TABLE VIII–2.—WORKER EXPOSURE TO BD AND LUNG CANCER RISK OVER 45 YEARS AT CURRENT EXPOSURE LEVELS AND LEVELS EXPECTED UNDER THE STANDARD—Continued

	8-hour time weighted average (ppm)							
	0–0.5	0.5–1.0	1	1.0–2.0	2.0–5.0	5.0–10.0	10+[c]	Total
Predicted Excess Deaths at New PEL[b]	14	3	0	0	0	0	0	17

[a] Based on OSHA 1-stage Weibull time-to-tumor model for lung tumors.
[b] Computed as level of lifetime risk times the number of exposed workers.
[c] Based on a median exposure for these workers of 60 ppm.
Source: Office of Regulatory Analysis, OSHA; Department of Labor.

The costs employers in the affected industries are estimated to incur to comply with the standard total $2.9 million in 1996 dollars. These costs, which are presented in Chapter V, the full economic analysis, are annualized over a 10-year horizon at a discount rate of 7 percent. Table VIII–3 shows annualized costs by provision of the standard; the most costly provisions are those requiring engineering controls ($1.6 million per year) and respiratory protection ($0.7 million per year). Table VIII–4 analyzes compliance costs by operation and shows that BD products manufacture will incur over two-thirds of the standard's costs of compliance.

TABLE VIII–3.—ANNUAL COSTS OF THE FINAL BUTADIENE STANDARD, BY PROVISION

Provision	Annualized costs
Engineering Controls	$1,551,000
Exposure Goal Program	104,000
Respirators	685,000
Exposure Monitoring	364,000
Objective Data	3,000
Medical Surveillance	72,000
Leak and Spill Detection	27,000
Regulated Areas	4,000
Information and Training	12,000
Recordkeeping	29,000
Total	2,851,000

TABLE VIII–4.—ANNUAL COSTS OF THE FINAL BUTADIENE STANDARD, BY INDUSTRY SECTOR

Industry sector	Annualized costs
Crude Production	$333,000
Monomer	210,000
BD Products	2,252,000
Stand-Alone Terminals	53,000
Petroleum Refining	3,000
Total	2,851,000

Chapter VI of the economic analysis analyzes the impacts of compliance costs on firms in affected operations. The final rule is clearly economically feasible: annualized compliance costs are less than 0.5 percent of estimated sales in every industry and are less than 4 percent of profits in every industry (see Table VIII–5). Costs of this magnitude will not affect the viability even of marginal firms.

TABLE VIII–5.— ESTIMATED SALES AND PROFITS OF ESTABLISHMENTS AFFECTED BY THE 1,3–BUTADIENE RULE

	SIC	Sales per average establishment ($000)	Pre-tax profit per average establishment in SIC	Annualized cost per establishment	Cost as percentage of sales	Cost as percetage of profit
Crude 1,3–Butadiene Production	2869	$53,998	$5,645,237	$12,341	0.02	0.22
1,3–Butadiene Monomer Production	2869	53,998	5,645,237	17,502	0.03	0.31
1,3–Butadiene Product Production:						
—ABS Resins, Butadiene Copolymers (<50% butadiene)	2821	38,000	2,015,155	31,724	0.08	1.57
—Butadiene Copolymers (.50% butadiene), Neoprene, Nitrile Rubber, Chloroprene Rubbers, EPDM Polymers, Styrene-Butadiene Rubber (SBR Latex), Polybutadiene	2822	16,243	1,328,956	31,724	0.20	2.39
—Adipontrile/Hexamethylene	2869	53,998	5,645,237	31,724	0.06	0.56
—Fungicides	2879	42,694	1,681,885	31,724	0.07	1.89
Petroleum Refining	2911	525,273	19,100,851	22	Negligible	Negligible
Stand-Alone Terminals	4226	2,400	287,273	10,556	0.44	3.67

Source: US Department of Labor, OSHA, Office of Regulatory Analysis, 1996.
Negligible denotes less than 0.005 percent.

Under the Regulatory Flexibility Act, OSHA is required to determine whether its regulations have a significant impact on a substantial number of small entities. The small firm standards established by the U.S. Small Business Administration (SBA) for industries using 1,3-butadiene are as follows: 1,500 employees for firms in SIC 2911 (petroleum refining); 1,000 employees for firms in SICs 2869 (industrial organic chemicals, which includes BD crude and monomer producers) and 2822 (synthetic rubber); 750 employees for firms in SIC 2821 (plastic Table VIII–5 materials and resins); 500 employees for firms in SIC 2879 (agricultural chemicals, which includes some producers of BD products); and annual receipts of $18.5 million for firms in SIC 4226 (special warehousing and storage, which includes stand-alone terminals). Using these definitions, OSHA identified two small firms among crude

BD producers, one small firm among monomer producers, 10 small firms among BD product manufacturers, and no small firms among stand-alone terminals. Because the ownership of one stand-alone terminal could not be identified, OSHA assumed that there would be one small stand-alone terminal. For each of these industries, OSHA estimated revenues and costs for small firms based on the average size of the small firms using BD. The typical petroleum refining establishment has fewer than 1,500 employees. However, because OSHA did not have data on the number of firms with fewer than 1,500 employees, the Agency relied on establishment data to examine possible impacts on small petroleum refineries.

Table VIII–6 presents the results of the regulatory flexibility screening analysis and shows estimated compliance costs and economic impacts relative to revenues and pre-tax income for affected small businesses at the four-digit SIC code level. This approach reflects extreme case impacts because the impacts on small firms are analyzed using average per-establishment compliance costs. As shown in the table, compliance costs as a percentage of industry revenues never reach one percent; they range from less than 0.005 percent to 0.44 percent for establishments in all affected industries. Estimates of compliance costs as a percentage of profits range from less than 0.005 percent to 3.67 percent. Such impacts are not large enough to be significant. In addition, the impacts reflected in the table are likely to be overestimated because Table VIII–6 they are based on extreme-case costs.

TABLE VIII–6.—ESTIMATED SALES AND PROFITS OF ESTABLISHMENTS AFFECTED BY THE 1,3-BUTADIENE RULE

	SIC	Definition of small entity per the SBA	Average sales per small establishment ($million)	Pre-tax profit per small establishment in SIC	Annualized cost per establishment	Cost as percentage of sales	Cost as percentage of profit
Crude 1,3-Butadiene production	2869	1,000 employees	51.30	$5,363,182	$12,341	0.02	0.23
1,3-Butadiene Monomer production	2869	1,000 employees	10.60	1,108,182	17,502	0.17	1.58
1,3-Butadiene product production:							
ABS Resins, Butadiene Copolymers (<50% butadiene).	2821	750 employees	50.00	2,651,515	31,724	0.06	1.20
Butadiene Copolymers (.50% butadiene), Neoprene, Nitrile Rubber, Chloroprene Rubbers, EPDM Polymers Styrene-Butadiene Rubber (SBR Latex), Polybutadiene.	2822	1,000 employees	24.00	1,963,636	31,724	0.13	1.62
Adiponitrile/Hexamethylenediamine	2869	1,000 employees	10.60	1,108,182	31,724	0.30	2.86
Fungicides	2879	500 employees	30.40	1,197,578	31,724	0.10	2.65
Petroleum refining	2911	1,500 employees	45.80	1,655,455	22	Negligible	Negligible
Stand-alone terminals	4226	$18.5 million (receipts).	2.40	287,273	10,556	0.44	3.67

Source: US Department of Labor, OSHA, Office of Regulatory Analysis, 1996.
Negligible denotes less than 0.005 percent.

Thus, because this standard will not have a significant impact either on the smallest establishments (as defined by the SBA) or on the typical establishment in this industry, OSHA certifies that this final standard will not have a significant economic impact on a substantial number of small entities.

OSHA also examined the impact of this standard on increased expenditures by State, local or tribal governments. OSHA found that none of the affected employers were State, local, or tribal governments. Further, since the total costs of the standard are $2.8 million, the stand will not increase expenditures for the private sector by more than $100 million. As a result, OSHA certifies that, for the purposes of the Unfunded Mandates Reform Act of 1995, as well as E.O. 12875, this rule does not include any federal mandate that may result in increased expenditures by State, local and tribal governments, or increased expenditures by the private sector of more than $100 million.

IX. Environmental Impacts

In accordance with the National Environmental Policy Act (NEPA), OSHA has reviewed this standard for occupational exposure to BD and determined that this action will have no significant impact on the external environment. The new standard can be achieved through a combination of engineering controls, work practices, and respirator use in maintenance situations. OSHA reviewed the extent to which any of the engineering controls or work practices might have an environmental impact. OSHA found that these controls will have no significant adverse impact on the eternal environment because no additional solid waste would be contaminated with BD and that any new releases to the external atmosphere would constitute an insignificant increase in emissions. Indeed, most of the recommended controls would prove advantageous from an environmental viewpoint. For example, such controls as replacing slip-tube gauges with magnetic gauges, use of closed loop sampling systems, and the use of dual mechanical seals all serve to reduce both worker exposures and emissions to the environment. Other controls, such as exhaust ventilation in laboratories, leave environmental emissions unchanged.

Based on its review, OSHA concludes that there will be no significant impact on the environment external to the work place as a result of the promulgation of this standard.

X. Summary and Explanation of the Final Standard

OSHA has determined that the requirements set forth in this final standard are those which, based on currently available data, are necessary and appropriate to provide adequate protection to employees exposed to BD. In the development of this standard, OSHA carefully considered the comments received in the docket in response to the proposed rule as well as information received in the BD docket by OSHA since initiation of this

rulemaking. OSHA believes that these provisions are, in large part, similar to the requirements recommended by the labor/industry group in the recent reopening of the BD rulemaking record. (Ex. 118–12A)

A. Scope and Application

The final rule covers all occupational exposure to 1,3-butadiene, with certain exceptions which are described below. OSHA does not believe there are any impacts in construction or maritime employment, but, consistent with OSHA's policy, the standard is being made applicable to these sectors to avoid gaps in coverage and to protect workers in unusual circumstances. Coverage in longshoring and marine terminals would only be triggered if BD is present outside sealed intact containers.

The final rule contains three exemptions from the scope and application; all three exemptions are typically included in OSHA chemical-specific health standards. These exemptions address situations in which the Agency has concluded that the likelihood of significant exposure is quite low. The final rule's exemptions are as follows:

(a)(2)(i) Except for the recordkeeping provisions in paragraph (m)(1), this section does not apply to processing, use, or handling of products containing BD or to other work operations and streams in which BD is present where objective data are reasonably relied upon that demonstrate that the work operation or the product or the group of products or operations to which it belongs may not reasonably be foreseen to release BD in airborne concentrations at or above the action level or in excess of the STEL under either the expected conditions of processing, use, or handling that will cause the greatest possible release or in any plausible accident.

(a)(2)(ii) This section also does not apply to work operations, products or streams where the only exposure to BD is from liquid mixtures containing 0.1% or less of BD by volume or the vapors released from such liquids, unless objective data become available that show that airborne concentrations can exceed the action level or STEL under reasonably predictable conditions of processing, use or handling that will cause the greatest possible release.

(a)(2)(iii) Except for labeling requirements and requirements for emergency response, this section also does not apply to storage, transportation, distribution or sale of BD or liquid mixtures in intact containers or in transportation pipelines sealed in such a manner as to fully contain BD vapors or liquid.

The language of this section, with a single exception, reflects the joint recommendations of the labor-industry group. The exception relates to the suggested language in the labor/industry agreement ''or in any credible accident'' at the end of paragraph (a)(2)(i).[8] (Ex. 118–12A) OSHA believes that this phrase lacks clarity and has chosen to use the word ''plausible'' instead of ''credible'' to better convey the Agency's intent. Dow Chemical Company, which reviewed a draft of the Agreement, objected to the use of the phrase ''credible accident'' because Dow personnel were unsure of its meaning. (Ex. 118–16, p. 3) Additionally, OSHA has modified the definition of objective data to more clearly delineate its intended source and use.

Although the agreement itself offered little explanation for each of the recommended exemptions, the submission of CMA, a participant in the joint discussions, sheds some light on the issue of why the term ''credible accident'' was included. They felt that the ''focus in applying the (objective data) exemption should be on reasonably predictable conditions of processing, use or handling associated with each product, stream or work operation.'' (Ex. 118–13, p. 3) CMA said that the addition of the phrase ''credible accident'' was meant to trigger only the emergency response requirements of the standard when objective data demonstrate that exposures may reasonably be foreseen to exceed the action level or STEL during a ''credible accident.''

OSHA believes that the phrase ''credible accident'' is unnecessary because paragraph (a)(2)(i) already states that objective data may be used to address situations that can reasonably be foreseen. However, OSHA has decided to include the phrase ''any plausible accident'' to stress the point that the objective data criteria are not intended to be so circumscribed that it is impossible to meet them. OSHA acknowledges that a constellation of unforeseen circumstances can occur that might lead to exposure above the action level or STEL even when the objective data demonstration has been correctly made, but believes that such occurrences will be rare. OSHA further believes that compliance with other regulations, such as the Process Safety Management standard (29 CFR 1910.119), will provide additional assurance that such accidents will not occur.

OSHA proposed to exempt ''processing, use, or handling of products containing BD where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release * * *'' (55 FR 32736 at 32803) The proposed regulation also included a requirement that the employer keep the data supporting the exemption as long as such data were relied upon.

Roger Daniel of the CMA BD panel objected to the requirement that in order to be relied upon as objective data, the data must reflect include the ''greatest possible release.'' He argued that ''* * * to verify the greatest possible release and thereby obtain an exemption, employers could be forced to conduct extensive worst case analyses for every product.'' (Ex. 112, p. 133)

OSHA agrees that a worst-case demonstration for each product is not necessary to qualify for this exemption under the ''objective data'' provision of the scope and application paragraph of the standard. Due to concern that the proposed language might be overly difficult to interpret, OSHA has modified the language in the standard to reflect this and added a definition of the term ''objective data.'' The definition now states that ''objective data means monitoring data, or mathematical modelling or calculations based on composition, chemical and physical properties of a material, stream or product.'' The exemption allows use of objective data, and states that when objective data are used to exempt employers from the BD standard, the data must demonstrate that the work may not ''reasonably be foreseen'' to release BD above the action level or the STEL.

