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Part II

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION PREAMBLE TO RULE REGULATING EXPOSURE TO BENZENE

[43 FR 5918, February 10, 1978]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Benzene

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Permanent standard for the regulation of benzene.

SUMMARY: This standard is based on a determination by the Occupational Safety and Health Administration (OSHA) that the available scientific evidence establishes that employee exposure to benzene presents a cancer hazard—specifically, the hazard of developing leukemia. Therefore, in accordance with OSHA's regulatory approach to the control of employee exposure to carcinogens, this standard limits employee exposure to benzene to the lowest feasible level, in this case 1 part benzene per million parts of air (1 ppm) as an 8 hour time—weighted average concentration, with a ceiling level of 5 ppm for any 15 minute period during the 8 hour day. The standard also prescribes limits on eye and skin contact with benzene.

The standard provides for the measurement of employee exposure, engineering controls, work practices, personal protective clothing and equipment, signs and labels, employee training, medical surveillance and record-keeping.

EFFECTIVE DATE: March 13, 1978.

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SUPPLEMENTARY INFORMATION: This permanent Occupational Safety and Health standard is issued pursuant to sections 6(b), 6(c) and 8(c) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1593, 1596, 1599; 29 U.S.C. 655, 657), the Secretary of Labor's Order No. 8-76 (41 FR 25059) and 29 CFR Part 1911. The new standard on occupational exposure to benzene which appears at 29 CFR 1910.1028, applies to all employment in all industries covered by the Act. For reasons set out below, the standard does not apply to the distribution or use of gasoline and other fuels, used as fuels, subsequent to discharge from bulk terminals. Moreover, the standard applies labelling and training requirements only to sealed, intact containers of benzene.

This document also amends Table z-2 of 29 CFR 1910.1000 by adding a footnote which provides that benzene exposures not covered by the new § 1910.1028 are still covered by the exposure level and other requirements of § 1910.1000. Pursuant to section 4(b)(2) of the Act, OSHA has determined that this standard is more effective than corresponding standards now applicable to the maritime and construction industries and currently contained in Subpart B of Part 1910, and Parts 1915, 1916, 1917, 1918 and 1926 of Title 29, Code of Federal Regulations. Therefore, those corresponding standards are superseded by the new standards in § 1910.1028. A new paragraph (c) is added to § 1910.19 to clarify the applicability of this new benzene standard to the construction and maritime industries.

I. Background

Benzene (C_6H_6) is a clear, colorless, non-corrosive, highly flammable liquid with a strong, rather pleasant odor. Benzene's low boiling point and high vapor pressure cause it to evaporate rapidly under ordinary atmospheric conditions, giving off vapors nearly three times heavier than air.

Benzene is produced primarily by the petrochemical and petroleum refining industries by a process called catalytic reformation, which converts certain lower octane hydrocarbons into higher octane aromatics. These two industries are responsible for 94 percent of the total U.S. production of benzene. Recovery through catalytic reformation, including the benzene formed from the hydroalkylation of toluene, accounts for almost 80 percent of the total quantity produced. Recovery of coal-derived benzene, primarily as a by-product of the coking process in steel mills, was once the major source of benzene. Today, however, it accounts for only 6 percent of the total U.S. production.

The production of benzene is rapidly expanding with approximately 11 billion pounds produced in 1976. Only eleven other chemicals and only one other hydrocarbon (ethylene) are produced in greater tonnage in the U.S. Approximately 86 percent of this benzene is used chiefly as an intermediate in the production of other organic chemicals, including styrene, phenol, and cyclohexane. The remaining amount is used primarily in the manufacture of detergents, pesticides, solvents and paint removers. Benzene is also present as a component of motor fuels, averaging less than 2 percent in gasoline.

The first major industrial use of benzene, however, was as a solvent in the rubber industry just preceding World War I. During World War I, benzene production was stimulated greatly by the demand for and resulting production of toluene in the manufacture of explosives. The large quantities of benzene which were produced, resulted in its more widespread use as a starting point for the manufacture of various organic compounds. This situation led to greatly increased uses

whereas the retrospective method detects overt and fatal toxic effects subsequent to termination of employment.

OSHA is aware of the varying quality of the individually reported studies. Based on a review of the entire set of studies, taken as a whole, the accumulated evidence is conclusive that benzene exposure is causally related to the induction of leukemia (a cancer of the blood-forming system), various cytopenias (decreased levels of a formed element in the circulating blood), aplastic anemia (a non-functioning bone marrow) and to development of chromosomal aberrations.

The evidence supportive of this conclusion is derived from: (a) A high degree of association of blood dyscrasias with benzene exposure; (b) the apparent lack of a similar association with other known volatile chemicals in the same workplace; (c) outbreaks of hematotoxicity temporarily related to the introduction of benzene to an industry and conversely, a reduction in blood-related disease when other solvents are substituted for benzene; and (d) the experimental demonstration of marrow toxicity in animals solely exposed to benzene (Goldstein, Ex. 43B, p. 133).

The following studies are representative, although by no means all inclusive, of the published literature on the chronic effects of benzene exposure. These investigations do, however, illustrate the diversity and variability of the effects which dominate published reports. There are also several recent reviews and summaries concerning the hematological effects resulting from benzene exposure (See: Vigliani and Forni, Ex. 2-15; National Research Council, Ex. 2-4; NIOSH, Ex. 2-3, 2-5; NYU report; Ex. 43.B and ORC/Jandl, P.C. 34; Snyder and Kocsis, Ex. 2.B-288, and the International Workshop on the Toxicology of Benzene ("International Workshop") (Ex. 18).

2. *Non-Malignant Blood Disorders.*

a. *Human studies.* The most common effect resulting from chronic exposure to benzene is a decrease in the levels of erythrocytes (red blood cells), leukocytes (white blood cells) and thrombocytes (platelets) in the circulating blood. In simplified terms, a decline in red cells is termed anemia, a decrease in the level of white cells is leukopenia and a decline in the platelet count is called thrombocytopenia. Persons found to have depressed blood cell counts may or may not depending, in part on the severity of the decline, display overt physical symptoms. Anemia results in a decreased capacity of the blood to transport oxygen to various parts of the body, and persons so diagnosed may appear pale and weak and fatigue easily. However, the non-specific symptoms may develop gradually and not require medical attention until there are significant declines in red cell counts and blood hemoglobins. Chronic anemia may also result in physiological adjustments by the cardiovascular system and exacerbate difficulties in those with coexisting disease such as coronary insufficiency or chronic obstructive bronchopulmonary disease (Wintrobe, Ex 2A-107, p. 532). Since white cells provide a defense against many diseases, persons with leukopenia are prone to recurrent infections. Goldstein has written that "Infections are a dreaded complication of bone marrow toxicity and not uncommonly associated with a cause of death in benzene-induced pancytopenia"[1] (Ex 43B, p. 144). Thrombocytopenia results in an impaired clotting of the blood, and persons with this disorder may exhibit bleeding tendencies, such as easy bruising, nosebleeds, and hemorrhage.

Pancytopenia and aplastic anemia are more serious conditions in which all 3 formed elements are depressed. These non-cancerous diseases may, in and of themselves, be fatal. An additional concern is that some or all of these disorders induced by benzene, may, if allowed to continue, either progress to or represent a preleukemia stage which may eventually evolve into a frank leukemia.

Among the early studies describing benzene toxicity was that of Selling (Ex 2-12). He observed a significant depression in the levels of circulating blood cells in workers employed where benzene was used as a solvent for rubber. Because of the depressed condition seen in the marrow of his patients and the results of extensive animal experiments (where he was able to produce both destructive and "regenerative" effects by subcutaneous injection of benzene), Selling suggested that the cause of the cytopenias observed in the workers was due to an aplasia of the marrow.

An important early milestone of the benzene literature was the 1922 report by Hamilton entitled "The Growing Menace of Benzene (Benzol) Poisoning in American Industry" (Ex 159.C).

The document attempted to alert the medical community to the dangers associated with chronic benzene poisoning which was less well known than acute toxicity. This was followed several years later by the reports of the National Safety Council (NSC) which reported the prevalence of known cases by chronic benzene poisoning. These results are summarized by Jandl as follows:

The magnitude of toxicity—primarily consisting of lowered blood cell counts—was

[1] In the NYU review of "A Critical Evaluation of Benzene Toxicity", Goldstein uses the term pancytopenia in a general sense, defined as a decrease in the level of circulatory erythrocytes, granulocytes, and platelets. His rationale is that there is excellent evidence which suggests that all of these cell lines originate from a common precursor stem cell (Exhibit 43B, p. 135). While noting that aplastic anemia is, in a pure sense, an absence or a decrease in identifiable granulocyte, erythrocyte, and platelet precursors within the marrow itself, Goldstein finds that it is useful to include aplastic anemia or hypoplastic anemia under the category of pancytopenia. This is because in some human cases of pancytopenia induced by benzene and in some animal experiments, a hyperplasia of the bone marrow is observed; also there exists the possibility that sampling errors may affect attempts to quantitate bone marrow precursor cells, since only a small fraction of the marrow is observed by aspiration techniques.

However, Jandl feels that aplastic anemia is not a sufficiently explicit term to describe failure of "marrow to provide an adequate population of dividing blood cells for the 3 series of formed elements," and observes that the terminology "aplastic anemia" has been applied to states of chronic or non-acute marrow suppression, whether or not anemia was the most striking feature (ORC/Jandl PC 34, p. 83, Add. 3(i)). Other terms used synonymously have been "hypoplastic anemia, bone marrow failure, refractory anemia and aregenerative anemia." Based on the degree of severity exhibited, Jandl recognizes 2 phases of marrow failure:

"[B]y convention, a diminution in the level of all blood cells produced in the marrow accompanied by evidence that bone marrow cellularity is deficient, but from which recovery occurs, usually, termed 'pancytopenia.' And by convention, a more sustained, more severe, more likely fatal suppression of the marrow is termed 'aplastic anemia.'" (P.C. 26B, p. 83, Add. 3(i)).

OSHA recognizes the usefulness and the technical reasons for Jandl's establishment of quantitative diagnostic criteria for various non-malignant blood disorders and his "reassignment" of diagnoses contained in the literature according to this classification scheme. However, for convenience sake, the terms "pancytopenia" and "aplastic anemia" are used interchangeably throughout the preamble except when discussing particular points contained in Jandl's review. In these instances, the terminology will reflect Jandl's more definitive nomenclature.

noted that these submissions were characterized by the American Iron and Steel Institute as largely "• • • anecdotal in nature" (Ex. 36, p. 64). In further support of its position, industry cites the 1974 NIOSH criteria document recommendation that a 10 ppm TWA as a "conservative limit" (Ex. 2-2, p. 73).

It is clear, there is no dispute that bone marrow toxicity can result from exposure to benzene above 25-40 ppm range. Furthermore, it is recognized that higher dosages produce increased response and that lower dosages are associated with reduced response. It is not clear, what adverse health effects occur below 20 ppm.

There are suggestions of hematological alterations (other than chromosomal aberrations) at concentrations below 25 ppm. Pagnotto et al. indicated that such effects occurred among workers employed in rubber coating industy exposed to concentrations for the most part between 6 and 25 ppm benzene (Ex 2A-116; Tr. pp. 360-361). Horiguchi has reported small changes in leukocyte function concentrations as low as 10 ppm, in the absence of any marrow change and with only slight variations in leukocyte count and leukocyt phagocytic activity among workers exposed to benzene in concentrations of 0.8-6 ppm (Ex 2A-161, p. 7). And there are also other reports of less apparent effects at airborne levels of 6-16 ppm in workers who do not exhibit characteristic hematological abnormalities. (Kahn and Muzyka, Ex 2A-260). It is not possible at this time to establish with any confidence a consistent dose-response relationship between benzene exposure and adverse health effects.

Where exposure information is available, it is generally area sampling and not personal exposure data that is reported. It is difficult to determine individual worker exposure based on area sampling. Compounding this difficulty are problems related to the fluctuating character of occupational exposure; the small amount of long-term data; and the fact that in small populations, workers with heightened sensitivity may not be encountered. At lower exposure levels, there is a paucity of data to provide a basis for definitive conclusions as to the extent of nonmalignant effects. In this regard Battle states that:

> [E]ven a cursory study of the literature reveals a distressing lack of exposure-hematologic effect data particularly in the low benzene exposure area of less than 10 parts per million. (PC 26C, p. 2).

Moreover, the absence of pre-exposure hematological values for comparative purposes limits the usefulness of the few studies and reports which are available, because we cannot tell whether a particular worker studied with blood values at either extreme of the normal range is suffering adverse effects. Therefore, the available literature is insufficient to permit construction of dose-effect curve.

As indicated above, the quality of evidence available in the record is considered insufficient to permit meaningful conclusions concerning exposure to benzene at low levels and resulting health effects. Industry participants have cited the 10 ppm level established by the ACGIH as evidence that this level can be considered safe. However, in establishing TLV's, ACGIH recognizes that for some workers harmful health effects may result from exposure to the toxic substance at levels below the TLV. Therefore, the 10 ppm TLV for benzene is recognized by ACGIH as a level which does not protect all workers from material impairment of health.

Leukemia aside, with benzene we are dealing with an etiological agent well-documented to produce a variety of blood abnormalities, some of which are fatal. OSHA is aware of several studies reporting blood abnormalities at levels below 25 ppm, at levels perhaps as low as 10 ppm. Because of these considerations, and the wide range of human sensitivity to benzene, OSHA cannot determine a minimum effect level for benzene and, furthermore, cannot conclude that 10 ppm provides sufficient protection against non-neoplastic effects to all workers. OSHA recognizes that prudent public health policy, and established toxicological principles necessitates setting the permissible exposure limit sufficiently below the levels at which adverse effects have been observed to assure adequate protection for all exposed employees. It is customary to use a safety factor of 10-100 or greater depending on the seriousness of the toxic effects and the nature of the data being relied upon. That is, the lowest levels at which effects had been observed would be reduced by the safety factor chosen in establishing the exposure limit. Taking this approach in the case of benzene would lead to a permissible exposure substantially less than 10 ppm without regard to the issue of leukemia and the view that no safe level can be established for the carcinogenic risk.

IV. Leukemia

A. Definition and Description of the Disease

Robbins defines leukemia as:

> Leukemia may best be considered as a neoplasm (cancer) of the white blood cells and is so classified in the International Lists of Causes of Death. It is characterized chiefly by: The appearance of abnormal, immature white cells in the circulating blood; diffuse and almost total replacement of the bone marrow with the leukemic cells; and widespread infiltrates of the liver, spleen, and other tissues, analogous to metastatic dissemination of solid tissue cancer. (Ex. 2-24, p. 728).

Once leukemia is diagnosed there is virtually no chance of recovery. There are different categories of leukemia, depending on the duration of the disease, I.E., acute or chronic; an increase or non-increase in the number of abnormal cells, i.e., leukemia or aleukemia; and the cell type involved, i.e., myelord, monocytic or lymphoid. Goldstein also emphasizes that, "there are other differences between various subtypes of leukemia in terms of incidence, clinical course, prognosis and presumably etiological mechanism" (Ex 43B, p. 156).

The most prevalent subtype of leukemia in adults, and the type most commonly associated with benzene is acute myelogenous leukemia (AML). This disease is variously known as acute myeloid leukemia, acute granulocytic leukemia, and acute myeloblastic leukemia (ORC/Jandl, PC 34). There are several variants of AML, probably related to the pluripotential of the precursor cell and include erythroleukemia, (DiGuglielmo's Syndrome) and acute monocytic leukemia (myelomonocytic, or monomyelocytic). (ORC/Jandl, PC 34, p. 71).

Despite advances in leukemia therapy and the fact that half the adults diagnosed with AML enter into a remission (generally averaging 6 to 8 months) the prognosis of this disease remains poor (ORC/Jandl, P.C. 34, p. 73). Those who enter into remission have life expectancies averaging from 12 to 18 months, and those who fail to respond to therapy have a 50 percent survival rate of only 3 to 6 months. Aksoy noted that in his experience, for cases of benzene-induced leukemias, the period of survival after discovery was short, usually less than 6 months (Tr-275).

Myeloproliferative disorders, including chronic myelogenous leukemia (CML) have only occasionally been attributed to benzene. Lymphocytic leu-

the findings of many studies that there is an excess leukemia risk among benzene exposed employees.

Allied Chemical Corp. submitted a post-hearing comment containing mortality data for employees with potential benzene exposure (P.C. 22). Death certificates were obtained for all workers dying between 1961 and mid-1977. Rough exposure information was derived by back extrapolation, limited exposure data, and subjective reports of employees regarding signs and symptoms. Based on these estimates of benzene exposure, there was no observed cluster of leukemia in operations having benzene exposure. Because this study was presented to OSHA after the hearing closed, more specific details concerning the estimate of exposure, the method utilized for obtaining estimates of person-years at risk, or how the death certificates were coded were not obtained.

In 1974, Thorpe reported that the incidence of leukemia, among a population of 38,000 workers exposed to low levels of benzene over a ten year period (1962-1972), was not statistically different from that expected on the basis of the general population (Ex. 2-34). However, the study has been criticized for the relaxed casefinding techniques and analytical methods (Brown, Ex. 2A-35). Thorpe himself acknowledged the following serious methodologic deficiencies:

1. Validity of leukemic diagnoses.
2. Quantitative determination of exposure levels.
3. Adequacy of retiree follow-up.
4. Complete occupational histories.

