaps because of the the way the term had been used in other standards (*see e.g.*, 29 CFR 1910.1008 (c), (d)(3), (f), (g).

The primary purpose of the "designated area" is to focus attention on the fact that a particularly hazardous substance is being used and to ensure, where appropriate, that appropriate protective measures are observed by employees working in or near the vicinity. The purpose is not to restrict the use of large areas of laboratory space. Since the term "regulated area" has a more restrictive meaning in other OSHA standards, OSHA decided it was unnecessarily confusing to use the same term in this standard to mean something less restrictive. Therefore, OSHA has decided to use the term "designated area" in the final standard in lieu of "regulated area". "Designated area" means an area which may be used for work with "select carcinogens," reproductive toxins or substances which have a high degree of acute toxicity. A designated area may be the entire laboratory, an area of a laboratory or a device such as a laboratory hood.

The proposed standard did not define employee. Recommendations that the term be defined were included in the record, see for example, Exs. 8–32, 8–96 and 8–104. The final standard defines employee as an individual employed in a laboratory workplace who may be exposed to hazardous chemicals in the course of his or her assignments. Such individuals may actually work in the laboratory or because of their work assignments may be required to enter a laboratory where potential exposures may occur. In the latter category, OSHA considers maintenance and custodial personnel as meeting the definition of employee. The definition of employee would not include occasional visitors to the laboratory such as guests or sales personnel.

The term, "carcinogen," as defined by the proposed standard has been replaced by the term "select carcinogen" in the final standard. The proposal defined a carcinogen as a substance regulated by OSHA as such or identified by IARC or NTP as a carcinogen or potential carcinogen. Under the proposal, laboratories working with carcinogens were required to implement more rigorous procedures under their CHP, including the use of fume hoods. Objections were raised to this blanket approach (*see e.g.*, Exs 8–19, 8–107, 10–9 and Tr. 112–113). Many substances in this category could be regarded as weak carcinogens, particularly in the context of laboratory use. Therefore the final laboratory standard uses a modified term, "select carcinogens," in defining those chemicals for which additional carcinogen provisions, including the designated area provision, may apply.

As noted above, the final standard defines "select carcinogen" as any substance regulated as a carcinogen by OSHA, and known human carcinogens identified by IARC or NTP. Potential carcinogens listed by IARC and NTP are considered "select carcinogens" for purposes of this standard only if they meet the stated criteria for demonstrating moderate to high carcinogenic potency in animal studies.

The definition of "Chemical Hygiene Plan" has been amended in a minor way to clarify that its purpose is twofold. It is a written plan which is to be developed and implemented by the employer that sets forth procedures, and other work practices which are capable of: (1) Protecting employees from the health hazards associated with hazardous chemicals in that workplace and (2) meets the requirements outlined in paragraph (e) of this section. Paragraph (e) specifies the elements to be addressed and instructs the employer to ensure that the CHP is capable of keeping employee exposure below designated PELs.

The definition of "laboratory scale" is retained in the final standard. The purpose of this definition is to focus on the magnitude of the operations which are covered. OSHA rejected the option to specify quantity limits as criteria for "laboratory scale," realizing that any limit specified would be arbitrary. However, the concept of quantity is certainly relevant. Therefore, the most reasonable approach is to define laboratory scale in relation to the size of

containers used in reactions, transfers and other operations and, in general terms, to the quantity of materials handled. The proposed definition of "laboratory scale" referred to work with substances in which the containers used for reactions, transfers and other handling of substances are designed for manual use, being small enough to be easily and safely manipulated by one person. The final standard revises the definition slightly to eliminate the requirement that containers be manipulated manually. Several commenters (see Exs. 8–112 and 10–2) pointed out that laboratory work frequently involves automated procedures. It was not OSHA's intention to exclude such operations from coverage. Other comments (Exs. 4–45, 8–50, and 8–64) suggested that the definition be amended to allow for non-routine tasks such as assistance from co-workers in handling 5-gallon drums and gas cylinders used in laboratory operations. As pointed out in the preamble to the proposed standard at 51 FR at 26673, the intent of the definition is not to exclude the use of facilitative mechanical aids when needed (and similarly would not preclude the assistance of co-workers when necessary). OSHA believes that the definition of "laboratory scale," as revised, is broad enough to satisfy the concerns of these particular commenters without further revision.

The definition of "laboratory use of hazardous chemicals" modifies the proposed term "laboratory use of toxic substances" in a minor way. A new criterion has been added to read as follows: "The procedures involved are not part of a production process, nor in any way simulate a production process."

For the sake of clarification, OSHA wishes to point out that criterion (d), "protective laboratory practices and equipment are available to minimize the potential for employee exposure to hazardous chemicals," is not intended to imply that such practices are implemented and such equipment are available in a particular laboratory. Rather the intent refers to the fact that a body of information, accepted by safety and health experts, is available regarding the effectiveness of such practices and equipment in protecting laboratory workers. It was never OSHA's intention to exclude laboratories from coverage by the standard in the event these practices and equipment were not immediately available in a particular laboratory workplace. To the contrary, OSHA believes that any laboratory in which this criterion is not met currently clearly stands to benefit significantly from this standard.

OSHA has concluded, on the basis of persuasive arguments in the record, (*see*, for example, Exs. 8–9, 8–20, 8–74) that the final laboratory standard should include training on "physical hazards" consistent with the Hazard Communication Standard. Therefore, the definition of physical hazard as used in the Hazard Communication Standard as well as the definitions of associated terms are incorporated in the final laboratory standard.

The final standard also includes a definition for "reproductive toxins," since employers will be required to include additional protective measures in the Chemical Hygiene Plan where appropriate for work involving such substances. The final standard defines "reproductive toxins" the same way as the Hazard Communication Standard.

Paragraph (c). Permissible Exposure Limits

The final standard retains the requirement that laboratories comply with the permissible exposure limit (PELs) in effect for general industry. The Agency determined that such action was necessary to ensure that there would be no diminution in the health protection of laboratory workers.

OSHA has reviewed the complete record established for this rulemaking and has found no opposition to retaining compliance with the existing PELs. However, the comment submitted by Public Citizen (Ex. 8–70) made OSHA aware of a need to clarify what constitutes a permissible exposure limit for purposes of this standard. Public Citizen pointed out that OSHA proposed to retain permissible exposure limits (described as measurement of an 8-hour time weighted average) but did not mention the short-term exposure limit (STEL) in effect for some OSHA regulated substances. The comment correctly indicated that short-term exposures may be more dangerous than an equivalent dose occurring over a longer period of time.

Reference to permissible exposure limits does not cover 8-hour time-weighted averages (TWAs) only. The air contaminants standard (29 CFR 1910.1000), for example, designates ceiling values, acceptable ceiling concentrations as well as 8-hour time-weighted averages for various substances. Certain substance specific standards include both 8-hour TWAs and STELs under the term permissible exposure limit. (For example, see Occupational Exposure to Formaldehyde (52 FR 46292, December 4, 1987), and Occupational Exposure to Benzene (52 FR 34563, September 11, 1987).)

For purposes of this standard, permissible exposure limit refers to any established OSHA exposure limit whether it be a TWA, ceiling, STEL, or excursion. In addition, prohibition of eye and dermal contact where specified by an OSHA standard also remains in effect.

Paragraph (d). Employee Exposure Determination

While most agreed with the concept of requiring laboratory compliance with existing PELs, two commenters pointed out that the lack of monitoring and medical examination requirements left open the possibility that an employee could be exposed to levels greater than permitted by an OSHA limit for a substance and have less protection than an employee in a workplace covered by the relevant substance specific standard. Margaret Seminario of the AFL–CIO stated that:

> The standard should require that initial environmental monitoring be conducted for chemicals and agents which are used on a regular basis (i.e. more than 30 days a year). If exposures are more than one half the permissible exposure limit, semi-annual monitoring should be conducted until 2 consecutive sets of measurements show exposures below the action level. This is similar to the monitoring requirements under other OSHA health standards. Laboratory workers who are exposed to chemicals and agents on a regular basis should be afforded the same degree of protection. (Ex. 8–75).

Dr. Daniel Teitelbaum of the Denver Clinic Medical Center also pointed out the need for consideration of action levels in addition to exposure limits:

> In this standard, air monitoring is not required because of the highly variable nature of exposures which might occur in the laboratory. For many substances, usage will be brief and transient and these materials must be used in hoods or with other gear which should protect the users. For some substances like lead and arsenic, however, exposures even below the PEL may cause physiological changes which indicate early toxicity.
>
> For those materials for which a specific definition of exposure at some level below the PEL such as the action level for lead, has been included in another standard, that definition of exposure should be the applicable definition when these chemicals are used in the analytical work of the laboratory. Such provisions should apply particularly to lead, arsenic, asbestos, acrylonitrile, and many other materials for which there is good data on adverse, but sub-clinical, effects of low exposure. (Tr. 38–39).

In reviewing the issues raised in these comments, OSHA considered several points. First, in establishing a standard

particularly appropriate to laboratories. It was never OSHA's intention to allow a lesser degree of protection for laboratory employees than for other employees.

Second, this standard is based on the premise that laboratories should be accorded special treatment partly because quantities of particular substances are small and the substances themselves are frequently changing. If these conditions did not occur there would be no need for a separate laboratory standard and the workplace should remain subject to the other OSHA General Industry standards as required. Therefore, OSHA concurs with the comments from Ms. Seminario and Dr. Teitelbaum. Since minimal exposures are a premise of this standard, OSHA considers it appropriate that, where exposures are routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring or medical surveillance requirements, the employer shall comply with those exposure monitoring and medical surveillance requirements. By use of the word "routinely," OSHA intends to convey a condition which would be similar to an industrial setting where the ambient concentration of a substance is at a characteristic level as a result of the workplace conditions and the particular process involved. Factors which might raise the possibility of overexposure include the following: (1) The manner in which the chemical procedures or operations involving the particular substance are conducted (*e.g.* use of open vessel instead of a closed system); (2) the existence of historical monitoring data which shows elevated exposures to the particular substance for similar operations; (3) the use of a procedure which involves significant quantities or is performed over an extended period of time; or (4) signs or symptoms of exposure (*e.g.* skin and eye irritation, shortness of breath, nausea, headache, *etc.*) which are experienced by the employee.

The final standard requires that if, based on conditions such as those cited above, there is reason to believe that a regulated exposure level related to a standard which contains exposure monitoring and medical surveillance requirements is present in excess of the action level (or in the absence of an action level, the PEL), then the employer must conduct employee exposure monitoring for the substance in question. If it is found that the action level or PEL is routinely exceeded, then the employer must comply with the monitoring and medical provisions of the relevant standard until the exposure level is brought to or below that prescribed by the particular standard or until the substance is no longer used in the same procedure. If the exposure monitoring discloses a level below the action level (or PEL where no action level exists), then no further monitoring is required and the employer continues to comply only with this laboratory standard. However, it should be noted that termination of monitoring as prescribed by the relevant standard for a particular overexposure episode does not preclude future monitoring in accordance with the requirements in paragraph (d)(1) for recurring exposure to that particular substance.

Since, as stated earlier in the discussion of this paragraph, this standard is justified on the basis of limited exposures, this provision will impose no burden at all on most employers, and where exposures are high, it will place no unreasonable burden on employers.

Paragraph (e) Chemical Hygiene Plan

The final standard retains the provisions for a written Chemical Hygiene Plan (CHP) that is to be formulated and implemented by the employer. The CHP must outline specific work practices and procedures which are necessary to ensure that employers are protected from health hazards associated with hazardous chemicals with which they work.

The Chemical Hygiene Plan concept was generally supported in submissions to the record (see e.g. Exs. 8–10, 8–20, 8–27, 8–73, 8–97, 8–106 and 10–16). The importance of such plans in providing employee protection was indicated by the Procter and Gamble Company:

> Written safe work practices are often the most important component of a good safety program, especially when they are used as the basis for periodic education and training of employees. The written Chemical Hygiene Plans (CHP) required in the proposal are appropriate for laboratory uses of toxic substances. Consistent with the performance orientation, the final standard should list the elements to be addressed in the CHP, while allowing maximum flexibility for employers to develop the appropriate CHP's for their laboratory operations. (Ex. 8–73).

A question asked during the course of this rulemaking was whether a CHP would be required for each individual laboratory in establishments with many separate laboratory operations or whether a single, facility-specific plan would suffice. Considering the performance orientation of this standard and the diversity in laboratory operations, OSHA believes that this question should be decided locally by the facilities covered. Ideally, the plan should be specific enough to a particular workplace that it does not require employees to familiarize themselves with extraneous material that is not relevant. However, it is not the intention of this standard to dictate the approach that the employer may find effective in meeting the objectives of the CHP or the manner in which it is implemented.

The final standard, like the proposal, specifies certain elements that must be addressed by the CHP but generally leaves the particular details to the employer's discretion. Non-mandatory guidance on the development of an acceptable and effective Chemical Hygiene Plan is provided in Appendix A.

The term "hazardous chemical" (replacing toxic substance as defined in the proposed standard) is defined for the purpose of demonstrating when the CHP is to be implemented. Thus, if any chemical meeting the definition of "hazardous chemical" as it relates to health hazards is used by the laboratory, the CHP is to be implemented for the laboratory in general and must automatically cover any hazardous chemical present.

The employer's Chemical Hygiene Plan must be readily available to employees, employee representatives and, upon request, to the Assistant Secretary or designee. The employer must review the CHP at least annually and update it as necessary.

The Plan must include several specific elements which are deemed necessary to ensure laboratory employee protection. Although specific elements are required, they are general enough to allow a performance approach. Furthermore, in view of the fact that most laboratory employers already have health and safety programs which include some or most of these elements the specification does not impose a significant regulatory burden on employers.

The employer's Chemical Hygiene Plan must incorporate standard operating procedures (SOP's) which are appropriate for the particular laboratory workplace for all work involving hazardous substances. Only a few comments in the public recored addressed standard operating procedures. Three commenters (Exs. 8–20, 8–106 and 10–16) supported the provision as essential in performing work with toxic and hazardous substances. Other commenters (see Exs. 8–84, 8–95 and 8–114) suggested that the provision was too restrictive, particularly for research settings.

However, further examination of these particular comments underscored what OSHA believes was a lack of understanding of the intended purpose of the provision.