The objective data may be, at least partially, comprised of monitoring results. For example, data collected by a trade association from its members that meet the definition of objective data may be used. However, a single employer's initial monitoring results would not be sufficient to meet the criteria for objective data under this standard (see discussion of objective data in Definitions section of this preamble). A showing by initial monitoring that the level of BD is below the action level does greatly reduce the responsibilities of the employer; however, it would not support an

[8] This section does not apply to processing, use, or handling of products containing BD or to other work operations and streams in which BD is present where objective data are reasonably relied upon that demonstrate that the work operation or the product or the group of products or operations to which it belongs may no reasonably be foreseen to release BD in airborne concentrations at or above the action level or in excess of the STEL under either the expected conditions of processing, use, or handling that will cause the greatest possible release or in *any credible accident.*

exemption from the standard. Instead, to qualify as objective data, OSHA means employers' reliance on manufacturers' worst case studies, laboratory studies, and other research that demonstrate, usually by means of exposure data, that meaningful exposures cannot occur. Paragraph (a)(3) requires that all such data be maintained by the employer as long as they are relied upon to support the exemption.

In comments received during the recent re-opening of the record, Total Petroleum suggested that objective data be kept as long as they are relied upon and for 5 years thereafter. (Ex. 118–5) However, OSHA believes that keeping these data for as long as they are used is a better use of resources, and this requirement is included in the final rule.

OSHA has allowed the use of objective data in past standards to exempt employers from initial monitoring requirements and hence, from most of the provisions of these standards, e.g., formaldehyde 29 CFR 1910.1048, asbestos 29 CFR 1926.1101. The American Petroleum Institute (API) and others voiced support for this approach. (Ex. 108; 112)

The objective data definition is discussed more extensively in the definition section of this preamble.

The following paragraphs deal with the comments and testimony received during the rulemaking on topics related to the scope and application of the standard. Some of these comments would appear to address both the objective data exemption and an exemption for materials containing less than 0.1% BD. This is due, in part, to the fact that the proposal did not contain an exemption for the latter materials, and commenters objected to having to make a demonstration using objective data that materials containing less than 0.1% BD would not release BD at levels in excess of the action level or STEL in order to be exempted. OSHA has reexamined the issue and has included the 0.1% BD cutoff in the final rule paragraph (a)(2)(ii).

Crude Oil and Refinery Products

Oil refiners indicated that BD is absent from crude oil, and requested that OSHA explicitly exempt oil and gas well drilling, production and servicing operations, and transportation of crude oil from the standard. (Ex. 108; 109; 91) They also indicated that, although BD may be an undesirable intermediate by-product with trace quantities in enclosed streams in modern petroleum refinery processes, BD is normally destroyed, so it would not be present in refined products, such as gasoline, motor fuel, or other fuels. They asked for an exemption for those refined products.

A site visit report was submitted to the rulemaking record by OSHA's contractor, Kearney/Centaur, which described the processes at a refinery. (Ex. 23–119) The site visit report contained the following conclusions:

> The concentrations of 1,3-butadiene in the process streams studied rarely if ever exceed 2500 ppm. * * * The contents of the streams are released to the atmosphere only in extremely small quantities through sampling, or by significant spills, leaks or accidents. * * * Employees are rarely in close proximity to the sampling points or any other potential release point. * * * Monitoring data show that exposures are well below the proposed limits, below the actions levels and even below measurable levels in most cases. (Ex. 23–119)

Based on these comments and data in the docket, OSHA has included the exemption for ''streams'' containing less than 0.1% BD, such as those found in refineries, and in the final rule has included streams among the items for which an objective data exemption can be claimed.

Polymers

Duke Power asked OSHA to exempt finished BD polymer from the BD standard to be consistent with the vinyl chloride and acrylonitrile standards, so that the utility would not need to maintain records of objective data. (Ex. 32–12) The Rubber Manufacturers Association (RMA) said that ''synthetic rubbers made from polymerized BD are used extensively by (their 200 companies) members in manufacturing a wide range of these rubber products.'' (Ex. 32–13). In the preamble to the proposal, OSHA acknowledged that ''[i]t is likely that in a number of products made from, containing or treated with BD, there may be insignificant residual BD present to the extent that minimal exposure would be expected.'' (55 FR 32736 at 32787) RMA indicated that four studies indicated the levels of BD in the samples from their plants range from 4 ppb to 0.2 ppm. These values are clearly well below the 0.1% cutoff in the final rule and the percentage exemption would therefore apply.

Intact Containers

Exxon Chemical Company, a producer of BD, which ships it by several modes of transportation (ship, barge, tankcar, tanktruck and pipeline) indicated that there is no potential for BD exposure since BD-containing streams are totally contained in pressurized equipment during transportation. (Ex. 32–17) Exxon said: ''The developing and maintaining the 'objective' data would be very cumbersome (for many carriers and shipment points and various kinds of BD-containing streams) * * * time-consuming and would not contribute to reduced exposure.'' Exxon asked OSHA to provide a general exemption for intact transportation containers. The Independent Liquid Terminals Association (ILTA), whose members own or lease facilities in which BD is stored, asked OSHA to establish a concentration cutoff and to grant reasonable exemptions from the standard. (Ex. 32–18) Roger Daniel of the CMA panel made a similar request. (Tr. 1/18/91, p. 1174) The labor-industry agreement also recommended exemption of intact containers and pipelines from the standard except for labeling and emergency provisions. (Ex. 119)

OSHA is allowing the exemption of ''storage, transportation, distribution or sale of BD or liquid mixtures in intact containers or in transportation pipelines sealed in such a manner as to fully contain BD vapors or liquid,'' OSHA is not excluding by this exemption, the situation where BD-containing material is being transferred to or from containers, pipelines, or vehicles. Data have shown that there is a potential for significant exposure to BD during these operations. For example, exposure data indicate high potential exposure during unloading of railcars and tank trucks in both monomer and polymer production facilities. (Ex. 30) Such operations are not exempt from the standard-they are not considered ''sealed'' for purposes of this standard and do not ''fully contain BD vapors or liquid.''

Mixtures of Less Than 0.1% BD

The final rule contains a specific, though qualified, exemption for instances where materials containing less than 0.1% BD are present.

In the proposal, OSHA discussed the application of the Hazard Communication Standard (29 CFR 1910.1200) to materials containing less than 0.1% of BD, a carcinogen, but did not specifically include an exemption for these materials.

Jack Hinton of Texaco, representative of API, which represents over 250 companies involved in all aspects of the petroleum industry, indicated that

> * * * many petroleum streams and products will have little or no BD present (and that) much of the petroleum industry, such as production, transportation and marketing operations would qualify for these case-by-case exemptions. (Ex. 74; Tr.2/20/91, p.1842–44).

Since the ''objective data'' obligation could impose a burden on their

industry, Mr. Hinton urged OSHA to expand the exemption to include the processing, use and handling of streams containing BD, as well as products. (Tr. 2/20/91, pp. 1842–44)

Similarly, CMA stated, ''* * * facilities that manufacture, process or use BD often have very extensive, integrated operations.'' (Ex. 32–28, p. 108; Ex. 112, p. 134) At these facilities, BD is found at quantities below 0.1% not just in the immediate area of BD production, but in many other streams and products as well. Under these circumstances, the burden of generating ''objective data'' which would qualify for the exemption would be ''so enormous as to largely eliminate its value.'' (Ex. 112, p. 134).

Exxon Chemical Company also indicated that ''BD is present in a large number of product and intermediate streams throughout chemical plants and refineries.'' (Ex. 32–17) According to Exxon, there is very little exposure potential at low levels, since precautions are taken to contain these flammable materials and its rapid dispersion as a gas at ambient condition. Exxon suggested an exemption for product and intermediate streams containing less than 0.1 percent BD ''as is used in the Hazard Communication Standard and in the Benzene Standard.'' They claimed that their resources to develop ''objective data'' could be devoted to ''more productive activities aimed at exposure reduction.'' Arco Products Company stated that ''potential exposures are of extremely short duration in the refining business'' and asked for the exemption of ''streams with less than 0.1% as in the benzene final standard.'' (Ex. 32–20)

OSHA has found that, on the basis of the record and comments of participants in the rulemaking, as well as the recommendations of the labor/industry group, the exemptions as stated above are justified. The criteria for each exemption are helpful in assuring that only very low exposure to BD is possible when the exemptions apply.

The exemptions from the scope of the standard closely resemble those in the benzene standard. The exclusion of products containing less than 0.1 percent BD is consistent with the Hazard Communication Standard, which has this as a cutoff for application of certain requirements to carcinogens (paragraph (a)(2)(ii)).

The basis for the exemptions for sealed containers and pipelines containing mixtures with more than 0.1 percent BD is that it is unlikely for such containers and pipelines to leak sufficient BD to expose employees over the action level on a regular basis. Further, sealed containers and pipelines with liquids containing more than 0.1 percent BD are covered by the emergency provisions of the standard (e.g., personal protective equipment, medical screening). Sealed containers and pipelines are also covered by the Hazard Communication Standard, 29 CFR 1910.1200. If the containers or pipelines contain more than 0.1 percent BD, employers are required to: label the containers and pipelines to indicate that they contain BD, a carcinogen; to have employee training specifying what to do if the container was opened or broken; and to supply employees with material safety data sheets. Labeling and training provisions of the Hazard Communication Standard provide protection in normal situations where a container or pipeline breaks so that employees will know how to handle and clean up the material safely. The emergency provisions of the Hazardous Waste and Emergency Response Standard would cover emergency situations caused by major releases.

Further, operations where the containers and pipelines are opened or the chemicals contained in them are used are covered because of the possibility of exposure above the action level or PELs. It should be noted that while the Hazard Communication Standard generally exempts materials containing less than 0.1 percent of a carcinogen, any material containing BD (defined as a potential carcinogen in this standard) that is capable of causing exposure above the action level is covered even if the 0.1 percent exemption applies. Specifically this provision states:

> If the chemical manufacturer, importer or employer has evidence to indicate that a component present in the mixture in concentrations of less than one per cent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health risk to employees in those concentrations, the mixture shall be assumed to present the same hazard. (29 CFR 1910.1200(d)(5)(iv))

OSHA also notes that a similar provision is included in the standard for DBCP (1,2-dibromo-3-chloropropane). (29 CFR 1910.1044).

B. Definitions

Action level means airborne concentration of BD of 0.5 ppm calculated as an eight (8)-hour time-weighted average (TWA). OSHA has determined that the final PEL for BD is 1 ppm and the final action level for BD is one half that level, 0.5 ppm. OSHA notes that this is the action level recommended in the Labor-Industry Joint Recommendations. (Ex. 119)

Due to the variable nature of employee exposures to airborne concentrations of BD, an action level provides a means by which the employer may have greater assurance that employees will not be exposed to BD over the PEL on days when measurements are not taken.

The action level also increases the cost-effectiveness and performance orientation of the standard while improving employee protection. Employers who can, in a cost-effective manner, develop innovative methodology to reduce exposures below the action level will be encouraged to do so in order to save on the expenses for the monitoring and medical surveillance provisions of the standard. Their employees will be further protected because their exposures will be less than half of the permissible exposure limit. They will also avoid the need to implement controls specified under paragraph (g) of this section, Exposure Goal Program.

The statistical basis for using an ''action level'' has been discussed in connection with several other OSHA health standards (see, for example, acrylonitrile (29 CFR § 1910.1045; 43 FR 45809 (1978)). In brief, the standard does not require the employer to monitor employee exposure on a daily basis. This would be prohibitively expensive. Use of the action level is a method that gives the employer confidence that if employees are exposed to less than the action level on days when measurements are taken, they are most likely not exposed over the PEL on days when no measurements are taken—all other factors being equal. Where exposure measurements are above the action level, the employer cannot reasonably be confident that the employee may not be overexposed. Therefore, requiring periodic employee exposure measurements to be made where exposures are at or above the action level provides the employer with a reasonable degree of confidence that employee exposures have been adequately characterized. (Ex. 23–59)

Use of the action level concept will result in the necessary inclusion of employees under this standard whose exposures are above the action level and for whom further protection is warranted. The action level mechanism will also greatly limit the percentage of workplaces covered under the standard because employers whose employees are under the action level will be exempt from most provisions of the standard. The action level concept,

therefore, provides an objective means of tailoring different sections of the standard to those employees who are at the greatest risk of developing adverse health effects from exposure to BD.

Unique to the BD standard is paragraph (g), Exposure Goal Program, which is also triggered at the action level. This program, which OSHA included at the recommendation of the Labor/Industry group, is described further in the Summary and Explanation of paragraph (g).

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

Authorized person means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures, or any other person authorized by the Act or regulations issued under the Act. Due to the highly hazardous nature of BD exposure, the number of persons designated as authorized should be limited, insofar as possible.

Business day is newly defined in the final rule as any Monday through Friday, except those days designated as federal, state, local or company holidays. (Ex. 18–12A) This term is used in the paragraph dealing with employee notification of monitoring results, (d)(7), in which OSHA had proposed that notification occur within 15 working days after the receipt of monitoring results. The joint labor/industry group recommended 5 business days instead. In addition, they recommended that the notification of the corrective action being taken when monitoring results indicate exposures in excess of the PELs be required within 15 business days, (paragraph (d)(7)(ii)). OSHA has accepted the recommendations because it is protective of workers. As a general rule, OSHA health standards require notification within 15 days of receipt of results. Quicker notification is, of course, desirable, but feasibility considerations usually make the 15-day period the shortest practical. However, in this case, the parties agreed that 5-day notification is feasible and desirable and OSHA wholeheartedly endorses the concept.

OSHA has also allowed 15 business days between medical evaluations and notification of employees of their results. This change was recommended by the labor/industry agreement and was not proposed by OSHA in 1990. OSHA believes that the requirement of paragraph (j)(7) requiring that written notification of the medical opinion be provided by the employer within 15 business days of the examination or other medical evaluation is reasonable and adequately protective of worker health.

1,3–Butadiene means an organic compound with chemical formula $CH_2{=}CH-CH{=}CH_2$ which has a molecular weight of 54.15 gm/mole. Its Chemical Abstracts Registry Number is 106–99–0. The definition was needlessly lengthy in the proposal and has been shortened.

OSHA has added a definition for the *complete blood count* required in the medical screening and surveillance section. Because the definition may vary, OSHA believes that a definition which includes each component of what the Agency requires to be included in a *complete* blood count is needed. These components (which are laboratory tests performed on whole blood specimens) are: White blood cell count (WBC), hematocrit (Hct), red blood cell count (RBC), hemoglobin (Hgb), differential count of white blood cells, red blood cell morphology, red blood cell indices, and platelet count.