As in the case of the Tabershaw/Cooper study, OSHA cannot separate the benzene-exposed workers from those with little or no exposure. This difficulty, compounded by the 4 deficiencies listed above, also precludes reliance upon the finding of the Thorpe study.

University of Pittsburgh investigators (Lloyd, Redmond, Ex. 113) have published a notable series of epidemiological studies of steelworkers mortality. *AISI (P.C. 36, pp. 59-60)* cited the above studies as evidence of no leukemia risk among benzene-exposed coke oven workers. Most notably, the industry cited the fact that byproduct plant coke oven workers were not found to have been at excess risk (P.C. 36, p. 60) and recommended that coke ovens be excluded from the benzene standard (P.C. 36, p. 100).

However, as Bickmore stated:

> • • • In all 35, the expected, the incident (SIC) of mortality and expectation is so low as to preclude any meaningful statistical calculations by the professionals that made the study. (Tr. 3314)

These coke oven worker studies were designed to assess worker risk of exposure to coke oven emissions (Ex. 113 p. 1) (P.C. 27C p. 1, P.C. 27D p. 1). Given the small numbers of observed and expected rates of leukemia, and in the absence of a study designed to assess coke oven worker exposure to benzene, OSHA believes it inappropriate to rely on these studies as evidence that there is not a leukemia risk of exposure to benzene.

During the hearing, Stallones discussed the unpublished study of 3,600 Shell Oil Company workers with "potential" benzene exposure (Ex. 115C.2). Among this population he testified that he observed no excessive leukemia mortality in the three year period ending in 1976. Stallones could not determine how many workers were exposed to benzene. In fact, clerks and officer workers were included in the study group. Again, failure to correctly identify or define a benzene-exposed cohort limits the usefulness of this study.

A series of published and unpublished epidemiologic studies investigating the mortality experience of rubber workers have been entered into the hearing record. (McMichaels et al. Ex. 2-36, -37, 2B-295); Monsan and Nakano (Ex. 2-83); Fox et al. (Ex. 2-61); Andjelkovic (Ex. 2-54); Occupational Health Studies Group, UNC (Ex. 187.B). These studies have, in general, shown excess of lymphoma and leukemia among rubber workers. The leukemia was predominantly lymphatic, a cell type not commonly associated with benzene. The proportion of rubber workers actually exposed to benzene in these studies is undetermined. The presence of other chemical exposures raises the question of an alternative causative agent for the excess of lymphatic leukemia and lymphoma observed among rubber workers. In view of these considerations, these studies provide no additional evidence for the leukemogenic potential of benzene.

There has been discussion whether benzene is a *primary carcinogen* (can directly effect a neoplastic alteration without host-mediated activation); a *secondary carcinogen* (chemicals which may increase susceptibility of cells, to a primary carcinogen); a *procarcinogen* (requires biochemical alteration prior to effect); or a *co-carcinogen* (which requires the interaction of another chemical to elicit a neoplastic response). (Olson, Tr. 2892; NRC, Ex. 2-4, p. ii; API/NPRA Brief, P.C. 33, p. 86-87; Aksoy, Tr. 177; Furst, Tr. 1744; Stockinger; P.C. 32-H, 53); Weisburger, P.C. 32-I; Tabershaw Tr. 2549, 2545). The evidence is, at present, insufficient to choose among these alternatives. Namely, what is apparent, however, is the effect of benzene exposure—a significantly increased risk of death from leukemia.

Types of leukemia clearly associated with benzene exposure include acute myelogenous leukemia (AML) and its variants. For example, Aksoy testified that among 40 cases of leukemia among benzene-exposed workers in Turkey, AML and its variants were the most frequently observed form (Ex. 60, p. 7). In the experience of Vigliani and his coworkers, only acute or subacute myelogenous leukemias were observed (Ex. 2-49). The predominant cell type found by Infante (Ex. 2A-271) and others were also myelogenous in character. This well-established association between benzene and AML is in concert with the well-known toxic effects of benzene on bone marrow stem cells (Goldstein, Ex. 43B, p. 162).

In contrast to the definitive relationship between benzene and the induction of AML and its variants, there is considerable scientific debate concerning the association between benzene exposure and the development of chronic forms of leukemia (CLL and ML). Jandl has stated that "• • • lymphoid leukemia is not a feature of benzene toxicity." (ORC/Jandl, P.C. 34, p. 59), and Lamm ruled out chronic leukemia, not as a "possibility", but as a "probability" (Tr. 2558). Aksoy found no cases of CML among the workers he studied. (Ex. 60, p. 6-F), and no cases of CLL were seen by the Italian investigators. A different result has been reported by several French studies which have reported a relatively high incidence of CLL. In some instances, there were more cases of CLL than AML. They also report a higher incidence of CML than would be expected based on Aksoy's and Vigliani's findings. Supporting the high incidence of CLL in the French studies is the report by Tarreef which describes

lationship of benzene to the induction of leukemia. Although these studies, for the most part involve high exposure levels, it is OSHA's view that once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population. OSHA therefore believes that occupational exposure to benzene at low levels poses a carcinogenic risk to workers. The Agency, however, recognizes that not all individuals exposed to benzene will suffer harmful effects. The benzene record establishes that there may be individual effect levels. However, there is no way of ascertaining which workers in any exposed population are susceptible and to what levels.

OSHA further recognizes that determinations of carcinogenicity are normally based on animal studies, and when available, human evidence. OSHA acknowledges that, at the present time, there is no unequivocal animal model demonstrating the induction of leukemia. However, the lack of an animal model does not diminish the conclusive nature of human evidence demonstrating benzene's leukemogenicity.

OSHA acknowledges that there are many unresolved issues concerning the relationship between benzene exposure and leukemia:

Whether benzene is a co-carcinogen, a procarcinogen, etc.

Whether benzene exposure is causally related to induction of forms of leukemia other than AML and its variants.

Whether blood dyscrasias, such as aplastic anemia always precede benzene leukemia.

To what extent are leukemia deaths attributable to occupational exposure to benzene.

What factors identify a sensitive population.

These questions are on the frontier of scientific and medical knowledge and, given the mandate of the Act, OSHA cannot wait for answers while workers are exposed to this life—threatening substance. There is no doubt that benzene is a carcinogen and must, for the protection and safety of workers, be regulated as such. Given the inability to demonstrate a threshold or establish a safe level, it is appropriate that OSHA prescribe that the permissible exposure to benzene be reduced to the lowest level feasible.

4. *Chromosome studies.* OSHA has examined both the original literature of benzene-induced chromosomal changes and the material contained in recent reviews of the subject (NRC Report, Ex. 2-4, section entitled: Chromosome Effects; Forni, Ex. 156.H and; Wolman, NYU Report Ex. 43.B, Chapter VI). Evidence derived from human studies together with similar results obtained from experimental investigation clearly demonstrates that benzene can induce visible damage to chromosomes in lymphocytes and blood-forming cells. For example, Tyroler noted that: "I think there is rather convincing evidence that the chromosomal aberrations are associated with exposure to benzene." (Tyroler, Tr. 3100; also see International Workshop, Ex. 17, p. 6). The effects may be manifested as numerical alterations and/or structural rearrangements of the chromosomal material and include additions or deletions of chromosomes, segments of whole chromosomes or chromosome sets, in addition to exchanges which result in morphologically aberrant chromosomes (Wolman, NYU Report, Ex. 43.B, p.—). Forni has observed that the aberrations produced by benzene exposure are non-specific and are similar to those produced by ionizing radiation. (Ex. 156.H). To what extent these events are detrimental to human health is not known.

a. HUMAN STUDIES

There are numerous reports on chromosomal evaluations in worker populations both with and without clinical symptomatology resulting from exposure. In general, these studies reveal that there are statistically significant increases in chromosomal damage in those occupationally exposed to benzene. The chromosome alterations have been classified as either unstable changes (i.e., fragments, dicentric, tricentric and ring chromosomes) and stable changes (i.e. abnormal monocentric chromosomes due to deletions, translocations, inversions and trisomies). Aneuploidy (abnormal chromosome number) and/or polyploidy (a multiple chromosomal set) have also been observed. The early reports focused on the examination of workers exhibiting benzene hemopathy (a disease of the blood). As early as 1964 Pollini and Columbi published such a study. (Ex. 2-17). Examination of cultured bone marrow cells and peripheral lymphocytes showed increased frequencies of aneuploid cells and structural aberrations. A second study by the same group (Ex. 2-4, reference 50) of 4 patients with temporary or progressive blood dyscrasias revealed that the incidence of heteroploid (abnormal number) chromosomal patterns ranged around 70% both in the blood and in the marrow of each subject. The authors were, however, unable to establish a correlation between the duration and degree of exposure and either the frequency of chromosome aberration or the degree of toxicity. Other cytogenetic studies of subjects with benzene-related hemopathies have yielded similar findings (e.g. Forni and Moreo, Ex. 2-18 and 2-19, Sellyei and Keleman, Ex. 2A-258; Aksoy et al., Ex. 2-57; and Erdogan and Aksoy, Ex. 2A-192). Variables which make these case reports difficult to interpret and compare include: differential diagnoses, the use of lymphocytes artifically stimulated to grow in some cases and bone marrow cells in others; the occasional lack of "normal" baseline chromosomal breakage frequency; and the occurrence in some cases of pre-existing familial chromosome aberrations (Wolman, Ex. 43-B, p. 129). In spite of the limitations of these reports, Wolman has stated that some trends have been observed—additional chromosomes have been identified in several reports, tetraploidy (4 sets of chromosomes) or polyploidy were seen in some cases and in many instances an increased frequency of chromosome breakage was reported but not well documented. Wolman states that:

the clearest picture of the relationship between benzene exposure and chromosomal changes emerges, not from experimental studies or reports of human disease, but from studies of occupationally exposed workers (Ex. 43.B, p. 130).

The National Research Council (Ex. 2-4) considers the 1969 study by Vigliani and Forni (Ex. 2-20) to be one of the most systematic of this type reported. The results of cytogenetic analysis of 25 subjects who had recovered from benzene hemopathy were compared to the findings of controls matched for sex and age. In most cases, increased ratios of both stable and unstable chromosome aberrations were still present several years after cessation of exposure to benzene and/or recovery from poisoning, whereas the hematological analysis revealed normal blood counts in most cases. Follow-up cytological analyses of these subjects showed an overall decrease in unstable changes, and generally, a persistence or an increase in stable alterations. Other cytogenetic surveys of workers industrially exposed to benzene are: (Forni et al., Ex. 2-20; Girard et al., Ex. 2-40; Hartwich and Schwanitz, Ex. 217-129; and Vigliani and Forni, Ex. 2-14).

OSHA is also aware of several cytogenetic studies of workers chronically exposed to airborne concentrations of benzene probably less than 25 ppm. Several indicate an increase in chromosomal damage (Hartwich and Schwanitz, Ex. 129; Girard et al., Ex. 2-65 or 2-283, and Berlin et al. Ex. 2A-218) while others present negative findings (Forni, Ex. 156.H; Tough et al., Ex. 2-21B, and Burgatti, Ex. 2A-226).

The final standard provides for medical surveillance in addition to semi-annual routine blood testing. Where routine medical surveillance reveals an abnormal blood picture, the employer is required to refer the employee to a hematologist. Where emergency situations occur, the employer is required to provide a urinary phenol test and, if urinary phenols are elevated, a repeat complete blood count (CBC); if the CBC reveals abnormalities then the employee must be examined by a hematologist. The cost of these non-routine examinations was not estimated by ADL since they would not have been required by the proposal. There is, of course, no certain way of determining the number of employees who will need examination by a hematologist. To calculate these additional costs, therefore, OSHA has assumed that 5% of all employees will have abnormal blood pictures and will be re-referred to a hematologist, and that the added cost will be $100 per referral.

Other Costs

Total costs for other compliance activities, such as engineering controls, respirators, training, and signs and labels have also been assessed. These costs are based essentially on the cost factors furnished by ADL since the ADL costs were generally accepted by industry participants.

Capital costs for engineering controls have been determined for industries with operations above the permissible exposure limit on the basis of the type of engineering controls available for the individual industry. Many of the industries covered by the benzene standard involve the storage and movement within a closed system of liquids containing benzene in various concentrations. Emissions occur at such points as pumps, pipe line joints, compressors, sampling points, and gauging stations. (Vol. 1, 4-35). Engineering controls for these systems consists of replacing worn pumps and compressors with equipment specifically designed to minimize emissions, replacing gaskets to ensure tight fit of joints, welding joints, and the installation of automative gauging and closed loop sampling devices. Specific units of these systems have been costed by ADL and aggregate costs shown below are based on an estimated number of these units which are required for a typical plant. To determine respirator costs, OSHA has used ADL's cost per employee for respirators. (Vol. II C-8, 9). For personal protective equipment, which is required by the standard for employees who may be exposed to eye or repeated dermal contact with benzene, the cost of $13.16 per employee per year has been used. This cost in[illegible] loves, apron, face- [illegible] 8).

Training costs, which include costs for preparation, materials, employee's time, and instructor's time, have been estimated at $110 per facility plus $14 per employee (Vol. II C-11).

In calculating recordkeeping cost, OSHA has utilized the ADL cost factor (Vol. II C-12) for record maintenance but adjusted this cost to reflect the decrease in the records required by the final standard. In its testimony, AISI expressed the view that recordkeeping would require the addition of one record clerk per facility (Tr. 3165-317 I). However, the final standard significantly reduces the monitoring records and eliminates medical records for employees whose exposure is below the action level. Therefore, application of ADL's cost formula will give a reasonable approximation of the recordkeeping burden.

For most firms, a normal cost for labels has been determined on the basis of ADL's cost of estimate (Vol. II, C-13). No cost has, however, been determined for signs. Detailed data on a plant-by-plant basis were not available to OSHA. Therefore, no costs for this compliance activity are included within the cost estimates shown herein. OSHA recognizes that these costs will occur but is of the opinion that they will be relatively small for all firms covered.

Compliance costs for the following industries have been calculated by OSHA using the compliance factors described above.

Petroleum Refineries

It is estimated that petroleum refineries will incur greater compliance costs than any other industry sector. This is primarily due to the large number of refinery workers who are exposed to petroleum products, almost all of which contain benzene. There are 48 refineries engaged in the production of benzene and 275 refineries which do not produce benzene but maintain process streams with benzene concentrations.

At the 48 refineries which produce benzene, there are approximately 1,440 exposed workers. On the basis of the exposure data made available by ADL and industry witnesses, it appears that approximately 20% of these employees are exposed above the permissible exposure limit. OSHA has, therefore, applied the ADL sampling protocol and calculated costs on the assumption that initial measurement will show approximately 300 workers exposed above the permissible exposure limit. The remaining exposed workers were divided for cost calculation purposes. Capital investment to reduce exposure levels has been estimated at approximately $24 million extrapolating from a model plant analysis. This cost [illegible] ment of seals (ADL, E-1) and similar indicated improved maintenance and repair. No estimate is made for shut down time since it is anticipated that any controls including modifications of pumps and compressors, would be installed during normal down time (Tr. 536). OSHA does not concur in the API view (Scarborough statement p. 36-7) that additional down time is needed since normal maintenance procedures of highly flammable material require purging of lines, and replacement of seals, pumps, etc. First year operating costs for these refineries are estimated at approximately $600,000.

Cost estimates for the 275 refineries which do not produce benzene were based on API's and ADL's data as to 98,000 exposed employees. (ADL, Vol I, p. 419; add API reference for that number). ADL relied in part on the results of an API questionnaire which indicates a wide range of exposures from negligible to as high as 25 ppm. (ADL pp. 4-16 to 4-17). API's witness indicated that exposures at refineries were very low with most below the proposed permissible exposures limit and many below the action level (Tr. 1467-1468). Other testimony indicates similar exposure patterns (Grospiron statement, pp. 4-6). The API post hearing submissions suggest that refinery workers move frequently from one post to another so that they are not exposed to hydrocarbon vapors for extended periods of time (API, PH5). Initial monitoring results showing 8 hour TWA measurements of 0.13 ppm and lower were cited by API. (API PH 8-9.) In the face of conflicting data of this sort, it was assumed that approximately 5,000 workers initially could be found to be exposed above the permissible exposure limit, that approximately 5,000 would be exposed at levels between the permissible exposure limit and the action level, and that the remaining 88,000 would be below the action level. This distribution indicates somewhat higher exposure levels that API's testimony suggests, but lower levels than the results of the API questionnaire survey might be construed to indicate and is, therefore, intended to be a reasonable estimate. Using this distribution, OSHA estimates first year operating cost for compliance to be approximately $12.8 million. It may be noted that approximately $2 million of the indicated first year cost is for exposure measurements. Since many refineries have apparently made such measurements, actual first year compliance costs may be substantially lower than the estimates listed herein.

The cost of capital investment in engineering controls is estimated to be $110 million, for control of leaks from seals and valves, control of sumps and [illegible] disposal areas and control of

basis of the quality and cost of available substitutes. OSHA believes that th[illegible]soning followed by ADL in this qua[illegible]ative analysis is reasonable.

Using an estimate of relatively inelastic demand for benzene (elasticity = −0.5) (ADL pp. 6-11) and an estimated price increase of approximately 1 percent, ADL estimated that demand for benzene would fall by approximately 0.2 percent (16 million pounds) in the short run and by approximately 0.5 percent (54 million pounds) in the long run for refineries and steel companies producing benzene. Since the demand for benzene is growing moderately, these decreases would represent a slight decrease in the amount of growth, rather than an absolute decline from current levels of production. Foreign trade accounts for only 5 percent of U.S. supply and is not expected to be a significant factor affecting domestic producers, considering the small projected change in price.