OSHA did not specify the contents to be covered under the SOP's, as they would vary with each facility and would best be determined by the employer. The purpose of SOP's is to assure that work practices and policies that the employer may deem necessary to protect employees from chemical hazards in the laboratory are in place. SOP's, for example, may specify general safety precautions (e.g. safety glasses, eating and drinking area restrictions, general housekeeping practices) accident response, disposal procedures and spill clean-up procedures.

The employer must also include in the plan criteria which would invoke the use of specific exposure control measures. Such criteria may be based on the degree of toxicity of the substances to be used, the exposure potential of the chemical procedures to be performed and the capacity of the engineering controls, administrative practices or protective equipment to control employee exposures effectively. Additional requirements must be included in the CHP where appropriate to protect employees working with particularly hazardous chemicals such as select carcinogens, reproductive toxins and chemicals exhibiting a high degree of acute toxicity.

The final standard also requires that employers incorporate in their Chemical Hygiene Plan measures to assure the proper functioning of fume hoods and other protective equipment. As in the proposed standard, the final standard does not specify face velocities for fume hoods. OSHA's rationale for this approach was explained in the preamble to the proposed standard (see 51 FR at 26671). In brief, the preamble stated that OSHA recognized that there was considerable debate over what optimum velocities should be in light of differences in hood design and methods of operation. Moreover, it was felt that requiring specific face velocities was not consistent with the performance orientation of the standard.

Most commenters agreed with OSHA's approach in not specifying face velocities for fume hoods. For example, the Aluminum Company of America stated:

> OSHA asked whether the Standard should specify face velocities for lab hoods. We feel it should not include a specification because ventilation needs vary with the specific design and use of lab hood. Nevertheless, adequate and continuing performance of lab hoods is critical to employee health protection and we support the requirement that the Chemical Hygiene Plan address the proper use and functioning of laboratory hoods. (Ex. 8-46).

Other commenters sharing this view included Exs. 8-18, 8-19, 8-20, 8-36, 8-42, 8-48, 8-58, 8-65, 8-79, 8-91, 8-107, 8-111 and Tr. 137-139. There are some comments in the record which suggest a need for OSHA to specify face velocities for fume hoods in the final rule. (See e.g. Exs. 8-66, 8-96, 8-108 and 10-14). However, these comments offered little or no substantive information to persuade OSHA to abandon the performance approach which allows the employer to determine the appropriate face velocities on the basis of design, use patterns and other factors which influence the effectiveness and proper functioning of the fume hood.

In addition, the employer's Chemical Hygiene Plan must identify those procedures, activities or operations which the employer believes to be of a sufficiently hazardous nature to warrant prior approval from the employer or the employer's designee before implementation.

The CHP required by the final standard retains many of the elements of the proposed standard. Certain revisions have been made, however, in response to comments and evidence in the record. In particular, OSHA has altered its position regarding the handling of carcinogens under this final standard. Under the proposed standard employers were required to include in the CHP additional protective measures for work with carcinogens. A carcinogen was defined as a substance that met one of the following criteria: (1) Is regulated by OSHA as a carcinogen or (2) is identified by the International Agency for Research on Cancer (IARC) or the National Toxicology Program (NTP) as a carcinogen or potential carcinogen. (See 51 FR at 26678).

The additional protective measures that were to be taken when handling these substances included: (1) Establishing a regulated area, defined as a laboratory, an area of a laboratory or a device such as a laboratory hood for which access is limited to persons who are aware of the hazards of the substances in use and the precautions that are necessary; (2) requiring that all work be conducted in a fume hood or equivalent containment device; (3) specifying procedures for the protection of vacuum lines and pumps from contamination and the safe removal of contaminated wastes; and (4) specifying personal hygiene practices and appropriate protective apparel for work in a regulated area.

Numerous comments were submitted on the approach taken in the proposed standard with respect to carcinogens and the relationship of carcinogens to other highly toxic substances which give rise to both chronic and acute effects. Regarding the proposed standard's overall approach to carcinogens, specific issues were raised that included: (1) The carcinogen definition; (2) the application of identical requirements for all substances identified as carcinogens without regard to potency, concentration, physical properties or use conditions; and (3) the rationale for requiring special provisions for work with carcinogens while allowing employers to determine appropriate employee protection for work with other substances considered to be equally hazardous.

The proposed carcinogen provisions proved to be controversial. In several cases (see Exs. 8-12, 8-59, 8-95, 8-96, 8-118, and 10-9) commenters recommended that the definition be restricted to OSHA regulated carcinogens, suggesting that otherwise more stringent precautions would be imposed on laboratories than on other industries using the same materials. These comments also objected to the inclusion of substances listed by IARC and NTP since such substances had not been subjected to the regulatory review process. With respect to these particular concerns, it is important to remember the premise upon which the proposed standard was based, i.e., the need for special considerations for the laboratory use of toxic and hazardous substances regardless of their regulatory status.

A significant number of commenters (see Exs. 8-19, 8-20, 8-26, 8-30, 8-37, 8-41, 8-52, 8-68, 8-68, 8-69, 8-84, 8-93 and 10-5) expressed concerns that the carcinogen definition and associated provisions did not consider the wide variation in carcinogenic potency nor make allowances for such factors as concentration, quantity, physical properties or conditions surrounding the substances' use. The following excerpts are examples of comments addressing these particular concerns:

The California Institute of Technology, (Ex. 8-30) stated:

> In the description of the chemical hygiene plan * * * the rules call for "additional employee protection for work with carcinogens or potential carcinogens as defined herein" * * * The problem is that weak and negligible carcinogens (using the OSHA definition of a carcinogen) would be included * * * Including weak or negligible carcinogens in the list of chemicals that require additional employee protection would actually do a disservice to employees because it would dilute the attention paid to

the hazards involved in the use of truly toxic materials.

Conoco (Ex. 8–69) stated:

Conoco appreciates the difficulty of defining "toxic substance" in order to prescribe appropriate work practices for carcinogens and potential carcinogens. However, the standard as written does not permit the employer to take into account the potential health hazards related to relative potency and degree of exposure. Conoco is concerned that without such flexibility the standard will needlessly burden employers by requiring restrictive work practices, such as regulated areas, which are not justified by the potential health risks presented because either the quantities are minute or the exposure is minimal.

Genencor Inc. (Ex. 8–51) stated:

In the proposed standard, all carcinogens are to be handled with the same level of control without regard to relative risk, quantity handled, concentration, physical properties (solid, liquid, vapor pressure) and method of use. This is not in accordance with the issuance of a performance standard or good industrial hygiene practices.

Los Alamos National Laboratory suggested that the proposed carcinogen provisions were appropriate for certain carcinogenic substances and certain use conditions but also pointed out the need for more flexibility as stated in the following excerpt:

Substances proven to be carcinogenic to humans or demonstrating high carcinogenic potency in animals should be controlled extremely well as proposed. However, the standard should allow for less stringent requirements where the operation involves only very dilute solutions (for example <0.1 or 0.01 percent, depending on the potency of the substance), or the substance has demonstrated carcinogenic potency only under high doses. (Ex. 8–20).

In addition to the concerns expressed in the comments discussed above, there were others that pointed out that there are numerous substances used in laboratories which present hazards both chronic and acute as severe as those presented by carcinogens. Dr. Emmett Barkley of the National Institutes of Health, for example, suggested that the regulatory approach taken in the proposal inappropriately implied that carcinogens may be the most hazardous of toxic substances to which laboratory workers may be exposed. He stated: "This is not the case. There are numerous chemicals whose acute toxicity is more hazardous than any currently regulated carcinogen." (Ex. 14, p. 4).

Similarly, Stephen R. Larson, Director of the Office of Environmental Health and Safety at Northeastern University suggested that the proposed standard overemphasized carcinogens and underemphasized the hazards of acutely toxic substances. He stated: "Carcinogenicity or cancer-production is only one of many possible manifestations of harm from a toxic substance. Acute poisoning resulting in death or permanent injury are other manifestations which should be of equal concern." (Ex. 8–29).

The Environmental Protection Agency (Ex. 10–1) supported the special handling provisions for carcinogens but suggested the need for additional protective measures for highly toxic substances which were not necessarily carcinogenic.

The Standard Oil Company (Ex. 8–42) questioned the rationale for requiring special carcinogen provisions. With respect to the carcinogen provisions, Standard Oil commented as follows:

* * * [S]ince OSHA does not require these or similar stringent practices for chemical substances having other toxic effects such as teratogenicity, mutagenicity or extreme acute toxicity * * * OSHA apparently believes that the implementation of prudent laboratory practices will generally afford adequate protection from these hazards.

Finally, there were comments (*see e.g.*, Exs. 8–19, 8–36, 8–42, 8–54, 8–66, 8–83, 8–107, 8–117, 8–118 and 10–9) which recommended that OSHA allow more flexibility in determining how best to handle particularly hazardous substances, including known carcinogens. Consider, for example, the comment submitted by Exxon Research and Engineering Company (Ex. 8–96). C.R. Lipuma, Manager of Technology Support commented:

* * * [I]t has been and still is in the best interest of research laboratories to take the approach of following good laboratory practices. This not only applies to potential carcinogens, but reproductive risk source materials and chemicals that have specific organ effects *e.g.*, hepatotoxins, neurotoxins and the like. We believe the current emphasis on certain specific chemicals because they are suspect carcinogens, could result in employees in certain areas being over-cautious or even refusing work based on emotional response due to unnecessary extra attention. Simultaneously, these same employees may reduce their respect for other potentially hazardous material. We need to assure all employees follow procedures to protect themselves from the event of chemical exposures of any kind.

The comment from Hoffman-LaRoche Inc. (Ex. 8–111) emphasized the need for flexibility in determining when specific additional precautions are called for. The comment stated: "[S]ome degree of flexibility should be accorded to the employer in deciding the circumstances under which a regulated area is needed or whether a fume hood or other closed system is required."

After careful consideration of the evidence presented regarding the proposed approach to handling carcinogens, OSHA has made the following decisions with respect to the final standard:

(1) Narrowed the definition to "select carcinogen" to connote a category of chemicals where the evidence strongly indicates human carcinogenicity;

(2) Considered carcinogens in the context of laboratory work as only a subset of other particularly hazardous substances; and

(3) Allowed employers flexibility to assess the need for additional protective measures and to determine the appropriate precautions to effectively control exposures to particularly hazardous substances, including carcinogens.

Because the Hazard Communication Standard used the term, "carcinogen," in its definition of "hazardous chemical" (see appendix A of the HCS) and this standard tries to be consistent with the HCS definitions, it was necessary to distinguish the broad range of carcinogens covered in HCS from the narrower range covered in these special provisions of the laboratory standard. For this reason, the new term, "select carcinogen," was coined which refers to the subgroup of carcinogens for which there are special considerations in this standard.

In accordance with the recommendations in the comments regarding which carcinogens should be subject to special provisions, OSHA has designated four categories of carcinogens to be referred to as "select carcinogens" and therefore subject to special consideration in the employer's Chemical Hygiene Plan. For the purposes of this standard, "select carcinogen" includes any substance which meets one of the following criteria: (1) Is regulated by OSHA as a carcinogen or (2) is listed under the category, "known to be carcinogens," in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or (3) is listed in Group 1 ("carcinogenic to humans") by the International Agency for Research on Cancer (IARC) (latest edition of Monograph).

In addition, a substance listed either by NTP under the category, "reasonably anticipated to be carcinogens," or listed by IARC in Group 2A or 2B shall be considered a select carcinogen only if it has "additional qualifications;" that is, has been shown to cause significant tumor incidence in experimental animals in accordance with any of the following criteria: (a) After inhalation

exposure of 6–7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m³ (b) after repeated skin application of less than 300 mg/kg of body weight) per week; or (c) after oral dosages of less than 50 (mg/kg of body weight) per day.

(Group 2A, according to IARC, is usually reserved for exposures for which there was at least limited evidence of carcinogenicity to humans. Group 2B, according to IARC, usually refers to the combination of sufficient evidence in animals and inadequate data in humans.)

Chemicals falling under IARC's Group 3 ("could not be classified as to their carcinogenicity in humans") are not considered as select carcinogens under this standard. This does not mean, however, that OSHA disputes the evidence linking these chemicals with carcinogenicity; it merely indicates that the Agency believes that the provisions of the Chemical Hygiene Plan outlined in the standard, if properly implemented, will adequately protect employee working with these substances.

If data corresponding to these criteria do not appear in the IARC or NTP documentation or in other existing literature for these substances, then they need not be treated as "select carcinogens" under this standard. However, it is the responsibility of the employer to determine whether such data exist.

The "additional qualifications" for substances listed by IARC and NTP for which definite carcinogenicity in humans has not been established were added in response to the many participants who were concerned that the definition as previously proposed would require special treatment for substances which had demonstrated only limited evidence of carcinogenicity. These criteria, designed to establish that a given substance exhibits moderate to high carcinogenic potency, are taken from the National Research Council's 1981 report, "Prudent Practices for Handling Hazardous Chemicals in Laboratories" (Ex. 7–13). OSHA included a discussion of these referenced criteria in the proposed standard (51 FR 26672). However, at the time OSHA felt their inclusion might require extensive literature searches or laboratory experiments which OSHA believed might be unreasonable where only small amounts of these substances were used. Certain comments, however, recommended that employers be allowed to make such evaluations (*see e.g.*, Exs. 8–14, 8–19, 8–36, 8–118 and 10–9). Consequently, OSHA has decided that it would be more effective to allow the individual laboratory to make the determination as to whether a substance listed under NTP's category, "reasonably anticipated to be carcinogens" and IARC Groups 2A or 2B meets the criteria of moderate to high carcinogenic potency before requiring the special considerations prescribed in the final rule.

In addition to narrowing the definition of carcinogen by using the new term "select carcinogen" in the final rule, the Agency has considered carefully comments that questioned the selection of carcinogens alone for special emphasis in the Chemical Hygiene Plan. On the basis of concerns expressed in the record, OSHA has decided not to confine the need for special consideration to carcinogens only. Therefore, OSHA has decided to add substances with high acute toxicity and reproductive toxins to select carcinogens as substances which will need special consideration in the Chemical Hygiene Plan.

Reproductive toxins may manifest themselves in lethal effects on the fertilized egg, developing embryo or fetus or teratogenic (malformation) effects in the fetus. In addition, certain reproductive toxins may cause infertility in females and males.