Day means any part of a calendar day. Therefore, if a requirement is applicable to an employer whose employee is exposed to BD on 10 days in a calendar year, that requirement is applicable if the employee is exposed to BD for any part of each of 10 calendar days in a year.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee. This definition remains unchanged from that in the proposal.

OSHA proposed that *Emergency situation* would mean an occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in a substantial release of BD that could cause employee exposures that greatly exceed the PELs.

The provisions that the employer must comply with in case of an emergency situation include Respiratory Protection, Medical Screening and Surveillance, and Employee Information and Training. As is also the case in the benzene standard, OSHA does not intend that every leak will automatically constitute an emergency situation. The exposure must be high and unexpected. Thus, the nature of the emergency provisions is performance-oriented and relies upon judgement, for it is not possible to specify detailed circumstances which constitute an emergency.

In objecting to the proposed definition of emergency, Shell noted that ''a release does not necessarily equate to high employee exposure.'' (Ex. 32–27) OSHA also sought additional guidance in its definition of ''emergency;'' when the record was re-opened for comment on the labor/industry draft agreement, OSHA raised the issue by presenting a revised definition for comment. This was:

> * * * any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of BD.

The revised definition changed the conditions of release to qualify as an emergency from ''unexpected'' to ''uncontrolled'' to more clearly define what the agency considered to be an emergency situation which would trigger specific provisions of the standard (e.g., respirator use, limited medical screening and surveillance). OSHA asked whether the change provided adequate guidance to the public. Relatively few commenters dealt specifically with this issue. However, Bridgestone/Firestone, Inc. stated that ''* * * a controlled release, even in significant quantities, is not an emergency precisely because it can be controlled.'' (Ex. 118–14, p. 5) They recommended that OSHA define what constitutes a significant release as an ''uncontrolled release of BD that presents serious danger to employees in the workplace,'' noting that OSHA defined catastrophic release in 29 CFR 1910.119 as one posing a ''serious danger to employees.'' Bridgestone/Firestone feared that defining emergency as proposed might result in application of it to situations which are ''lawful, safe and managed by the standard through respirator use.'' (Ex. 118–14, p. 6)

Dow Chemical Company also submitted comments in support of defining emergency in terms of ''uncontrolled significant release of BD'' because of its consistency with other standards. (Ex. 118–16, p. 3)

Akzo Nobel Chemicals, Inc. suggested that the definition of an emergency should be:

> An uncontrolled dangerous event due to a combination of unforeseen circumstances, such as the spill of significant quantities of hazardous substances, fire or explosion, massive failure of equipment/personnel or other occurrences which require an immediate response by persons not working in the immediate area, except maintenance activities and which could result in harmful

exposures during hazardous activities, fires or explosions. (Ex. 118–3)

They also expressed the belief that use of the term ''uncontrolled'' is essential to the definition of an emergency, and that ''daily, foreseeable events are not emergencies.'' Azko Nobel gave, as an example, the rupture of a container, which they felt would constitute an emergency ''only when a dangerous amount of material escaped.'' Akzo Nobel felt that the definition of emergency should also depend on the type of responder needed to deal with the situation—that ''if the responders are persons outside the work area (other than maintenance type personnel) that fact suggests that an emergency is occurring.'' Akzo Nobel believes the definition of emergency must be tied to the amount of hazardous material released and the exposure resulting from it.

All these comments in general support OSHA's revised definition. Therefore, OSHA is adopting the revised definition for the reasons stated in the comments.

Employee exposure means exposure to airborne BD which would occur if the employee were not using respiratory protection. This definition is intended to apply to all variations of the term ''employee exposure'' that have essentially the same meaning, such as ''exposed employee'' and ''exposure.'' The definition is consistent with OSHA's previous use of the term ''employee exposure'' in other health standards (Asbestos, 29 CFR 1910.1001; Benzene, 29 CFR 1910.1028; Ethylene Oxide, 29 CFR 1910.1047; Cadmium, 29 CFR 1910.1027).

Objective data are redefined in the final rule to clarify and better define what OSHA believes they entail. Objective data are defined as:

monitoring data, or mathematical modelling or calculations based on composition, chemical and physical properties of a material, stream or product.

In the proposed rule, the term ''objective data'' was used to provide an exemption from the scope and application of the rule and was not specifically defined in the definition section.[9]

There appeared to be some confusion as to what was meant by objective data as presented in the proposal. OSHA has determined that a specific definition of objective data is necessary, and it has included it in the definition section.

OSHA believes that objective data may include such data as: (1) Information provided by the manufacturer or a determination that air concentrations will not exceed the action level or STEL, under foreseeable conditions of use, based on the information provided by the manufacturer; (2) representative data or collective industry data which are relevant to the materials, process streams, and products for which the exemption is being documented, under foreseeable conditions of use.

Charles Adkins, then Director of OSHA's Health Standards Programs Directorate, explained at the hearing that ''. . . you are allowed to make a calculation to determine whether or not you need to do monitoring or not. . . . If you're below the action level, you do not need to do anything.'' (Tr. 1/15/91, pp. 29–31) Indeed, to qualify for an exemption does not necessarily ''. . . have to be actual data collected or experimental data. . . . (The employer) . . . can make . . . appropriate calculations, and if he can support his calculation, that would be considered part of his objective data.'' (Tr. 1/15/91, p. 30)

The definition of objective data contained in the final rule adopts the one contained in the Labor-Industry Joint Recommendations. (Ex. 119) OSHA believes that such a definition meets the intent of the proposal. While OSHA does not require employers to perform complex modeling to avail themselves of the objective data exemption, it should be noted that there may be times when it would be difficult or inappropriate to attempt to use objective data. This issue was discussed in the formaldehyde standard, wherein the Agency stated that complex modeling exercises may not be a substitute for employee exposure monitoring

. . . in workplaces where many complex factors must be considered to use objective data, a high degree of uncertainty will be associated with trying to assess employee exposure from objective data. In these instances employers should conduct exposure monitoring instead of relying on objective data so that they can have confidence that they are in compliance with the standard's provisions. (52 FR 46100, 46255–46256, 12/4/87)

However, if carefully used in appropriate circumstances, OSHA believes that objective data may be useful in minimizing needless exposure monitoring.

Permissible Exposure Limits, PELs means either the 8 hour Time Weighted Average (8-hr TWA) exposure or the Short-Term Exposure Limit (STEL). The two limits are often referred to as PELs in various documents and this definition clarifies what is meant by ''PELs.''

Physician or Other Licensed Health Care Professional has been incorporated into the standard's medical screening and surveillance provisions to include persons certified, registered, or licensed to perform various activities required by the standard. OSHA's authority does not supersede a state's right to license, register, or certify individuals to perform these tasks. Therefore, in the final rule, OSHA has replaced the word ''physician'' with the phrase ''physician or other licensed health care professional'' to allow individuals to perform duties under the provisions of the standard which they are permitted to perform in their jurisdiction through their licensure, registration, or certification.

Regulated area means an area where airborne concentrations of BD exceed or can reasonably be expected to exceed the permissible exposure limits. The definition of regulated areas in the final rule is the same as the proposed definition. Texaco was concerned that the phrase ''can reasonably be expected'' is open to varied interpretations or could be misunderstood, and recommended that regulated areas be required only where exposure monitoring indicates that air concentrations of BD are above the PELs. (Ex. 32–26) OSHA believes workers will be better protected where a regulated area is required even if one of the PELs is not exceeded at all times. The specific requirements for a regulated area are discussed in the summary and explanation for paragraph (e) below.

This section is newly defined in the final rule to clarify that this term is synonymous with the 1,3-Butadiene Final Rule.

C. Permissible Exposure Limits

Since 1970, the PEL for 1,3-butadiene has been 1,000 parts per million (ppm) as an 8-hour TWA. The final rule reduces the permissible exposure limits to 1 ppm as an 8-hour time-weighted average (TWA) and to 5 ppm as a 15-minute short-term exposure limit (STEL). As part of this rulemaking, OSHA is deleting from Table Z–2 of 29 CFR 1910.1000 the exposure limit of 1000 ppm as an 8-hour TWA for BD. OSHA has determined that the former PEL presented a significant risk of cancer to employees exposed to BD and

[9] This section does not apply to the processing, use or handling of products containing BD where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release. (55 FR 32803)

that compliance with the new standard will substantially reduce that risk. The basis for the 8-hour TWA–PEL and STEL is discussed in the sections of this preamble dealing with health effects, risk assessment, significance of risk, and in the economic analysis. This section briefly summarizes some of that discussion.

As discussed earlier in the Health Effects section, in the NTP bioassays, mice exposed to BD via inhalation developed cancer at multiple sites. When these data were used to estimate risk via a quantitative risk assessment, the data indicated that risk at the former PEL was quite high and should be lowered. In addition, epidemiologic studies of BD-exposed worker groups have suggested that BD induced leukemia in a dose responsive manner. In the proposal, OSHA's preliminary risk assessment found its ''best'' estimate of risk, derived from the female mouse heart hemangiosarcoma data using the multistage model, predicted 147 excess deaths per 1,000 workers at the former PEL of 1,000 ppm.

In 1990 OSHA proposed a PEL of 2 ppm as an 8-hour TWA and 10 ppm as a short-term limit, based in part on its preliminary risk assessment, which estimated an excess cancer risk of 5.1 per 1,000 workers at the proposed PEL of 2 ppm. As discussed earlier in this preamble, economic and technologic feasibility considerations led OSHA to propose a PEL of 2 ppm, although the preliminary risk assessment estimated that there was still significant remaining risk at that level of BD. As discussed in the Quantitative Risk Assessment section, OSHA used a more recent lower dose NTP mouse study to estimate risk. That estimate using lung cancer in female mice, the most sensitive cancer site in the most sensitive species, was 8.1 excess cancers per 1,000 workers exposed to 1 ppm BD over a 45-year working lifetime (the estimate at 2 ppm for this site was 16.2 lung cancers per 1,000 workers).

In light of the need to reduce the significant residual risk remaining at a PEL of 2 ppm, OSHA determined that it must reevaluate the record evidence to assure that significant risk is reduced to the extent feasible. This review, discussed at length earlier in this preamble, has led OSHA to conclude that an 8-hour time-weighted average permissible exposure limit of 1 ppm is both feasible and is needed to further protect worker health.

Throughout this rulemaking there was consensus that the existing PEL adopted by OSHA in 1971, 1,000 ppm, which ACGIH had developed as a TLV for BD to prevent irritation and narcosis, was inadequate to protect workers from the hazard presented by this chemical (e.g., IISRP, Ex. 34–4, CMA Ex. 32–28, American Lung Association, Ex. 32–10). However, there was *not* unanimity as to the appropriate level. OSHA's expert witness, Dr. Philip Landrigan, stated the following:

> * * * I was distressed to see that in setting the PEL at two parts per million that you decided to accept the occurrence of five excess deaths per thousand exposed workers which translates to 5,000 excess deaths per million exposed workers. It seems to me that this is not consistent with optimal practice and if the agency has a chance to reconsider that risk assessment and possibly lower the standard from the proposed PEL of two parts per million, I certainly would like to ask you to reconsider. * * * Five thousand cancer deaths seems like a lot to me. (Tr. 1/15/91, p. 204)

In testimony and submissions to the rulemaking record, NIOSH recommended that the permissible exposure level be set at the lowest feasible levels and recommended 6 parts per billion on the basis of its assessment of risk. (Ex. 32–25, Tr. 1/17/91, p. 681) NIOSH's quantitative risk assessment was based on NTP's lower dose mouse study and application of a time-to-tumor model (see Quantitative Risk Assessment and Ex. 90). Although some of the underlying assumptions made by NIOSH in its analysis differ from those OSHA has used in a subsequent time-to-tumor analysis, the level of risk estimated by NIOSH further contributed to OSHA's concern regarding the level of risk estimated to remain at the proposed PEL of 2 ppm.

Other risk assessments were submitted which yielded lower estimates of risk. (Shell Oil Company, Ex. 32–27; CMA, 28–14) Each of the risk assessments in the record is discussed in the section of this preamble dealing with the quantitative risk assessment.

At the time of the public hearings, industry representatives opposed lowering the PEL below 2 ppm. For example, participants from Shell stated that they had already ''set an internal standard at 2 ppm,'' and felt a lower level would not increase employee protection. (Shell, Ex. 32–27, 34–7) This was echoed in the comments of styrene-butadiene latex manufacturers. (Ex. 34–5) In fact, IISRP felt that a 10 ppm PEL was low enough to eliminate significant risk. They described the difficulties the polymer industry anticipated at lower PELS. (Ex. 34–4, 32–33)

Labor representatives, particularly the United Rubber Workers, and supporters, among them: Irving Selikoff, Cesare Maltoni, Sheldon Samuels, Myron Mehlman, and Louis Beliczky, urged OSHA to adopt a PEL of 0.2 ppm. (Ex 32–1, 34–6) Diane Factor, representing the AFL–CIO, said that ''OSHA must conduct an analysis that attempts to show feasibility below 2 ppm and not stop at the industry acceptable level.'' (Tr. 1/17/91, p. 839)

Dr. Myron Mehlman, Professor of Environmental and Community Medicine at UMDNJ, Robert Wood Johnson Medical School, New Jersey, testifying on behalf of the United Rubber, Cork, Linoleum and Plastic Workers of America, AFL–CIO, and the Sierra Club, stated his opinion that a PEL of 2 ppm was ''dangerously high.'' (Ex. 79) He urged OSHA to ''adopt a 0.05 to 2 ppm PEL and 0.2 to 1 ppm STEL to protect the health of workers and the environment. (Tr. 2/20/91, p. 1776) The Department of Health Services, State of California, performed a quantitative risk assessment using the NTP–I mouse study data and urged OSHA to ''* * * consider the feasibility of adopting 1 ppm or a lower level.'' (Ex. 32–16)

The issues raised by participants and OSHA's concern about the level of risk remaining at the 2 ppm PEL led OSHA to conclude that further scrutiny and re-analysis of the record data were necessary and prudent to assure that the limit set by the Agency is that which is reasonably necessary and appropriate and that reduces significant risk to the extent feasible, particularly in view of the high degree of carcinogenicity of BD.