The price of benzene is determined by petroleum refiners, who supply 95 percent of the market. Since coke oven producers will incur higher compliance costs than the benzene producing refineries, they will be able to recover only part of their costs through price increases and will be adversely affected by the standard. It appears probable that some producers of benzene from coking operations will choose to sell their light oil to other firms rather than continuing to produce benzene (AISI). Similarly, some refineries now producing benzene may elect to change their product mix to eliminate benzene production. These decisions will be made by benzene producers on the basis of many factors affecting the profitability of benzene production and not on the basis of the impact of this standard alone.

No data were submitted in the hearings that provided a basis for estimating the number of firms that may eliminate benzene production. It was not contended, however, that any producing firm will be forced to close or be forced into an unprofitable position as a result of the compliance costs associated with this standard.

Impact of Price on Employment and Productivity

Since ADL projected no absolute decrease in total production of benzene, it did not project employment losses for benzene producers. API witnesses questioned this on the basis of their challenge of the analysis of demand elasticity, price change, and reduction of demand. (Scarbrough, pp. 24-25; Henderson) OSHA reasons, however, that if these elements of the analysis are acceptable, the conclusion that production employment will not decline is valid, although some reallocation due to structural changes in the industries may occur.

API also argued that increased labor cost resulting from compliance programs could lead to some substitution of capital for labor. (Henderson, p. 10) In its testimony, ADL pointed out that the productivity of both labor and capital would decline in the same order of magnitude and that this would indicate that substitution would not occur. (TR p. 584) ADL also submitted that the industry sectors in question are quite capital intensive and that for this reason, "it is not anticipated that the proposed regulation would have any observed effect upon the utilization rate for labor in these industries." (ADL post hearing. Ex. 15N)

OSHA recognizes that some decline in overall labor productivity may result from adding compliance personnel such as technicians and hygienists to the work force of benzene producers, although the direct productivity of production workers is not affected. This decline was estimated by ADL to be approximately 1.4 percent for coke producers and 0.6 percent for refineries (ADL, Ex. 5A, Table 6.5, p. 6-16).

Benefits

The legislative history and language of the Occupational Safety and Health Act, as distinguished from some other environmental and safety legislation, clearly indicate that Congress has already arrived at a judgment concerning the balancing of cost and benefit, with the result that worker safety and health are to be heavily favored over the economic burdens of compliance. Specifically, Section 6(b)(5) of the Act provides that

> the Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments and such other information as may be appropriate. In addition to the attainment of the *highest degree of health and safety protection* for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

Thus, while feasibility is an appropriate consideration, the Secretary is directed to set standards which attain the "highest degree of health and safety protection for the employee * * *."

This does not mean, however, that a systematic evaluation of costs and benefits is not to be encouraged within the limits of the estimation techniques. In considering the issue of feasibility in this rulemaking, as in others, OSHA has carefully evaluated the cost of compliance which may be incurred by the directly affected employers and their ability to comply. Additionally, OSHA believes that a standard for a substance which has been found to pose a cancer risk to workers, in this case benzene, must assure maximum benefit (i.e., prevention of serious illness or death), constrained only by the limits of feasibility.

There is general agreement that benzene exposure cases leukemia as well as other fatal diseases of the bloodforming organs. In spite of the certainty of this conclusion, there does not exist an adequate scientific basis for establishing the quantitative dose response relationship between exposure to benzene and the induction of leukemia and other blood diseases. The uncertainty in both the actual magnitude of expected deaths and in the theory of extrapolation from existing data to the OSHA exposure levels places the estimation of benefits on "the frontiers of scientific knowledge." While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number may be appreciable. There is general agreement that even in the absence of the ability to establish a "threshold" or "safe" level for benzene and other carcinogens, a dose response relationship is likely to exist; that is, exposure to higher doses carries with it a higher risk of cancer, and conversely, exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established. In light of the uncertainties in this area of scientific knowledge, OSHA believes that it is required by prudence and by the statutory mandate to adopt a highly protective posture in considering the evidence for health benefits.

Various witnesses argue that cost benefit or cost effectiveness should be the primary criterion for regulatory decision. OSHA was criticized by industry participants for failure to consider what benefits would be derived from reducing the current permissible exposure level for benzene (API brief, page 92, 96; AISI brief, page 89, 97). The Council on Wage and Price Stability (CWPS) also suggested that OSHA estimate the incremental reduction in health risks which are associated with the reduction in employee exposure to benzene (Bosworth letter, 9/12/77, to Bingham).

Both CWPS and industry suggested ways in which this could be achieved. CWPS suggested that OSHA apply the expected lifetime incidence rates of leukemia and the increased incidence rates revealed by the scientific studies to the benzene exposed population to derive the number of expected

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regulatory action to be taken on non-gasoline motor fuels after review of the data and recommendations of the joint Federal task force and evaluation of the information furnished in response to OSHA's notice on gasoline. For these reasons, OSHA has exempted from the permanent benzene standard the storage, transportation, distribution, dispensing, sale or use as a fuel of all fuels (including gasoline, jet fuel, and diesel fuel) subsequent to their discharge from bulk terminals.

Closed Systems

Some participants requested exemption from the standard for workplaces where benzene is present solely in closed systems. The record evidence, however, indicates that closed systems frequently develop leaks, and that it is the amount of the solvent exposed to air (Tr. 3111-3) which, among other variables, is a major determinant in the degree of exposure. Accordingly, OSHA has retained coverage of closed systems in the final benzene standard. However, in the absence of leaks, exposures from closed systems should be below the action level and the impact of the standard in such operations should be minimal.

Laboratories

Still another segment of industry requested an exemption from the benzene standard. Many comments requested that research facilities in both industrial and academic laboratories be exempted from the benzene standard (Com. Nos. 14, 20, 57, 62, L.C. 12, L.C. 13) particularly where the permissible exposure limit is not exceeded (Com. 56, 58). Some comments suggested that separate requirements be developed for laboratory use of benzene (L.C. 12, L.C. 13). These requirements could include mandatory use of hoods (L.C. 9, Com. 21) of a specified velocity (L.C. 8, Com. 18) and periodic medical surveillance (Com. 18, 28, 29, 64, 70); annual inspection in lieu of monitoring (Com. 28); written safety rules (Com. 18) and container labeling (Com. 39) were also suggested. In the alternative, it was suggested, OSHA should promulgate separate regulations for all chemicals used in laboratories (L.C. 12, L.C. 13), since laboratories use a variety of chemicals, and compliance with separate regulations for each chemical, it was argued, would be burdensome (Com. 58).

The requests for exemption from the benzene standard or for special treatment of laboratories were largely based on the view that there exists a lesser, or slight, risk of exposure to benzene for laboratory technicians. In support of this contention, laboratories pointed to the manner in which they use benzene. Laboratories, it was stated, generally use small quantities of benzene at a time (Com. 10, 28, 38). One laboratory reported that sometimes a sample is dissolved in only one ml of benzene (L.C. 2). That laboratory estimated that an individual laboratory technician, who analyzed 25 samples per day, 7 days a week, would use less than four gallons of benzene a year (L.C. 2). When not in use, benzene is stored in closed containers (L.C. 1).

The argument that laboratory technicians are trained in the hazards of chemicals was also made to support the view of lesser risk. One laboratory reported that it conducted blood tests every four months for twenty years of its technicians, and found no problem (Com. 4). Another reported that in thirty-five years, none of its employees developed leukemia even though exposures in the laboratory were between 1 and 20 ppm (Com. 31).

Another reason advanced for exemption or separate treatment of laboratories was the burden and cost of implementing exposure monitoring, engineering controls and medical surveillance (Com. 4, 5, 10). One industry comment argued that responsible research and quality control laboratories normally provide and encourage annual physical examinations that include the essentials of the proposed medical surveillance program (Com. 38).

OSHA has determined that applying the provisions of this benzene standard to laboratories is consistent with OSHA's responsibility to protect the health and safety of workers. The record indicates that exposure levels in laboratories vary greatly. While monitoring samples of one laboratory indicated levels of only .01 ppm (Com. 28), others indicated levels as high as 20 ppm (Com. 31; Ex. 39-3). Furthermore, it appears that protective measures vary from lab to lab (Tr. 3157). One chemist, who worked frequently and for several hours a day with benzene during his six years in a research lab that he described as "one of the most prestigious research institutions in the country," testified that employee exposures were not measured, hoods were not used, and there was no medical surveillance program (TR 3492-6). Moreover, there does not appear to be any firm basis to believe that training alone in handling of chemicals adequately protects all laboratory employees from the hazards of exposure to benzene.

Based on the above evidence, OSHA believes that laboratory employees are exposed to the leukemogenic hazards of benzene and, therefore, must be covered by this standard. OSHA does not subscribe to the view that laboratories should be exempted from the benzene standard and that protection for employees exposed to benzene should await promulgation of separate regulations for all chemicals used in laboratories. OSHA is not currently developing a laboratory standard, and the result of exemption of laboratory workers from the benzene standard would, consequently, deprive them of the necessary protection against the hazards of benzene exposure for some time to come. Furthermore, the provisions of the standard relating to methods of compliance are performance oriented and, therefore, will encompass the suggested special requirements for laboratories. For example, the requirement that the employer institute engineering controls and work practices could be met by laboratories in many instances through the use of properly designed hoods. Also, the inclusion of an action level will minimize the monitoring and medical surveillance requirements in laboratories where employee exposure measurements indeed are low.

Although OSHA has not included special provisions just for laboratories, the provisions of the standard accommodate several of the suggestions of the participants, as noted above. Those laboratory operations where benzene exposure levels are at or below the action level will need to be monitored only initially, and medical surveillance of employees engaged in those operations will not be required. When benzene is sealed in containers, the laboratory employer will be required only to train his employees in the hazards of exposure to benzene, and assure that the container is properly labelled, and provide protective clothing where necessary.

Coke Oven Batteries

Steel industry participants requested an exemption from the benzene standard for coke oven workplaces which are covered by the coke oven emissions standard. Although coke oven emissions at coke oven batteries are regulated by § 1910.1029, it is OSHA's view that there is a need to apply to these workplaces the requirements of the benzene standard, as well. The coke oven standard regulates the benzene soluble fraction of total particulate matter present during the carbonization of coal for the production of coke to protect workers from the risk of developing cancer of the lung and urinary tract. The coke oven standard, however, was not designed to protect coke oven employees from the hazards to the hematopoietic system which can result from exposure to benzene. Benzene exposure can occur from leaks in the ovens or in the collection system or from residual vapors left in the ovens when they are opened and the hot coke is pushed out (Little study, B-21). Accordingly, in order to protect workers from the hematopoietic hazards presented by exposure to benzene, OSHA has concluded that inclusion of all coke oven workplaces in the benzene standard is necessary.

The unloading and loading of gasoline, crude oil, and other refined products from marine vessels results in limited exposure to shoreside personnel ranging between 0.01 ppm. to 0.82 ppm. with an 8 hour TWA of .2 ppm. (Tr. 2271.) The shoreside personnel's potential for exposure occurs during the connecting and disconnecting of the hoses and loading arms, an activity of limited duration. (Fuller Ex. 115, A.3, p. 4.) The unloading and loading of benzene from marine vessels, however, may result in higher employee exposures. The transportation by barge accounts for the majority of the total benzene transported. (A.D. Little, Ex. 5A, 4.24, 4.42.) The connecting and disconnecting, opening and closing of valves and the monitoring of fill levels are the typical operations in which employees will actively be involved. These operations are all of limited duration and, consequently, employees would spend little of their time involved in them. The remainder of the employees' time would be spent elsewhere removed from exposure. Therefore, work practice controls would be extremely effective in reducing employees' exposures to benzene during the unloading and loading of marine vessels. (A.D. Little Vol. 1, May 1977 p. 4.27.)

One methodology discussed to reduce exposure to vapors is a marine vapor recovery system (Fuller, Ex. 115-A.3). However, at the present time, questions concerning fire and explosion risk, and potential structural damage to barges have, not as yet, been adequately resolved.

The exposures measured during the unloading of gasoline at bulk terminals are low. Sexton, an industry spokesman, reported that the highest long-term samples on individual truck operators was 0.41 ppm., with the vast majority being below 0.2 ppm. (Ex. 115-A.10.) These terminals from which the exposure data was obtained represent examples of the various types of truck loading techniques and different physical characteristics of the terminals, such as loading rates, covered versus uncovered loading racks, and floating roof tops.

Data presented by Williams Pipeline also showed exposure levels, for the most part, below 0.5 ppm. on an 8 hr. TWA basis. It, therefore, appears that one or a combination of these available engineering controls will be sufficient to reduce employee exposure below the permissible exposure limit.

Approximately 94% of the benzene produced is derived from petroleum through the process of catalytic reforming, recovery from pyrolysis of gasoline and hydroalkylation of toluene. Many of the processes used to produce benzene involve completely enclosed units such as reactors. However, these processes do contain vents and other sources of leaks, which can result in significant exposures (A. D. Little, Vol. II-B11).

Control of emissions can be accomplished by such activities as removal and reinstalling equipment such as pumps, compressors, machining of parts, cutting and welding of piplines, fabrication of equipment, replacement of gaskets. Also, the use of automatic gauging devices, closed loop sampling systems, vapor recovery units, floating roof installations and rupture discs has been suggested (Ex. 5A, 4-53).

The majority of employees exposed at petrochemical plants are already within the permissible exposure limit. (Ex. 111-A, pp. 4-7.) At only four of twelve plants surveyed, exposures were above 1 ppm. (ADL. May 1977 p. 10, Table 2), and of those four plants only two were above 5 ppm. The fact that eight of those twelve plants were already within the permissible exposure limit suggests that other plants can be rehabilitated with existing technology to achieve levels within 1 ppm.

The record indicated that exposures to benzene vary between 0.1 ppm and 20 ppm. (Com. 28, 31). The differences in exposure levels appear to be due to the particular protective measures employed in the laboratory. (Tr. 3157, 3492-6). On the basis of this evidence, OSHA has determined that the use of a properly operating laboratory hood is one available engineering control which is currenty reducing employee exposures (See ADL 4-41) well below the permissible exposure limit. The type of control selected will be dependent upon the individual laboratory. (ADL May 1977 pp. 4-40 and 4-41.)

The two segments of the steel industry wherein benzene exposure occurs are the coke oven battery and the light oil distillation plants. Exposures at the coke oven batteries range between 0.02 ppm and 0.31 ppm. (Ex. 135 p. 4 and Attachment 2). It is thus apparent that the steel industry's compliance with the Coke Oven Emission Standard will maintain benzene exposures well below the action level.

Within the distillation plants, equipment is used to distill the benzene out of the light oil. It is in this operation that the steel industries claim that in certain situations it will not be feasible to reduce exposures through engineering controls. It appears, however, that those situations are limited to the older "coke driven by-products plants" (between 30, 40, and 50 years old). (PC 36 AISI Brief, p. 87-88) and does not exist for the newer plants which currently have low exposure levels.

As the Courts of Appeals have emphasized, OSHA is not restricted to the status quo. Standards may be set which require improvement in existing technologies or which require the development of new technology and OSHA is not limited to setting standards based solely on devices currently available, at least where new technology appears on the horizons to limit exposures below the permissible exposure limit. (See e.g. *Society of Plastics Industry* v. *U.S. Department of Labor*, 509 F. 2d 301 (C.A. 2. 1975) cert. denied.) Certainly here, the evidence indicates that technological controls to reduce exposures, if they are not universally used, do exist (Ex. 5A, 4-37).

Benzene exposure may occur in a variety of industries when solvents containing small quantities of benzene are utilized. Some examples are the rubber industry, the manufacture and use of adhesives, paint manufacturing and application, metal can production and commercial printing. Evidence in the record indicates that, with the exception of paint remover firms for the most part have restricted the use of benzene as a raw materials. It appears, therefore that the percent of benzene coupled with presently available engineering controls, such as local exhaust systems, results in minimal employee exposures, (May 1977 ADL p. 4-27, 4032).

Based on the record of the benzene rulemaking, OSHA has concluded, as indicated above, that the permanent benzene standard is technologically feasible. Furthermore, OSHA has determined that this standard better effectuates the purposes of the act than the national consensus standard for benzene.

Dermal and Eye Exposure Limits: Paragraph (c)(2). The final standard, like the emergency temporary standard and the proposed standard, prohibits all eye contact and skin contact with liquid benzene. This requirement is based on OSHA's policy that, in dealing with a carcinogen, all potential routes of exposure (i.e. inhalation, ingestion, and skin absorption) be limited to the extent feasible.

Although the record evidence does not conclusively establish what the effects of contact with benzene are on the eyes or the skin, participants generally did not oppose a requirement for restricting such contact. Indeed some participants indicated that they already provide protective clothing and equipment to their employees in order to protect them from possible hazards of contact with liquid benzene.

The record evidence on the effect of liquid benzene on the eyes or the skin is extremely limited. No scientific data as to the effects of benzene on the eyes was presented during the rulemaking proceeding. The few studies of skin effects on animals and humans (Ex. 2-48, 2-47, 2-48, TR 2459-90) are not definitive as to the extent of benzene that is absorbed through the intact skin or as to the comparative

result. Redetermination of exposure must also take place after the cleanup of spills and the repair of leaks, ruptures or other breakdowns. One comment suggested that redetermination not be required in these instances (L.C. 19). OSHA has not adopted this suggestion. Spills, leaks, etc., can result in very high exposure levels (Tr. 1299; P.C. 30, p. 48), and the requirement to redetermine exposures after cleanup or repair provides one method of ascertaining that proper corrective methods have been instituted and employee exposures are not significantly altered.