Substances with high acute toxicity such as hydrogen cyanide, hydrogen sulfide and nitrogen dioxide are included under the category of substances for which employers must consider the need for special precautions. Such substances may be fatal or cause damage to target organs as a result of a single exposure or exposures of short duration.

OSHA believes that employees should be made aware of the deleterious effects of these categories of substances discussed above through effective training which is reinforced where appropriate through written procedures in the employer's Chemical Hygiene Plan.

A number of commenters (Ex. 8–32, 8–35, 8–65, 8–66, and 8–87) objected to the inclusion of special mandatory provisions for designated substances such as carcinogens, stating that this would unnecessarily impinge on the employer's flexibility to deal with the hazards presented in their laboratories in the most expeditious manner. OSHA still believes that special consideration and emphasis may be needed when dealing with substances that are particularly hazardous. However, because of the wide degree of exposure and use conditions that may affect the actual degree of hazard to workers in a given situation, OSHA is providing the employer some added flexibility in the final rule. Employers are required to focus their attention on certain types of substances and at least consider protective procedures for such substances explicitly in their Chemical Hygiene Plans, but the specific procedures which were required by the proposal are required by the final rule only where the employer has determined them to be appropriate. The provisions that must be included where deemed appropriate by the employer for work with select carcinogens, reproductive toxins and substances with a high degree of acute toxicity are: (1) The establishment of a designated area; (2) use of containment devices such as fume hoods or glove boxes; (3) procedures for safe removal of contaminated waste; and (4) decontamination procedures.

OSHA has replaced the term, "regulated area," with "designated" area in the final standard in response to comments that objected to the proposed provision. The definition of a regulated area as proposed meant a laboratory, an area of a laboratory or device such as a laboratory hood for which access is limited to persons who are aware of the hazards of the substances in use and the precautions that are necessary. In particular, Exs. 8–12, 8–24, and 8–86 voiced concern regarding this provision. Vista Chemical Company, for example, commented:

> The establishment of regulated areas for work with carcinogens in laboratories and laboratory areas is impractical in many cases and inconsistent with the criteria used for the establishment of regulated areas in other standards. Laboratory fume hoods are seldom dedicated to one type of chemical use in manufacturing quality control labs * * * Use of carcinogenic material requiring the establishment of a regulated area is seldom continuous. (Ex 8–86).

OSHA recognizes that even though the definition of a regulated area used in the proposed standard was significantly different from the way it is usually defined in other OSHA standards, it may have been interpreted the same. In OSHA's substance specific standards, regulated areas are required to be established where exposures to the substance exceed the PEL. In these instances an actual demarcation is implied to set these areas aside from other areas of the workplace and access is restricted to authorized personnel, thereby limiting the number of workers exposed. Typically, a medical surveillance program is required to be established and implemented for employees assigned to a regulated area. In other OSHA standards, such as those regulating the 13 Carcinogens, for

example, (see 29 CFR 1910.1003–1910.1016) employees working in regulated area needed to use special protective clothing and to shower before leaving the plant. OSHA recognizes that exposures of this magnitude are not typically found in laboratories, and given the nature of laboratory operations, restricted access to a work area or other restrictions may not be practical. However, OSHA believes that in the case of work involving select carcinogens, reproductive toxins and substances of high acute toxicity, especially in work areas where other less toxic chemicals are being used simultaneously, some method of limiting exposures and alerting all workers in the vicinity to the potential hazard may be warranted. Therefore, OSHA is using the less restricive term, "designated area," in the final standard. A "designated area" differs from a regulated area in that the only duty associated with it is to post the area and assure that all employees working in the area are informed of the hazardous substances used there.

Under the final standard, fume hoods or equivalent containment devices are required to be considered by the employer for handling "select carcinogens," reproductive toxins, and substance with high acute toxicity only in certain circumstances. Circumstances that may require the use of containment devices include: the use of volatile substances, manipulations that may result in the generation of aerosols; and any manipulation, handling or reaction that may result in the uncontrollable release of the substance. (These were adopted from various safety guidelines including the "NIH Guidelines for the Laboratory Use of Chemical Carcinogens" and "Handling Chemical Carcinogens in the Laboratory Problems of Safety," IARC Scientific Publications No. 33, as well as from comments (see Exs. 8–66, 8–111 and 10–9) submitted to the record).

Because the "designated area" as used in this final standard is not as restrictive as the "regulated area" used in the proposal, and access is not limited, OSHA felt that it was essential to require employers to consider an additional provision for the protection of laboratory workers. The new provision requires the employer to consider whether decontamination procedures for the "designated area" are appropriate. These procedures would vary with the type of substance used. OSHA believes that such a provision may be necessary to minimize potential exposure to select carcinogens, reproductive toxins and substances of high acute toxity for other workers present in the designated area.

The provisions in the proposed standard which required employers to specify appropriate protectives apparel to be worn by employees while working within a regulated area and specify appropriate hygiene practices have been deleted from the final rule with respect to designated areas since OSHA believes that this concern is already adequately covered under the general requirements of the Chemical Hygiene Plan.

The proposed Chemical Hygiene Plan also included provisions requiring the employer to evaluate laboratory operations and specify the criteria for operations that would need prior approval. Clearly, an employer might decide that certain operations involving highly toxic noncarcinogenic material or highly volatile toxic material needed prior approval and impose additional precautions at the time of such approval.

In addition, the final standard instructs employers to pay particular attention to the selection of controls for any other chemicals known to be extremely hazardous.

The employer's Chemical Hygiene Plan shall also make provision for employee training and information, medical consultation and examinations. However, for purposes of clarity these elements are included in the final standard under separate paragraphs and merely referenced in the CHP.

The final standard also requires that employers designate a Chemical Hygiene Officer to provide technical assistance in the development and administration of the Chemical Hygiene Plan. If deemed appropriate, the employer may establish a Chemical Hygiene Committee to assume this function. The designated individual(s) must be qualified by experience or training to carry out these responsibilities. However, OSHA intentionally did not define the skills needed to qualify as a Chemical Hygiene Officer since the requisite background experience and qualification would vary according to the complexity of the operation. Similarly, the final standard does not mandate what position or job classification the designated individual must hold in the employer's organizational structure. This is left entirely up to the employer. For example, the chemical hygiene responsibilities might be assigned to an individual presently serving as the safety officer, to a laboratory supervisor or to any other employee considered by the employer to be capable of carrying out such responsibilities. There was only minimal comment in the record which specifically addressed the need for employers to assign an employee to develop and carry out the Chemical Hygiene Plan. Moreover, record evidence, including information in the Booz, Allen and Hamilton Laboratory Profile Study (Ex. 7–11), indicates that many employers currently have an employee assigned to safety and health responsibilities associated with their operation. OSHA believes that such actions attest to the recognized need that an effective employee protection program such as that required by the Chemical Hygiene Plan can best be achieved if coordinated and implemented by an individual assigned to carry out such functions.

There is further evidence in the record which suggests that even though laboratories have assigned individuals to oversee safety and health concerns, in many cases these individuals are not given the necessary authority to successfully carry out their responsibilities. See, for example, the testimony of Dr. Alan Todd, Director of Industrial Hygiene, Stewart-Todd Associates. Dr. Todd stated:

> * * * [I]t is all too common to find that the safety officer who's typically a senior staff member has been saddled with the health and safety responsibility. At the same time, they are not given the authority to follow through in exercising reasonable control of laboratory materials and activities by their peers or those who work for them (Tr. 89).

The fact that OSHA is now requiring that employers designate a chemical hygiene officer should provide considerably more authority and responsibility to persons who function in this capacity.

Another concern expressed in the record was that the Chemical Hygiene Plan required by the Laboratory Standard duplicated many of the provisions of the Hazard Communication Standard. (*See, e.g.* Exs. 8–21, 8–32, 8–33, 8–35, 8–42, 8–47, 8–52, 8–54, 8–64, 8–85, 8–88, 8–98, 8–101, 8–105, and 8–112.) In particular, commenters questioned the need for a written Chemical Hygiene Plan in cases where laboratories associated with manufacturing operations have expanded the HCS program to all employees regardless of whether their work is in production or laboratory operations. Some commenters, among those cited above, requested that OSHA allow laboratories the option to comply with either the Laboratory Standard or the Hazard Communication Standard.

In response to this concern, OSHA believes that several points should be

considered. First, there is a basic difference between the intended objectives of the Laboratory Standard and those of the Hazard Communication Standard. The goal of the HCS is to communicate to employees the hazards of chemicals in the workplace. The employer's duties with respect to the HCS are directly related to the communication of information regarding hazards, including a description of any specific control measures that have been established to protect employees. The HCS, however, does not mandate the use of recommended control measures, but merely requires that information about appropriate control measures is communicated to the employees.

The Laboratory Standard, on the other hand, is designed to provide a comprehensive approach for the protection of laboratory workers which is more appropriate to laboratory conditions than compliance with the substance specific standards in 29 CFR part 1910, subpart Z. The Laboratory Standard requires that employers protect workers through the development and implementation of work practices and control measures expressly tailored to the individual laboratory workplace.

Both standards require that employees be trained regarding the hazards of the chemicals to which they may be exposed. For the most part, the training provisions required by the Laboratory Standard are identical to those of the HCS. There are, however, several additional training elements which are specific to the laboratory standard and the chemical hygiene plan in particular. For example, the employee shall be trained on the details of the Chemical Hygiene Plan which includes standard operating procedures, prior approval protocols, and procedures for handling select carcinogens, reproductive toxins, and substances with a high degree of acute toxicity where appropriate. In addition, employees shall be informed of the location and availability of known reference material pertaining to the hazards, safe handling and disposal of chemicals in the laboratory. OSHA does not believe that these provisions which are felt to be essential for the protection of laboratory workers will result in undue compliance burdens.

Finally, wherever there may be duplication of any requirement, there is no need to perform the function twice. If an employer is complying with the Hazard Communication Standard, either by choice or necessity, his activities will automatically satisfy any identical requirement of this standard.

Paragraph (f) Training and Information

In the preamble to the proposed laboratory standard, OSHA proposed that the training and information provisions supersede those of the Hazard Communication Standard (HCS). (*See* 51 FR at 26661.) At the time the proposed standard was published, only laboratories in the manufacturing sector (SIC codes 20–39) were covered by the HCS training provisions. Since then, the Hazard Communication Standard was expanded to include laboratories and other businesses in non-manufacturing sectors as well. (52 FR 21852, August 24, 1987).

The training provisions of the proposed laboratory standard and the HCS are similar in intent; the major differences are summarized as follows: First, the proposed laboratory standard required that employees be trained only in areas related to health hazards. The HCS requires training for both physical and health hazards. Second, in lieu of specific training on chemical hazards, the proposed standard required that employees be informed of available references pertaining to the hazards and safe handling of toxic substances. The HCS explicitly requires that employees be trained in methods and observations to detect the presence or release of hazardous chemicals in the work area and protective measures including those instituted by the employer.

OSHA's rationale for the approach to training taken in the proposed laboratory standard was based in part on the evidence available at that time. This evidence indicated that, given the qualifications of laboratory personnel, the multiple chemicals typically used and changing procedures, the proposed training requirements were more relevant to laboratory operations than were the HCS provisions. OSHA, however, solicited comments as to whether the training section should more closely mirror the provisions of the HCS.

The training provisions of the proposed standard were supported in several of the comments submitted (Exs. 8–19, 8–36, 8–76, 8–107, 8–112, 8–116, and 10–17). For example, Dow Chemical Company stated:

> OSHA asks for comments on whether the training and education section of this proposal should more closely mirror those of the HCS. We believe the performance oriented approach of this present proposal is more appropriate for laboratory personnel. As OSHA has been told many times, laboratory work is usually done by, or under the direction of highly trained personnel. The individuals usually have inquiring minds, and if informed where or how to get additional information on a substance, will seek it out. Laboratory work can be extremely variable and can range from the more routine quality assurance work, which utilizes the same materials day after day, to basic research work where the materials may change daily. The HCS requires training and education each time a new hazard is introduced. In basic research type operations, this could be frequently. More general type training with a reference library or information source is preferable in achieving the desired goal of each individual feeling responsible for his or her own health and safety. (Ex. 8–112).

Similar support was offered by E.I. Du Pont De Nemours & Company:

> The proposal as presented is well suited to laboratory operations. In many respects it parallels the HCS requirements. It also supplements the HCS requirements in order to respond to training needs specific to laboratories. Changes in the proposal to make the provisions identical to the requirements for industrial plants would render them less effective for laboratories. (EX. 8–19.)

In contrast, others (Exs. 8–9, 8–20, 8–23, 8–38, 8–66, 8–70, 8–75, 8–91, 8–97, 8–98, Tr. 135 and Tr. 234) suggested that the proposed provisions were not sufficient to effectively apprise workers of the hazards and precautions necessary to safely handle toxic substances in laboratories. For example, Dr. J. H. Carver commenting as a private citizen and Senior Genetic Toxicologist stated:

> The training and education sections of the Proposed Chemical Hygiene Plan appear to be inadequate as outlined; they should adhere more closely to those provisions of the Hazard Communication Standard which requires training in the physical and health hazards of the chemicals in the work area. Information regarding available reference material is not sufficient (Ex. 8–9.)

In his testimony presented at the informal hearing, Norman Steere, consultant in laboratory safety, expressed the following views on the proposed training provisions:

> I do not believe that the elements of the training program required by the proposed standard are sufficient to achieve effective communication about hazards and precautions for laboratory employees. Merely informing employees of the availability of reference material on the hazards and safe handling of toxic substances will not be effective unless the employee is highly motivated, and given on-the-job time to learn the necessary technical terminology and study the reference material. (Tr. 135).

Additional comments asserted that although many laboratory workers are trained in particular sciences, this fact does not obviate the need for specific training regarding hazards and safe handling of chemicals with which they work. Such views were reflected in the

comments of the Los Alamos National Laboratory:

* * * We strongly believe that the training requirements should go beyond only informing employees of available reference materials on the hazards of chemicals in the work area, and should include actual training on the health and physical hazards of the chemicals. Although many laboratory personnel have advanced degrees and are highly competent in their fields of study, that does not make them expert in the hazards associated with chemicals. The hands-on work with chemicals will also often be performed by a technician whose training was primarily acquired on the job, and who has very little knowledge of the hazards that may be involved * * * Those with advanced degrees sometimes demonstrate a cavalier attitude towards the potential hazards, and it is important that laboratory employees receive training to recognize hazards. (Ex. 8–20).