Joint Recommendations of Labor/Industry Group Regarding PELs

The March 1996 industry/labor agreement recommended that OSHA adopt a PEL of 1 ppm and a STEL of 5 ppm (also an action level of 0.5 ppm). OSHA is pleased that this group of interested parties have reached the same conclusion as the Agency in this regard. The joint recommendations suggest a STEL of 5 ppm, but questioned whether the record would support this STEL. IISRP nonetheless agreed that the PELs included in the recommendation are feasible in view of the fact that the final rule allows the use of respirators in intermittent, short-duration work. OSHA's own analysis also shows that a 1 ppm TWA and 5 ppm STEL are technologically and economically feasible and necessary to substantially reduce significant risk of material impairment of health. (See the extensive discussions in the health effects, risk assessment, significant risk and feasibility sections.) Therefore, OSHA is promulgating these limits in its final rule for BD.

Short-Term Exposure Limit (STEL)

The proposed STEL was five times the proposed PEL, 10 ppm. The final rule includes a STEL which is five times the new 8-hour TWA limit, or 5 ppm.

The choice of the level of the STEL was a concern to a number of rulemaking participants. The CMA Butadiene Panel did not feel a STEL was needed at all and strongly objected to its being lower than 10 ppm. (Ex. 32–28) The SB latex manufacturers expressed a similar view. (Ex. 34–5) CMA alleged that the STEL provision lacked a legal basis and that the analyses on which OSHA based its proposed STEL were flawed. (Ex. 32–28) Others objected to the STEL on the basis that BD lacked acute health effects. (Ex. 32–19; 32–26; 32–27; 32–33; 60)

A major labor participant in the rulemaking, URW, urged OSHA to adopt a lower STEL of 1 ppm. (Ex. 34–6) As Kenneth Cross stated in his testimony for URW,

''Based on more recent toxicological, medical and epidemiological data, some of which was unavailable to OSHA when it sent its proposed standard to OMB about two years ago, the URW feels more secure with a 0.2 part per million PEL and one part per million STEL.'' (Tr. 2/20/91, p. 1750)

OSHA's expert witness, Dr. Ronald L. Melnick of NTP, presented data suggesting that a STEL will reduce risk. He performed a ''stop-exposure'' study that he described as follows:

Groups of 50 male mice were exposed to one of the following regimens: (a) 625 ppm for 13 weeks; (b) 200 ppm for 40 weeks; (c) 625 for 26 weeks; or (d) 312 ppm for 52 weeks. After the exposures were terminated, these groups of animals were placed in control chambers for the remainder of the 104 week studies * * * Survival was markedly reduced in all of the stop-exposure groups due to the development of related malignant tumors. The tumor incidence profiles in the * * * groups show that lymphocytic lymphomas, hemangiosarcomas of the heart, alveolar-bronchiolar neoplasms, forestomach squamous cell neoplasms, Harderian gland neoplasms, and preputial gland neoplasms were increased compared with controls even after only 13 weeks of exposure to 625 ppm * * * at comparable total exposures, the incidence of lymphocytic lymphoma was greater with exposure to a higher concentration of 1,3-butadiene for a short time compared with exposure to a lower concentration for an extended duration. (Ex. 42)

Dr. Melnick concluded as follows:

The stop-exposure studies show that multiple organ site neoplasia occurs in mice after only 13 weeks of exposure to 1,3-butadiene. It is likely that shorter exposure durations would also produce a positive carcinogenic response * * * the stop-exposure studies show that *the concentration of 1,3-butadiene is a much greater contributing factor than is the duration of exposure* [emphasis added]. (Ex. 42, p. 17)

Industry representatives objected in particular to using the thymic lymphomas induced in the mouse due to the potential role of an endogenous retrovirus in eliciting this response, and more generally, to the use of this study as the basis for imposing a STEL. (e.g., Exs. 112, 113) In its post-hearing comments, the CMA 1,3–Butadiene Panel stated:

The relevance of these studies to an assessment of the human cancer risks from 15-minute exposures to butadiene at levels up to 64 ppm (the highest exposure that would be consistent with an 8-hour TWA of 2 ppm) is highly doubtful. This is particularly the case where: (1) A dose-rate effect is evident in mice only for lymphomas and only at high exposure concentrations; (2) the MuLV retrovirus is known to be a significant factor in BD-induced lymphomas in the $B_6C_3F_1$ mouse; (3) the lymphomas do not appear to play a significant role in BD-induced carcinogenicity in the * * * mouse at the lower levels of exposure of interest to OSHA * * * (4) there is no evidence that concentration is more important than duration of exposure for any other tumor type.

NIOSH disagreed, and objected to OSHA's omission of the lymphomas from the quantitative risk assessment provided in the proposal. NIOSH stated:

OSHA's justification for eliminating these tumors was that lymphomas may be related to the presence of an endogenous leukemia virus in the $B_6C_3F_1$ mouse used in the NTP bioassay. The endogenous leukemia virus should have increased the background rate of lymphoma in both the control and exposed animals, and thus the potential confounding effect of this virus was controlled for in OSHA's risk assessment. It is still possible that the increased lymphoma incidence observed in the * * * mouse was related to an interaction between the virus and 1,3-butadiene. However, OSHA also cites evidence that a similar lymphoma response was observed in a study of NIH-Swiss mice exposed to BD, and indicated that this strain of mice is not known to carry the leukemia virus * * * (Ex. 32–25, p. 4)

NIOSH also cited evidence that retroviruses may be associated with certain leukemias and lymphomas in humans and pointed out that ''even if 1,3-butadiene interacts with a leukemia virus, a similar mechanism might conceivably be involved in producing tumors'' in exposed workers. (Ex. 32–25, p. 5) OSHA agrees with the opinion expressed by NIOSH and rejects industry's arguments that the observations in the ''stop-exposure'' study are irrelevant.

Some further support for a STEL comes from a recent report describing analysis of an epidemiologic study of BD-exposed workers entitled ''A Follow-up Study of Synthetic Rubber Workers'' by Delzell et al. (Ex.117–1) One part of this study pertains to the risk of leukemia in workers exposed to BD in what the authors termed ''peak-years.'' Peak years are estimates of the number of times per year a worker was exposed above 100 ppm (a peak) during 15 minute periods. This estimate was then multiplied by 225, the number of workdays in a year. This value was used as a variable in Poisson regression analysis. There was an association between peak-years and leukemia risk, even after controlling for BD ppm-years (cumulative BD exposure) as well as other covariates. The relationship was said to be ''irregular'' since the risk ratios were 1.0, 2.6 and 0.8 for BD peak-years categories of 0, >0–199 and 200+, respectively. The underlying reason for the lack of a dose-response is unclear; however, the finding of a statistically significant elevation in relative risk for peak exposure, even when total cumulative exposure is accounted for, is of concern and appears to support the need to control peak exposures.

OSHA further notes that the basis for adopting a STEL does not rest solely on the points raised above; in 1986, the US Court of Appeals for DC reviewed OSHA's ethylene oxide standard, which did not contain a STEL. (*Public Citizen Health Research Group* v. *Tyson,* 796 F2d, D.C. Cir., 1986). The reason given by OSHA for not including a short-term limit in the ethylene oxide standard was that a dose-rate effect had not been demonstrated by record data. The Court held that the OSH Act compels the Agency to adopt a short term limit if the rulemaking record shows that it would further reduce a significant health risk and is feasible to implement regardless of whether the record supports a ''dose-rate'' effect (796 F. 2nd at 1505). This decision states that

If in fact a STEL would further reduce a significant health risk and is feasible to implement, then the OSH Act *compels* the agency to adopt it (barring alternative avenues to the same result). OSHA *shall* set the standard which most adequately assures, to the extent feasible, on the basis of best available evidence, that no employee will suffer material impairment of health.'' (29 U.S.C. 655(b)(5) (1982)) Since OSHA has found that a significant health hazard remains even with the 1 ppm PEL, the agency must find either that a STEL would have no effect on that risk or that a STEL is not feasible. (796 F.2d 1479 (D.C. Cir. 1986))

Without a STEL, employees could have exposures to BD as high as 32 ppm, albeit for short periods (15 minutes). Since many workers experience intermittent exposure to BD,

for example, during sampling, transport and laboratory work, imposing an 8-hour limit alone would not control these higher peak exposures. The STEL by controlling such peak exposures, will reduce total cumulative dose, thereby reducing significant risk further, as stated by the Court. In addition, properly installed and maintained engineering controls should prevent high variability in exposures generally. As a general rule, it is good industrial hygiene policy to control excessive variabilities as a STEL will do.

OSHA has concluded that the adoption of a 5 ppm STEL for BD is appropriate to further reduce the significant residual risk of cancer that remains from exposure to BD at the revised TWA PEL of 1 ppm. In addition, there is some evidence of a dose-rate effect as described above. Specifically: (a) The ''stop-exposure'' study of Melnick which demonstrated that ''at comparable total exposures, the incidence of lymphoma was greater with exposure to a higher concentration of BD for a short time compared with exposure to a lower concentration for an extended duration'' (Ex. 114, p. 125); (b) although a retrovirus in $B6C3F_1$ mice likely played a role in the induction of thymic lymphoma, the fact that BD exposure in another strain of mouse that did not express the virus also developed the same type of cancer, strongly suggests that BD induced this tumor very early after exposure; and, (c) the suggestive data from the cohort study of Delzell et al., indicating the importance of ''peak-year'' exposure to risk of leukemia.

D. Exposure Monitoring

Section 6(b)(7) of the OSH Act (29 U.S.C. 655) 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 requiring air sampling for employee exposure to BD include the prevention of overexposure of employees; the determination of the extent of exposure at the worksite; the identification of the source of exposure to BD; and collection of exposure data by which the employer can select the proper control methods to be used to reduce exposure and to evaluate the effectiveness of the control methods selected. Monitoring helps employers to meet the legal obligation of the standard to assure that their employees are not exposed to BD in excess of the permissible exposure levels, and to be able to notify employees of their exposure levels. In addition, collection of exposure monitoring data enables the examining physician to be informed of employee exposure levels, which may be useful in forming the physician's medical opinion (see paragraph (k)).

Many provisions of the final rule are quite similar to those proposed. However, some felt that clearer or more concise language should be used. Thus, the specific language of the exposure monitoring provisions varies somewhat from that of the proposal. Moreover, additional modifications have been made, as appropriate, in response to record information and recommendations contained in the record.

The final rule does not require that exposure monitoring be performed wherever BD is present. Under certain circumstances, outlined in the scope and application (paragraph (a) of this section), objective data may be used in lieu of the monitoring required by paragraph (d) of the final rule.

In the final rule, as in other standards, various provisions of the standard are triggered if an employee is exposed above the action level, and are not required if the employee is exposed below the action level. Thus the importance of correctly determining employee exposure cannot be over emphasized.

Paragraph (d)(1) requires the employer to determine the exposure for each employee exposed to BD. This does not mean that separate measurements for each employee must be taken but rather that the rule allows this obligation to be fulfilled by determining ''representative employee exposure.'' Paragraph (d)(1)(I) requires that samples collected to fulfill this requirement be taken within the employee's breathing zone (also known as ''personal breathing zone samples'' or ''personal samples''). (Area sampling is required under the standard only following emergencies.) The samples used to determine whether an employee is exposed above the action level must represent the employee's exposure to airborne concentrations of BD over an eight-hour period without regard to the use of respirators (See ''Employee exposure'', as defined in the definitions section).

In certain circumstances sampling each employee's exposure to BD may be required for initial monitoring. However, in many cases, the employer under paragraph (d)(1) may monitor selected employees to determine ''representative employee exposures.'' Representative exposure sampling is permitted when there are a number of employees performing essentially the same job, with BD exposures of similar durations and magnitude, under essentially the same conditions. Where there are groups of employees whose job functions are similar, OSHA permits the use of representative monitoring to characterize employee exposures to enable the employer to design a cost-effective monitoring program. In designing a representative monitoring plan, OSHA intends that employers select a sufficient number of employees within a group of employees who are engaged in similar work for sampling such that their exposures adequately characterize the exposures of all employees within the group. In addition, the employees who are judged as likely to have the highest exposures to BD within the group should be selected for monitoring to ensure that exposures of the remaining employees in the group are not underestimated. Although the employer is free to use formal statistical approaches for characterizing the exposures of a group of similarly exposed employees, OSHA does not require such approaches be used, and allows the employer to use professional judgement to select employees for monitoring and for attributing exposure results to employees whose exposures were not measured. The rationale for designing the representative monitoring plan and for selecting employees whose exposures were monitored can be retained as part of the exposure monitoring records required to be maintained by the employer under paragraph (l)(2) of the final rule.

To measure representative 8-hour TWA exposures, at least full-shift sampling must be conducted for each job function in each job classification, in each work area, and for each shift (paragraph (d)(1)(ii)). At least one sample covering the entire shift, or consecutive representative samples taken over the duration of the shift, must be taken. Representative 15-minute short-term employee exposures are to be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the short term exposure limit for each shift for each job classification in each work area (paragraph (d)(1)(iii)).

To eliminate unnecessary monitoring and improve the cost-effectiveness of the standard, paragraph (d)(1)(iv) also allows employers who can document that exposure levels are the same for similar operations during different work shifts to sample only the shift for which the highest exposures are expected to

occur. The employer must be able to demonstrate that employees on the shifts who are not monitored are not likely to have exposures higher than those of employees on the shifts monitored.

Paragraph (d)(2) requires all employers who have a place of employment covered under the scope of this standard to perform initial monitoring for their employees. In addition, the final standard requires that the initial monitoring be conducted within 60 days of the effective date of the final standard or the introduction of BD into the work place. This effective date provision (proposed paragraph (d)(2)(ii)) has been moved to the paragraph containing the other start-up dates, paragraph (m)(2)(I). Although Dow in a recent submission expressed concerns that additional time might be needed to set up an exposure monitoring program, OSHA believes that initial monitoring can be completed within the allowed period of time. (Ex. 118–16) The parties to the labor/industry agreement also recommended a start-up date for the initial monitoring under the standard of 60 days from the effective date. (Ex. 118–12A) Additional flexibility is provided in paragraph (d)(2)(ii), in that monitoring data collected up to two years prior to the effective date may be relied upon as initial monitoring data, provided that it has been collected in accordance with the requirements of this paragraph.