The final standard further requires that employers notify each of their employees of the exposure measurement which represents that employee's exposure. This requirement is discussed in detail under Recordkeeping.

It should also be noted that paragraph (m) of the standard requires the employer to allow employees or their designated representatives an opportunity to observe the monitoring. The specific provisions of paragraph (m) are discussed below.

Methods of compliance: paragraph (f). The final standard, as the proposed standard, requires employers to institute engineering and work practice controls to reduce employee exposure to benzene to or below the permissible exposure limits, except to the extent that such controls are not feasible. This requirement is in accord with OSHA's policy that feasible engineering and work practice controls must be used as the primary methods of reducing employee exposures. This policy is based on the view that the most effective means of controlling employee exposures is to contain concentrations at their source through use of mechanical means combined with work practices rather than reliance on the variability of human behavior so critical to the successful use of respirators. Thus, the standard also provides that, in situations where feasible engineering controls and work practices are insufficient to reduce exposure to the permissible limits, the controls must nonetheless be used to reduce exposures to the lowest achievable level, and then be supplemented by the use of respiratory protection.

In reaching the decision to require engineering and work practice controls as the primary methods of reducing benzene exposures, OSHA has carefully considered the objections of various participants. While recognizing that in many situations engineering and work practice controls are the preferred methods of reducing exposures to or below the permissible levels, several participants recommended that the hierarchy of control measures be eliminated and employers be allowed the freedom of selecting the control measure to be instituted. (Tr. 3140). These participants particularly objected to the requirement that engineering controls and work practices be used to reduce exposure to the lowest achievable level even if that level is above the permissible exposure limit. Various arguments were made in support of this position. One participant pointed out that, where the controls will not reduce exposures sufficiently, respirators will have to be used anyway. This employer suggested that OSHA mandate the continued search for controls which are sufficient to reduce employee exposure, but allow employers to select any appropriate method of reducing exposures (Com. 43). As was pointed out in the benzene hearing (Ex. 59, p. 12), as well as in other OSHA rulemaking proceedings, respirators are the least satisfactory means of control because of difficulties inherent in their design and use. Respirators are capable of providing good protection only if they are properly selected for the types and concentrations of airborne concentrations present, properly fitted and refitted to the employee, worn by the employee, and replaced when they have ceased to provide protection. While it is theoretically possible for all of these conditions to be met, it is more often the case that they are not. Consequently, the protection of employees by respirators is not always effective and is, therefore, permitted only in certain specified circumstances. For example, proper facial fit, is essential but, due to variations in fit, individual facial dimensions and the limited range of the facepiece configurations, such fit is difficult to achieve. (Tr. 332-335) Often the work involved is strenuous and the increased breathing resistance of the respirator reduces their acceptability to employees. Safety problems presented by respirators must also be considered. Respirators limit vision. Speech is also limited. Voice transmission through a respirator can be difficult, annoying and fatiguing. Movement of the jaw in speaking also causes leakage. Communication may make the difference between a safe efficient operation, on the one hand, and confusion and panic, especially in difficult and dangerous jobs, on the other hand. Moreover, skin irritation can result from wearing a respirator in hot, humid conditions and such irritation can cause considerable distress and disrupt work schedules. It is clear, therefore, that respirators cannot be considered as the primary means of employee health protection. Nevertheless, respirators do provide some protection and OSHA has concluded that under certain limited circumstances, where no alternatives are available, respirators may be used to reduce employee exposures.

Industry participants further argued against a system of priorities because of alleged unfeasibility of engineering controls. Most of these participants' objections to methods of compliance, however, lie in the area of economic rather than technological feasibility (Com. 49, p. 5; Com. 54, p. 2; Com. 73, p. 3). As discussed below, OSHA has determined that this standard is feasible and that the implementation of engineering and work practice controls is for the most part technologically feasible. However, OSHA realizes that, under some particular circumstances, engineering and work practice controls may not be technologically feasible in a particular work operation. Therefore, the standard explicitly recognizes that an employer may demonstrate the infeasibility of engineering and work practice controls as to one or more operations in a particular process, and in these circumstances use respirators to provide the required protection. The question of whether an employer has met its burden of establishing that engineering and work practice controls are infeasible in a particular work operation involves the consideration of many complex factors and a rational balance process. Factors such as levels of exposure, useful remaining life of the equipment and the effort made by the employer to implement such controls are relevant.

In addition to the obligation to institute engineering and work practice controls, except to the extent that such controls are not feasible, the final standard also requires that each employer establish and implement a plan, including schedules for reducing exposures to within the permissible exposure limit or to the greatest extent feasible, solely by engineering and work practice controls. These written plans must be furnished upon request for examination and copying to representatives of the Assistant Secretary and the Director. These plans must be reviewed and updated periodically to reflect the current status of exposure control. Some participants felt that the requirement for written plans was burdensome and unnecessary (Com. 45, 59). OSHA, however, views the requirement for written plans as an essential part of the compliance program since it will encourage employees to actually achieve the controls and also provide the necessary documentation to OSHA, employers and employees of the compliance methods chosen, the extent to which controls have been instituted and plans to institute further controls to achieve safe and healthful workplaces.

A compliance issue relating to the requirement for engineering controls and work practices in this final benzene standard involves the relationship of that requirement to the covered employers' legal obligation as to engineering controls under the prior

hemolytic states and other abnormalities. Because of the non-specificity of these two assays relative to benzene toxicity, the time-consuming nature and instability of the reticulocyte preparations, these particular tests were the object of much comment and criticism. Several commentators stated that although these tests were of little value on a routine basis, they should be made part of a preplacement or baseline exam (Com. 28, 72). Based on a review of this issue, OSHA believes that these two particular blood examinations should be included as a part of the initial laboratory tests only, to provide a more comprehensive picture of a worker's hematological profile, for possible later comparative purposes.

Several hematologists stressed the importance of obtaining pre-exposure data as a baseline against which latter comparisons could be made (ORC/Jandl, P.C. 34, p. 36; Battle, P.C. 26C; Goldstein Ex. 75, p. 5). The initial exam requirement of the standard applies to both employees already exposed to benzene at or above the action level as well as to new or reassigned employees who may be exposed at or above the action level. In the first case, the blood data obtained is not, of course, a true non-exposed baseline, but may be useful at a later date should significant changes in blood values occur. In addition, since the standard requires that an initial laboratory exam be performed for all new or reassigned employees prior to their actual exposure to benzene at or above the action level, pre-exposure baseline data will gradually become increasingly available in the years subsequent to promulgation of this standard.

As an aid to physicians for comparing the results of the most recent blood testing with early data, the recordkeeping paragraph requires that, at the completion of the differential count, the slide of a peripheral blood smear be made permanent and stored for possible future reference. Retention of the slide allows the examining physician to directly compare the most recent findings with earlier ones, especially with respect to possible changes in morphology of the blood cells; counting data alone would not permit this type of comparison.

Doc Chemical suggested that kidney and liver function tests should be performed as a part of the preplacement examination (Tr. 2967). OSHA recognizes that these laboratory examinations may identify conditions indicative of an impaired ability to detoxify benzene. However, given the low permissible exposure limit mandated by this standard, OSHA concluded that requirement of these tests would be excessively burdensome. In this regard, Goldstein testified that he saw no value to incorporate these tests (Tr. 380).

Periodic Examination

The medical surveillance section requires that a brief updated history be taken semiannally at the time of one of the blood examinations. Battle suggested that such a history include queries as to exposure to drugs or chemicals as well as recent illnesses since the last history (P.C. 26C). Because these agents may act to adversely affect the hematopoietic system and may be reflected in the blood picture, OSHA agrees with these particular suggestions and has incorporated all of them into the requirements for the interval history.

The periodic laboratory tests are similar to those specified for the initial exam, except that serum bilirubin and reticulocyte assays are deleted since, as stated above, the two assays are required only in establishing a baseline. Comments received by OSHA concerning the frequency of interval blood examination ranged from quarterly (ORC, P.C. 34, p. 11; Tr. 3382, Tr. 270) to 3 times a year (Com. 28; Tr. 3328; Battle, P.C. 26C), semiannually, (Tr. 3138) to those who felt the frequency should in some manner vary according to the exposure level (e.g., Tr. 2965, 6-10, 6-37, 6-47, 6-64, 6-76, 41-3, 41-19). Dow expressed the view that the frequency should be the decision of the responsible physician and related to the medical condition of the employee and the environmental control of the specific work area (Tr. 2965). As detailed previously, there is insufficient information in the record to allow a precise determination of optimum testing frequency. No completely reliable information exists on the number of months which elapse between the first laboratory signs of a blood disorder and the onset of clinical disease or what effect a particular time delay has on therapeutic outcome. There is no reason for casualness about the testing frequency though, since even if a blood change were to progress steadily downhill, early detection and treatment may provide substantial benefit. It is OSHA's judgement, following examination of the various options available, that a six month interval between routine blood examinations is appropriate.

The standard contains a provision, applicable to both the initial, periodic and emergency exams, requiring that employees' abnormal test results must be referred to a hematologist for further evaluation should certain specified warning signs appear. This provision, which was not a part of the proposal, is in response to recommendations that: (1) A hematologist be included in some manner in the medical surveillence program (ORC/Jandl, P.C. 34); (2) specific quantitative guidelines including ranges (Ex. 6-60) be given physicians and; (3) that additional laboratory tests should be given if an abnormal count becomes manifest or significant changes occur relative to baseline values (NPRA, Tr. 3325-3331; AISI, Tr. 3283-84; ARCO, P.C. 32C). With respect to item (1), an industry participant testified that it was already the practice at his company to refer workers to hematology specialists if blood abnormalities are discovered (Joyner, Tr. 2286-87), and Dow remarked that they discussed abnormal blood findings of workers with the hematologists (Tr. 3021). Also Arco commented that, if abnormal conditions arise among its employees exposed to benzene, follow-up examinations are given and medical treatment performed until blood tests reveal values within the normal range (P.C. 32C). Also, Dow disclosed that, for its employee exposed to benzene, an increased medical surveillence program would result if conditions such as an undiagnosed anemia or leukocytosis were detected (Tr. 2984-85). Sakol has noted that ineffective and inappropriate medical treatment was given to workers apparently suffering hematological disorders from benzene exposure which ultimately evolved into a frank leukemia (Tr. 303). This incident further illustrates the need for a specialist's evaluation, if abnormalities are detected.

Again it should be emphasized that the question of what constitutes the earliest laboratory evidence of chronic benzene toxicity is not known with certainty (ORC/Battle, P.C. 26C, p. 3). It is known that the level of all 3 blood cell lines may be variously affected by exposure. However, examination of the benzene literature reveals that the hematological boundaries of what is considered "normal" have varied. More recent tabulation of normal ranges are those published by NIOSH (Ex. 2-2, p. 135); Wintrobe (Ex. 2-107, p. 1791, 1794, 1795) and those submitted by Jandl (ORC/Jandl, PC 34, p. 29). The normal range of hematological values presented generally agree quite well, especially those given by Jandl and Wintrobe. It is OSHA's conclusion that laboratory findings beyond these ranges must require additional evaluation by a blood specialist. In specifying the values beyond which findings are considered abnormal, OSHA utilized the values in the above citations to yield the widest range (often the range limits do not exactly coincide) in order to minimize the burden on the employer in borderline cases.

However, as illustrated by Goldstein, it may be possible for some individuals to experience a significant hematological response to benzene exposure and yet exhibit blood values within the range normal for the population as a whole (Goldstein, Tr. 356). To identify such workers for referral to a hema-

in making these determinations. Likewise, the requirement that the employee be provided with a copy of the physician's written opinion will assure that the employee is informed of the result of the medical exam and may take appropriate action. Comments suggesting that the physician's opinion be communicated only if there are problems or only upon request are not acceptable to OSHA on the basis that the employer has the ultimate responsibility to assure the protection of the worker's health. Where the findings are negative, transmittal of the doctor's opinion also provides necessary information to both parties that the employee's health has not been adversely affected and provides documentary evidence that the prescribed tests were performed and were evaluated.

Other aspects of paragraph (i) of the medical surveillance section are to be discussed under Recordkeeping, paragraph (1).

Mandatory Removal and Rate Retention

Among the issues in the benzene rulemaking were whether OSHA should include a mandatory removal requirement—that is, a provision prohibiting the exposure of an employee to benzene if the employee would be placed at increased risk of material impairment to health because of such exposure, and whether OSHA should include a rate retention provision—that is, a provision requiring the transfer of such employee to another job or providing that removal for medical reasons should not result in loss of earnings or seniority status to the affected employee. These issues, as OSHA has previously stated (41 FR 46780), are related and must be addressed together. Both employee and industry participants expressed their views as to several aspects of these issues in prehearing comments, in testimony during the hearing and in post hearing arguments. Subsequent to the close of the record in this proceeding, however, OSHA conducted an informal public hearing on mandatory removal and rate retention for workers exposed to lead as part of the rulemaking proceeding on lead. Consideration of the critical issue of medical removal protection is being undertaken for several pending standards together. Once this consideration is completed, OSHA will consider the extent to which the conclusions on medical removal protection are appropriate for benzene and will propose the inclusion of those provisions in the benzene standard. The final standard published today, therefore, does not address the issues of mandatory removal and medical removal protection.

Employee Information and Training: Paragraph (j). The standard requires each employer to provide training to each of his employees who is or may be exposed to benzene. The need to train employees was not disputed by participants in the rulemaking proceeding. Some comments, however, suggested limiting the training to certain employees. One industry comment requested that workers in closed system operations be excluded from training (Com. 47). Testimony at the hearing, however, revealed that leakages in closed systems are not unusual occurrences and that employee exposure during leaks can reach high levels. One comment suggested the exclusion of workers in open system operations where the benzene content is 1 percent or less (Com. 47). However, as stated above, it has been established that a consistent predictable relationship between the amount of benzene in a mixture and exposure levels does not exist and this suggestion has, therefore, been rejected. Another comment suggested the exclusion of laboratory personnel from training requirements on the ground that laboratory personnel have a good understanding of the hazardous nature of benzene (Com. 70). A laboratory technician, however, testified that during his six years working with many toxic chemicals, including benzene, he received no training (Tr. 3493) and indeed neither he nor his coworkers were aware of the fact that there was an OSHA standard limiting exposure to benzene (Tr. 3492). Information and training are essential for the protection of an employee. Each employee can do much to protect himself if he is fully informed of the hazards in his workplace and the protective equipment he should use. Furthermore, each employee, who is fully informed of the obligations which the standard imposes upon the employer, can determine if he is working in a safe and healthful environment. For the reasons stated herein, OSHA believes that training must be provided to all employees in workplaces where benzene is present.

A trade association, while not disputing the need for training, suggested that employee training not be included in the benzene standard but await development of a comprehensive employee information and training standard based on the report of the Advisory Committee on Hazardous Materials Labeling and/or NIOSH's criteria document entitled "A Recommended Standard • • •.

An Identification System for Occupationally Hazardous Materials" (L.C. 14). OSHA deems it necessary for the protection of the health of employees to include the training requirements in the benzene standard at this time.

The standard specifies the contents of the training program. The information which must be imparted to the employee must include the nature of benzene related health problems, the necessity for exposure control, and the purposes of medical surveillance and respiratory protections. No participants objected to any of these items. Two participants suggested that employees should also be trained in "early symptom diagnosis to detect acute leukemia" (Ex. Dow Venable statement, pg. 3; Tr. 3192; Ex. 154; Tr. 2963-3056). These participants, however, testified that the most common manifestations of acute leukemia are fatigue and nosebleeds and that these symptoms are not specific to acute leukemia (Tr. 3193).

The signs and symptoms of benzene-induced diseases are described in considerable detail in Appendix A and Appendix C. Both the proposed standard and the final standard specifically require that the employees be informed, among other things, of the information contained in Appendix A and Appendix C. (In this connection, the employee should be instructed to report promptly the development of any of these symptoms which could be attributed to benzene exposure.) In view of the requirement to include the information contained in the appendices as part of the training program, an additional requirement on early symptom diagnosis would be redundant. Similarly, since Appendix B details the volatility of benzene, OSHA has not adopted NIOSH's suggestion (Baier statement, Ex. 84A p. 11) that the standard further emphasize training on the flammability of benzene.

In addition to informing employees, the standard requires that the employer make available to his employees a copy of the standard and its appendices. This requirement is intended to assure that employees understand their rights and duties under the standard.

A public participant suggested that employers be required to hold classes for the training of each employee. (Ex. 183 p. 5) OSHA has not included any specific requirement to this effect in the final standard, preferring to leave the manner of training up to the individual employers. Some employers will need to train individuals on a one-to-one basis, depending on the number of employees at a particular workplace or involved in particular operations. Employers with a few employees may find it burdensome or disruptive of work schedules to conduct training in class sessions.

The employer is also required to provide, upon request, all materials related to the training program to the Secretary and the Director. This requirement is intended to provide an objective check of compliance with the content requirements of the training program.