Dr. Inara Brubaker, testifying on behalf of the American Chemical Society, agreed that laboratory workers were highly trained with respect to their particular scientific disciplines but pointed to a deficiency in the training provisions of the proposed standard. Dr. Brubaker testified:

Most laboratory workers are highly trained in the sciences, and when they are not, they are usually supervised by someone who is * * * This training has provided these professionals with a better background than most workers as to the hazards, exposures and appropriate means of protection in handling toxic substances. However, since safe work practice decisions are often made by the laboratory worker a comprehensive training program is the single most important aspect of worker protection * * * The proposed training and safety program falls short of informing laboratory employees of potential hazards to which they may be exposed. Merely informing workers of available reference material * * * will not be sufficient to ensure employee health and safety. The ACS believes that the training * * * should be at least as extensive as that required by the Hazard Communication Standard * * * (Tr. 234–235).

In contrast, others objected to OSHA's proposal to have the training provisions of the laboratory standard supersede the provisions of the HCS. For example, Public Citizen stated:

* * * While manufacturing workers (and soon all workers, when OSHA expands the HCS as it has been instructed to do so by the Court) have a right to be educated about the specific hazards of the chemicals they handle, laboratory workers will not have this right because the proposed standard would exempt laboratories from this facet of the HCS. In contrast, the proposal would merely require employees to be informed of available reference materials on laboratory hazards. Thus, meaningful training requirements are shipped away, and workers are left with what they already have—the opportunity for self-education. (Ex. 8–70).

After careful consideration of the complete record, OSHA has concluded that relevant portions of the HCS training and information section, with appropriate modification, should be incorporated into this standard.

The proposed training provisions may have relied too heavily on information which suggested that most laboratory personnel were already knowledgeable about the hazards related to the chemicals with which they work and the precautions necessary to protect themselves. Record comments (*see e.g.* Tr. 134–136, and Tr. 382) indicate this cannot be assumed to be the case for all laboratory workers. Even those with advanced degrees are not necessarily trained in the safety and health aspects associated with chemical exposures. OSHA also agrees with the recommendations in the record that laboratory employees should have the benefit of training in physical hazards. Physical hazards are often responsible for subsequent adverse health effects, *e.g.*, explosions and fire could lead to the release of toxic fumes and vapors to which employees may be exposed. Moreover, the failure to require training concerning the potential physical hazards posed might encourage a false sense of security concerning the range of hazards presented.

In reaching its decision to incoroprate the HCS training provisions into this final standard, OSHA also considered the experience that labortaories in the manufacturing sector have had with the Hazard Communication Standard. These laboratories have been subject to the HCS training provisions for several years. In addition, laboratories outside of the manufacturing sector were required to come into compliance with the HCS training provisions by May 23, 1988. OSHA believes that to introduce completely different requirements for employee training in the final laboratory standard might be unnecessarily confusing to employers and employees as well. With the framework of the training program already in place under the HCS, OSHA believes that the modifications to existing laboratory training programs necessary to accommodate the provisions added by the final laboratory standard are minimal but essential for an effective training program for laboratory workers.

Employee training shall include the methods and observations that may be used to detect the presence of hazardous chemicals in the work area including any measures that the employer has instituted; the physical and health hazards associated with chemicals in the work area and appropriate protection measures including emergency procedures; and the details of the employer's Chemical Hygiene Plan.

Since this is a performance oriented standard, the amount and complexity of the training which must be implemented will vary with the complexity of the operations and the potential hazards.

The final standard therefore requires that employers provide employees with information and training so that they will be apprised of both physical and health hazards associated with hazardous chemicals present in their workplace. Such information and training is to be provided at the time of the employee's initial assignment and prior to assignments involving new hazardous chemicals or new exposure situations. The required training does not necessarily involve training for each specific chemical that the employee will use but rather the approach may be directed to classes or groups of hazardous chemicals. In addition, information to be communicated and made available to employees include the following: (1) The contents of the final standard and its appendices; (2) the employer's Chemical Hygiene Plan; (3) The PELs for OSHA regulated substances used in the work area and recommended exposure limits for other hazardous chemicals in the absence of an OSHA standard; (4) signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and (5) the availability of reference materials on the hazards, safe handling, storage and disposal of hazardous chemicals. Reference material would include, but not be limited to, MSDSs that may be available from chemical suppliers.

Pertinent reference materials concerning the hazards, safe handling, storage and disposal of hazardous chemicals used in the laboratory are an essential part of an effective employee protection program. As required by the Hazard Communication Standard, such hazard information is to be provided by the material safety data sheet that accompanies the shipment of the chemical. However, in the event such information is not received or is incomplete, or in cases where the chemical is generated by the laboratory, additional reference material may be necessary. The final standard requires that where reference material, including material safety data sheets, are known to be available, the employer shall inform employees of their location and availability. The standard places no restrictions on the form in which reference materials should be kept, and some employers may wish to utilize

computer technology. This format is acceptable as long as employees are aware of the procedures necessary to access the information from this source.

Paragraph (g) Medical Consultation and Medical Examinations

At the time the standard was proposed, OSHA's available information indicated that, given the multiple chemicals used and the unpredictable exposure situations typical of most laboratory operations, exposure monitoring was not practical. Additionally, routine medical surveillance was indicated to be prohibitively expensive and have little value because of the wide variety of substances to which workers were exposed and the difficulty in identifying indicators of adverse health effects.

OSHA, however, recognized that the potential for overexposure still existed and attempted to strike a balance in the proposal between adequate medical monitoring and practical utility. The proposal required employers to provide employees with an exposure evaluation in cases where there was reason to believe overexposure to a toxic substance had taken place. The exposure evaluation would be conducted by the Chemical Hygiene Officer and would provide an assessment of the conditions associated with the suspected overexposure. Among the factors to be considered in conducting an exposure evaluation were the chemical and physical properties of the substance involved, the quantity in use, the potential for overexposure associated with the operation involved and an estimation of the duration of exposure (51 FR at 26873). If the exposure evaluation indicated that an overexposure was likely to have occurred, the affected employee would be given an opportunity for medical consultation. The consultation included physician review of the exposure evaluation results and a conference with the affected employee, if necessary, to determine the need for medical examinations in a particular instance and, if indicated, follow-up medical procedures.

OSHA's proposed approach to medical protection for laboratory workers was supported by several participants in their response to this issue. For example, Dr. W. Emmett Barkley, former Director of the Division of Safety at the National Institutes of Health testified as follows:

> The provisions for exposure evaluation and medical consultation are sensible for most compounds and uses in the laboratory, and they reflect the current state of knowledge regarding the efficacy of medical surveillance initiatives within the laboratory setting.
>
> Overt exposures to toxic substances should initiate thorough evaluation to assess the degree of exposure. If it is determined that an overexposure has occurred, it is imperative that employees be provided with medical consultations and follow-up treatments, as necessary. (Tr. 111).

Further support was presented in the comment submitted by the Chemical Manufacturers Association (CMA):

> We agree fully with the proposal that each chemical hygiene plan should provide for medical consultation in all cases where an exposure evaluation indicates the likelihood of overexposure. Such consultations should be followed up by medical examinations or medical surveillance if recommended as a result of the medical consultation. (Ex. 8–65).

Other comments agreed with parts of OSHA's exposure evaluation/medical proposal. For example, the comment submitted by Vulcan Chemicals stated:

> While the provision for an exposure evaluation for employees who may have been overexposed to a toxic substance is a reasonable requirement, the requirement for a mandatory medical consultation for such employees is ill conceived. The exceedance of the OSHA permissible exposure limit or the ACGIH TLV does not automatically place an employee at such a risk that medical consultation is necessary * * * The PEL or TLV describes an exposure level to which an employee may be exposed for a working lifetime without harmful effects. Thus, the mere exceedance of this level may not result in a harmful effect. (Ex. 8–68).

However, other comments related to this issue recommended that OSHA require employers to institute a more comprehensive approach to ensure that employees have the full benefit of an appropriate medical protection program. See, for example, Exs. 8–15, 8–23, 8–38, 8–50, 8–70, 8–75, 8–76, and Tr. 48 which share the concerns expressed by the U.S. Department of Agriculture:

> The proposed rule includes provisions for an exposure evaluation and medical consultation whenever an employee may have been overexposed to a toxic substance * * * However, the proposed rule lacks a preventive health orientation by linking these provisions to only incidents of suspected or actual over exposure to toxic substances * * * (Ex. 10–6).

The requirement for an exposure evaluation as a means to trigger medical consultation for employees was criticized by several participants. For example, Maureen Hamilton, CIH, Director of Environmental Health Sciences at NHS, Inc. stressed the impracticality of this provision. She stated:

> The use of "exposure evaluations" when an employee feels he or she has been overexposed to a toxic substance is impractical. Trying to recreate a situation after the fact is virtually impossible and always open to debate. (Ex. 8–84).

Dr. Daniel Teitelbaum, Director of Medical Toxicology at Denver Clinic Medical Centers and expert OSHA witness was opposed to the exposure evaluation concept for different reasons. Dr. Teitelbaum testified as follows:

> I do not believe that employees should be required to be approved for a visit to a physician by a non-health professional when a potentially serious exposure to a chemical hazard is believed by the employee to have occurred. On the contrary, the employee should be encouraged to seek consultation from a physician or occupational health nurse at once if there is a reasonable belief that an exposure to a toxic substance has taken place * * * It is often not appreciated that following exposure to many chemicals, there is a golden period during which appropriate treatment may prevent the occurrence of serious and life-threatening illness. If one delays treatment for these injuries until after the symptoms begin, the patient may suffer increased morbidity or die because treatment is given too late. (Dr. Daniel Teitelbaum, Tr. (43–44).)

After careful consideration of the information submitted with respect to the exposure evaluation as a mechanism to determine the need for medical consultation for affected employees, OSHA agrees that this approach would rely too heavily on subjective judgment. As Dr. Teitelbaum pointed out in his testimony (Tr. 43–44) on this issue, a non health professional such as the Chemical Hygiene Officer may not necessarily recognize the nuances that influence appropriate judgment calls. For these reasons, this approach is not used in the final standard.

Some commenters recommended a more comprehensive approach to medical coverage for laboratory workers than that outlined in the proposed standard, citing the benefits of baseline medical examinations, periodic reexaminations and medical surveillance (see e.g. Exs. 8–15, 8–22, 8–38, 8–70 and 8–76). However, it is important to note the experience of a major research center, the National Institutes of Health. According to Dr. W. Emmett Barkley, former Director of the Division of Safety, in the past, the NIH applied the "kitchen sink" approach in its efforts to implement a medical program for laboratory workers.

> * * * [F]or 10 years we had what I will call a "kitchen sink" approach to medical surveillance. Annually, we provided everything we thought was relevant to physical examinations. We recorded every compound for which people used in their work, both viruses and chemicals, and we evaluated this after a six-year use period, and

found that it was not effective as a means for addressing worker safety. The resources that we put into that could more effectively be used to monitoring the processes by which people carried out their work and educating and enforcing practices more vigorously. (Tr. 120).

Dr. Barkley subsequently described the role of medical consultation as used at the NIH:

> We do, however, provide medical consultation for any situation where an overt exposure to a chemical or biological system occurs, whether it be through inhalation, skin contact, self-innoculation or what have you. We feel that this is very, very important, not only to maintain a record of the event, but to see whether there are processes or procedures that we could follow to see whether there was the degree of exposure, and we also look at it from the standpoint of how we might prevent this occurrence again. (Tr. 121).

In deciding the type of medical program that would be appropriate for laboratory workers, it is important to keep in mind the nature of exposure conditions in a typical laboratory covered by this standard. Typically, chemicals used and procedures performed change frequently. Moreover, according to information in the record, it is not always known in advance which chemicals will be involved in a laboratory procedure. (See, for example, Ex. 3–72 and Ex. 7–2.) OSHA believes that these conditions seriously confound the effectiveness of a medical surveillance program. Similarly, OSHA is not convinced, given the unpredictable array of chemicals in laboratories, that general baseline examinations would provide meaningful correlation in the event of future adverse exposures unless certain conditions are known in advance.

In reaching this conclusion, OSHA does not suggest that medical provisions are not needed under any circumstances to protect laboratory workers. The difficulty arises in establishing a rational approach as to when such provisions should apply. Clearly, if an employee exhibits signs or symptoms related to exposure to a hazardous chemical or if an employee is subjected to events such as spills, leaks, explosions or other unexpected occurrences where there is a likelihood of exposure to hazardous chemicals, that employee should be afforded an opportunity to receive appropriate medical attention.

The final laboratory standard provides for medical attention under these circumstances. Specifically, the standard requires that employers provide employees with an opportunity to receive appropriate medical examinations whenever the employee exhibits signs or symptoms associated with exposure to a hazardous chemical. The employer shall also provide employees with an opportunity to receive a medical consultation whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a significant exposure to a hazardous chemical. The medical consultation is provided for the purpose of determining the need for a medical examination. The employee shall be afforded an opportunity to receive any examinations recommended by the physician. All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided at a reasonable time and place without cost to the employee.

OSHA believes the situations described above should be covered as a minimum in any medical program designed for laboratory workers. However, beyond the circumstances just mentioned and on the basis of the rulemaking record, OSHA has provided additional protection in the event that workplace exposures routinely exceed those extremely small exposures upon which this standard was predicated. In the earlier discussion in this preamble concerning Employee Exposure Determination (paragraph (d)), exposure conditions are described under which the employer must comply with the medical and monitoring provisions of a relevant standard that are triggered by exposure over an action level (or PEL where there is no action level). Those conditions involve routine exposure levels in excess of an action level (or PEL in the absence of an action level) for an OSHA regulated substance for which there are monitoring and medical surveillance requirements. The result of the addition of this provision is that if there appears to be an identifiable condition in terms of overexposure, *i.e.*, exposure levels above the action level (or in the absence of an action level, the PEL), signs or symptoms of exposure, or the occurrence of an unusual event such as an explosion, leak or spill, then medical attention will be provided.