The employer is required to perform initial monitoring of employee exposures to BD where objective data are not available to satisfy the condition for exemption. If the results of initial monitoring indicate employee exposures are below the action level, the employer may discontinue monitoring for those employees and is relieved of some other obligations under the final rule (e.g., medical surveillance, use of personal protective equipment, development of an exposure goal program, establishment of regulated areas). Thus, the employer can focus attention and resources on employees whose exposures are more significant. Therefore, even if operations are not specifically exempted from the proposal, keeping exposure levels below the 0.5 ppm ''action level'' will relieve employers from some duties under the standard. A similar approach is used in a number of OSHA standards (acrylonitrile, 29 CFR 1910.1045; arsenic, 29 CFR 1910.1018; ethylene oxide, 29 CFR 1910.1047).

Paragraph (d)(2)(ii) of the proposal has been modified as shown in paragraph (d)(1)(ii) in the final rule to allow monitoring data produced within 2 years prior to the effective date of the standard to be relied upon to satisfy the initial monitoring requirement. OSHA had proposed a one year limit on the use of this grand-fathered monitoring data, but at the suggestion of a number of participants in the rulemaking and the labor/industry agreement, OSHA has agreed that allowing a two year period is reasonable for this standard. (Ex. 112; 113; 118–12) Dow Chemical Company in comments on a draft of the labor/industry joint recommendations asked that OSHA allow the use of data which are over two years old to serve as initial monitoring data. (Ex. 118–16) Dow said that such data ''that are consistent with current data reflecting no process changes that might have increased exposure over the time period of interest'' should be included as initial monitoring data. OSHA believes that expanding the period to two years allows adequate latitude to the employer in determining the need for initial monitoring.

In addition, the final rule now more clearly states what OSHA means by conditions under which historical monitoring data may not be used and initial monitoring is required. Rather than stating that historical data may be used only if the conditions under which the monitoring was conducted ''remain unchanged,'' it now states that the conditions ''* * * have not changed in a manner that may result in new or additional exposures.'' This language was recommended by the labor/industry group and has been found acceptable and OSHA believes that it more clearly articulates its intent than the corresponding provision in the proposal; therefore it is included in the final rule. (Ex. 118–12A) However, OSHA notes that employers will likely wish to monitor following installation of controls to determine their effectiveness.

Paragraph (d)(3) describes the requirement for periodic monitoring and its frequency. CMA suggested that the OSHA BD standard should have the same monitoring frequency as OSHA's benzene standard. (Ex. 112) The initial submission of the labor/industry group recommended that OSHA require more extensive sampling than the Agency had proposed to qualify as initial monitoring and establish a baseline. Specifically the group recommendation stated:

> Establish a baseline of at least 8 samples. The samples may be taken in a single year, so long as at least one sample is taken in each quarter, and no two are taken within 30 days of each other. The employer may utilize monitoring data from the previous two years to satisfy the initial monitoring requirement as long as process has been consistent. (Ex. 119)

The labor/industry group also recommended less frequent periodic monitoring than the quarterly monitoring OSHA proposed when exposures exceeded the PELs. The labor/industry group recommended:

> After the baseline has been established, monitoring is * * * every 6 months if exposure exceeds PEL or STEL * * * Annually if exposure is at or above the AL [action level] but below the PEL. (Ex. 119)

In the Federal Register notice re-opening the record, OSHA raised its concerns as follows:

> OSHA is concerned that the taking of 8 samples to establish a baseline may not be an effective use of scarce industrial hygiene resources in that the number of samples taken may be far less important than the quality of the samples used to characterize the exposure of BD employees. Are there other ways to improve OSHA's traditional approach of monitoring at least the one most exposed employee in each job classification on each shift? (61 FR 9381, 9383, 3/8/960)

In its submission, Texas Petro Chemicals objected to the 8 sample baseline because they said that they do not have BD exposure for four quarters of the year and do not monitor in winter due to ''high mobility'' of their employees during the winter and the ''strong potential for samples to be invalid'' due to problems with the sampling devices during bad weather. (Ex. 118–6) Dow Chemical Company objected to specification of the number of sampling events and the schedule suggested by the agreement. Dow felt this did not allow the employer adequate flexibility in evaluating employee exposures. (Ex. 118–16, p. 4) Hampshire Chemical Corporation felt that it was unclear what was meant by the 8 baseline samples described in the notice. (Ex. 118–8) The American Petroleum Institute expressed its preference for a more performance-oriented approach to exposure monitoring strategies. (Ex. 118–11)

In comments of the Chemical Manufacturers Association, who participated in the labor/industry discussion resulting in the agreement, the following view was expressed:

> The parties to the negotiations have revisited the exposure monitoring provisions. The agreement's monitoring scheme now would follow OSHA's traditional requirement for initial representative monitoring to detect job classifications where the action level is exceeded * * * It is only the periodic monitoring that is required where there are exceedances that could involve the taking of eight samples * * * After this periodic monitoring had been completed, additional periodic monitoring would occur at the

frequency proposed * * * sampling could be terminated when there are two consecutive low measurements. (Ex. 118–13, p. 4–5)

Similar comments were received from the International Institute of Synthetic Rubber Producers, Inc. (Ex. 118–12, p. 4)

The labor/industry agreement was more fully discussed by the group in a submission received during the period when the record was re-opened for comment. (Ex. 118–12) Numerous modifications to OSHA's proposed provisions for an exposure monitoring program for BD were endorsed by the group. (Ex. 119) Primarily these dealt with the sampling strategy. OSHA has carefully evaluated the suggested changes and has, for the most part, included them in the final rule.

The periodic monitoring paragraphs have been modified upon the basis of the record and the recommendations of the labor/industry group. Paragraph (d)(3) states that ''If the monitoring required by (d)(2) of this section reveals exposure at or above the action level but at or below both the 8-hr TWA and the STEL, the employer shall repeat the representative monitoring required by paragraph (d)(1) every twelve months.'' OSHA proposed that such monitoring be repeated at least every six months. However, OSHA believes that the additional monitoring[10] required in the final rule for those whose BD levels remain above the PELs will compensate for less frequent periodic monitoring in situations where the level is likely to remain lower. It must be noted here that additional monitoring requirements are triggered whenever there is a change in process or personnel which may result in new or additional exposures to BD. A similar schedule for periodic monitoring is required in the benzene standard. (29 CFR 1910.1028)

The results of initial monitoring represent the data which will be used to determine when further periodic monitoring will be required. If the initial monitoring of employees reveals exposures that are between the action level and the 8-hour TWA, then the employer must repeat monitoring annually (paragraph (d)(3)(I)). While these employees have been shown to be exposed to levels of BD below the 8-hour TWA, their levels of exposures are not so far below the PELs that monitoring could safely be discontinued. Even minor changes in engineering controls or work practices could result in exposures increasing to levels above the PEL. Remonitoring on an annual basis will enable the employer to be confident that the controls are working or, in the event exposures are shown to exceed the 8-hour TWA, will alert the employer as to the need for additional controls, and for changes to a more frequent monitoring program.

The draft regulatory text submitted by the labor/industry group recommended marked changes to paragraph (d)(3) (ii) and (iii) which OSHA believes will provide even greater protection to workers than that proposed by the Agency in 1990. (Ex. 118–12A)

The requirements in paragraphs (d)(3) (ii) and (iii) of the final rule provide for periodic monitoring in situations in which either the 8-hr TWA or STEL is exceeded to be carried out quarterly ''until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period * * * after which such monitoring must occur at least every 6 months.'' However, if the monitoring result indicates that exposure is below the action level as indicated by 2 consecutive samples taken at least 7 days apart, monitoring may cease unless the conditions change, (see (d)(5)). A single low sampling result is inadequate to allow monitoring to terminate; for various reasons, it may be artifactually low perhaps due to process changes during the time of sampling. OSHA believes that such differences are unlikely to persist for more than a week and has determined that this period is minimal to assure that exposures are truly low enough for the employer to stop monitoring.

Paragraph (d)(3)(iv) has also been modified to allow less frequent monitoring when the initial monitoring results exceed either PEL, but two consecutive subsequent samples taken at least 7 days apart indicate that BD levels no longer exceed either PEL but remain above the action level. In this situation, monitoring is required annually. OSHA proposed that such monitoring take place every six months.

OSHA believes that although this approach differs from the Agency's usual approach to monitoring, it will meet the need for determining the level of BD exposure in the workplace and will focus on situations having higher exposure potential. The conditions of use of BD in production and manufacturing present exposure patterns that are more likely to be predicted by initial monitoring than is the case for some of the other substances OSHA has regulated, such as asbestos, where exposures primarily occur during disturbing or removing the material in various forms. OSHA agrees that monitoring carried out as scheduled in the agreement is more likely to reflect the ''true'' exposure level in a workplace than monitoring at a single point in time. OSHA notes, however, as is the case in other standards, the sampling must be performed according to provisions of the standard—i.e., they must be personal samples, representative of each shift and job, etc.

If exposures are above the 8-hour TWA limit, then the employer must remonitor every six months. If the employee's exposure is above the STEL, the employee shall repeat such monitoring at least every six months until the employee's exposure falls to or below the STEL. If, in subsequent monitoring, results indicate that an employee's exposure, as determined by two consecutive measurements taken at least seven days apart, falls from above the 8-hour TWA to between the 8-hour TWA and the action level, then monitoring need only be done annually, unless production changes lead to higher exposures. Similarly, when two consecutive measurements indicate that the exposure has dropped below the action level, further monitoring can be discontinued.

Paragraph (d)(4) allows employers to terminate monitoring for those employees whose initial monitoring results are below the action level. When the two consecutive exposure measurements (paragraph (d)(3)), taken at least seven days apart, indicate that exposure has dropped below the action level, further monitoring for these employees can be discontinued, unless production changes lead to higher exposures. OSHA recognizes that monitoring may be a time-consuming, expensive endeavor and therefore offers employers the incentive to be allowed to discontinue monitoring for employees whose sampling results indicate exposures below the action level. The intent of this provision is to allow the employer to stop monitoring employees whose exposure to BD falls below the action level. OSHA believes that this provision will encourage employers to keep exposures to BD below the action level in their workplaces, thereby keeping exposures to a minimum and saving employers the time and expense of monitoring. Moreover, employers will also benefit because most of the other requirements of the standard are not triggered when exposures are below the action level.

Employees will continue to be protected from excess BD exposure,

[10] If the monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the 8-hour TWA (or STEL), the employer shall repeat the representative monitoring required by paragraph (d)(1)(ii) (or d(1)(iii)) at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period, after which such monitoring must occur at least every six months.

even after periodic monitoring has ceased, because of the requirements in paragraph (d)(5) (additional monitoring). Additional monitoring is required by paragraph (d)(5)(i) when there has been a process or production change or a change in control equipment, personnel or work practices which may result in new or additional exposures to BD. When the employer suspects a change which may result in new or additional BD exposure, the employer is obligated to obtain new employee exposure measurements. Instead of listing or trying to define every situation where the employer must monitor for new or additional exposures to BD, OSHA intends by this provision that employers will institute this additional monitoring when the employer has any reason to suspect a change. It should be noted that since the PEL and action level are relatively low, even a small change in production procedures may cause employees whose exposures were below the action level to have exposures that are above the PELs.

Paragraph (d)(5)(ii) requires additional monitoring to be conducted whenever leaks, ruptures or other breakdowns occur. Such occurrences can result in very high exposures. After the clean-up or repair of the leak, employers must re-determine airborne exposure levels for those employees who may be exposed at their worksites. These additional exposure measurements provide a good method of ascertaining that proper corrective methods have been effective and employee exposures are not significantly altered from what they were prior to the leak or spill.

In commenting on the requirement to do additional monitoring after leaks or breakdowns, BP felt that ''This requirement seems arbitrary since BD is volatile and will rapidly dissipate, especially if the leak is outdoors.'' (Ex. 32–8) CMA suggested OSHA delete the requirement to ''repeat the monitoring which is required by paragraph (d)(2)(I)'' and instead require employers to ''monitor (using personal or area monitoring as appropriate) after the clean up of the spill or repair of the leak, rupture or other breakdown to insure that exposures have returned to the level that existed prior to the incident.'' (Ex. 112) The labor/industry group recommended a similar change which OSHA has determined to be appropriately protective. Paragraph (d)(5)(ii) of the final rule states:

Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure above the 8-hour TWA limit or above the STEL, the employer shall monitor (using leak source (e.g., direct reading instruments), area or personal monitoring, as appropriate) after the cleanup of the spill or repair of the leak, rupture or other breakdown to ensure that exposures have returned to the level that existed prior to the incident.

OSHA believes that this provision will allow the employer greater flexibility in deciding whether additional monitoring is necessary and to determine whether the level of BD in the workplace has returned to low levels following such incidents. OSHA further notes that since the odor threshold for BD is very near the permissible limits, if the odor is detected, then a release has occurred and monitoring must take place to assure that exposure has returned to a level below the action level. OSHA recognizes that not every worker will recognize the odor of BD at a specific concentration in air.

Paragraph (d)(6) requires employers to use monitoring and analytical methods which have an accuracy (at a confidence level of 95%) of not less than plus or minus 25% for airborne concentrations of BD above a PEL and within plus or minus 35% for airborne concentrations of BD at or above the action level and below the TWA limit of 1 ppm. Methods of measurement are presently available to detect BD to this accuracy level (±25% or ±35%) at levels of 0.155 ppm. One such method is described in Appendix D.

Sampling and analysis may be performed by portable direct- reading instruments, real-time continuous monitoring systems, passive dosimeters or other suitable methods. Employers have the obligation to select a monitoring method which meets the accuracy and precision requirements of the standard under the unique conditions which exist at the worksite.

Paragraph (d)(7)(i) further requires that employers notify each of their employees in writing, either individually or by posting in an appropriate location accessible to affected employees, the results of personal monitoring samples. OSHA proposed that the employer do this within 15 working days after the receipt of the results. However, the labor/industry agreement recommended a period of 5 business days for the notification by the employer to take place. (Exs. 119, 118–12a) OSHA agrees that this will provide information to the employee in a more expedient way. The quicker notification takes place, the better. Evidence indicates that this industry can comply with a shorter, and more desirable, time period. (Ex. 118–12A)

When exposures over the PEL occur, paragraph (d)(7)(ii) requires the employer to notify affected employees in writing of what corrective action is being taken to lower exposure to BD to below the PEL, and to inform the employee of the schedule to complete this action. Such notification must be completed within 15 business days of the employer's receipt of the sampling results. (See paragraph (b) for the definition of ''business day.'') The requirement to inform employees of the corrective actions the employer is going to take to reduce the exposure level to below the PELs is necessary to assure employees that the employer is making efforts to furnish them with a safe and healthful work environment, and is required by section 8(c)(3) of the Act. Mandating the schedule for the completion of such activities is needed so that the employee can be informed when to expect correction of the situation and the employee can be assured that corrective action will take place in a specified time frame.