The standard requires that training of employees be conducted within

cation of the leaks will, of course, minimize exposure and minimize the reporting requirement. Some industry participants recommended that the standard include a method for "deregulating" the regulated areas once exposures fall below the permissible exposure limits. (Com. 45, Com. 53, Com. 57) OSHA does not feel that a formal method for deregulation is necessary. Since the standard does not require maintenance of a regulated area except where exposures are above the permissible exposure limit, the regulated area requirement does not apply where the employer has reduced the exposure levels below the permissible exposure limit. Nor would a deregulation procedure contribute to the protection of employees. Moreover, if formal deregulation were required, it would be necessary for the employer to file an additional notification with the OSHA area office should conditions change thereafter and the exposure again exceed the permissible exposure limits. In view of these considerations, a formal deregulation procedure would appear to be unnecessarily burdensome.

Monitoring: paragraph (e). Significant changes have been made in the monitoring section of the final standard in response to comments by participants. Briefly, the final standard requires all covered employers to make measurements to determine whether any employee may be exposed to airborne concentrations of benzene, and imposes different measuring requirements depending on whether exposure measurements are above or below certain levels.

The monitoring requirements are imposed pursuant to Section 6(b)(7) of the Act (29 U.S.C. § 655) which mandates that any standard promulgated under section 6(b) shall, where appropriate, "provide for monitoring or measuring of employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees." The purposes of monitoring are to determine the extent of exposure, to identify the source of exposure to the hazard and to enable the employer to select proper control methods and evaulate the effectiveness of the selected methods. Thus, monitoring enables employers to meet the legal obligation of the standard to assure that their employees are not exposed to benzene in excess of prescribed levels. Additionally, monitoring enables employers to notify the employees of their exposure level, as required by section 8(c)(3) of the Act, and provides information necessary to the examining physician.

The need to conduct exposure monitoring was generally accepted by participants in the rulemaking process (P.C. 35MCA brief, p. 55-b; P.C. 36; ORC brief, p. 7). Many comments, however, objected to the proposal's requirement to measure airborne exposures in all workplaces "where benzene is present" (P.C. 33; API brief, p. 127a; P.C. 34; ORC brief, pp. 7-8). Participants argued that the use of the term "present" is so broad as to encompass each and every employee at a facility (Ex. 6, No. 53). It was also argued that benzene is present in the ambient atmosphere (Ex. 6, No. 43; Ex. 84B. 18, Ex. 84A, p. 7) with the result that every work operation in every city would probably have to be monitored (Ex. 6, No. 43, p. 12). OSHA's objective is to minimize all occupational exposures to benzene. The term "presence" was used in the proposal to convey the intent that, whenever the exposure of any employee to benzene concentrations resulted from workplace operations at the place of employment, the employer was required to measure that exposure. OSHA does not intend that employees, who might be exposed solely from other sources, such as ambient levels of benzene, be covered by the monitoring requirements. In view of the confusion as to the meaning of the term "presence," the final standard does not use that term but instead specifies the general classes of occupational activities which can result in employee exposure to benzene, and requires monitoring where any of these activities are conducted.

In conducting the monitoring of exposures, the standard does not require that each individual employee's exposure level be measured. Although individual measurement is the ultimate indicator of employee exposure, OSHA believes that a requirement for individual measurements may be too burdensome. Accordingly, the standard requires that the measurements be made by monitoring which is representative of each employee's exposure to benzene over an eight-hour period without regard to the use of respirators. It should be noted that the requirement for representative monitoring does not preclude an employer from taking individual exposure measurements of each of his employees; individual measurements are certainly considered to be representative; and the representative monitoring requirement is the minimum that the employer must meet.

In establishments having more than one work operation involving the use of benzene, the monitoring to be representative must pe performed for each type of employee exposure within each operation. One participant requested that area sampling be permitted in order to lessen the burden and cost of monitoring each employee with a different job function (Ex. 6, No. 49, p. 4). Although the final standard does not specifically require personal sampling, monitoring under the standard must determine breathing zone exposures. Appendix B, IV, therefore, recommends that air sampling be taken in the employee's breathing zone. Area samples are generaly not as direct a measure of employee exposure, and consequently, may not meet the requirement for representative monitoring, although where area sampling can be correlated with breathing zone exposures, area sampling may be used. OSHA, however, notes that while there are techniques to correlate area sampling with breathing zone exposures, these are generally more burdensome than personal sampling and involve much more sophisticated data collection and analysis, including the performance of personal sampling to assure the correlation.

Some participants suggested that employers with several places of employment, in which there are workplaces with identical processes or operations, be permitted to monitor only a representative number of such locations (Ex. 6; Ex. 50, p. 3; Ex. 60, p. 7). The fact that work operations are in different geographical locations would not in itself preclude representative monitoring. However, it is the employer's responsibility to assure that indentification of conditions, characteristics, activities, climate, etc. exist so that monitoring at particular sites would actually be representative of employee exposure at other sites.

The employer is also required to use a method of monitoring and measurement with an accuracy (at a confidence level of 95%) of not less than plus or minus 25% for concentrations of benzene of 1 ppm or more. Methods of measurement are presently available to detect benzene to this accuracy level (Tr. 342-3) and one such method is described in Appendix A, II, E. Industry participants expressed concern that consistent compliance with these accuracy requirements will be impossible. (PC 36; AISI brief pp. 106-108.) The record, however, indicates that, even where benzene is present with other organic solvents, the OSHA Analytical Method will still enable employers to measure low levels of benzene well within the accuracy requirement of the standard. (Tr. p. 343.) Indeed, it was suggested at the hearing that there is an alternate method for sampling, passive dosimeters, which may comply with the accuracy reqirements contained in the proposal. (Tr. 2381.)

As earlier indicated, the standard requires all covered employers to initially measure the airborne exposure of all of their employees. Some participants objected to this requirement and recommended that initial monitoring be limited to those workplaces where there is a probability of exposure to benzene in excess of the permissible

retrospective mortality studies and also experimental evidence. These studies represent the best available evidence upon which OSHA must make a decision. This decision is not predicated on any particular study, but is based on an assessment of the entire set of evidence taken as a whole.

OSHA recognizes that only recently has there been a well-designed study which may indicate a leukemogenic response among benzene-exposed animals. (Nelson, Ex. 178) In any event, the best evidence to date is that based on direct human experience. Based upon such evidence, OSHA concludes that benzene is and must be regulated as an occupational carcinogen.

Comment and testimony from industry for the most part, does not dispute the leukemogenic potential of benzene (e.g. Eckhardt, Ex. 115.B. 1, pg. 3; Tabershaw Tr. 2545). However, industry argues that this relationship is valid only at high exposure levels. In support of this view, they cite as evidence that: (a) the documented cases of benzene-induced leukemia were among employees who were, most probably, exposed to high concentrations, and (b) that several studies of undefined numbers of workers who may have been exposed to low levels of benzene did not demonstrate a leukemia excess (The benzene studies are described under Health Effects: Leukemia). Industry also believes that observable blood disorders precede the development of benzene-leukemia and that such hematological abnormalities are reversible (ORC, PC 34, p. 2; Tabershaw Tr. 2543 Jandl, PC 26B, Allied P.C. 22, p. 7). They conclude that the present exposure limits of 10 ppm TWA and 25 ppm ceiling are sufficiently protective to guard against the development of non-malignant blood disorders and, consequently, that limiting exposure to such levels will also protect against leukemia. (ORC, PC 34; Jandl, PC 26B; Tabershaw, Tr. 2546.)

The issue of the levels at which cancer is induced by chemical agents and whether or not there is a "threshold" has been a major issue in every OSHA rulemaking concerning the regulation of occupational carcinogens (See preambles to Carcinogen standard (39 FR 3758); Vinyl Chloride (39 FR 35892); Coke Oven emissions (41 FR 46742). The benzene hearing was no exception. As in the case of arsenic, the lack of an unequivocal animal model (Kraybill, Tr. 758) requires that the Secretary's decision rely primarily on data obtained from human evidence. However, the epidemiologic method is by its very nature, a retrospective view of the evidence, i.e. findings of a recent excess of mortality among workers may relate to initial exposures occurring as much as 20 years or more previously and which most certainly correlate to exposures at higher concentrations than present levels. Because of these variables, it is extremely difficult to derive definite conclusions as to the quantitative health risk to the workers at exposures near 1 ppm. Studies which report negative findings, such as those studies conducted by Stallones, Tabershaw-Cooper and Thorpe suffer from the disadvantage of not being able to clearly define an exposed cohort, i.e. the indentification of a group of workers actually exposed to benzene and to what levels they were, in fact, exposed. (Stallones, Ex. 115.C; Tabershaw-Cooper, Ex. 149A; Thorpe, Ex. 2-34). OSHA recognizes that it is extremely difficult to reconstruct and define employee exposures retrospectively. Therefore, given the uncertainty of the definition of exposure and the potential for dilution of mortality excess among those actually exposed to benzene and other methodological deficiencies, OSHA is reluctant to place substantial reliance upon these negative reports. Thus, there is little definitive information available pertaining to the leukemogenic risk of an adequate size cohort of workers exposed to benzene less than 10 ppm and who have been followed for an adequate amount of time. Furthermore, it is OSHA's view following a careful review of the record that, at the present time, it is impossible to derive any conclusions regarding dose-response relationships for benzene (Goldstein, Ex. 75, p. 2 NRC, Ex. 2-4 p. 11) beyond the general observation that higher exposure levels carry a greater risk than do lower exposure levels. What is apparent however, is that a decrease in exposure level and/or duration will result in a decreased risk of leukemia.

OSHA also recognizes that, in some published cases with adequate documentation, leukemia attributable to benzene exposure developed after observable changes in the peripheral blood, i.e., various cytopenias, pancytopenia and/or aplastic anemia. (Goldstein, Ex. 43B, p. 166.) However, many cases of benzene-induced leukemias were recognized as such only after a patient with overt physical symptoms presented himself to a physician. Similarly, Snyder stated that, in the cases of pancytopenia and aplastic anemia, individuals "exposed to benzene usually do not approach their physicians until late stages in the disease." (Ex. 156.2, p. 2.) As a result, the hematological picture before the onset of disease is often not known. Moreover, because of the well-known reserve proliferative capacity of the bone marrow it is possible that marrow damage may occur without being reflected in the peripheral blood. (Goldstein, Ex. 43.B, p. 175; Wintrobe, Ex. 2-107, p. 676.) Olson acknowledged that alterations in bone marrow activity can occur despite a normal blood count (TR. 2894). Moreover, Goldstein noted that some individuals may have significantly depressed blood values, and yet remain within normal ranges. For this reason, a pancytopenic response to hematotoxic agents may go unrecognized. Therefore, OSHA believes that the scientific evidence is insufficient for adoption of the hypothesis that a preceding prodromal blood syndrome is a necessary prerequisite for the development of benzene leukemia. In this regard, Goldstein in his testimony cautioned that benzene may act as a direct-initiator of a neoplastic response.

OSHA is also aware that in many instances, non-malignant blood disorders resulting from chronic exposure to benzene may be reversed by removal from benzene exposure. However, the apparent high degree of reversibility, as set forth in Jandl's review, is open to question as pointed out in the Health Effects section.

Furthermore, a most characteristic finding which pervades the published literature, is that physiologic factors which cannot be identified a priori, such as nutritional state, genetic constitution, variations in metabolism of benzene and exposure (both occupational and non-occupational) to other marrow depressants, and the variables of age and sex may act to modify the individual's response. (Browning, Ex. 31, pp. 26 ff; Shaw, Tr. 421; Snyder, Ex. 156, p. 2.) For example, Browning stated, "• • • [t]here is no doubt that both men and women differ markedly in their response to similar conditions of exposure." (Ex. 31, p. 2.) Therefore, unqualified identification of high-risk subgroups cannot be made at present. Because of these uncertainties, this standard is designed to protect the most sensitive as well as the more resistant members of benzene-exposed worker populations by limiting exposure to the maximum extent feasible.

It is, therefore, clear from an examination of the record that a determination of a precise level of benzene exposure which presents no hazard cannot be made and that the corollary question of whether a "safe" level of exposure to benzene exists cannot be answered. The agency is aware of and has examined scientific opinion and data submitted by industry that thresholds for carcinogens may exist. However, prudent public health policy requires a conservative course of action until such evidence is of a definitive nature.

In its conclusionary document the International Workshop also stated: "[t]he workshop discussed but could not agree on whether there was a concentration below which there would be no leukemogenic effect clearly attributable to benzene" (Ex. 17, p. 7). Kray-

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Proposed Percentage Exclusion

The proposal and the emergency temporary standard both would have exempted from coverage those operations utilizing liquid mixtures containing 1 percent or less benzene by volume. The proposal would have limited this 1 percent exemption to the first year of the standard after which period only liquids containing 0.1 percent or less benzene by volume would be exempted. The proposed percentage exemption was based on some indication that exposures resulting from the use of mixtures containing less than 1 percent benzene would generally be less than 1 ppm (42 FR 27453-4). It was also anticipated that the percentage exclusion would lead to a reduction of the benzene content in solvents or to substitution of other substances for benzene with the result that employee exposure to benzene would be reduced or eliminated. As a result of evidence developed during the benzene rulemaking, however, OSHA has determined that the percent exclusion cannot be supported on this basis. The benzene record indicates that there is no consistent predictable relationship between the percent of benzene in a liquid mixture and the resultant airborne exposure to benzene (Tr. 3120). Studies conducted by the University of North Carolina demonstrated that exposure levels varied considerably during various work operations utilizing liquid mixtures containing the same percent of benzene (Tr. 3090-3091). Support for the conclusion that a less than one percent benzene solution can result in exposures above 1 ppm is found in testimony suggesting that other factors than the percent of benzene in the liquid may be determinative of exposure levels. Thus, NIOSH testified that employees working with No. 6 fuel which contains only 0.1 percent benzene were exposed to levels as high as 60 ppm under certain conditions of confined space, poor ventilation or elevated temperatures (Tr. 754). The University of North Carolina data also revealed that exposure levels in heavy duty tire spraying utilizing rubber solvents were 1.3 ppm when sprayed by the regular full time operator but reached 5.2 ppm and 7.3 ppm when sprayed by a substitute operator (Tr. 3093). This suggests that work practices are also determinative of exposure levels. To maximize protection of employees, it is necessary to reduce their exposure to benzene, to the lowest feasible limit. Since the percentage of benzene in a liquid is not in itself necessarily controlling of the employee's exposure level, the proposed percentage exemption, would not achieve this objective. Accordingly, the final standard does not contain a percentage exemption and thus applies to all liquid mixtures containing benzene regardless of the percent of benzene.

It is OSHA's view that the absence of a percentage exemption does not eliminate all incentive to reduce the amount of benzene in liquid mixtures. Where another substance is totally substituted for benzene, this standard will obviously not apply. Additionally, it should be noted that the inclusion of an action level will effectively limit the burden of this standard where employee exposure is found to be low because of its limited presence in a mixture.

Benzene Substitutes

In lieu of the percentage exception, OSHA considered the option of exempting from the standard certain benzene substitutes, such as toluene and xylene (although they may contain small amounts of benzene). An exemption of this type would encourage employers to discontinue the use of benzene and utilize a substitute in order to avoid the requirements imposed by the benzene standard. These substances themselves, however, do contain varying amounts of benzene and, as stated above, there is no evidence of a consistent direct predictable correlation between the amount of benzene and exposure levels. Thus, it was concluded that toluene and xylene, to the extent they contain benzene and result in benzene exposure, would be covered by the standard.

Action Level

OSHA recognizes that the lack of a percentage exemption substantially expands the coverage of the benzene standard to operations which may otherwise have been exempt. In many of these operations, exposure levels below the permissible exposure limit have already been achieved. To minimize the impact of the standard on those employers who have attained these low exposure levels, the final standard provides for an action level. This action level is a benzene exposure equal to one-half of the permissible exposure limit above which certain precautionary measures, such as periodic monitoring and medical surveillance programs must be conducted and below which only a very limited number of the standard's requirements will apply. Thus employees who have an initial exposure measurement below the 0.5 ppm TWA action level will not have to be monitored periodically. If the initial monitoring exposure measurement is below the action level, no further monitoring is necessary until such time as a redetermination may be required as a result of a process, control or personnel change. Furthermore, medical surveillance of individual employees whose initial exposure measurements are below the action level would not be required. Nor would regulated areas need to be established or engineering or work practices instituted or respirators provided. All other provisions of the standard, however, would apply and the employer would need to train his employees in the hazards of benzene exposure, to properly label his products and to maintain the record of the initial exposure measurement and, if any, the record of the redetermination measurement.

The adoption of an action level had been recommended by several participants to the rulemaking. NIOSH, recommended that an action level for periodic monitoring and routine periodic medical exams be incorporated for the purpose of assuring that no employee is exposed above the permissible exposure limit (Tr. 749-750). Industry participants advocated a level which would trigger the periodic monitoring of employee exposure (Com. 24; Com. 72; P.C. 36 AISI brief p. 74, FT. no. 168). A need for an action level is also suggested by the record evidence that some minimal exposure to benzene occurs naturally from animal and plant matter (Tr. 749-750; 759-760). Naturally occurring benzene concentrations, it appears, may range from 0.02 to 15 parts per billion (Ex. 117, p. 1). Additionally, it was suggested by certain employers that their operations be exempted from the requirements of the standard because those operations involve only intermittent and low level exposures to benzene. The use of the action level concept should accommodate these concerns in all cases where exposures are indeed extremely low since it substantially reduces the monitoring of employees who are below the action level and removes for these employees the requirement for medical surveillance. At the same time, employees with significant overexposure are afforded the full protection of the standard.