In view of the foregoing evidence OSHA believes that the provision of the final standard with respect to employee medical protection is sound and adequately protective of employee health. It is also reasonably necessary and appropriate to achieve this goal.

Paragraph (h). Hazard Identification

OSHA's proposed laboratory standard did not include special provisions for labeling. However, OSHA solicited comments regarding the need for such provisions. (51 FR at 26676).

Among those commenters who responded to this issue, several (see Exs. 8–48, 8–79, 8–106 and 8–108) specifically recommended that OSHA retain for this standard the labeling requirements of HCS as they pertain to laboratories. OSHA believes that this action is appropriate. OSHA also recognizes that labeling practices may best be implemented by the individual employer as part of the Chemical Hygiene Plan.

Therefore, the requirements of OSHA's Hazard Communication Standard concerning retention of labels and material safety data sheets accompanying incoming shipments of hazardous chemicals have been incorporated into this standard. This action does not represent an increased obligation on employers. Employers are to ensure that labels on incoming containers of hazardous chemicals are not removed or defaced. In addition, material safety data sheets which accompany incoming shipments of hazardous chemicals are to be maintained and made accessible to employees.

To avoid any confusion which could arise regarding hazard identification relating to the Hazard Communication Standard as distinct from that relating to this standard, OSHA has added three clarifying statements regarding laboratory-generated chemical substances. First, if a chemical substance whose chemical composition is known is produced in the laboratory for its own exclusive use, OSHA requires that available hazard information be provided to employees who may be exposed to the substance. MSDS and label preparations as required under the Hazard Communication Standard do not apply since, still qualifying under the laboratory use and laboratory scale definitions, the laboratory remains covered by this standard and is thus exempted from those requirements of the HCS.

Second, employers who produce a chemical byproduct whose composition is unknown shall make the assumption that the substance is hazardous and require that it be handled according to the Chemical Hygiene Plan in paragraph (e) which provides for appropriate employee protection for hazardous chemicals. OSHA believes that in this particular case, if the hazardous properties of a chemical substance are unknown, the most prudent approach to employee protection is to handle the material as if it were known to be

hazardous. By following this approach, the employer will not be required to conduct literature searches or perform actual tests to evaluate the hazard.

Finally, the standard clarifies the employer's responsibility where a chemical is produced in the laboratory and shipped to another user outside of the laboratory. With respect to the substance produced, the employer has become a manufacturer and therefore is subject to all the relevant provisions of the Hazard Communication Standard including requirements for the development of a material safety data sheet and labeling. However, if manufacturing is not the laboratory's principal concern, the laboratory standard remains in effect for those activities unrelated to the manufacturing operations.

Regarding shipment of waste materials, the Hazard Communication requirement will not apply in any case. Any requirement under EPA regulations regarding waste disposal will, of course, continue to apply. However, OSHA regards waste disposal by a laboratory to be a normal laboratory function. Thus, the Hazard Communication Standard will not apply as it would in the case of a substance which would be produced for and shipped to another organization.

Paragraph (i). Use of Respirators

This provision requires that any use of respirators which is necessary to maintain exposures below PELs must comply with the requirements in the respiratory protection standard, 29 CFR 1910.134. Consistent with other OSHA health standards, any necessary respiratory equipment must be provided without cost to employees. These provisions do not impose any new requirements on laboratory employers, but are included here to remind the employer of the existing compliance duty.

Paragraph (j). Recordkeeping

Section 8(c) of the Act authorizes the promulgation of regulations to make, keep and preserve such records regarding the employer's activities relating to the Act as are necessary or appropriate for the enforcement of the Act or for the development of information regarding the causes and prevention of occupational illnesses. The information currently before OSHA indicates that exposure monitoring and medical records prescribed herein are necessary and appropriate to both the enforcement of the standard and the development of information regarding the causes and prevention of workplace illnesses.

OSHA received only minimal comment regarding the recordkeeping requirements included in the proposed standard. One comment, (Ex. 8–104), requested clarification as to whether all medical records or just those pertaining to the overexposure were to be retained. OSHA believes that this point is clarified in the final standard in that any medical and exposure record created in connection with the standard shall be kept in accordance with 29 CFR 1910.20. Section 1910.20 is the generic standard for access to employee medical and exposure records. Section 1910.20 provides that records must be kept for the duration of employment plus 30 years and has detailed provisions for the transfer of records. OSHA has access to both medical and exposure records, subject to the Agency rules at 29 CFR 1913.10. An extensive discussion of the provisions and rationale for § 1910.20 can be found in the Federal Register of September 29, 1988 (53 FR 38140).

Paragraph (k). Effective Date

The final rule becomes effective 90 days following publication in the Federal Register. The standard provides a start-up date. The completion of preparation and implementation of the Chemical Hygiene Plan is not required until one year after the publication date.

The Agency received only minimal comments on the effective date and start-up date included in the proposed standard. Several commenters agreed that the time intervals were appropriate, (*see, e.g.*, Exs. 8–38 and 8–65). Others, however, felt that a longer start-up interval of up to two years was necessary, but provided no persuasive arguments (Exs. 8–33, 8–53, 8–91, and 8–111).

OSHA has carefully reviewed the provisions of the standard in terms of the length of time that would be required for employers to come into full compliance. Many employers have already instituted or are in the process of developing employee protection programs for which only minor modifications may be necessary to achieve compliance with this standard. OSHA believes that the effective date and start-up date set by the standard are reasonable and sufficient for all affected employers, including those beginning a new program, to become familiar with the contents of the preamble, standard and appendices and to complete and implement the Chemical Hygiene Plan.

Paragraph (l). Appendices

Two appendices are included in the final standard. The primary purpose of these appendices is to provide guidance to the employer in developing and implementing an appropriate Chemical Hygiene Plan. Appendix A is a distillation of pertinent parts of "Prudent Practices for Handling Hazardous Chemicals in Laboratories." Appendix B is a list of references which may be helpful to the employer in developing a Chemical Hygiene Plan. None of the statements in the appendices should be construed as establishing any mandatory requirements which are not otherwise imposed by the standard. Minor changes have been made in some instances to the appendices in the final rule. These changes reflect certain suggestions made by commenters (*see, e.g.*, Exs. 8–19, 8–107) to improve the clarity of the information presented.

VII. Federalism and State Plan Applicability

This standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting state policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective as the Federal standards in providing safe and healthful employment and places of employment.

In short, there is a clear national problem related to occupational safety and health for employees exposed to hazardous chemicals in laboratories. Those States which have elected to participate under section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while

ensuring that their standards are at least as effective as the Federal standard.

The 25 States with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of publication of a final rule. The States are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, Wyoming. For New York and Connecticut, plans cover only state and local government employees. Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these States.

VIII. Authority and Signature

This document was prepared under the direction of Gerard F. Scannell, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Pursuant to sections 6(b) and 8(c) and 8(g)(2) of the Act, OSHA hereby amends 29 CFR part 1910 by adding a new § 1910.1450 as set forth below.

List of Subjects in 29 CFR Part 1910

Laboratories, Occupational safety and health.

Signed at Washington, DC, this 22nd day of January 1990.

Gerard F. Scannell,

Assistant Secretary for Occupational Safety and Health.

Part 1910 of title 29 of the Code of Federal Regulation (CFR) is hereby amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The authority citation for part 1910, subpart Z is amended by adding the following citation at the end. (Citation which precedes asterisk indicates general rulemaking authority.)

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657; Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable; and 29 CFR part 1911. * * * Section 1910.1450 is also issued under sec. 6(b), 8(c) and 8(g)(2), Pub. L. 91–596, 84 Stat. 1593, 1599, 1600; 29 U.S.C. 655, 657.

2. Section 1910.1450 is added to subpart Z, part 1910 to read as follows:

§ 191.1450 Occupational exposure to hazardous chemicals in laboratories.

(a) *Scope and application.* (1) This section shall apply to all employers engaged in the laboratory use of hazardous chemicals as defined below.

(2) Where this section applies, it shall supersede, for laboratories, the requirements of all other OSHA health standards in 29 CFR part 1910, subpart Z, except as follows:

(i) For any OSHA health standard, only the requirement to limit employee exposure to the specific permissible exposure limit shall apply for laboratories, unless that particular standard states otherwise or unless the conditions of paragraph (a)(2)(iii) of this section apply.

(ii) Prohibition of eye and skin contact where specified by any OSHA health standard shall be observed.

(iii) Where the action level (or in the absence of an action level, the permissible exposure limit) is routinely exceeded for an OSHA regulated substance with exposure monitoring and medical surveillance requirements, paragraphs (d) and (g)(1)(ii) of this section shall apply.

(3) This section shall not apply to:

(i) Uses of hazardous chemicals which do not meet the definition of laboratory use, and in such cases, the employer shall comply with the relevant standard in 29 CFR part 1910, subpart 2, even if such use occurs in a laboratory.

(ii) Laboratory uses of hazardous chemicals which provide no potential for employee exposure. Examples of such conditions might include:

(A) Procedures using chemically-impregnated test media such as Dip-and-Read tests where a reagent strip is dipped into the specimen to be tested and the results are interpreted by comparing the color reaction to a color chart supplied by the manufacturer of the test strip; and

(B) Commercially prepared kits such as those used in performing pregnancy tests in which all of the reagents needed to conduct the test are contained in the kit.

(b) *Definitions*—

"*Action level*" means a concentration designated in 29 CFR part 1910 for a specific substance, calculated as an eight (8)-hour time-weighted average, which initiates certain required activities such as exposure monitoring and medical surveillance.

"*Assistant Secretary*" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"*Carcinogen*" (see "select carcinogen").

"*Chemical Hygiene Officer*" means an employee who is designated by the employer, and who is qualified by training or experience, to provide technical guidance in the development and implementation of the provisions of the Chemical Hygiene Plan. This definition is not intended to place limitations on the position description or job classification that the designated indvidual shall hold within the employer's organizational structure.

"*Chemical Hygiene Plan*" means a written program developed and implemented by the employer which sets forth procedures, equipment, personal protective equipment and work practices that (i) are capable of protecting employees from the health hazards presented by hazardous chemicals used in that particular workplace and (ii) meets the requirements of paragraph (e) of this section.

"*Combustible liquid*" means any liquid having a flashpoint at or above 100 °F (37.8 °C), but below 200 °F (93.3 °C), except any mixture having components with flashpoints of 200 °F (93.3 °C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

"*Compressed gas*" means:

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70 °F (21.1 °C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130 °F (54.4 °C) regardless of the pressure at 70 °F (21.1 °C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100 °F (37.8 °C) as determined by ASTM D–323–72.

"*Designated area*" means an area which may be used for work with "select carcinogens," reproductive toxins or substances which have a high degree of acute toxicity. A designated area may be the entire laboratory, an area of a laboratory or a device such as a laboratory hood.

"*Emergency*" means any occurrence such as, but not limited to, equipment failure, rupture of containers or failure of control equipment which results in an uncontrolled release of a hazardous chemical into the workplace.

"*Employee*" means an individual employed in a laboratory workplace who may be exposed to hazardous chemicals in the course of his or her assignments.

"*Explosive*" means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

"*Flammable*" means a chemical that falls into one of the following categories:

(i) "*Aerosol, flammable*" means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a

flame protection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;

(ii) "*Gas, flammable*" means:

(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of 13 percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than 12 percent by volume, regardless of the lower limit.

(iii) "*Liquid, flammable*" means any liquid having a flashpoint below 100 °F (37.8 °C), except any mixture having components with flashpoints of 100 °F (37.8 °C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) "*Solid, flammable*" means a solid, other than a blasting agent or explosive as defined in § 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

"*Flashpoint*" means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24–1979 (ASTM D 56–79))-for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100 °F (37.8 °C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7–1979 (ASTM D 93–79))-for liquids with a viscosity equal to or greater than 45 SUS at 100 °F (37.8 °C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278–78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.

"*Hazardous chemical*" means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic systems, and agents which damage the lungs, skin, eyes, or mucous membranes.

Appendices A and B of the Hazard Communication Standard (29 CFR 1910.1200) provide further guidance in defining the scope of health hazards and determining whether or not a chemical is to be considered hazardous for purposes of this standard.

"*Laboratory*" means a facility where the "laboratory use of hazardous chemicals" occurs. It is a workplace where relatively small quantities of hazardous chemicals are used on a non-production basis.

"*Laboratory scale*" means work with substances in which the containers used for reactions, transfers, and other handling of substances are designed to be easily and safely manipulated by one person. "Laboratory scale" excludes those workplaces whose function is to produce commercial quantities of materials.

"*Laboratory-type hood*" means a device located in a laboratory, enclosure on five sides with a moveable sash or fixed partial enclosed on the remaining side; constructed and maintained to draw air from the laboratory and to prevent or minimize the escape of air contaminants into the laboratory; and allows chemical manipulations to be conducted in the enclosure without insertion of any portion of the employee's body other than hands and arms.

Walk-in hoods with adjustable sashes meet the above definition provided that the sashes are adjusted during use so that the airflow and the exhaust of air contaminants are not compromised and employees do not work inside the enclosure during the release of airborne hazardous chemicals.

"*Laboratory use of hazardous chemicals*" means handling or use of such chemicals in which all of the following conditions are met:

(i) Chemical manipulations are carried out on a "laboratory scale;"

(ii) Multiple chemical procedures or chemicals are used;

(iii) The procedures involved are not part of a production process, nor in any way simulate a production process; and

(iv) "Protective laboratory practices and equipment" are available and in common use to minimize the potential for employee exposure to hazardous chemicals.

"*Medical consultation*" means a consultation which takes place between an employee and a licensed physician for the purpose of determining what medical examinations or procedures, if any, are appropriate in cases where a significant exposure to a hazardous chemical may have taken place.

"*Organic peroxide*" means an organic compound that contains the bivalent —O—O— structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

"*Oxidizer*" means a chemical other than a blasting agent or explosive as defined in § 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

"*Physical hazard*" means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

"*Protective laboratory practices and equipment*" means those laboratory procedures, practices and equipment accepted by laboratory health and safety experts as effective, or that the employer can show to be effective, in minimizing the potential for employee exposure to hazardous chemicals.