Paragraph (d)(8) requires employers to allow employees or their designated representatives an opportunity to observe employee exposure monitoring. This provision is also required by section 8(c)(3) of the OSH Act. The proposed rule contained this provision in a separate paragraph (paragraph (l)), however, in developing the final rule, OSHA determined that observation of monitoring more logically belonged in the paragraph dealing with exposure monitoring and has included it in paragraph (d).

E. Regulated Areas

Paragraph (e) (1) of the final rule requires employers to designate areas in which occupational exposures to BD exceed or can reasonably be expected to exceed the PELs as ''regulated areas.'' In response to comments, the wording of this requirement was made consistent with the definition of ''regulated area'' used in the standard. (Exs. 32–26; 32–27; 32–28) A similar recommendation was made by the labor/industry group. (Ex. 118–12A)

The purpose of a regulated area is to ensure that employers make employees aware of the presence of BD in the workplace at levels above either of the PELs, and to limit access to these areas to as few employees as possible. The establishment of a regulated area is an effective means of limiting the risk of exposure to substances known to pose a risk of material impairment of health or functional capacity. Because of the serious nature of the outcome of possible exposure to BD and the need for persons entering the area to be provided with properly fitted respirators, the number of persons given

access to the area must be limited to the employees needed to perform the work in the area.

Paragraphs (e)(2) and (e)(3) are identical to the proposed paragraphs. Paragraph (e)(2) limits access to regulated areas to authorized persons. This provision makes clear that exposure over the PEL triggers the need for a regulated area, but that inadvertent releases which are covered under paragraph (i), Emergency Situations, would not trigger the requirement for a regulated area.

Consistent with the performance orientation of the standard, paragraph (e)(3) does not specify how employers are to demarcate their regulated areas. Factors that the Agency believes are appropriate for employers to consider in determining how to mark their areas include consideration of the configuration of the area, whether the regulated area is permanent, the airborne BD concentration, the number of employees in adjacent areas, and the period of time the area is expected to have exposure levels above the PEL. Permitting employers to choose how best to identify and limit access to regulated areas is consistent with OSHA's belief that employers are in the best position to make such determinations, based on their knowledge of the specific conditions of their workplaces.

Paragraph (e)(4) requires that whenever an employer at a multi-employer worksite establishes a regulated area he or she must communicate effectively the location and access restrictions pertaining to the regulated area to other employers with work operations at the worksite. Such communication will lessen the possibility that unauthorized persons will enter the area or that workers not involved in BD-related operations will be inadvertently exposed. OSHA requires employers whose employees are exposed to BD at concentrations above either of the PELs to be responsible for coordinating their work with that of other employers whose employees could suffer excessive exposure because of their proximity to the source of exposure to BD. Only one comment was received on the proposed multi-employer provision. (Ex. 32–27) That commenter requested OSHA to clarify that this provision applies only to employers whose employees are potentially exposed to BD. This interpretation is correct: the intent of this provision is to ensure that employers who establish regulated areas communicate with other employers whose employees could inadvertently enter the area. However, in response to this comment and at the suggestion of the labor/industry group, OSHA has made clear that the workers who may have access to the regulated area must be told where such areas exist and of their restricted access to them. Accordingly the phrase ''whose employees may have access to these areas'' has been added to paragraph (e)(4).

The regulated area provision underscores OSHA's concern that employees at nearby sites be aware of the existence of a BD exposure hazard so that they will remain outside the boundaries delineating the regulated area. Requiring the employer who establishes a regulated area to notify other employers whose employees might be placed at risk by the presence of high concentrations of BD is consistent with other OSHA standards, e.g., 29 CFR 1910.1048 (Formaldehyde).

F. Methods of Compliance

The final standard, like the proposed standard, requires employers to institute engineering and work practice controls to reduce the exposures of employees to or below the permissible exposure limits (both the 8-hour TWA limit and the STEL), to the extent feasible. If the employer establishes that engineering and work practice controls are inadequate to lower exposures sufficiently to or below either of the PELs, the employer must nevertheless implement engineering and work practice controls to reduce exposures as low as possible and provide supplemental protection with respirators selected in accordance with paragraph (h). The methods of compliance requirements in the final rule are similar to those in all of OSHA's other substance-specific health standards.

The primary reliance on engineering and work practice controls to maintain employee exposures to or below the PELs is consistent with good industrial hygiene practice and with the Agency's traditional adherence to this hierarchy of controls. This hierarchy specifies that, in controlling exposures, engineering controls and work practices are to be used in preference to respiratory protective equipment. In this final rule, respirators may be used by employees only in emergencies; where engineering and work practice controls are not feasible, adequate, or have not yet been installed; or during intermittent, non-routine work operations that are limited in duration.

Engineering controls involve the installation of equipment, such as forced air ventilation, or the modification of a process to prevent or contain chemical releases. Work practice controls reduce employee exposures by altering the manner in which a task is performed. An example of a work practice control would be to train a tank car unloader to stand upwind rather than downwind of the tank car's hatch during the operation.

Respirators have traditionally been accorded the last position in the hierarchy of controls because of the many problems associated with their use. For example, the effective use of respirators requires that they be individually selected and fitted for each employee, conscientiously worn, carefully maintained, and replaced when necessary; these conditions may be difficult to achieve and maintain consistently in many workplace environments. Furthermore, unlike engineering and work practice controls, which permit the employer to evaluate their effectiveness directly by air monitoring and other means, it is considerably more difficult to directly measure the effectiveness of respirators on a regular basis to ensure that employees are not unknowingly being overexposed. Finally, in the case of butadiene, respirator cartridges and canisters used to purify the air inhaled by the employee have limited capacity. Data relied on by OSHA to develop the respiratory protection requirements of the final rule show that cartridges will not be able to provide adequate protection over an entire workshift (see discussion for paragraph (h), Respiratory Protection).

Industry representatives were in agreement that respirators should not be relied upon as a first line of defense if feasible engineering and work practice controls are available to protect employees from exposure to butadiene. (Ex. 34–4; 60; 61; 66A; 113). For example, James L. McGraw, representing the IISRP, commented as follows:

> It has long been recognized that engineering controls should be the primary means of reducing occupational exposures to regulated substances. Respirators are useful as supplementary controls to protect workers during emergencies, if engineering controls fail or break down, while feasible engineering controls or work practices are being designed or implemented, or for mobile or short-term work, such as some maintenance operations * * *. At ASRC and, as I understand, throughout the industry, respirators are generally used only for short-duration tasks where the potential for exposure may be relatively high, (and) * * * are generally worn by workers for only a small fraction of the shift * * *. Moreover, because they inhibit worker mobility, obstruct vision and make communication among workers difficult, serious safety risks may be posed

where respirators are used over long periods of time * * *. The required use of respirators over extensive periods of time is also psychologically stressful, especially for employees not accustomed to such use. All of these factors significantly impair worker mobility and productivity. (Ex. 34–4, pp. 7–9)

Thus, according to the hierarchy of controls concept, use of installed equipment, such as well-designed and maintained local exhaust ventilation, is a superior compliance method because its effectiveness does not depend to any marked degree on human behavior, and the operation of such equipment is not as vulnerable to human error as is the use of personal protective equipment. The Agency has also found that modified work practices can aid in achieving compliance with the PELs without introducing the safety and comfort problems inherent with respirator use.

Based upon the evidence in the rulemaking record and the Economic Analysis, OSHA finds that the use of engineering and work practice controls will reduce employee exposures to or below the butadiene PELs for practically all work situations, without having to rely on excessive respirator use. Some of the controls applicable to the production of butadiene monomer and polymers include:

—Installation of closed-loop sampling ports for quality-control sampling of process streams;
—Use of self-circulating-type sampling cylinders;
—Replacement of pumps equipped with single mechanical seals with those having dual seals;
—Use of an on-line chromatographic system to minimize the need for manual process sampling;
—Replacement of slip-tube gauges with magnetic level gauges in loading/unloading operations;
—Routine venting and purging of transfer lines between loading and unloading operations;
—Prohibiting air recirculation in quality-control laboratories (i.e., use of 100 percent make-up air);
—Ensuring that samples are removed from sample cylinders within enclosed, ventilated cabinets, and implementing closed-systems for injection into chromatographs;
—Voiding and purging sample cylinders outside of the laboratory or within an exhausted hood; and
—Purging process lines with nitrogen followed by steam or water cleaning prior to performing equipment maintenance.

OSHA recognizes that there may be situations where engineering and work practice controls are not feasible due to a unique feature or condition. These situations are recognized in paragraph (f)(1) of the final rule, which permits the use of approved respiratory protection where employers can demonstrate that engineering and work practice controls are not feasible. In such situations, the burden of proof is appropriately placed on the employer to make and support a claim of infeasibility because the employer has better access to information specific to the particular operation that is relevant to the issue of feasibility.

Paragraph (f)(2) requires employers whose employees are exposed above either of the PELs to establish and implement a written compliance plan that describes the methods to be used to reduce employee exposures to or below the PELs. The plan must provide for this to be accomplished where feasible with engineering and work practice controls, which must include surveys for leak detection on a periodic basis. The written plan must include a schedule for implementation and must be furnished upon request for examination and copying to OSHA, NIOSH, and affected employees or their representatives.

In the preamble to the proposal, OSHA raised concerns about and solicited comments on the suggestion in the JACA report that worker exposures to BD originating from pump leaks could be controlled more cost-effectively with the use of leak detection programs rather than by engineering means, such as installation of pumps with dual mechanical seals. (Ex. 30) OSHA also questioned whether use of a continuous air monitoring system equipped with an alarm might be an equally effective alternative control technology (55 FR 32736 at 32791).

In response, OSHA received many comments indicating that implementation of engineering controls is a far superior control strategy than primary reliance on leak detection, and these comments urged the Agency to retain its original performance-oriented language in the methods of compliance paragraph. For example, Michael J. Murphy of Monsanto commented as follows:

It is Monsanto's position that the actual method of maintaining the integrity of engineering controls and process equipment should not be specified by OSHA. The appropriate utilization of preventative maintenance programs, periodic leak detection surveys, continuous monitoring systems and an educated workforce should be left up to the employer's professional judgment. So long as the overall process is maintained in a fashion which minimizes employee exposures as determined by personal monitoring, the actual method of compliance should not be a specific item. (Ex. 32–19, p. 6)

In their post-hearing comments, NIOSH indicated that continuous monitoring systems might be useful in some situations, but only as an ''* * * adjunct to engineering containment features * * *.'' (Ex. 101, p. 2) Similarly, Dr. Norman Morrow, of Exxon Chemical Company and chairman of the CMA Butadiene Panel, commented that use of double seals on pumps combined with a good leak detection and repair program would provide more protection to workers than would continuous monitoring systems. (Ex. 54, p. 7) The feasibility of relying primarily on continuous monitoring systems to maintain low worker exposures was also questioned by CMA in their post-hearing submission:

In a monomer or crude facility which is out of doors and spread over a large area, a very large number of such analyzers would be required to provide any warning of potential high ambient levels. It is likely that even a very large and costly system would fail to detect butadiene excursions because of changing wind patterns, areas not covered, downtimes for maintenance, cycle times between measurements, etc. * * * [B]y contrast, engineering controls such as dual or tandem pump seals serve as a true primary safeguard against worker exposure. * * * Thus, OSHA should expressly recognize that continuous analyzers or monitoring systems, although perhaps beneficial in certain situations as part of a leak detection program, should not supplant engineering controls which directly protect workers against butadiene exposures. (Ex. 112, p. 125)

After reviewing these comments, OSHA is convinced that primary reliance on either manual leak detection programs, as suggested by JACA, or continuous monitoring systems, would not provide worker protection equivalent to that afforded by engineering and work practice controls; therefore, OSHA is retaining the performance-oriented language originally proposed for the methods of compliance requirements, which allows employers to design their own compliance programs so long as they adhere to the general principles for the hierarchy of controls set forth in paragraph (f)(1).

Furthermore, in paragraph (f)(2) of the final rule, OSHA specifies that the compliance program must include a leak detection program, but leaves the specific design of the program up to the employer. OSHA believes that leak detection is a vital element of the compliance program for butadiene, given the high volatility of the substance, and given that leaks, if not

detected in timely fashion, can be a significant source of employee exposure.

Howard Kusnetz of Shell Oil objected to the proposal's requirement that compliance programs include leak detection:

> OSHA should not require the compliance program to include a periodic leak detection survey. If this is to be an effective performance standard, the facility needs the maximum flexibility to develop an effective program. The engineering control or work practice that reduces exposure may not need leak detection to be effective. This requirement will be a significant drain of resources and not result in enhanced employee protection. This is a significant departure from other health standards such as benzene and is already being addressed by EPA requirements. (Ex. 32–27, p.2)

Other rulemaking participants identified leak detection as an important component of an effective compliance program for butadiene. For example, Frank Parker of Environmental Technologies Incorporated, testifying for OSHA, stated that use of double seals on pumps combined with a good leak detection and repair program would effectively control exposures to butadiene (Tr. 1/17/91, p. 534). In post-hearing testimony, NIOSH explained that leaks from process equipment were one of the major sources of employee exposure:

> NIOSH supports the contention that 1,3-butadiene processing involves closed systems and that exposures are the direct result of leaks in these systems. There are only relatively few points * * * in which the integrity of these closed systems are likely to be (intentionally) broken. * * * Prompt repair of leaks can appreciably reduce exposures, and techniques such as Hazard and Operability Studies * * * should help even more by anticipating and preventing the leaks. (Ex. 101, pp. 1–2)

Similarly, as discussed above, several participants agreed that leak detection programs combined with primary reliance on engineering controls were the most effective approach for maintaining low employee exposures to BD; a routine leak detection program is one of the control elements specified in the exposure goal program recommended in the joint labor/industry agreement. (Ex. 118–13A) Furthermore, contrary to Mr. Kusnetz's assertion, OSHA has required compliance programs to contain provision for leak detection in its final rule for another highly volatile carcinogen, ethylene oxide (See 29 CFR 1910.1047(f)(2)(ii)).