In developing this regulatory approach to occupational exposure from benzene, OSHA considered the request of those participants to the rulemaking who pressed for exemption from the benzene standard of their particular operations.

Bulk Terminals

The final standards apply to bulk terminal operators but exclude exposure from gasoline, motor fuels and other fuels subsequent to the discharge from the bulk terminal.

During the rulemaking, bulk terminal employers requested that their gasoline operations be exempted from the benzene standard. Bulk terminals are the primary distribution facilities in the gasoline marketing network. A bulk terminal is the first distribution point of gasoline after the gasoline is processed by the refinery. Gasoline

these exposures. It may reasonably be inferred, therefore, that all workers are exposed to benzene levels below the action level. Compliance costs, estimated on the basis of the reasoning used above, are approximately $39.6 million for first year operations and $2.5 million for recurring annual operations.

In determining these compliance costs, OSHA has assumed 10 wells per facility in contrast to API's reference to each well as a separate facility. It is probable that even this computation overestimates first year and recurring annual operating costs, since the costing formula for initial measurments allocates substantial charges on a per facility basis, amounting for example to approximately 90 percent of first year costs. The estimated first year costs would be reduced by the amount appropriate for measurements already performed pursuant to the benzene guidelines or the ETS. Monitoring costs would further be reduced where exposures at one workplace are representative of exposures at another.

Transportation

Companies engaged in the transportation of benzene and benzene contaminated products are covered by the benzene standard. OSHA's costs analysis, therefore, covers the transportation by pipeline, marine tanker, barge, tank car and tank truck of benzene and benzene products.

The cost analysis for pipelines is based on approximately 3,000 facilities. This figure was furnished by an API witness (Scarborough) who testified that there were 3,000 pipeline facilities employing 12,000 exposed workers. A witness for Williams Pipe Line Company estimated that there are 17,000 exposed pipeline workers (Bailey). The Williams figures, however, may represent total employment, including administrative and clerical workers. OSHA has utilized the figure of 3,000 facilities in combination with the two estimates of exposed workers to yield a range of estimated compliance costs. On this basis first year operating costs are estimated to be approximately $2.7 million and recurring annual costs for personal protective equipment, training and recordkeeping approximately $800,000. Since the standard does not require labelling of pipelines, no labelling cost is included. Neither have engineering controls been assessed since monitoring measurements indicate that all workers will be below the action levels (Bailey).

The number of affected tank car facilities (loading and unloading) was estimated by ADL to be approximately 100, with an average of one exposed worker per facility. (Table 5-1) The exposures of these workers will be dependent on the quantity of the various benzene-containing products shipped through the facility, the methods of loading and unloading cars, and the effectiveness of efforts to avoid leaks and spills. Conditions are somewhat similar to other facilities at which benzene and benzene-containing liquids are stored and transferred. Following the sampling protocol used throughout this analysis, costs were assigned on the basis that 20 percent of the exposures are above the permissible exposure limit, 40 percent between the permissible exposure limit and the action level, and 40 percent below the action level. It should be noted that, since it was estimated that only one worker per facility would be exposed, monitoring cost were estimated on the basis of 100 employees monitored. Engineering controls are to be installed at these facilities that will effectively control benzene emissions, bringing the exposure levels of all exposed workers below the action level. On the basis of this reasoning, it was estimated that compliance costs will be approximately $215,000 for first year operations, $16,000 for recurring annual costs, and $200,000 for capital investment.

Analysis of tank truck facilities shows a pattern very similar to that for tank cars. The rationale just described yield the following estimates: 200 affected facilities, 200 exposed workers, first year operating costs approximately $428,000, recurring annual costs approximately $37,000 and capital investment $100,000.

Barges are used for the transportation of benzene from refineries to points of utilization. Barges also transport various refined petroleum products primarily for discharge at bulk terminals. It is estimated that there are 480 employees and 240 barge facilities involved in the transportation of benzene. The record indicates that employee exposure during loading and unloading exceeds the permissible exposure limit (Ex. 5A, 4-24). For cost calculation purposes, OSHA has estimated that 20% of the employees are above the permissible exposure limit, forty percent are between the action level and the permissible exposure limit, and forty percent are below the action level. On this basis first year operating costs are calculated at $526,000, recurring annual costs are calculated at $95,000 and capital investment is estimated to be $420,000.

Barges and marine tankers are also used for the transportation of gasoline. The distribution of these exposures, however, appear to resemble those encountered during gasoline production and distribution. In that case, the average cost of compliance per employee in his transportation, loading and unloading operations [illegible] per employee.

Laboratories

Benzene exposures occur in chemical laboratories where benzene and other petroleum-based solvents are used. Where careful laboratory procedures are followed, such as the use of properly functioning hoods and appropriate work practices, exposures should be very low. In order to estimate the range of possible costs, OSHA calculated the cost on the basis of two scenarios. One scenario assumes that 10 percent of the exposed workers are initially exposed above the action level but below the permissible exposure level. The second scenario assumes 5 percent of the exposed workers are initially exposed above the permissible exposure level, 10 percent are exposed between the action level and the permissible exposure level, and all others are below the action level. On this basis, first year operating costs range from approximately $4.5 million to $10.9 million. Recurring annual costs would be approximately $2.4 million, if all workers exposures drop below the action level after the first year, which is expected as a result of appropriate controls and work practices.

Rubber Products

The ADL study examined the potential for benzene exposure in plants manufacturing rubber tires and other products, such as belts, hoses, fittings, and coated fabrics. ADL identified 206 affected tire producing facilities employing 11,400 exposed workers. The study cited data indicating that exposure levels were generally in the range of 1-3 ppm and may be considerably higher (ADL, Ex. 5A, pp. 14-19; Tr. 4-20). Similar testimony was provided by Drs. Tyroler and Harris of the University of North Carolina based on their studies of benzene exposure in the rubber industry. (Tr. 3083-3095) Both studies indicated that control of exposure could be achieved, reducing exposure levels to below the action level, by substitution of materials and enforcement of appropriate work practices, and that engineering controls would not be required. (Tyroler, Tr. 3086) Compliance costs were estimated, therefore, on the basis of all exposed workers being exposed initially above the permissible exposure limit, and exposures reduced to below the action level after controls have been instituted in tire manufacturing plants.

First year operating costs were estimated to be approximately $15.8 million and recurring annual costs approximately $407,000.

The analysis of firms producing other rubber products was based on the same considerations of workers exposed and compliance activities. For these firms first year operating costs were calculated at approximately $18.1 million, and recurring annual costs at [illegible] and on 197 facilities with [illegible] exposed workers.

may pose or reflect a potential health risk and as such, must be considered in the larger purview of adverse health effects associated with benzene.

V. Economic Considerations

In setting standards for toxic substances, the Secretary is required by section 6(b)(5) of the Act to give due regard to the question of feasibility. Section 6(b)(5) mandates that final standards be set which most adequately assure employee safety and health "to the extent feasible, on the basis of the best available evidence" and further requires that, in the development of occupational safety and health standards, "considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." While the precise meaning of feasibility is not clear from the Act, it is OSHA's view that the term may include the economic ramifications of requirements imposed by standards. The determination that OSHA has the authority to consider economic feasibility factors in developing standards has been endorsed by the courts. *Industrial Union Dept., AFL-CIO* v. *Hodgson*, 499 F. 2d 467 (C.A.D.C., 1974); *AFL-CIO* v. *Brennan*, 530 F. 2d 109 (C.A. 3, 1975). As pointed out by the D.C. Circuit Court of Appeals, Congress did not intend the Secretary to promulgate standards which drive entire industries or large numbers of employers out of business. On the other hand, "standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely; further, the Court said, the concept of economic feasibility does not "necessarily guarantee the continued existence of individual employers." *Industrial Union Dept., AFL-CIO* v. *Hodgson*, supra, at page 478.

In accordance with the Secretary's position, it has long been OSHA's practice to analyze the economic feasibility of proposed standards where significant economic impact on employers covered by the proposals seem likely, to make such analysis available to affected parties for comment and subsequent hearing prior to issuance of final rules, and to invite the submission of other information on the economic impact and feasibility of proposed standards. In developing a final standard, therefore, OSHA evaluates the economic feasibility of the final standard on the basis of the information developed by its own studies of the proposal and submissions by the public during rulemaking.

To assess the economic feasibility of the proposed standard for benzene, OSHA undertook an extensive study of the proposal's economic impact on various affected industries. This study was conducted for OSHA by Arthur D. Little, Inc. (ADL). (Ex. 5A, 5B). The ADL study has provided basic economic data for the evaluation of the economic impact of the permanent benzene standard on the major affected industries. Additional information for this purpose was obtained through OSHA's analysis and consideration of all other economic data, comments, arguments and testimony submitted at the benzene hearing, in pre-hearing comments and in post-hearing comments and briefs. On the basis of the best available evidence, therefore, OSHA has determined, as explained in detail below, that the permanent benzene standard is economically feasible.

Compliance Costs

Estimates of total costs of compliance with the permanent benzene standard for the major affected industries studies are as follows: First year operating costs for all industries combined are estimated by OSHA to be approximately in the range of $187 million to $205 million recurring annual costs are estimated at approximately $34 million and investment in engineering controls is expected to be approximately $266 million. Estimates of these costs for various individual industry sectors are analyzed below. As that analysis reveals, the greatest economic impact of the standard falls on the larger and more stable industries, such as petroleum refining and petrochemical production, which can readily absorb the costs or shift them forward to consumers. No testimony was offered by these industries that the proposed standard for benzene would imperil their existence. Even the higher projection of some costs by the American Petroleum Institute and other participants would not raise any serious question concerning the economic feasibility of the standard or the ability of the regulated industries to bear the additional costs.

The benzene standard, in its final form will require all industries that produce or use benzene, petrochemicals, products and services involving the use of solvents derived from petroleum, as well as production of crude and refined petroleum products, and primary distribution of gasoline, to undertake an initial determination of the extent to which their employees are exposed to benzene. The results of the initial exposure measurements will determine the types of activities each firm will be required to take to comply with the provisions of this standard. Where exposure measurements are below the action level (0.5 ppm), firms will have to provide information and training in the hazards related to benzene to their employees, comply with the labelling requirements, and retain the records of initial measurements. These compliance activities account for the entire first year operating costs for many of these industries. Firms with exposure levels above the action level will incur additional first year costs for monitoring and medical examination programs. Finally, those firms with exposure levels above the permissible exposure level will have additional first year costs for installation of appropriate engineering and work practice controls, and for respirators. It is assumed that engineering controls are all installed in the first year and reduce exposure levels to below the permissible exposure limit. However, those firms with continuing exposure measurements above the action level will have recurring annual costs for monitoring and medical surveillance. Regardless of the airborne exposure measurements, employees in operations with potential exposure to eye or repeated skin contact will have to be provided with appropriate personal protective equipment. Thus, some firms and industries will have higher and more sustained cost burdens than others.

OSHA's estimates of costs for compliance with the final standard differ from estimates of the proposal's compliance costs in part because the standard in its final form differs from the proposal in areas which significantly impact on the cost of compliance. ADL estimated the proposal's compliance costs for 20 industry sectors engaged in benzene production (petroleum and coke), petroleum refining, chemical processing, benzene transportation, and other industries, such as rubber manufacturing and laboratories (ADL, Vol. 1, Ch 5). ADL provided detailed cost estimates for each industry and for each compliance activity required by the proposal. Total costs for all surveyed industries were estimated by ADL as follows: First year operating costs were approximately $124 million, recurring annual costs were approximately $74 million, and costs for implementation of engineering controls were approximately $267 million. In developing each of these estimates, ADL used the control with the least cost as the basis of their calculations. In other words, where alternative methods of compliance are available to employers in an industry, and indeed may be more attractive to employers, the higher cost method was considered an optional process improvement, and only that portion of its total cost required to produce compliance was allocated to compliance with the proposed regulation (ADL, Vol 1, pp. 5-3). Additionally, ADL assumed compliance with the previous OSHA regulation (29 CFR 1910.1000, Table Z-2) requiring an exposure limit of 10 ppm TWA and a ceiling limit of 25 ppm, thus assessing to the benzene proposal only the incremental cost associated with

the latency periods also reported. However, Forni and Vigliani have noted that, occasional cases of acute leukemia with a long latency period may still be observed (Ex.2-50, p. 215) and Aksoy, while reporting that no additional cases of leukemia among shoeworkers were diagnosed in 1976, noted that this did not preclude the development of additional cases in the future (Tr. 159).* The question of latency periods for benzene-induced leukemias has not been resolved and requires further investigation.

Another area of discussion is the question of identifying individuals who may be particularly sensitive to the hematotoxic effects (including the development of leukemia) of benzene. Several witnesses including industry participants generally expressed the view that there probably were differences in sensitivity (Sakol Tr. 228; Shaw Tr. 412; Snyder Ex. 54.2, p. 25, Thorpe, Eckard Tr. 2052; Furst Tr. 1791-42). It appears from the evidence that there are individuals in given populations who may, because of genetic factors and/or concurrent or prior exposure to other environmental agents, be especially sensitive to benzene-induced blood disorders.

Aksoy and his colleagues reported a possible familial link in benzene-induced leukemias in 5 of 40 workers indicating a possible genetic predisposition to benzene's harmful effects (Ex. 60, pp. 8-10). Also, Jandl on the basis of tentative data has attempted to identify a subpopulation with risk factors predisposing to increased sensitivity to benzene (ORC/Jandl, PC 34, pp. 43-44). These include:

a. Those between the ages of 16 and 30;

b. Those with prior exposure to benzene or exposed to radiation in excess of that required for diagnostic purposes, and;

c. Those with evidence of a history of other less severe myeloproliferative disorders such as remitted aplastic anemia, certain abnormal circulating blood cells, or those with persistent abnormalities in one or more blood cell types.

Other predisposing factors may include exposure to drugs or alcohol which may act to modify the metabolism of benzene. These postulated effects are not consistently observed or universally accepted by investigators. In his testimony, Shaw stated that there was no way to determine who is susceptible to benzene and who is not (Tr. 420). And despite "well substantiated information" concerning the increased sensitivity of certain groups to benzene, the International Workshop was unable to develop and provide specific guidelines on this matter (Ex. 17, p. 7). These sensitive individuals, interspersed among the working population, are certainly among those who are at highest risk of material impairment from benzene exposure. The size of this group is unknown. It is the purpose of this regulation (especially the permissible exposure level and detailed medical surveillance protocol) to not only minimize harmful effects of benzene exposure, but also provide early diagnosis and treatment should such effects occur.

c. Animal studies. The wide variety of non-malignant hematological disorders observed in humans exposed to benzene which range from simple anemia, and leukopenia to aplastic anemia have been experimentally induced in animals. However, attempts to demonstrate the development of leukemia in animals exposed to benzene has met with less success. Until recently, a study by Lignac in 1932 was the only animal study known to OSHA in which leukemia has been observed in animals exposed to benzene. (Ex. 2-38). Fifty-four mice (28 females; 26 males) were given subcutaneous injections of benzene (0.001 ml in 0.1 ml of olive oil) for 17 to 21 weeks. Nine mice were initially excluded following intercurrent infection and an additional 12 were lost through atrophy of various organs, especially the spleen. Lignac attributed these 12 deaths to the size to the dose of benzene. Eight of the remaining 44 mice developed leukemia or Kundrat's lymphosarcoma and died 4 to 11 months after receiving the first injection. The absence of concurrent controls makes interpretation of the results problematic and uncertain. Failure to identify the mouse strain studied has frustrated efforts to independently confirm the findings.

Other studies have failed to reproduce Lignac's results. Amiel in 1960 utilized four inbred strains of mice and subjected them to the same experimental program outlined in Lignac's study. (Ex. 2-39). No leukemia or aplastic hemopathies were observed. Ward et al. administered benzene subcutaneously to a strain of mice which is known to be responsive to leukemogenic agents. (Ex. 2-40). A slight increase in the percentage of granulocytic leukemias was observed in the benzene-treated mice as compared with the controls; however, the authors viewed the increase as not statistically significant.

In a letter transmitted Aug. 9, 1977 to Eula Bingham, Asst. Secretary of Labor, Nelson described preliminary results of an inhalation experiment using rats and mice (Ex. 178). Animals were exposed to benzene vapors 6 hours per day, 5 days per week for up to 2 years. Two possible leukemias were observed in a group of 40 strain CD mice exposed to 300 ppm. In one animal, elevated WBC counts were observed 193 days after exposure, with death following 3 days later. The autopsy findings were consistent with CML, a disease not known to arise spontaneously in this strain. The second mouse exhibited the presence of abnormal blast forms in the peripheral blood after 211 days of exposure and died 4 days later. Whether this finding indicates AML, a disease previously observed in this strain, or acute lymphoblastic or stem cell leukemia (spontaneous incidence about 4 percent) had not been resolved at the time the report was submitted.

One of the 40 rats exposed to 100 ppm benzene developed an elevated WBC count after 240 days of exposure with the cell counts continuing to increase slowly. Peripheral blood smears showed some immature neutrophils. This finding is compatible with a diagnosis of CML, a disorder which is relatively rare for the rat. However, a non-leukemic leukemoid process could not be excluded.

Nelson characterized the results of the study as:

> • • • slender evidence of the production leukemia. Nevertheless, despite the shakiness, we believe these results to be extremely suggestive and provide an urgent basis for intensive further study (Ex. 178).