"*Reproductive toxins*" means chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis)

"*Select carcinogen*" means any substance which meets one of the following criteria:

(i) It is regulated by OSHA as a carcinogen; or

(ii) It is listed under the category, "known to be carcinogens," in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or

(iii) It is listed under Group 1 ("carcinogenic to humans") by the International Agency for Research on Cancer Monographs (IARC) (latest editions); or

(iv) It is listed in either Group 2A or 2B by IARC or under the category, "reasonably anticipated to be

carcinogens" by NTP, and causes statistically significant tumor incidence in experimental animals in accordance with any of the following criteria:

(A) After inhalation exposure of 6–7 hours per day, 5 days per week, for a significant portion of a lifetime to dosages of less than 10 mg/m³;

(B) After repeated skin application of less than 300 (mg/kg of body weight) per week; or

(C) After oral dosages of less than 50 mg/kg of body weight per day.

"Unstable (reactive)" means a chemical which is the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks, pressure or temperature.

"Water-reactive" means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

(c) *Permissible exposure limits.* For laboratory uses of OSHA regulated substances, the employer shall assure that laboratory employees' exposures to such substances do not exceed the permissible exposure limits specified in 29 CFR part 1910, subpart Z.

(d) *Employee exposure determination*—(1) *Initial monitoring.* The employer shall measure the employee's exposure to any substance regulated by a standard which requires monitoring if there is reason to believe that exposure levels for that substance routinely exceed the action level (or in the absence of an action level, the PEL).

(2) *Periodic monitoring.* If the initial monitoring prescribed by paragraph (d)(1) of this section discloses employee exposure over the action level (or in the absence of an action level, the PEL), the employer shall immediately comply with the exposure monitoring provisions of the relevant standard.

(3) *Termination of monitoring.* Monitoring may be terminated in accordance with the relevant standard.

(4) *Employee notification of monitoring results.* The employer shall, within 15 working days after the receipt of any monitoring results, notify the employee of these results in writing either individually or by posting results in an appropriate location that is accessible to employees.

(e) *Chemical hygiene plan—General.* (Appendix A of this section is non-mandatory but provides guidance to assist employers in the development of the Chemical Hygiene Plan.) (1) Where hazardous chemicals as defined by this standard are used in the workplace, the employer shall develop and carry out the provisions of a written Chemical Hygiene Plan which is:

(i) Capable of protecting employees from health hazards associated with hazardous chemicals in that laboratory and

(ii) Capable of keeping exposures below the limits specified in paragraph (c) of this section.

(2) The Chemical Hygiene Plan shall be readily available to employees, employee representatives and, upon request, to the Assistant Secretary.

(3) The Chemical Hygiene Plan shall include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection:

(i) Standard operating procedures relevant to safety and health considerations to be followed when laboratory work involves the use of hazardous chemicals;

(ii) Criteria that the employer will use to determine and implement control measures to reduce employee exposure to hazardous chemicals including engineering controls, the use of personal protective equipment and hygiene practices; particular attention shall be given to the selection of control measures for chemicals that are known to be extremely hazardous;

(iii) A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment;

(iv) Provisions for employee information and training as prescribed in paragraph (f) of this section;

(v) The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the employer's designee before implementation;

(vi) Provisions for medical consultation and medical examinations in accordance with paragraph (g) of this section;

(vii) Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer and, if appropriate, establishment of a Chemical Hygiene Committee; and

(viii) Provisions for additional employee protection for work with particularly hazardous substances. These include "select carcinogens," reproductive toxins and substances which have a high degree of acute toxicity. Specific consideration shall be given to the following provisions which shall be included where appropriate:

(A) Establishment of a designated area;

(B) Use of containment devices such as fume hoods or glove boxes;

(C) Procedures for safe removal of contaminated waste; and

(D) Decontamination procedures.

(4) The employer shall review and evaluate the effectiveness of the Chemical Hygiene Plan at least annually and update it as necessary.

(f) *Employee information and training.* (1) The employer shall provide employees with information and training to ensure that they are apprised of the hazards of chemicals present in their work area.

(2) Such information shall be provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. The frequency of refresher information and training shall be determined by the employer.

(3) *Information.* Employees shall be informed of:

(i) The contents of this standard and its appendices which shall be made available to employees;

(ii) The location and availability of the employer's Chemical Hygiene Plan;

(iii) The permissible exposure limits for OSHA regulated substances or recommended exposure limits for other hazardous chemicals where there is no applicable OSHA standard;

(iv) Signs and symptoms associated with exposures to hazardous chemicals used in the laboratory; and

(v) The location and availability of known reference material on the hazards, safe handling, storage and disposal of hazardous chemicals found in the laboratory including, but not limited to, Material Safety Data Sheets received from the chemical supplier.

(4) *Training.* (i) Employee training shall include:

(A) Methods and observations that may be used to detect the presence or release of a hazardous chemical (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(B) The physical and health hazards of chemicals in the work area; and

(C) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used.

(ii) The employee shall be trained on the applicable details of the employer's written Chemical Hygiene Plan.

(g) *Medical consultation and medical examinations.* (1) The employer shall provide all employees who work with hazardous chemicals an opportunity to receive medical attention, including any follow-up examinations which the examining physician determines to be necessary, under the following circumstances:

(i) Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory, the employee shall be provided an opportunity to receive an appropriate medical examination.

(ii) Where exposure monitoring reveals an exposure level routinely above the action level (or in the absence of an action level, the PEL) for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements, medical surveillance shall be established for the affected employee as prescribed by the particular standard.

(iii) Whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the affected employee shall be provided an opportunity for a medical consultation. Such consultation shall be for the purpose of determining the need for a medical examination.

(2) All medical examinations and consultations shall be performed by or under the direct supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

(3) *Information provided to the physician.* The employer shall provide the following information to the physician:

(i) The identity of the hazardous chemical(s) to which the employee may have been exposed;

(ii) A description of the conditions under which the exposure occurred including quantitative exposure data, if available; and

(iii) A description of the signs and symptoms of exposure that the employee is experiencing, if any.

(4) *Physician's written opinion.* (i) For examination or consultation required under this standard, the employer shall obtain a written opinion from the examining physician which shall include the following:

(A) Any recommendation for further medical follow-up;

(B) The results of the medical examination and any associated tests;

(C) Any medical condition which may be revealed in the course of the examination which may place the employee at increased risk as a result of exposure to a hazardous chemical found in the workplace; and

(D) A statement that the employee has been informed by the physician of the results of the consultation or medical examination and any medical condition that may require further examination or treatment.

(ii) The written opinion shall not reveal specific findings of diagnoses unrelated to occupational exposure.

(h) *Hazard identification.* (1) With respect to labels and material safety data sheets:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced.

(ii) Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees.

(2) The following provisions shall apply to chemical substances developed in the laboratory:

(i) If the composition of the chemical substance which is produced exclusively for the laboratory's use is known, the employer shall determine if it is a hazardous chemical as defined in paragraph (b) of this section. If the chemical is determined to be hazardous, the employer shall provide appropriate training as required under paragraph (f) of this section.

(ii) If the chemical produced is a byproduct whose composition is not known, the employer shall assume that the substance is hazardous and shall implement paragraph (e) of this section.

(iii) If the chemical substance is produced for another user outside of the laboratory, the employer shall comply with the Hazard Communication Standard (29 CFR 1910.1200) including the requirements for preparation of material safety data sheets and labeling.

(i) *Use of respirators.* Where the use of respirators is necessary to maintain exposure below permissible exposure limits, the employer shall provide, at no cost to the employee, the proper respiratory equipment. Respirators shall be selected and used in accordance with the requirements of 29 CFR 1910.134.

(j) *Recordkeeping.* (1) The employer shall establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations including tests or written opinions required by this standard.

(2) The employer shall assure that such records are kept, transferred, and made available in accordance with 29 CFR 1910.20.

(k) *Dates*—(1) *Effective date.* This section shall become effective May 1, 1990.

(2) *Start-up dates.* (i) Employers shall have developed and implemented a written Chemical Hygiene Plan no later than January 31, 1991.

(ii) Paragraph (a)(2) of this section shall not take effect until the employer has developed and implemented a written Chemical Hygiene Plan.

(l) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

Appendix A to § 1910.1450—National Research Council Recommendations Concerning Chemical Hygiene in Laboratories (Non-Mandatory)

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3. Chemicals of Moderate Chronic or High Acute Toxicity
4. Chemicals of High Chronic Toxicity
5. Animal Work with Chemicals of High Chronic Toxicity

F. Safety Recommendations

G. Material Safety Data Sheets

Foreword

As guidance for each employer's development of an appropriate laboratory Chemical Hygiene Plan, the following non-mandatory recommendations are provided. They were extracted from "Prudent Practices for Handling Hazardous Chemicals in Laboratories" (referred to below as "Prudent Practices"), which was published in 1981 by the National Research Council and is available from the National Academy Press, 2101 Constitution Ave., NW., Washington DC 20418.

"Prudent Practices" is cited because of its wide distribution and acceptance and because of its preparation by members of the laboratory community through the sponsorship of the National Research Council. However, none of the recommendations given here will modify any requirements of the laboratory standard. This Appendix merely presents pertinent recommendations from "Prudent Practices", organized into a form convenient for quick reference during operation of a laboratory facility and during development and application of a Chemical Hygiene Plan. Users of this appendix should consult "Prudent Practices" for a more extended presentation and justification for each recommendation.

"Prudent Practices" deals with both safety and chemical hazards while the laboratory standard is concerned primarily with chemical hazards. Therefore, only those recommendations directed primarily toward control of toxic exposures are cited in this appendix, with the term "chemical hygiene" being substituted for the word "safety". However, since conditions producing or threatening physical injury often pose toxic risks as well, page references concerning major categories of safety hazards in the laboratory are given in section F.

The recommendations from "Prudent Practices" have been paraphrased, combined, or otherwise reorganized, and headings have been added. However, their sense has not been changed.

Corresponding Sections of the Standard and this Appendix

The following table is given for the convenience of those who are developing a Chemical Hygiene Plan which will satisfy the requirements of paragraph (e) of the standard. It indicates those sections of this appendix which are most pertinent to each of the sections of paragraph (e) and related paragraphs.

Paragraph and topic in laboratory standard	Relevant appendix section
(e)(3)(i) Standard operating procedures for handling toxic chemicals.	C, D, E
(e)(3)(ii) Criteria to be used for implementation of measures to reduce exposures.	D
(e)(3)(iii) Fume hood performance	C4b
(e)(3)(iv) Employee information and training (including emergency procedures).	D10, D9
(e)(3)(v) Requirements for prior approval of laboratory activities.	E2b, E4b
(e)(3)(vi) Medical consultation and medical examinations.	D5, E4f
(e)(3)(vii) Chemical hygiene responsibilities.	B
(e)(3)(viii) Special precautions for work with particularly hazardous substances.	E2, E3, E4

In this appendix, those recommendations directed primarily at administrators and supervisors are given in sections A–D. Those recommendations of primary concern to employees who are actually handling laboratory chemicals are given in section E. (Reference to page numbers in "Prudent Practices" are given in parentheses.)

A. General Principles for Work with Laboratory Chemicals

In addition to the more detailed recommendations listed below in sections B–E, "Prudent Practices" expresses certain general principles, including the following:

1. *It is prudent to minimize all chemical exposures.* Because few laboratory chemicals are without hazards, general precautions for handling all laboratory chemicals should be adopted, rather than specific guidelines for particular chemicals (2, 10). Skin contact with chemicals should be avoided as a cardinal rule (198).

2. *Avoid underestimation of risk.* Even for substances of no known significant hazard, exposure should be minimized; for work with substances which present special hazards, special precautions should be taken (10, 37, 38). One should assume that any mixture will be more toxic than its most toxic component (30, 103) and that all substances of unknown toxicity are toxic (3, 34).

3. *Provide adequate ventilation.* The best way to prevent exposure to airborne substances is to prevent their escape into the working atmosphere by use of hoods and other ventilation devices (32, 198).

4. *Institute a chemical hygiene program.* A mandatory chemical hygiene program designed to minimize exposures is needed; it should be a regular, continuing effort, not merely a standby or short-term activity (8, 11). Its recommendations should be followed in academic teaching laboratories as well as by full-time laboratory workers (13).

5. *Observe the PELs, TLVs.* The Permissible Exposure Limits of OSHA and the Threshold Limit Values of the American Conference of Governmental Industrial Hygienists should not be exceeded (13).

B. Chemical Hygiene Responsibilities

Responsibility for chemical hygiene rests at all levels (8, 11, 21) including the:

1. *Chief executive officer,* who has ultimate responsibility for chemical hygiene within the institution and must, with other administrators, provide continuing support for institutional chemical hygiene (7, 11).

2. *Supervisor of the department or other administrative unit,* who is responsible for chemical hygiene in that unit (7).

3. *Chemical hygiene officer(s),* whose appointment is essential (7) and who must:

(a) Work with administrators and other employees to develop and implement appropriate chemical hygiene policies and practices (7);

(b) Monitor procurement, use, and disposal of chemicals used in the lab (8);

(c) See that appropriate audits are maintained (8);

(d) Help project directors develop precautions and adequate facilities (10);

(e) Know the current legal requirements concerning regulated substances (50); and

(f) Seek ways to improve the chemical hygiene program (8, 11).

4. *Laboratory supervisor,* who has overall responsibility for chemical hygiene in the laboratory (21) including responsibility to:

(a) Ensure that workers know and follow the chemical hygiene rules, that protective equipment is available and in working order, and that appropriate training has been provided (21, 22);

(b) Provide regular, formal chemical hygiene and housekeeping inspections including routine inspections of emergency equipment (21, 171);

(c) Know the current legal requirements concerning regulated substances (50, 231);

(d) Determine the required levels of protective apparel and equipment (156, 160, 162); and

(e) Ensure that facilities and training for use of any material being ordered are adequate (215).

5. *Project director or director of other specific operation,* who has primary responsibility for chemical hygiene procedures for that operation (7).

6. *Laboratory worker,* who is responsible for:

(a) Planning and conducting each operation in accordance with the institutional chemical hygiene procedures (7, 21, 22, 230); and

(b) Developing good personal chemical hygiene habits (22).

C. The Laboratory Facility

1. *Design.* The laboratory facility should have:

(a) An appropriate general ventilation system (see C4 below) with air intakes and exhausts located so as to avoid intake of contaminated air (194);

(b) Adequate, well-ventilated stockrooms/storerooms (218, 219);

(c) Laboratory hoods and sinks (12, 162);

(d) Other safety equipment including eyewash fountains and drench showers (162, 169); and

(e) Arrangements for waste disposal (12, 240).