OSHA believes that the language contained in paragraph (f)(2) of the final rule gives employers considerable latitude in designing effective leak detection programs. OSHA has not specified a minimum frequency for performing leak detection, the methods to be used by employers for performing leak detection, nor the locations where periodic leak detection must be performed. OSHA believes that the employer, with his or her knowledge of specific processes and workplace conditions, is in the best position to make these decisions. The employer must perform leak detection as often as is reasonable, given the specific circumstances of the work operation. The intent of the provision as worded in the proposal was to ensure that employers include a leak detection program as appropriate to their workplace within the compliance program, and that this information be available to affected employees or their representatives. Because the preponderance of professional opinion contained in the record provides support that leak detection programs are important supplements to engineering control programs, OSHA has accordingly retained this requirement in the final rule.

The paragraph describing the proposed written compliance program requirements also contained a cross reference to paragraph (h) of the proposed standard dealing with written emergency plans. OSHA has deleted this cross reference in the final rule, recognizing that the written emergency plan is required regardless of whether the requirement for a written compliance program is triggered by exposures exceeding the PELs. This deletion was also included in the regulatory text from the joint labor/industry agreement.

Paragraph (f)(2)(iv) prohibits the use of employee rotation as a method of reducing exposure to BD to or below the PELs. This requirement, which remains unchanged from the proposal, reflects a long-standing Agency policy that rotation of employees is an unacceptable practice for reducing exposures of employees to potential carcinogens. Although this approach may reduce the risk of cancer among individual workers who are periodically rotated out of tasks involving such exposure, the practice places a larger pool of workers at risk. OSHA received no objection to retaining this requirement for the butadiene standard, and its inclusion was supported by the joint labor/industry agreement. OSHA wishes to make clear that other kinds of administrative controls are acceptable so long as they do not involve exposing employees who would otherwise not be exposed. Acceptable practices include methods such as scheduling certain maintenance tasks where there is a potential for high exposures during the work shift where there are the fewest employees present in the area.

The text of the joint labor/industry joint recommendations included one other change in the language of proposed paragraph (f), clarifying that no written compliance program would be required ''if the initial (exposure) reading has been reliably determined to have been in error.'' (Ex. 118–13A) None of the participants of the joint agreement provided a specific rationale explaining the need to include this language; however, one rulemaking participant, Richard Olson of Dow Chemical, offered an explanation after reviewing a draft of the agreement:

> Occasionally, one sample may be over a permissible exposure level because of some circumstance such as an analytical error or perhaps an unusual, unanticipated action taken by the employee. In such cases, the situation surrounding the data point should be investigated but that individual sample should not necessarily instigate a full-blown program as it may not be representative of actual average conditions. (Ex. 118–16, p. 6)

For these reasons, Mr. Olson suggested that the language contained in the draft regulatory text from the agreement not be limited to circumstances involving only analytical error, but also be applied to other unusual events.

In the final rule, OSHA did not include the language regarding erroneous sample results that was contained in the labor/industry regulatory text. Clearly, no employer action should ever be based on an erroneous reading. In addition, OSHA believes such language is unnecessary since it has never been the Agency's intent or practice to require employers to comply with a provision of a standard based on the results of a single sample so long as the employer has adequate documentation that the result is unusual and does not reflect typical workplace conditions. Conversely, OSHA would not expect an employer to discontinue complying with a provision of the standard simply because a single sample suggests employees are not exposed above either of the PELs, if the weight of information available to the employer indicates otherwise. Indeed, OSHA believes it more likely that gross sampling and analytical errors will tend to understate rather than overstate exposures for a variety of reasons (for example, due to sampling pump fault or failure, taking samples under conditions of high humidity or where other hydrocarbons are present, sample loss from breakthrough or due to improper sample storage or handling, or

inefficient desorption of the sample from the media).

OSHA believes that employers should base their compliance actions on the totality of information and data available to them about their workplaces and employee exposures, and on their best professional judgment. If in the employer's best judgment, a sample result is obtained that is not credible or is perceived as unlikely, the employer should, as Mr. Olson suggests, investigate the probable causes by ensuring that process and engineering equipment are functioning properly, by talking with affected employees to determine if there were any unusual occurrences or practices that may be associated with the result, and conduct repeat monitoring to help confirm that the questionable result is not representative of typical workplace conditions. On the other hand, should the employer instead choose to rely on a minimal program to assess employee exposures and a sample result indicates that an operation is associated with worker exposures above the PELs, OSHA believes it is prudent to presume that the result reflects typical exposure conditions and that a plan for implementing corrective measures is necessary.

G. Exposure Goal Program

Paragraph (g) of the final rule contains requirements for the employer to establish an exposure goal program where employee exposures are above the action level of 0.5 ppm TWA. As part of the exposure goal program, which was recommended by the labor/industry agreement, the employer must implement the following control measures:

—A leak prevention, detection, and repair program;
—A program for maintaining effectiveness of local exhaust systems;
—Use of technologies that minimize BD emissions from pumps;
—Use of gauging devices designed to limit employee exposures during loading operations;
—Use of controls such as vapor return systems to limit exposures during unloading operations; and
—A program to maintain BD concentrations below the action level in control rooms.

The employer is not required to implement the controls specified above if he or she demonstrates that the controls are not feasible, will not be effective in reducing exposures to or below the action level, or are not necessary to achieve exposures to or below the action level. In addition, nothing in the exposure goal program requires employers to use respiratory protective equipment to achieve the action level. The exposure goal program must be implemented within three years from the effective date of the standard, in accordance with paragraph (m); this is one year beyond the date that employers are required to have installed engineering and work practice controls to achieve the PELs.

The requirements in this paragraph were not originally included in the proposal, but were proposed as part of the joint labor/industry agreement for BD. In its supplemental Federal Register notice, OSHA requested comments on the exposure goal program. (61 FR 9382) Specifically, OSHA was concerned whether including specification-oriented requirements for engineering controls in the exposure goal program would lead to situations where:

—The use of alternative control methods that would be equally or more effective in reducing exposures would be discouraged or ignored;
—The employer would be unable to comply because the specified controls are not applicable to the operation(s) where exposures exceed the action level; or
—The required controls would not be needed because exposures could be reduced to or below the action level by work practices alone, thus forcing employers to spend capital resources unnecessarily to comply with the letter of the requirement.

Several other participants raised concerns similar to those of OSHA's, generally preferring a more performance-oriented approach that did not mandate the use of specific control methods. For example, Paul Bailey, representing the American Petroleum Institute, submitted the following comment:

> API has some concerns with the ''Exposure Goal Program'' * * *, particularly shifting the burden to employers (to prove that the required controls are not feasible or effective) * * *. The listed elements of the exposure goal program may be useful tools for controlling exposures, but it is important to provide flexibility for use of new exposure control technologies that may become available. (Ex.118–11)

API recommended that the specific elements of the program be contained in a non-mandatory appendix rather than specified in the regulatory text; this approach was also supported in Richard Olson's submission on behalf of Dow Chemical. (Ex. 118–16) Mr. Olson also stated that the exposure goal program would establish the action level as a ''de facto PEL,'' and expressed the concern that specifying control measures might cause employers to implement controls for operations that do not contribute to employee exposures exceeding the action level. However, Mr. Olson acknowledged that the language contained in the draft agreement would allow employers to exclude specified elements of the program where they are not needed to attain the action level. Representatives of three refineries or chemical producers submitted similar comments (Exs. 118–5, 118–6, 118–8), arguing that the program should not include specifically mandated control methods since it would ''discourage * * * (the use of) process-based controls in favor of equipment based controls * * *'' (Ex. 118–5) and would be ''* * *counterproductive to innovating new control strategies * * *'' (Ex. 118–6)

However, in describing the program further, the CMA Olefins Panel commented that the regulatory language contained in the labor/industry agreement addressed these concerns. They said:

> The program is meant to supplement, not replace, the requirement that an employer ''institute engineering controls and work practices to reduce and maintain employee exposure to or below'' the PEL * * *. Since the program is required only where exposures are above the action level, it in fact creates incentives to develop improved engineering controls or work practices that achieve greater reductions in exposure.
>
> In addition, under the program, an employer would not need to implement the listed components of an exposure goal program if the employer could show that the components are not feasible, effective, or necessary to reduce exposures to at or below the action level * * *. Thus, OSHA's concerns that the program may impose inapplicable or unwarranted requirements are unfounded. (Ex. 118–13, p. 6)

The Panel further stated that the program ''* * * is an innovative concept aimed at addressing industry feasibility concerns while creating incentives to minimize worker exposure by encouraging the use of specified engineering controls with which the industry has experience.'' According to the Panel, incentives for developing improved exposure control methods are brought about because the exposure control program would not be required where exposures are at or below the action level (Ex.118–13, p. ii).

The submission by the IISRP explained that the exposure goal program is part of a three-pronged framework developed to address concerns about minimizing worker exposures in a feasible manner. According to IISRP:

* * * OSHA's record does not demonstrate that a 2 ppm (TWA) PEL or a 10 ppm STEL is feasible in polymer operations. Recognizing, however, that union representatives wished to see butadiene exposures even lower than 1 ppm, industry worked to develop an overall standard that would minimize exposures and still be feasible. The result was a three-part framework:

(1) A PEL of 1 ppm, STEL of 5 ppm, and action level of 0.5 ppm, coupled with

(2) The flexibility to employ respirators to achieve such exposures for non-routine intermittent and limited in duration activities and

(3) The exposure goal program.

* * * [T]he exposure goal program does not raise the concerns expressed by OSHA. No goal program need be initiated when exposures are already below the action level by whatever engineering controls or work practices. Better * * * controls * * * are thus not discouraged; they may always be used to achieve (the) action level or lower exposures. (Ex. 118–12, pp. 4–5)

After considering these comments, as well as the actual regulatory language recommended in the joint labor/industry agreement, OSHA finds that it is both reasonable and appropriate to include the specified control measures in the requirement for the exposure goal program. First, OSHA finds it reasonable in that the control measures specified in the exposure goal program represent those that are readily available to industry and have been proven effective to achieve the action level in at least some workplaces. OSHA's analysis of the technological feasibility of the standard, based largely on the NIOSH study of BD plants, identified some of these controls as approaches that have been successfully used to achieve exposure levels well below the PELs (see the Economic Analysis discussion in this preamble). For example, Shell Oil in Deer Park, Texas, achieved median exposure levels of 0.3 ppm (TWA) by implementing a collection system to capture emissions from loading operations as well as a combination of magnetic and slip-tube gauges (Ex. 16–29); use of magnetic gauges for all loading operations would likely reduce exposures further. Replacement of pumps having single mechanical seals with dual-seal pumps, which is an improved pump technology specified under the exposure goal program, has been occurring within the BD industry over the past several years (see the Technological Feasibility chapter of the Economic Analysis). Other elements of the exposure goal program are not equipment-oriented, but instead are designed to ensure that process equipment and engineering controls are optimally maintained to minimize or capture BD releases; these elements include a leak prevention, detection and repair program and a program to maintain the effectiveness of local exhaust ventilation equipment. Finally, all of the control measures specified in the exposure goal program are those that labor and industry representatives jointly agreed were reasonable to include. (Ex. 118–13A)

OSHA also finds that the exposure goal program requirements are appropriate for two reasons. First, OSHA has determined that a significant risk of cancer is associated with lifetime exposure to the action level of 0.5 ppm; the estimated risk to workers exposed at this level is about 4 per 1,000 (see the Quantitative Risk Assessment section of this Preamble). OSHA finds that it is appropriate to expect employers who have not already done so to implement the commonly used approaches detailed in paragraph (g) for controlling exposures to BD in an effort to further reduce this risk. Second, OSHA believes it appropriate to craft the exposure goal program requirements in specification language because to do otherwise would effectively blur the distinction between the exposure goal program and the methods of compliance requirements of paragraph (f), a distinction that the CMA emphasized was critical. (Ex. 118–13, p. 6) OSHA has not made a determination that a 0.5 ppm TWA exposure level for BD was generally feasible in affected industry sectors; therefore, the burden of proof to demonstrate the infeasibility of engineering and work practice controls for achieving the 0.5 ppm action level in an operation cannot be placed on the employer. If the requirements for the exposure goal program were developed in performance-oriented language, even with the aid of a non-mandatory appendix to guide employers and OSHA in its interpretation, OSHA believes that the requirement would have no real meaning in terms of performance measures by which employers, employees, and OSHA could judge compliance. In this situation, the action level might well be interpreted as a ''*de facto* PEL'', as suggested by Mr. Olson. By including a minimum specification for the content of the program, employers and their employees, as well as OSHA, are provided with a clear set of performance measures while maintaining a distinction between the exposure goal program and methods of compliance requirements for the PELs.

Nevertheless, OSHA believes the final rule's requirement for the exposure goal program, as worded, provides employers with considerable flexibility in the design of the program. Key to providing this flexibility is the 3-year phase-in date for the program. OSHA believes that by extending the implementation date for the exposure goal program one year beyond the date for which employers must implement controls to achieve the PELs, employers will have sufficient time to explore whether the use of alternative engineering approaches, process modifications, or work practices will permit them to reduce exposures to or below the action level.

OSHA also finds that commenters' concerns about the program's supposed lack of flexibility in allowing for the use of alternative technologies is unwarranted, since the extended phase-in period for implementation of the exposure goal program will provide employers with additional flexibility to design their own programs using alternative engineering control methods and work practices. The longer phase-in period for the exposure goal program is also appropriate because it allows employers to focus their initial efforts on reducing employee exposures to or below the PELs, as required under paragraph (f).

However, if the required implementation date of the exposure goal program is approaching and employee exposures still remain above the action level, either because the alternative controls were not sufficiently effective or the employer was not proactive in identifying alternatives, OSHA finds it appropriate to require that the employer implement, at a minimum, the controls that have been proven effective within the BD industry and identified in the exposure goal program, to the extent that such controls are feasible and applicable to the affected operations, and will be effective in further reducing employee exposures to BD.