D. *Conclusions.* Leukemia is a serious world-wide problem. In this country alone, approximately 20,000 adults die annually from this disease, and about 12,000 individuals develop and die from AML each year (ORC/Jandl, P.C. 34, p. 72). However, based on the published literature the number of AML deaths attributable to benzene exposure is unknown. In this regard, Goldstein states: "The incidence of leukemia appears to be a small fraction of all benzene-induced hematotoxicity." (Ex. 54.B, p. 160). One rea-

*A short latency resulting from high exposures is another possible explanation.

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ficially because the families refused permission to release the names of the decedents for fear of loss of compensation and job. This testimony indicates an underestimation of the leukemic risk among Pliofilm workers.

Based on the hypothesis that the risk of leukemia was higher among workers who were exposed to benzene and medical X-rays, Ishimaru et al. conducted a retrospective epidemiological investigation examining the relationship between occupation and environmental factors, other than A-bomb exposure, and the incidence of leukemia in Nagasaki and Hiroshima between 1945 and 1967 (Ex. 2-33). Fifteen occupations were selected in which there had been exposure to either medical X-rays or solvents, especially benzene and its derivatives. This case-control study compared all cases diagnosed as definite or probable leukemias between 1945 and 1967 and residing at the time of the onset of the disease, in Hiroshima or Nagasaki. Controls were matched for city, sex, date of birth (±30 months), distance from the atomic bomb explosion, and residence in either city at the onset of disease. Four hundred ninety-two leukemia cases were identified, and matched controls were obtained for 413. Three hundred and three adult cases with the onset of leukemia at age 15 years or over and their controls were compared. The risk of leukemia was found to be significantly higher (about 2.5 times greater) among those with a history of employment in occupations in which various volatile solvents were used as compared to those without. The relative risk was 1.8 times higher for chronic leukemia and 2.9 times higher for acute. Eighteen of the leukemia cases associated with solvents were located in distant and non-exposed radiation areas and were considered too far from the A-bomb explosion for radiation to have enhanced the increased risk. Accepting the source of error inherent in the method which was used to collect the data, the results of this study nonetheless reinforce the observation that an increase in leukemia existed in that portion of the population exposed to radiation and employed in an occupation where solvents especially benzene, were used.

In 1970, Girard et al. published an epidemiological study (Ex. 2B-283) undertaken to determine previous exposure to benzene or toluene in 401 patients suffering from malignant hemopathies. Extensive interviews about [illegible] work environment [illegible] statistical analyses of solvents were utilized to estimate exposure. Their findings demonstrated that compared to a control group admitted for non-hematological diseases there was a statistically significant greater frequency of past exposures to benzene or toluene among subjects with aplastic anemia, chronic lymphocytic leukemia and acute leukemia.

In April 1977, NIOSH submitted to OSHA a preliminary report by Infante et al. of a study of leukemia among benzene-exposed workers employed in the production of natural rubber cast film (Pliofilm) (Ex. 2-57, Ex. 2A-271).

The study included all white males assigned to the Pliofilm production area who were hourly employees and who at any time between January 1, 1940 and December 31, 1949 had direct exposure to benzene at the Goodyear Akron and St. Mary's plants. Only the men employed in a section having known potential exposure to benzene ("wet side" in industry terminology (Rinsky, Tr. 818-820)) were included in the cohort. Men employed in the Pliofilm operations, but not in production jobs (so called "dry side" workers) were not included in the study. Follow-up of vital status was attempted from termination of employment to June 30, 1975 and was achieved for 75% of the total of 748 benzene-exposed workers. So as not to overestimate the true risk of lymphatic and hematopoietic malignancies associated with benzene exposure, the 25% of the cohort for whom vital status was not determined were assumed to be alive. Little or no quantitative exposure data existed for these plants.

Causes of death were determined from death certificates, and person-years at risk were determined by a modified life-table method. Person-years of observation and causes of death were determined from January 1, 1950 to December 31, 1975. Two control populations were used to generate the numbers of expected deaths in the study. The first comprised the U.S. white male population, while the second was white males employed in an Ohio fibrous glass production facility during the 1940's and who had achieved five years of employment by June 1, 1972.

The most striking finding was the observation of a statistically significant (p less than 0.002) five-fold increased risk of dying of leukemia compared to the U.S. male rates (7 deaths observed vs. 1.38 deaths expected, p less than 0.002), as well as to the fibrous glass workers (7 deaths observed, 1.48 deaths expected, p less than 0.002).

Criticisms of various aspects of this study were raised by participants to the rulemaking. The issue of what level of benzene the workers in the Infante et al. cohort were exposed to was the most discussed area. Participants criticized the information available in the Infante study. The study referred to a November 1946 report of the Industrial Commission of Ohio which indicated that: "Tests were made with benzol detectors and the results indicate that concentrations have been reduced to a safe level, and in most instances range from 0 to 10 or 15 parts per million." Comments at the hearing demonstrated that there were area exposures during this study period exceeding these levels, at times reaching values of hundreds of parts per million. Since no personal monitoring data are available, any conclusion regarding the actual individual time-weighted average exposure is speculative. Because of the lack of definitive exposure data, OSHA cannot derive any conclusions linking the excess leukemia risk observed with any specific exposure level.

The study was also criticized for combining the two separate plants in the same analysis. It was suggested that an independent analysis of the two plants would produce different results, thereby suggesting that factors other than similar exposure to a single agent (benzene) contribute to the excess leukemia. (Lamm, Tr. 2538). OSHA believes that the use of non-age-adjusted leukemia death rates, as utilized in Lamm's analysis, is inappropriate for the assessment of an event associated with age. Therefore, OSHA believes that this criticism is unsupportable on this basis. Moreover, the cohorts were combined based on the similarity of the processes in the two plants (Tr. 842). Also, because of the small number of subjects in the study cohort, the authors stated that it would be inappropriate to analyze the data separatedly for the two plants. (Infante, Tr. 935, 796-97).

A question has been raised by industry participants as to the validity of excluding the "dry side" (Pliofilm finishing) workers from the study cohort (Lamm, Tr. 2638-29; API, PC 33, p. 42-43). As explained by one of the authors, these workers were never intended for inclusion in the cohort following discussion with company personnel indicating there was no benzene exposure on the dry side (In-

cause respiratory air concentrations of the level of the MAC value (15 ppm for benzene). After the workers have been exposed for a sufficiently long time, one must assume that hematological damage will result.

In a recent survey, Aksoy et al. compared the hematological findings of 217 apparently healthy male workers who were exposed to as much as 210 ppm benzene when adhesives containing benzene were utilized (Ex. 2-11). The duration of exposure ranged from 3 months to 17 years. Hematological abnormalities were seen in 23.5% of the workers. Leukopenia, with or without thrombocytopenia, was the most common finding. In addition, relative to controls, benzene exposed workers were found to have a statistically significant reduction (p less than 0.001) in mean white cell and platelet counts. Aksoy and his colleagues reported a considerable variability in the 11 bone marrow specimens studied. The aspirates showed both hypocellularity and hypercellularity (a decrease and an increase in the number of cells present), a finding consistent with his previous reports. (See Aksoy et al. Ex. 2A-290). In 33 percent of the workers examined, the hemoglobin levels fell below the lower limit of normal. Aksoy was reluctant to ascribe the anemia to benzene exposure since it was correctable by iron therapy. However, Goldstein commenting on Aksoy's findings that "the mean corpuscular volume (MCV) was in the high normal to slightly elevated range (80-96 um³) which is unusual for iron deficiency and more in keeping with a benzene effect." (Ex. 43B, p. 140).

In 1977, Dow reported that 2 of the 594 individuals occupationally exposed to benzene died of non-malignant blood disorders, compared to 0.2 deaths expected (DOW/OH/Ex. 154, Table 6). One worker died of pernicious anemia 4 years after retirement. His exposure was estimated to have averaged 30 ppm for approximately 184 months. The second employee, who died of aplastic anemia, had an estimated exposure of 5 ppm for approximately 98 months. Because of the small numbers involved, the significance of Dow's findings is subject to some question, but the trend of excess death is consistent with the evidence presented above.

An issue deserving discussion is the similarity and difference between benzene-induced non-malignant blood disorders and those resulting from other causes. In the NYU report, Goldstein noted that:

> While the literature is inadequate to draw firm conclusions, the progression and outcome [fatality rate] of benzene-induced pancytopenias does not appear to differ substantially from that of published series of patients with idiopathic aplastic anemia (Ex. 43.B, p. 145).[*] (Ex. 43.B, p. 148)

The NRC report comes to a similar conclusion:

> [T]he available evidence does not indicate that the reported benzene-induced blood dyscrasias differ in any way from similar dyscrasias which are caused by other myelotoxic agents or for which the etiology is unknown (NRC, Ex. 2-4 p. 4).

On the other hand, Jandl contends that the high degree of reversibility of benzene-induced non-malignant blood disorders distinguishes these disorders from those caused by other agents which are idiopathic in nature. He reports that the chance for recovery in idiopathic aplastic anemia is 16%, that for drug-related aplastic anemia it is 33% and that based upon a review of 169 patients with benzene-induced aplasia reported between the years 1939-1975, the prognosis for recovery is 87%. (ORC/Jandl, Ex. 34, p. 37) Furthermore, he notes that milder forms of blood disorders resulting from benzene exposure appears to be 100% reversible (ORC/Jandl, PC 34, p. 39).

OSHA is aware that literature indicates that many cases of nonmalignant blood disorders may be reversed. For example, Maugeri has stated:

> the hemopathy due to benzol can, as in most cases studied by us, be cured if it is diagnosed immediately (Maugeri & Pollini Ex. 156, I p. 2).

Hernberg et al. in a follow-up study of 125 workers stated that: "the prognosis of these patients proved to be more favorable than might have been expected." (Ex. 2A-252, p. 209). Also, both Tabershaw and Aksoy have noted the reversibility of various cytopenias (Tr. 2547).

However, certain other investigators report that these disorders have persisted for as long as 12 years after cessation of benzene exposure. Goldwater and Tewksbury noted continued blood abnormalities in 10% of 108 men examined 24 months after exposure ended. (Ex. 141). Helmer observed abnormalities in 25% of 60 patients followed for 16 months, including 2 deaths. Rejcek and Rejskova found that 8 of 4500 workers manifested persistent leukopenia 12 years after exposure. (Cf. Hernberg, Ex. 2A-252, p. 204). Aksoy observed a further distinguishing feature of severe blood disorders resulting from benzene exposure. In over 100 cases of aplastic anemia classified as idiopathic or associated with etiological agents other than benzene, no cases of leukemia were observed (Aksoy, Ex. 60, p. 6A). This contrasts to the development of leukemia among some cases of aplastic anemia associated with benzene exposure.

As is apparent from the above discussion, there is no unanimity of opinion whether benzene-induced blood disorders persists, and are reversible after cessation of benzene exposure and whether such disorders differ from those resulting from other known or unknown causes.

OSHA recognizes that in many cases these disorders appear to be reversible, within the definitions of "normality" or "reversibility" used by the individual authors. However, it is not known whether for particular workers the blood indices actually return to pre-exposed or baseline valves. Because the original literature does not provide suitable long-term longitudinal analysis including adequate sample size, preexposure values nor baseline hematological values for comparative purposes on an individual basis, it is difficult to decide how much reliance can be placed on such studies. Moreover, the evidence is insufficient to determine whether or not individuals who have "recovered" are at greater risk to subsequent development of leukemia.

Finally, OSHA is unable to verify Jandl's quantitative estimates of recovery as the sources selected for his calculations are not adequately presented to permit the development of valid inferences. Consequently, the Agency does not believe it appropriate to conclude that these non-malignant blood disorders will in all cases, be reversed to the individual's normal values.

b. *Animal Studies.* One of the first studies describing experimentally induced benzene toxicity was published by Selling in 1916 (Ex. 2-12). He was able to produce both destructive and "regenerative" effects in rabbits by subcutaneous injections of commer-

[*] However, Goldstein does suggest three possible differences between benzene-induced pancytopenia and so-called idiopathic aplastic anemia; the first is the observance of marrow hyperplasia in benzene-induced disease; the second is the presence of lymphocytopenia; and the third is "relatively frequent but inconsistent" reports of red blood cell macrocytosis resulting from benzene exposure. (Ex. 43.B, p. 148)

rary standard was published on May 24, 1977 (42 CFR 26429). The evidence and findings supporting issuance of the emergency temporary standard and its amendment and a discussion of its provisions are set forth in the aforementioned FEDERAL REGISTER publications. The emergency temporary standard was to have been effective on May 21, 1977. However, as a result of challenges to that standard, filed both in the Court of Appeals for the District of Columbia (*Industrial Union, AFL-CIO* v. *Bingham*, No. 77-1395) and in the Court of Appeals for the Fifth Circuit (*API* v. *OSHA*, No. 77-1516), a temporary restraining order was issued by the Fifth Circuit on May 20, 1977, and the standard never officially went into effect.

On May 27, 1977, OSHA published a proposed permanent standard to control occupational exposure to benzene (42 FR 27452). The emergency temporary standard and its preamble, which the new proposal supplemented, were incorporated in that proposal. The FEDERAL REGISTER document setting forth the proposal also contained a notice of hearing scheduling an informal public hearing to be held pursuant to section 6(b)(3) of the Act, and requesting the submission of written comments, data, views and arguments on all the issues raised by the proposed permanent standard and the emergency temporary standard. Subsequently, on June 24, 1977 (42 FR 32263), OSHA excluded from the scope of the benzene hearing and from the final permanent standard those activities related to the storage, transportation, distribution, dispensing and sale of gasoline as a fuel subsquent to its discharge from bulk terminals. OSHA explained in that notice its intention to assess the regulatory action to be taken to protect workers involved in these activities after conclusion of the deliberations of a joint EPA-NIOSH-OSHA Task Force.

The public hearings on the benzene proposal were held July 19 through August 10, 1977. A total of 95 individuals appeared at these hearings as witnesses. Among the witnesses were employers and employer associations from a variety of industries: petroleum refining, petrochemical, oil and gas production, aviation fueling; and coke ovens and coke by-products. In addition, representatives of the affected workforce, including a number of employees who have been exposed to benzene, unions, government agencies, public interest groups and other interested parties appeared. Furthermore, comments were received from representatives of other industries, such as analytical and research laboratories, paint manufacturing, construction, maritime, and rubber manufacturing and from users of pure benzene as well as users of benzene contaminated solvents. Public participation was representative of a large segment of the benzene users. The verbatim transcript of the hearings, as well as the numerous comments, exhibits and briefs submitted to OSHA before, during and after the hearings, are part of this rulemaking record, along with other relevant documents. The hearing record was originally scheduled to close on August 20, 1977 but, at the request of industry participants, the record was kept open until September 2, 1977 for the submission of additional evidence and until September 27, 1977 for the submission of briefs, summaries and arguments.

In conjunction with the development of the proposed standard, OSHA prepared a draft environmental impact statement. The draft environmental statement was published in the FEDERAL REGISTER (42 FR 27455). On June 17, 1977, the Council on Environmental Quality published a notice of availability of the benzene draft environmental impact statement (Ex 7). In addition to the 45 day comment period specified in 29 CFR 1999.4(g), the environmental impact of the proposed standard was also an issue for the benzene hearing as provided by 29 CFR 1999.4(h) and the notice of proposed rulemaking (42 FR 27452). A notice of availability of the final environmental impact statement for benzene was published on February 3, 1978 by EPA (43 FR 4674).

In addition to the draft environmental impact statement, OSHA prepared an economic and inflationary impact assessment of the proposed standard evaluating factors relevant under section 6(b) of the Act (29 U.S.C. 655 (b)(5), Secretary of Labor's Order 15-75 (40 FR 54484) and Executive Orders Nos. 11821 (39 FR 41501) and 11949 (42 FR 1017). The notice of the proposed standard indicated that the economic impact of this proposal was to be considered at the hearing (42 FR 27452) and certified that the economic and inflationary impact of the proposed standard has been carefully evaluated in accordance with Executive Orders 11821 and 11949.

This permanent benzene standard is based on a careful consideration of the entire record in this proceeding, including materials relied on in the emergency temporary standard, materials referenced in the proposal, and the record of the informal rulemaking hearing including the transcript, exhibits and pre-hearing and post-hearing written comments. Copies of the official list of hearing exhibits, comments, and notices of intent to appear at the hearing can be obtained from the Docket Office, Docket H-059, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue NW., Washington, D.C. 20210.

III. PERTINENT LEGAL AUTHORITY

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every working man and woman. One means prescribed by Congress to achieve this goal is the authority vested in the Secretary of Labor to set mandatory safety and health standards.

Occupational safety and health standards provide notice of the requisite conduct or exposure level and provide a basis for assuring the existence of safe and healthful workplaces. The act provides that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. (Section 6(b)(5).)

Sections 2(b) (5) and (6), (20), (21), (22), and (24) of the Act reflect Congress' recognition that conclusive medical or scientific evidence including causative factors, epidemiological studies or dose-response data may not exist for many toxic materials or harmful physical agents. Nevertheless, standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, standards need only be based on the best available evidence. The legislative history makes it clear that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor, Report No. 91-1291, 91st Cong., 2d Session, p. 18 (1970). This Congressional

sible exposure limit. It is likely, however, that there will be many employees who work in the regulated areas for such periods of time or at such levels of exposure that they would without respirators be exposed to well above the permissible exposure limit. For this latter group, respirators would be required to reduce their exposure levels. To assure that these employees are adequately protected, it is necessary that the sign alert them to the need to wear respirators. Moreover, since even persons who are in a regulated area occasionally and are not exposed over the permissible exposure limits may face an increased risk of leukemia, OSHA does not believe that the respirator warning is such an overstatement as to necessitate elimination of that warning from the sign.