2. *Maintenance.* Chemical-hygiene-related equipment (hoods, incinerator, etc.) should undergo continuing appraisal and be modified if inadequate (11, 12).

3. *Usage.* The work conducted (10) and its scale (12) must be appropriate to the physicial facilities available and, especially, to the quality of ventilation (13).

4. *Ventilation*—(a) *General laboratory ventilation.* This system should: Provide a source of air for breathing and for input to local ventilation devices (199); it should not be relied on for protection from toxic substances released into the laboratory (198); ensure that laboratory air is continually replaced, preventing increase of air concentrations of toxic substances during the working day (194); direct air flow into the laboratory from non-laboratory areas and out to the exterior of the building (194).

(b) *Hoods.* A laboratory hood with 2.5 linear feet of hood space per person should be provided for every 2 workers if they spend most of their time working with chemicals (199); each hood should have a continuous monitoring device to allow convenient confirmation of adequate hood performance before use (200, 209). If this is not possible, work with substances of unknown toxicity should be avoided (13) or other types of local ventilation devices should be provided (199). See pp. 201–206 for a discussion of hood design, construction, and evaluation.

(c) *Other local ventilation devices.* Ventilated storage cabinets, canopy hoods, snorkels, etc. should be provided as needed (199). Each canopy hood and snorkel should have a separate exhaust duct (207).

(d) *Special ventilation areas.* Exhaust air from glove boxes and isolation rooms should be passed through scrubbers or other treatment before release into the regular exhaust system (208). Cold rooms and warm rooms should have provisions for rapid escape and for escape in the event of electrical failure (209).

(e) *Modifications.* Any alteration of the ventilation system should be made only if thorough testing indicates that worker protection from airborne toxic substances will continue to be adequate (12, 193, 204).

(f) *Performance.* Rate: 4–12 room air changes/hour is normally adequate general ventilation if local exhaust systems such as hoods are used as the primary method of control (194).

(g) *Quality.* General air flow should not be turbulent and should be relatively uniform throughout the laboratory, with no high velocity or static areas (194, 195); airflow into and within the hood should not be excessively turbulent (200); hood face velocity should be adequate (typically 60–100 lfm) (200, 204).

(h) *Evaluation.* Quality and quantity of ventilation should be evaluated on installation (202), regularly monitored (at least every 3 months) (6, 12, 14, 195), and reevaluated whenever a change in local ventilation devices is made (12, 195, 207). See pp. 195–198 for methods of evaluation and for calculation of estimated airborne contaminant concentrations.

D. Components of the Chemical Hygiene Plan

1. Basic Rules and Procedures (Recommendations for these are given in section E, below)

2. Chemical Procurement, Distribution, and Storage

(a) *Procurement.* Before a substance is received, information on proper handling, storage, and disposal should be known to those who will be involved (215, 216). No container should be accepted without an adequate identifying label (216). Preferably, all substances should be received in a central location (218).

(b) *Stockrooms/storerooms.* Toxic substances should be segregated in a well-identified area with local exhaust ventilation (221). Chemicals which are highly toxic (227) or other chemicals whose containers have been opened should be in unbreakable secondary containers (219). Stored chemicals should be examined periodically (at least annually) for replacement, deterioration, and container integrity (218–19).

Stockrooms/storerooms should not be used as preparation or repackaging areas, should be open during normal working hours, and should be controlled by one person (219).

(c) *Distribution.* When chemicals are hand carried, the container should be placed in an outside container or bucket. Freight-only elevators should be used if possible (223).

(d) *Laboratory storage.* Amounts permitted should be as small as practical. Storage on bench tops and in hoods is inadvisable. Exposure to heat or direct sunlight should be avoided. Periodic inventories should be conducted, with unneeded items being discarded or returned to the storeroom/stockroom (225–6, 229).

3. Environmental Monitoring

Regular instrumental monitoring of airborne concentrations is not usually justified or practical in laboratories but may be appropriate when testing or redesigning hoods or other ventilation devices (12) or when a highly toxic substance is stored or used regularly (e.g., 3 times/week) (13).

4. Housekeeping, Maintenance, and Inspections

(a) Cleaning. Floors should be cleaned regularly (24).

(b) Inspections. Formal housekeeping and chemical hygiene inspections should be held at least quarterly (6, 21) for units which have frequent pesonnel changes and semiannually for others; informal inspections should be continual (21).

(c) *Maintenance.* Eye wash fountains should be inspected at intervals of not less than 3 months (6). Respirators for routine use should be inspected periodically by the laboratory supervisor (169). Safety showers should be tested routinely (169). Other safety equipment should be inspected regularly. (*e.g.*, every 3–6 months) (6, 24, 171). Procedures to prevent restarting of out-of-service equipment should be established (25).

(d) *Passageways.* Stairways and hallways should not be used as storage areas (24). Access to exits, emergency equipment, and utility controls should never be blocked (24).

5. Medical Program

(a) *Compliance with regulations.* Regular medical surveillance should be established to the extent required by regulations (12).

(b) *Routine surveillance.* Anyone whose work involves regular and frequent handling of toxicologically significant quantities of a chemical should consult a qualified physician to determine on an individual basis whether a regular schedule of medical surveillance is desirable (11, 50).

(c) *First aid.* Personnel trained in first aid should be available during working hours and an emergency room with medical personnel should be nearby (173). See pp. 176–178 for description of some emergency first aid procedures.

6. Protective Apparel and Equipment

These should include for each laboratory:

(a) Protective apparel compatible with the required degree of protection for substances being handled (158–161);

(b) An easily accessible drench-type safety shower (162, 169);

(c) An eyewash fountain (162);

(d) A fire extinguisher (162–164);

(e) Respiratory protection (164–9), fire alarm and telephone for emergency use (162) should be available nearby; and

(f) Other items designated by the laboratory supervisor (156, 160).

7. Records

(a) Accident records should be written and retained (174).

(b) Chemical Hygiene Plan records should document that the facilities and precautions were compatible with current knowledge and regulations (7).

(c) Inventory and usage records for high-risk substances should be kept as specified in sections E3e below.

(d) Medical records should be retained by the institution in accordance with the requirements of state and federal regulations (12).

8. Signs and Labels

Prominent signs and labels of the following types should be posted:

(a) Emergency telephone numbers of emergency personnel/facilities, supervisors, and laboratory workers (28);

(b) Identity labels, showing contents of containers (including waste receptacles) and associated hazards (27, 48);

(c) Location signs for safety showers, eyewash stations, other safety and first aid equipment, exits (27) and areas where food and beverage consumption and storage are permitted (24); and

(d) Warnings at areas or equipment where special or unusual hazards exist (27).

9. Spills and Accidents

(a) A written emergency plan should be established and communicated to all personnel; it should include procedures for ventilation failure (200), evacuation, medical care, reporting, and drills (172).

(b) There should be an alarm system to alert people in all parts of the facility including isolation areas such as cold rooms (172).

(c) A spill control policy should be developed and should include consideration of prevention, containment, cleanup, and reporting (175).

(d) All accidents or near accidents should be carefully analyzed with the results distributed to all who might benefit (8, 28).

10. Information and Training Program

(a) Aim: To assure that all individuals at risk are adequately informed about the work in the laboratory, its risks, and what to do if an accident occurs (5, 15).

(b) Emergency and Personal Protection Training: Every laboratory worker should know the location and proper use of available protective apparel and equipment (154, 169).

Some of the full-time personnel of the laboratory should be trained in the proper use of emergency equipment and procedures (6).

Such training as well as first aid instruction should be available to (154) and encouraged for (176) everyone who might need it.

(c) Receiving and stockroom/storeroom personnel should know about hazards, handling equipment, protective apparel, and relevant regulations (217).

(d) Frequency of Training: The training and education program should be a regular, continuing activity—not simply an annual presentation (15).

(e) Literature/Consultation: Literature and consulting advice concerning chemical hygiene should be readily available to laboratory personnel, who should be encouraged to use these information resources (14).

11. *Waste Disposal Program.*

(a) Aim: To assure that minimal harm to people, other organisms, and the environment will result from the disposal of waste laboratory chemicals (5).

(b) Content (14, 232, 233, 240): The waste disposal program should specify how waste is to be collected, segregated, stored, and transported and include consideration of what materials can be incinerated. Transport from the institution must be in accordance with DOT regulations (244).

(c) Discarding Chemical Stocks: Unlabeled containers of chemicals and solutions should undergo prompt disposal; if partially used, they should not be opened (24, 27).

Before a worker's employment in the laboratory ends, chemicals for which that person was responsible should be discarded or returned to storage (226).

(d) Frequency of Disposal: Waste should be removed from laboratories to a central waste storage area at least once per week and from the central waste storage area at regular intervals (14).

(e) Method of Disposal: Incineration in an environmentally acceptable manner is the most practical disposal method for combustible laboratory waste (14, 238, 241).

Indiscriminate disposal by pouring waste chemicals down the drain (14, 231, 242) or adding them to mixed refuse for landfill burial is unacceptable (14).

Hoods should not be used as a means of disposal for volatile chemicals (40, 200).

Disposal by recycling (233, 243) or chemical decontamination (40, 230) should be used when possible.

E. Basic Rules and Procedures for Working with Chemicals

The Chemical Hygiene Plan should require that laboratory workers know and follow its rules and procedures. In addition to the procedures of the sub programs mentioned above, these should include the rules listed below.

1. General Rules

The following should be used for essentially all laboratory work with chemicals:

(a) *Accidents and spills*—Eye Contact: Promptly flush eyes with water for a prolonged period (15 minutes) and seek medical attention (33, 172).

Ingestion: Encourage the victim to drink large amounts of water (178).

Skin Contact: Promptly flush the affected area with water (33, 172, 178) and remove any contaminated clothing (172, 178). If symptoms persist after washing, seek medical attention (33).

Clean-up. Promptly clean up spills, using appropriate protective apparel and equipment and proper disposal (24 33). See pp. 233–237 for specific clean-up recommendations.

(b) *Avoidance of "routine" exposure:* Develop and encourage safe habits (23); avoid unnecessary exposure to chemicals by any route (23);

Do not smell or taste chemicals (32). Vent apparatus which may discharge toxic chemicals (vacuum pumps, distillation columns, etc.) into local exhaust devices (199).

Inspect gloves (157) and test glove boxes (208) before use.

Do not allow release of toxic substances in cold rooms and warm rooms, since these have contained recirculated atmospheres (209).

(c) *Choice of chemicals:* Use only those chemicals for which the quality of the available ventilation system is appropriate (13).

(d) *Eating, smoking, etc.:* Avoid eating, drinking, smoking, gum chewing, or application of cosmetics in areas where laboratory chemicals are present (22, 24, 32, 40); wash hands before conducting these activities (23, 24).

Avoid storage, handling or consumption of food or beverages in storage areas, refrigerators, glassware or utensils which are also used for laboratory operations (23, 24, 226).

(e) *Equipment and glassware:* Handle and store laboratory glassware with care to avoid damage; do not use damaged glassware (25). Use extra care with Dewar flasks and other evacuated glass apparatus; shield or wrap them to contain chemicals and fragments should implosion occur (25). Use equipment only for its designed purpose (23, 28).

(f) *Exiting:* Wash areas of exposed skin well before leaving the laboratory (23).

(g) *Horseplay:* Avoid practical jokes or other behavior which might confuse, startle or distract another worker (23).

(h) *Mouth suction:* Do not use mouth suction for pipeting or starting a siphon (23, 32).

(i) *Personal apparel:* Confine long hair and loose clothing (23, 158). Wear shoes at all times in the laboratory but do not wear sandals, perforated shoes, or sneakers (158).

(j) *Personal housekeeping:* Keep the work area clean and uncluttered, with chemicals and equipment being properly labeled and stored; clean up the work area on completion of an operation or at the end of each day (24).

(k) *Personal protection:* Assure that appropriate eye protection (154–156) is worn by all persons, including visitors, where chemicals are stored or handled (22, 23, 33, 154).

Wear appropriate gloves when the potential for contact with toxic materials exists (157); inspect the gloves before each use, wash them before removal, and replace them periodically (157). (A table of resistance to chemicals of common glove materials is given p. 159).

Use appropriate (164–168) respiratory equipment when air contaminant concentrations are not sufficiently restricted by engineering controls (164–5), inspecting the respirator before use (169).

Use any other protective and emergency apparel and equipment as appropriate (22, 157–182).

Avoid use of contact lenses in the laboratory unless necessary; if they are used, inform supervisor so special precautions can be taken (155).

Remove laboratory coats immediately on significant contamination (161).

(l) *Planning:* Seek information and advice about hazards (7), plan appropriate protective procedures, and plan positioning of equipment before beginning any new operation (22, 23).

(m) *Unattended operations:* Leave lights on, place an appropriate sign on the door, and provide for containment of toxic substances in the event of failure of a utility service (such as cooling water) to an unattended operation (27, 128).

(n) *Use of hood:* Use the hood for operations which might result in release of toxic chemical vapors or dust (198–9).

As a rule of thumb, use a hood or other local ventilation device when working with any appreciably volatile substance with a TLV of less than 50 ppm (13).

Confirm adequate hood performance before use; keep hood closed at all times except when adjustments within the hood are being made (200); keep materials stored in hoods to a minimum and do not allow them to block vents or air flow (200).

Leave the hood "on" when it is not in active use if toxic substances are stored in it or if it is uncertain whether adequate general laboratory ventilation will be maintained when it is "off" (200).

(o) *Vigilance:* Be alert to unsafe conditions and see that they are corrected when detected (22).

(p) *Waste disposal:* Assure that the plan for each laboratory operation includes plans and training for waste disposal (230).

Deposit chemical waste in appropriately labeled receptacles and follow all other waste disposal procedures of the Chemical Hygiene Plan (22, 24).

Do not discharge to the sewer concentrated acids or bases (231); highly toxic, malodorous, or lachrymatory substances

(231); or any substances which might interfere with the biological activity of waste water treatment plants, create fire or explosion hazards, cause structural damage or obstruct flow (242).

(q) *Working alone:* Avoid working alone in a building; do not work alone in a laboratory if the procedures being conducted are hazardous (28).