One comment pointed out that the warning sign ignores the flammability of benzene (Com. 50). NIOSH also recommended that the potential danger for fire be displayed on signs with equal prominence with the toxicological hazards. (Tr. 755) OSHA agrees. Benzene, as has been stated, is a highly flammable liquid. Accordingly, in the final standard, OSHA has added a requirement that the signs also contain the legend "Flammable—No Smoking" with equal prominence to the legend "Cancer Hazard."

Labels. The standard requires the use of caution labels on all containers of products containing any amount of benzene. This requirement imposes upon the employer the obligation to assure that all such containers within his workplace are at all times properly labeled. Some industry comments requested that OSHA define "container" (Com. 46, 55, 65) in terms of sizes and types of containers (Com. 53; Com. 72). Participants also appeared to be confused as to whether storage tanks, pipelines, tank cars and tank trucks are such containers as would be require labeling (Com. 60). The purpose of the labeling requirement is to assure that, wherever benzene is present in any quantity, employees are apprised of the hazard. The size or type of the container or its use as a storage vessel is, therefore, not material to this objective. In imposing the labeling requirement, however, OSHA does not intend to include pipelines, or to include trucks or other vessels transporting benzene products in sealed containers. At many points of pipelines, there is no employee exposure nor can the point at which benzene enters a product stream often be determined. Benzene in liquid mixtures, other than in gasoline, is often transported in closed containers, in which case labeling of the container is sufficient without a need for labeling the transport vehicle. Where benzene products not in containers are transported in barges or other tank vessels, such as tankers and tank trucks, it is, of course, necessary that the vessel be labeled. With regard to gasoline, the standard does not cover activities past the bulk terminal and, therefore, gasoline trucks would not require labelling. In view of the above, the standard specifically excludes from the labeling requirements pipelines and any transport vessels or vehicles where the benzene product is transported in sealed containers.

Some participants suggested that the labeling requirements apply only to containers which have liquids with greater than 1% benzene (Com. 53, 72). It was also suggested that labels be affixed only to containers from which exposure to benzene levels above the permissible exposure limit might be reasonably expected to occur so as to exclude a requirement to label finished products which might contain trace amounts of benzene (Com. 59). Since there is no known safe level of exposure to benzene, OSHA feels that, for employees to be adequately apprised of the hazard, all containers must be labeled in the same manner.

The standard requires that the caution labels remain affixed when benzene products leave the employer's workplace. Some comments questioned OSHA's jurisdiction to impose such a requirement (Com. 50, 55, 59). The purpose of this requirement is to assure that all employees, not only those of a particular employer, are apprised of the hazardous nature of benzene exposure. It is OSHA's view that informing employees of the hazards to which they are exposed is an important element in reducing occupational disease and injury and one of the significant purposes of the Occupational Safety and Health Act. Section 6(b)(7) of the Act, which explicitly provides for regulation requiring the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed, is broadly drawn. This section does not limit the employer's obligation of informing employees of hazardous conditions to the employer's own employee. When an employer manufactures, formulates or sells a product containing a toxic substance, that employer is exposing not only his own employees but also the employees of other employers involved in handling, transporting or using the product. The extent of the obligation to inform should be commensurate with the extent of the exposure. This is especially true where the manufacturer, formulator or seller will in many cases be the only employer capable, through his unique knowledge, of providing the information needed for protection of employees. A narrower reading of the statutory authority would defeat the protective purposes of the Act by withholding from employees down the line who come into any contact with the product, adequate information as to the hazard. Furthermore, the use of the labels will alert other employers, who utilize or handle the product and who would not otherwise know of the presence of benzene in their workplace, of their obligation to comply with the standard. OSHA, therefore, feels that this requirement is necessary and appropriate to effectuate the purposes of the Act.

The standard prescribes the legend that must be included on the label. This is to assure that employees are alerted to the fact that they are handling benzene and to the hazard involved. The record evidence establishes that a variety of code names have been used for benzene (Ex 61, Sakol) and that employers (Tr. 3383; 3516), workers (Tr. 3402) and physicians (Tr. 305-6) often do not know that the product contains benzene. Some participants suggested that labels state the percentage of benzene in the product (Com. 58, 21, 59). In order to keep the label information to a minimum and since there is no consistent predictable relationship between the amount of benzene in the product and the percentage level, the final standard does not require any such statement on the label.

Recordkeeping and reporting. The provisions for recordkeeping, reporting, availability of records and the transfer of records are similar to those in the proposal. Such changes as have been made in the final standard are in response to the request of public participants that OSHA reduce the burden imposed by these types of requirements. These provisions implement the requirements of section 8(c)(1) and (3) of the Act, and are consistent with OSHA's general policy concerning records and reports.

Records: paragraph (1) The standard requires a limited amount of recordkeeping. Employers must maintain exposure measurement records and medical records.

The need for keeping these records was generally accepted by the participants in the benzene rulemaking. The common purposes of these recordkeeping requirements is to assure the employer's compliance with the control measures designed for the protection of his employees, and to collect data vital to epidemiological and diagnostic investigations in order to resolve such questions as dose-response relationships in blood diseases caused by exposure to benzene. Furthermore, these records are useful for the employer by enabling him to identify areas of his operations where there is or may be a problem. Exposure measurement records assist in pinpointing those processes or operations which require additional efforts to reduce exposure to benzene. Medical records provide an

dard. (Com. 55.) OSHA, however, believes that the likelihood of eye or repeated skin contact and the resultant need for protective clothing must be assessed on the basis of individual workplace operations. One comment objected to the need for protective clothing or equipment where 1 percent or less benzene is present in the liquid benzene. There is, however, nothing to indicate that such percentages would create a sufficiently reduced hazard to warrant total elimination of the requirement.

The final standard requires the use of "impermeable" protective clothing and equipment. This requirement was in the emergency temporary standard. The proposal, however, would have simply required "appropriate protective clothing and equipment." Where eye and skin protection are required, the protective clothing and equipment to be "appropriate" must not allow liquid benzene to reach the eyes or skin. To make this clear, OSHA has adopted the language of the emergency temporary standard. The impermeable clothing must prevent all penetration of benzene. Thus, where impermeable gloves are used, liquid benzene should not seep through the cuff or any other opening in the glove. This could very well increase the hazard to the employee. It appears, on the basis of testimony from the industry expert witness, that, when a chemical substance on the skin is covered with a totally inclusive material, the rate of permeability of the substance through the skin is greatly increased (TR 2464; 2473).

Hygiene Facilities

Although normally required in carcinogen standards (See Coke Oven and Cancer Policy), the final benzene standard does not contain any requirement for hygiene facilities, such as waste disposal, housekeeping, showers, change rooms, or laundering of clothing.

The question of what, if any, hygiene facilities should be included in the final standard was at issue in the benzene rulemaking proceeding. The most common view of participants in that proceeding was that hygiene facilities were not necessary because of the volatility of benzene (L.C. 19). Almost all participants felt that no hazard would be created by the absence of hygiene facilities. One witness, however, testified that, in his opinion, the wife of a benzene exposed employee, who laundered her husband's work clothes daily died from benzene induced leukemia (Tr. 314). Unfortunately, no further information concerning this case was furnished. OSHA, consequently, finds that the record does not establish the need for a requirement for hygiene facilities.

Medical surveillance: paragraph (i). This standard requires that employers make available a medical surveillence program for those workers who are exposed to benzene at or above the action level of 0.5 ppm TWA. In addition, the regulation contains an emergency provision for the biological monitoring of employees exposed to a massive release of benzene.

Evidence contained in the record clearly indicates that a medical surveillence program is an appropriate measure. Hematologists, company physicians and other participants have recommended the inclusion of a medical surveillence provision in the final standard (Ex. 106; P.C. 30; Ex. 211; Ex. 17, Ex. 179, Bommarito, Tr. 3382). Also, a review of the record discloses that it is a current commmon practice of many industries to routinely examine their employees for evidence of benzene toxicity. (e.g. Wodka, Tr. 1263; Com. 26; Joyner, Tr. 2286; Dow, Tr. 2967, 3021; Ex. 77H.)

Section 6(b)(7) of the Act requires that employers make available medical examinations to ascertain whether the health of workers is adversely affected by exposure to toxic substances, where appropriate. The requirements contained in this regulation are designed to detect changes in the hematopoietic system resulting from chronic exposures to benzene which may be manifested in a range of blood disorders, including leukemia.

It is widely recognized that the major target organ in chronic benzene toxicity is the hematopoietic system, especially the bone marrow. This system has the attribute that a sample of the peripheral blood offers a unique biological "window" on the functioning and health of this system, providing much direct visual information not readily available for other organs or systems.

It is OSHA's view that a medical surveillance program directed toward the early detection of hematopoietic dysfunction by examination of peripheral blood samples is an appropriate measure. This determination receives support from: (1) Studies showing that early blood dyscrasias have been detected in workforces screened by laboratory tests (and often in workers displaying no obvious physical symptomatology) (Greenburg, Ex. 2-8, p. 419; Savilahti, Ex. 2-95, p. 1; Goldstein, Ex. 43B, p. 138); and (2) that even in cases of acute myelogenous leukemia, a period of remission, unfortunately brief, may be effected in a substantial proportion of those afflicted with this fatal disease by appropriate treatment. (ORC/Jandl, P.C. 34, p. 73-74). OSHA's decision is also supported by evidence that some cases of benzene-induced blood disorders may be reversed upon cessation of exposure and by appropriate treatment. (ORC/Jandl, P.C. 34, p. 39).

The medical surveillance provision of the proposed standard was the object of much comment and testimony. For example, over 45 separate comments addressed this issue in prehearing submissions alone. Additionally, substantial testimony was adduced during the hearing, and additional views were submitted to OSHA in the form of post-hearing comments. These suggestions addressed both the content and frequency of the examinations as well as what information should be elicited from the medical/work history portion.

OSHA, in formulating the provisions of the medical surveillance section, was aware of several problems. While there is no disagreement that the blood tissues are the most important organ relative to chronic benzene toxicity, there are as yet no consistent patterns of abnormalities, especially at low exposure levels, and no specific pathognomonic tests of benzene toxicity (Rosen, PC 23A, p. 2). Compounding this problem is the fact that it is difficult to separate cases of early benzene hematoxicity from more common minor blood disorders (Goldstein, Tr. 354). Associated with the problems of exam content is one of testing frequency. There are simply no precise estimates of the time course of the various abnormalities to allow determination of optimal testing frequency. Opinions based upon the lifespan of the blood cells are equally inapplicable in determining the frequency of such exams (Battle, P.C. 26C). While realizing that the more frequent the exams the greater the probability of detecting blood disorders induced by benzene, OSHA is also aware of the practical considerations of a medical surveillance program. Unlike the coke oven standard which applies to a defined number of workers employed in well characterized work sites, benzene is a component (usually as a contaminant) of a wide variety of refined petroleum solvents and, therefore, some benzene exposure occurs in a myriad of work sites and work operations. OSHA also recognizes that to be effective a medical surveillance program must be acceptable to a majority of workers subjected to the examination, the tests must display a high degree of accuracy and reproducibility, and the program should be able to be performed in a routine manner without unduly taxing medical resources. Given the above facts, the prescribed medical surveillance program is designed to accommodate the purpose of detecting early blood disorders resulting from benzene exposure without being overly burdensome and unduly intrusive.

The medical surveillance program consists of three main elements: (1) An initial and periodic examination for all those employees exposed to airborne benzene concentrations at or above the action level, (2) evaluation of ab-

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cords of individual exposure by designated representatives could result in a denial of access to the information by the employee where he is incapacitated and unable to inspect the records or simply not able to understand them. This would defeat the purpose of the availability provision which is to assure current employees that their exposure is properly monitored and assure former employees of access to information necessary for the continued protection of their heatlh. Furthermore, the Act recognizes (sections 2(b)(13); 8(c)(3); 8(f)(1)) the legitimate role of employee representatives in occupational safety and health. One industry comment suggested that employee representatives be formally designated in writing and that access to records also be requested in writing (Com. 15). OSHA does not deem it necessary to include such a requirement in the standard, but employers may establish procedures for access to records so long as the procedures do not restrict the employees' and former employees' to access.

The standard also requires that medical records also be made available, upon request, for examination and copying to the designated physicians or representative of both current and former employees. Some comments questioned the fact that the standard enables not only the employer but also the employee and his representative and OSHA and NIOSH to have access to medical records without specifying confidentiality or otherwise limiting circulation of the information (Com. 26, 48). OSHA recognizes that a physician's records may contain a wide range of personal and medical information deemed to be confidential or private. For this reason, the standard limits the contents of the medical record to such information as is related to benzene exposure. Indeed, the standard requires in paragraph (i) (6) (ii) that the employer advise the physician that the physician's opinion, which becomes a part of the medical record, should not reveal findings or diagnoses unrelated to occupational exposure. The need of the employer, the employee and OSHA and NIOSH to have access to this information has already been thoroughly discussed. Disclosure of the information to other persons is, of course, subject to protective requirements of any applicable laws or regulations.

To assure that the records will be preserved for the required retention period of forty years, the standard requires an employer, who ceases to do business, to transfer his records to his successor and, in the event that there is no successor, to transfer the records to the Director of NIOSH. One industry comment suggested that this section be deleted. (Com. 59). Allowing employers to dispose, at will, of the records of exposure measurements and medical surveillance would result, more often than not, in destruction of these records thus depriving employees of information necessary for evaluation of their health, as well as depriving NIOSH of information valuable to its scientific investigations.

Another participant suggested elimination of the requirement that the records be transferred to NIOSH by registered mail. (Com. 68). OSHA has adopted this suggestion and the permanent standard eliminates the requirement to use registered mail.

Reports. Paragraphs (d)(3), (e)(5), (f)(2), (i)(4)(i). The standard imposes notification requirements upon employers. This requirement is discussed above under *Regulated Areas.*

The standard also obligates the employer to give certain information to employees. The employer must notify each employee of the exposure measurement representative of his exposure. This notification must be made regardless of what the exposure level of the employee is. Two comments suggested that availability of exposure records was sufficient to inform employees of the results of their monitoring (Com. 46 Com. 53). Several comments suggested that the notification be required only where the employees' exposure is above the permissible exposure level (Com. 10, 15, 21, 41, 46, 53, 59) and that exposures below the permissible level be available to the employee upon request (Com. 10). OSHA believes that, consistent with section 8(c)(3) of the Act, every employee has the right to know what his exposure level is and whether it is above or below the permissible exposure level. Moreover, since the permissible exposure level is a feasibility level and not a "safe" level, the employee must know, for proper evaluation of his health by a physician in the present and future, the level of benzene to which he is exposed. Accordingly, the suggestions to modify the employee notification requirements have not been adopted.

The standard further requires that, where the employee's exposure is over the permissible exposure level, the employer must also state in the notification what corrective action the employer is going to take to reduce the exposure level. This is necessary to assure employees that the employer is making every effort to furnish them with a safe and healthful work environment, and implements section 8(c)(3) of the Act.

Notifications to employees of their exposure levels must be made in writing. Several comments objected to this requirement. Some comments suggested that the employer be permitted to notify employees by posting of a notice on the workplace bulletin board (Com. 15, 49, 59), thus relieving the employer of the burden of notifying each and every employee. It is OSHA's view that direct notification to each employee is necessary in order to assure that the employee, as required by section 8(c)(3) of the Act, is apprised of all hazards to which the employee is exposed.

The standard further requires that the notification be within five working days after receipt of the employer's measurement results. Several industry comments requested a change in the five day requirement so as to allow additional time for employers to comply. (Com. 47, 49, 54, 59). OSHA feels that, under ordinary circumstances, the five day limit fulfills the statutory requirement for promptness (section 8(c)(3)) yet allows employers sufficient time for the written notification.

The standard further obligates the employer to provide the employee with a copy of the examining physician's written opinion. One industry comment pointed out the large volume of letters per year which this notification would entail (Com. 53). However, in view of the necessity for each employee to have an evaluation of his health, OSHA is of the view that furnishing each employee with a copy of the physician's letter is not unreasonably burdensome.

Written compliance programs are also required by the standard. These are discussed above under *Methods of Compliance.* The employer is required to submit his compliance program, on request, to OSHA and NIOSH. Additionally, he must make this program available at the worksite for examination by OSHA and NIOSH and by his employees or their authorized representatives. One participant suggested that employers be required to give to each employee a notice of availability of the compliance program rather than merely making it available to the employee or his representative. OSHA feels that this would place an unnecessary burden upon the employer, and has not incorporated the suggestion.

Observation of monitoring: paragraph (m). The final standard requires that the employer provide affected employees or their designated representatives with an opportunity to observe the measuring of employee exposures. This opportunity is specifically required by section 8(c)(3) of the Act. The standard also sets forth certain procedures which must be complied with in connection with the observation of the monitoring. These procedures are designed to assure that the right to observe is meaningful and that the health and safety of the observer is protected during the observation.

A few industry participants requested that the observation of monitoring provision be deleted from the standard (Com. 65). Union participants objected