2. Working with Allergens and Embryotoxins

(a) *Allergens* (examples: diazomethane, isocyanates, bichromates): Wear suitable gloves to prevent hand contact with allergens or substances of unknown allergenic activity (35).

(b) *Embryotoxins* (34–5) (examples: organomercurials, lead compounds, formamide): If you are a woman of childbearing age, handle these substances only in a hood whose satisfactory performance has been confirmed, using appropriate protective apparel (especially gloves) to prevent skin contact.

Review each use of these materials with the research supervisor and review continuing uses annually or whenever a procedural change is made.

Store these substances, properly labeled, in an adequately ventilated area in an unbreakable secondary container.

Notify supervisors of all incidents of exposure or spills; consult a qualified physician when appropriate.

3. Work with Chemicals of Moderate Chronic or High Acute Toxicity

Examples: diisopropylflurophosphate (41), hydrofluoric acid (43), hydrogen cyanide (45).

Supplemental rules to be followed in addition to those mentioned above (Procedure B of "Prudent Practices", pp. 39–41):

(a) *Aim:* To minimize exposure to these toxic substances by any route using all reasonable precautions (39).

(b) *Applicability:* These precautions are appropriate for substances with moderate chronic or high acute toxicity used in significant quantities (39).

(c) *Location:* Use and store these substances only in areas of restricted access with special warning signs (40, 229).

Always use a hood (previously evaluated to confirm adequate performance with a face velocity of at least 60 linear feet per minute) (40) or other containment device for procedures which may result in the generation of aerosols or vapors containing the substance (39); trap released vapors to prevent their discharge with the hood exhaust (40).

(d) *Personal protection:* Always avoid skin contact by use of gloves and long sleeves (and other protective apparel as appropriate) (39). Always wash hands and arms immediately after working with these materials (40).

(e) *Records:* Maintain records of the amounts of these materials on hand, amounts used, and the names of the workers involved (40, 229).

(f) *Prevention of spills and accidents:* Be prepared for accidents and spills (41).

Assure that at least 2 people are present at all times if a compound in use is highly toxic or of unknown toxicity (39).

Store breakable containers of these substances in chemically resistant trays; also work and mount apparatus above such trays or cover work and storage surfaces with removable, absorbent, plastic backed paper (40).

If a major spill occurs outside the hood, evacuate the area; assure that cleanup personnel wear suitable protective apparel and equipment (41).

(g) *Waste:* Thoroughly decontaminate or incinerate contaminated clothing or shoes (41). If possible, chemically decontaminate by chemical conversion (40).

Store contaminated waste in closed, suitably labeled, impervious containers (for liquids, in glass or plastic bottles half-filled with vermiculite) (40).

4. Work with Chemicals of High Chronic Toxicity

(Examples: dimethylmercury and nickel carbonyl (48), benzo-a-pyrene (51), N-nitrosodiethylamine (54), other human carcinogens or substances with high carcinogenic potency in animals (38).)

Further supplemental rules to be followed, in addition to all these mentioned above, for work with substances of known high chronic toxicity (in quantities above a few milligrams to a few grams, depending on the substance) (47). (Procedure A of "Prudent Practices" pp. 47–50).

(a) *Access:* Conduct all transfers and work with these substances in a "controlled area": a restricted access hood, glove box, or portion of a lab, designated for use of highly toxic substances, for which all people with access are aware of the substances being used and necessary precautions (48).

(b) *Approvals:* Prepare a plan for use and disposal of these materials and obtain the approval of the laboratory supervisor (48).

(c) *Non-contamination/Decontamination:* Protect vacuum pumps against contamination by scrubbers or HEPA filters and vent them into the hood (49). Decontaminate vacuum pumps or other contaminated equipment, including glassware, in the hood before removing them from the controlled area (49, 50).

Decontaminate the controlled area before normal work is resumed there (50).

(d) *Exiting:* On leaving a controlled area, remove any protective apparel (placing it in an appropriate, labeled container) and thoroughly wash hands, forearms, face, and neck (49).

(e) *Housekeeping:* Use a wet mop or a vacuum cleaner equipped with a HEPA filter instead of dry sweeping if the toxic substance was a dry powder (50).

(f) *Medical surveillance:* If using toxicologically significant quantities of such a substance on a regular basis (*e.g.*, 3 times per week), consult a qualified physician concerning desirability of regular medical surveillance (50).

(g) *Records:* Keep accurate records of the amounts of these substances stored (229) and used, the dates of use, and names of users (48).

(h) *Signs and labels:* Assure that the controlled area is conspicuously marked with warning and restricted access signs (49) and that all containers of these substances are appropriately labeled with identity and warning labels (48).

(i) *Spills:* Assure that contingency plans, equipment, and materials to minimize exposures of people and property in case of accident are available (233–4).

(j) *Storage:* Store containers of these chemicals only in a ventilated, limited access (48, 227, 229) area in appropriately labeled, unbreakable, chemically resistant, secondary containers (48, 229).

(k) *Glove boxes:* For a negative pressure glove box, ventilation rate must be at least 2 volume changes/hour and pressure at least 0.5 inches of water (48). For a positive pressure glove box, thoroughly check for leaks before each use (49). In either case, trap the exit gases or filter them through a HEPA filter and then release them into the hood (49).

(l) *Waste:* Use chemical decontamination whenever possible; ensure that containers of contaminated waste (including washings from contaminated flasks) are transferred from the controlled area in a secondary container under the supervision of authorized personnel (49, 50, 233).

5. Animal Work with Chemicals of High Chronic Toxicity

(a) *Access:* For large scale studies, special facilities with restricted access are preferable (56).

(b) *Administration of the toxic substance:* When possible, administer the substance by injection or gavage instead of in the diet. If administration is in the diet, use a caging system under negative pressure or under laminar air flow directed toward HEPA filters (56).

(c) *Aerosol suppression:* Devise procedures which minimize formation and dispersal of contaminated aerosols, including those from food, urine, and feces (e.g., use HEPA filtered vacuum equipment for cleaning, moisten contaminated bedding before removal from the cage, mix diets in closed containers in a hood) (55, 56).

(d) *Personal protection:* When working in the animal room, wear plastic or rubber gloves, fully buttoned laboratory coat or jumpsuit and, if needed because of incomplete suppression of aerosols, other apparel and equipment (shoe and head coverings, respirator) (56).

(e) *Waste disposal:* Dispose of contaminated animal tissues and excreta by incineration if the available incinerator can convert the contaminant to non-toxic products (238); otherwise, package the waste appropriately for burial in an EPA-approved site (239).

F. Safety Recommendations

The above recommendations from "Prudent Practices" do not include those which are directed primarily toward prevention of physical injury rather than toxic exposure. However, failure of precautions against injury will often have the secondary effect of causing toxic exposures. Therefore, we list below page references for recommendations concerning some of the major categories of safety hazards which also have implications for chemical hygiene:

1. Corrosive agents: (35–6)

2. Electrically powered laboratory apparatus: (179–92)
3. Fires, explosions: (26, 57–73, 162–4, 174–5, 219–20, 226–7)
4. Low temperature procedures: (26, 88)
5. Pressurized and vacuum operations (including use of compressed gas cylinders): (27, 75–101)

G. Material Safety Data Sheets

Material safety data sheets are presented in "Prudent Practices" for the chemicals listed below. (Asterisks denote that comprehensive material safety data sheets are provided).

*Acetyl peroxide (105)
*Acrolein (106)
*Acrylonitrile (107)
Ammonia (anhydrous) (81)
*Aniline (109)
*Benzene (110)
*Benzo[a]pyrene (112)
*Bis(chloromethyl) ether (113)
Boron trichloride (91)
Boron trifluoride (92)
Bromine (114)
*Tert-butyl hydroperoxide (148)
*Carbon disulfide (116)
Carbon monoxide (92)
*Carbon tetrachloride (118)
*Chlorine (119)
Chlorine trifluoride (94)
*Chloroform (121)
Chloromethane (93)
*Diethyl ether (122)
Diisopropyl fluorophosphate (41)
*Dimethylformamide (123)
*Dimethyl sulfate (125)
*Dioxane (126)
*Ethylene dibromide (128)
*Fluorine (95)
*Formaldehyde (130)
*Hydrazine and salts (132)
Hydrofluoric acid (43)
Hydrogen bromide (98)
Hydrogen chloride (98)
*Hydrogen cyanide (133)
*Hydrogen sulfide (135)
Mercury and compounds (52)
*Methanol (137)
*Morpholine (138)
*Nickel carbonyl (99)
*Nitrobenzene (139)
Nitrogen dioxide (100)
N-nitrosodiethylamine (54)
*Peracetic acid (141)
*Phenol (142)
*Phosgene (143)
*Pyridine (144)
*Sodium azide (145)
*Sodium cyanide (147)
Sulfur dioxide (101)
*Trichloroethylene (149)
*Vinyl chloride (150)

Appendix B to § 1910.1450—References (Non-Mandatory)

The following references are provided to assist the employer in the development of a Chemical Hygiene Plan. The materials listed below are offered as non-mandatory guidance. References listed here do not imply specific endorsement of a book, opinion, technique, policy or a specific solution for a safety or health problem. Other references not listed here may better meet the needs of a specific laboratory. (a) Materials for the development of the Chemical Hygiene Plan:

1. American Chemical Society. Safety in Academic Chemistry Laboratories, 4th edition, 1985.

2. Fawcett, H.H. and W. S. Wood. Safety and Accident Prevention in Chemical Operations, 2nd edition, Wiley-Interscience, New York, 1982.

3. Flury, Patricia A., Environmental Health and Safety in the Hospital Laboratory, Charles C. Thomas Publisher, Springfield IL, 1978.

3. Green, Michael E. and Turk, Amos. Safety in Working with Chemicals, Macmillan Publishing Co., NY, 1978.

5. Kaufman, James A., Laboratory Safety Guidelines, Dow Chemical Co., Box 1713, Midland, MI 48640, 1977.

6. National Institutes of Health, NIH Guidelines for the Laboratory use of Chemical Carcinogens, NIH Pub. No. 81–2385, GPO, Washington, DC 20402, 1981.

7. National Research Council, Prudent Practices for Disposal of Chemicals from Laboratories, National Academy Press, Washington, DC, 1983.

8. National Research Council, Prudent Practices for Handling Hazardous Chemicals in Laboratories, National Academy Press, Washington, DC, 1981.

9. Renfrew, Malcolm, Ed., Safety in the Chemical Laboratory, Vol. IV, *J. Chem. Ed.*, American Chemical Society, Easlon, PA., 1981.

10. Steere, Norman V., Ed., Safety in the Chemical Laboratory, *J. Chem. Ed.* American Chemical Society, Easlon, PA, 18042. Vol. I, 1967, Vol. II, 1971, Vol. III 1974.

11. Steere, Norman V., Handbook of Laboratory Safety, the Chemical Rubber Company Cleveland, OH, 1971.

12. Young, Jay A., Ed., Improving Safety in the Chemical Laboratory, John Wiley & Sons, Inc. New York, 1987.

(b) Hazardous Substances Information:

1. American Conference of Governmental Industrial Hygienists, Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes, P.O. Box 1937 Cincinnati, OH 45201 (latest edition).

2. Annual Report on Carcinogens, National Toxicology Program U.S. Department of Health and Human Services, Public Health Service, U.S. Government Printing Office, Washington, DC, (latest edition).

3. Best Company, Best Safety Directory, Vols. I and II, Oldwick, N.J., 1981.

4. Bretherick, L., Handbook of Reactive Chemical Hazards, 2nd edition, Butterworths, London, 1979.

5. Bretherick, L., Hazards in the Chemical Laboratory, 3rd edition, Royal Society of Chemistry, London, 1986.

6. Code of Federal Regulations, 29 CFR part 1910 subpart Z, U.S. Govt. Printing Office, Washington, DC 20402 (latest edition).

7. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man, World Health Organization Publications Center, 49 Sheridan Avenue, Albany, New York 12210 (latest editions).

8. NIOSH/OSHA Pocket Guide to Chemical Hazards, NIOSH Pub. No. 85–114, U.S. Government Printing Office, Washington, DC, 1985 (or latest edition).

9. Occupational Health Guidelines, NIOSH/OSHA NIOSH Pub. No. 81–123 U.S. Government Printing Office, Washington, DC, 1981.

10. Patty, F.A., Industrial Hygiene and Toxicology, John Wiley & Sons, Inc., New York, NY (Five Volumes).

11. Registry of Toxic Effects of Chemical Substances, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Revised Annually, for sale from Superintendent of Documents U.S. Govt. Printing Office, Washington, DC 20402.

12. The Merck Index: An Encyclopedia of Chemicals and Drugs, Merck and Company Inc. Rahway, N.J., 1976 (or latest edition).

13. Sax, N.I. Dangerous Properties of Industrial Materials, 5th edition, Van Nostrand Reinhold, NY., 1979.

14. Sittig, Marshall, Handbook of Toxic and Hazardous Chemicals, Noyes Publications, Park Ridge, NJ, 1981.

(c) Information on Ventilation:

1. American Conference of Governmental Industrial Hygienists Industrial Ventilation, 16th edition Lansing, MI, 1980.

2. American National Standards Institute, Inc. American National Standards Fundamentals Governing the Design and Operation of Local Exhaust Systems ANSI Z 9.2–1979 American National Standards Institute, N.Y. 1979.

3. Imad, A.P. and Watson, C.L. Ventilation Index: An Easy Way to Decide about Hazardous Liquids, Professional Safety pp 15–18, April 1980.

4. National Fire Protection Association, Fire Protection for Laboratories Using Chemicals NFPA–45, 1982.

Safety Standard for Laboratories in Health Related Institutions, NFPA, 56c, 1980.

Fire Protection Guide on Hazardous Materials, 7th edition, 1978.

National Fire Protection Association, Batterymarch Park, Quincy, MA 02269.

5. Scientific Apparatus Makers Association (SAMA), Standard for Laboratory Fume Hoods, SAMA LF7–1980, 1101 16th Street, NW., Washington, DC 20036.

(d) Information on Availability of Referenced Material:

1. American National Standards Institute (ANSI), 1430 Broadway, New York, NY 10018.

2. American Society for Testing and Materials (ASTM), 1916 Race Street, Philadelphia, PA 19103.

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