The exposure goal program in paragraph (g) of the final rule incorporates two modifications from the language contained in regulatory text proposed by the joint labor/industry agreement (Ex. 118–12A). The joint agreement proposed that worker rotation be permitted as part of the exposure goal program. OSHA did not include this language in the final rule because of the Agency's long-standing policy of not allowing worker rotation to be used to control employee exposures to a carcinogen. As explained above in the Summary and Explanation for paragraph (f) (Methods of Compliance), employee rotation places a larger than necessary pool of workers at risk from exposure to BD. In other words, it would result in some employees being exposed to a cancer hazard to which they might not otherwise be exposed.

Since OSHA has estimated the lifetime cancer risk from exposure to BD to be about 4 per 1,000 workers at the action level of 0.5 ppm, use of employee rotation to achieve the action level provides no assurance that employees who are rotated into jobs with exposures around the action level will not be exposed to BD at levels representing a significant risk. Therefore, OSHA finds that employee rotation is not an appropriate method for achieving the action level. The second change involves the addition of clarifying language in the exposure goal program. The regulatory text contained in the joint labor/industry agreement stated that employers need not apply the control measures specified in the exposure goal program if such methods would not be ''effective.'' OSHA modified this language to make clear that such controls need not be implemented if the employer could demonstrate that they will ''not be effective in reducing employee exposures.'' OSHA believes that this better reflects the intent expressed in the joint labor/industry agreement.

H. Respiratory Protection

The respiratory protection requirements of the final standard for BD are in keeping with the requirements for respiratory protection in other OSHA health standards (e.g., Occupational Exposure to Lead, 29 CFR 1910.1025; Occupational Exposure to Benzene, 29 CFR 1910.1028), and with recent developments in the field. The provisions contained in the final rule have been changed from the proposal in some important respects in response to information and comments placed in the record. Comments received on the proposed BD respiratory protection provisions addressed broad issues of fit testing protocols, protection factors for various respirator classes, and other general respiratory protection issues. OSHA is currently evaluating these generic issues in the context of revising 29 CFR 1910.134, which is expected to be promulgated in the near future. The discussion of the appropriate respiratory protection for BD exposure that follows will identify those areas that are relevant to the broader issues being dealt with in the revision of 29 CFR 1910.134. The respiratory protection provisions contained in the final rule on BD reflect OSHA's current thinking on how some of these respiratory protection issues should be addressed. OSHA thus believes that the final rule for BD will be consistent with the revision of 29 CFR 1910.134.

Use of Respiratory Protection. Respirators are necessary as supplementary protection to reduce employee exposures when engineering and work practice controls cannot achieve the necessary reduction to or below the PELs. Paragraph (h)(1) identifies instances where the use of respiratory protection is permitted when employee exposures exceed the PELs. These are:

1. During the time interval necessary to install or implement feasible engineering and work practice controls;
2. In work situations where feasible controls are not yet sufficient to maintain exposures below the PELs;
3. During emergency situations; and
4. During non-routine work operations that are performed infrequently and in which exposures are limited in duration.

The first three instances are identical to those that were contained in the proposal. As to the fourth instance, i.e., ''non-routine work operations,'' OSHA originally proposed that respirators would be permitted for non-routine, limited-duration work operations *if the employer could demonstrate that engineering and work practice controls were infeasible.* OSHA received numerous comments arguing that OSHA should not impose a burden of proof on employers to demonstrate the infeasibility of engineering controls during such work operations.

The CMA Panel expressed support for allowing respirator use ''during the period necessary to install feasible engineering controls and where feasible * * * controls are not yet sufficient to reduce exposures below the PEL.'' (Ex. 118–13) However, in this submission and preceding ones, they objected to the proposal, which stated that respirators shall be used ''In work operations such as maintenance and repair activities, vessel cleaning, or other activities for which engineering and work practice controls are demonstrated to be infeasible, and exposures are intermittent in nature and limited in duration.'' (55 FR at 32805, 8/10/90) CMA's concern centered on the requirement to demonstrate the infeasibility of engineering controls before respirators could be used in short-term, intermittent work. (Ex. 112, p. 141–145) They felt that there were certain activities for which the infeasibility of engineering controls could not be demonstrated in ''an absolute technological sense,'' but the use of engineering controls would nevertheless be ''highly impracticable'' because the work activities are performed infrequently and the controls would prove to be very expensive. (Ex. 112, p. 142) CMA witness, Mr. Roger Daniel, gave the following example of such an activity:

> You may have 300 (pumps) in the plant and no one of those has to have any maintenance or cleaning activities to reestablish the integrity of the signal to that instrument more frequently than every two years. But because of the nature of the material that you're handling and the fact that it can slowly accumulate material * * * Periodically this has to be dealt with * * * you could put in lines to each of these blow-downs and collect from these 200 instruments just a little bit of liquid that has to be discharged * * * but from a practical standpoint, * * * [it] doesn't seem to make good sense. (Tr. 1/18/91. p. 1234–5)

In a pre-hearing submission CMA enumerated some situations where they believed engineering controls to be ''highly impracticable.'' Two of these were discussed in some detail. (Ex. 32–28) The first, ''blowing down of meter leads'' to clear instrument lines of accumulated debris was described as occurring only once every several years per instrument. CMA felt that installation of permanent blow-down lines leading to the flare, which would ensure the containment and destruction of BD, was not justified in this case. Second, they described breaking into and degassing pumps for maintenance as a work task that is performed twice weekly and lasts less than 10 minutes per occurrence. They felt that although it might be possible to build an enclosure around each of the pumps, the high cost of doing so was unjustified, due to the short-term nature of the task. (Ex. 32–28)

During the public hearing, Charles Adkins, then Director of OSHA Health Standards Programs, stated that in the context of the BD proposal, OSHA did not intend the term ''infeasible'' to mean an absolute technological infeasibility in the strictest sense, but that the intent was to limit respirator use to intermittent short duration situations where engineering controls are impracticable. He said that OSHA has:

> * * * always recognized that there [are] some situations that you don't consider it feasible. You don't put in an elaborate ventilation system to control exposures to some device that may break once every five years * * * and you * * * spend 30 minutes repairing that device. That's an appropriate time to use personal protective equipment. (Tr. 37, 1/15/91)

OSHA witness Frank Parker, a Professional Engineer and Certified Industrial Hygienist, testified that engineering controls were generally cost-effective, but that even when engineering controls are technologically feasible, respirators are ''going to be the most useful, practical approach'' in those situations in which there is ''sporadic (exposure) under unique conditions.'' (Tr. 1/17/91, p. 546)

In several other health standards, including the benzene standard, OSHA has specified some examples of activities for which engineering controls are not feasible. In the benzene rule respirators are required, ''In work operations for which the employer establishes that compliance with either the TWA or STEL, through the use of engineering and work practice controls are not feasible, such as some maintenance and repair activities, vessel cleaning, or other operations where engineering and work practice controls are infeasible because exposures are intermittent in nature and limited in duration.'' (29 CFR 1910.1028(g)(1)(ii)).

In the preamble to the benzene standard OSHA stated that

* * * engineering controls are often infeasible when exposures are intermittent in nature and limited in duration. For the same reason as maintenance and repair activities, extensive attempts at engineering controls are often not practical where exposures are both brief and occasional. It is both difficult to keep operable and a not very productive use of valuable industrial hygiene time, as well as often very costly, to try to provide engineering controls for very brief, intermittent exposures * * * In addition, for such intermittent and irregular exposures, employees can wear respirators with less difficulty. (52 FR at 34544, 9/11/87)

The labor/industry group recommended that respirators be specifically allowed ''in non-routine work operations which are performed infrequently and in which exposures are limited in duration.'' (Ex. 118–12A) OSHA considered all available information on this issue and has determined that such a provision is justified for BD. OSHA has therefore included the above language in the final rule in paragraph (h)(1)(ii).

The intent of this provision is not to allow employers to organize their workplace operations such that work is artificially broken down into tasks of small increments of time to allow wholesale respirator use when engineering controls are clearly practicable and therefore feasible under paragraph (f).

High exposures have been documented for workers performing certain activities such as cylinder voiding and sampling. Such activities may be performed intermittently and resulting exposures have been shown to be of short duration; however, since such operations are performed routinely, engineering controls need to be used to control exposures. OSHA does not intend that such routine activities be included in the paragraph (h)(1)(ii) exemption from the usual preference for engineering and work practice controls. Rather, paragraph (h)(1)(ii) contemplates that brief incidental maintenance activities be included. On the other hand, in the case of cylinder voiding (which would not be covered by paragraph (h)(1)(ii)), NIOSH recommended use of a laboratory hood or a vacuum exhaust with an enclosure. (Ex. 16–38; 16–39) For maintenance activities, NIOSH said ''maintenance technicians should follow decontamination procedures when working on process equipment. However, if it is not possible to completely decontaminate a process prior to the procedures, then respirators with organic vapor cartridges should be worn.'' (Ex. 16–38; 16–39)

In keeping with OSHA's intention to use a performance-oriented approach, where appropriate, the Agency has not defined either ''non-routine,'' ''infrequently,'' nor ''limited in duration'' in the final rule. Reasonable interpretations must be made. To qualify for the narrow exemption that permits the use of respirators without demonstrating the infeasibility of engineering or work practice controls, the task must meet all three criteria; it must be non-routine, infrequent, and of limited duration. OSHA believes that the vast majority of such activities qualifying under paragraph (h)(1)(ii) will consist of brief, intermittent maintenance operations such as those described by CMA (e.g., blowing down meter leads for 5 minutes once a year, or opening pumps for maintenance for 1 hour quarterly). (Ex. 32–28, p. 116)

Emergency Situations. Paragraph (h)(1)(iv) requires employers to ensure that employees use respiratory protective equipment during emergencies. The joint labor/industry agreement suggested changing ''emergencies'' to ''accidental release emergencies.'' Submissions by CMA (Ex. 118–13) and IISRP (Ex. 118–12) provided no explanation supporting the need to change the language in paragraph (h)(1)(iv). OSHA did not incorporate this change in the final rule since the language suggested by the labor/industry agreement may imply to some that a release must occur before an emergency is declared and respirators would be required. The language that was originally proposed and retained in the final rule, along with the definition of ''emergency'' in paragraph (b), make clear that employers must ensure that employees use respiratory protection during an unusual condition or occurrence where there is a *potential* for a release of BD, even if an actual release has not occurred. OSHA believes that this reflects common practice in the chemical industry. This provision of the final rule is consistent with other OSHA health standards and is necessary to ensure that employees do not become exposed should an unusual condition result in a release.

Respirator Selection. Paragraph (h)(1) of the final standard requires that employers provide respirators to employees when necessary and ensure that employees use the respirators properly. As in other OSHA standards, employers are to provide the respirators at no cost to the employees. OSHA views this allocation of costs as necessary to effectuate the purposes of the Act. This requirement makes explicit an Agency position which has long been implicit in the promulgation of health standards under section 6(b) of the Act.

Employers must select respirators from those certified as being acceptable for protection against BD or organic vapors by the National Institute for Occupational Safety and Health (NIOSH), under the provisions of 42 CFR part 84.

Paragraph (h)(2) of the final rule requires employers to select and provide respirators in accordance with the criteria specified in Table 1. In the proposal, OSHA would not have permitted the use of cartridge-type negative-pressure respirators because of concern that they would not be sufficiently protective due to the short breakthrough times associated with high BD concentrations. OSHA requested additional data and comment on the issue, and asked NIOSH to conduct another breakthrough study to provide more information about the effectiveness of organic vapor cartridges in atmospheres containing lower BD concentrations.

The respirator selection table in the proposal was the subject of numerous comments addressing two principal issues. (Ex. 32–3; 32–4; 32–7; 32–8; 32–14; 32–20; 32–22; 32–25; 32–27; 32–28; 112; 118–6; 118–12; 118–16) First, commenters stated that the table should allow the use of cartridge type respirators in limited applications, and that the table should include other kinds of available respiratory protective equipment, such as half-mask supplied air respirators and loose-fitting powered air purifying respirators. (Ex. 32–4; 32–22; 32–27; 32–28; 112; 118–6; 118–12; 118–16) Second, commenters questioned the assigned protection factors (APFs) used in the proposal, stating that OSHA should use APF's similar to those used in other OSHA health standards or those of the ANSI

Z88.2–1992 standard. (Ex. 32–7; 32–25; 112; 118–6; 118–16) NIOSH stated that if respirators other than a self-contained breathing apparatus (SCBA) or a supplied air respirator with auxiliary SCBA that NIOSH recommended are permitted, OSHA should use the APFs in the 1987 NIOSH Respirator Decision Logic. (Ex. 32–25) The ANSI Z88.2–1992 standard and NIOSH decision logic apply the same APFs to half-mask, negative-pressure respirators (10) and PAPRs equipped with a tight-fitting half mask (50); for other respirator types, ANSI generally assigns a higher APF than does NIOSH.

OSHA has determined that cartridge-type respirators will provide adequate protection for BD, based on new evidence and data on breakthrough times at low BD concentrations (described in the discussion of *Service Life* below) and on comments concerning whether BD had adequate odor warning properties that would permit employees to detect breakthrough well in advance of their being overexposed. (Ex. 32–25; 32–28; 112) NIOSH stated that BD does not have adequate warning properties, citing the paper by Amoore and Hautala (Odor as an aid to chemical safety: odor thresholds compared with threshold limit values and volatilities for 214 industrial chemicals in air and water dilution. *J. Appl. Toxicol.* 3:272–290) that lists an air odor threshold of 1.6 ppm for BD. (Tr. 1/17/91. p. 741) However, this value is a geometric average of all the literature survey odor data that Amoore and Hautala used in devising their odor threshold tables. On the other hand, Tom Nelson, testifying on behalf of CMA, cited the American Industrial Hygiene Association (AIHA) report, *Odor Thresholds for Chemicals with Established Occupational Standards,* which lists BD as having a geometric mean odor threshold of 0.45 ppm for detection and 1.1 ppm for recognition. (Ex. 32–28c) According to CMA, the AIHA report represents a more recent compendium of odor threshold data for chemical agents than does the Amoore and Hautala study. (Ex. 112) Since the mean odor threshold identified by this source is about half of the 1 ppm PEL, and more than 10-fold below the 5 ppm STEL, OSHA finds that most wearers of air purifying respirators should still be able to detect breakthrough before a significant overexposure to BD occurs. Accordingly, OSHA is permitting the use of air purifying respirators equipped with either organic vapor cartridges or canisters in the final rule. In addition, OSHA will permit employers to provide single-use, half mask respirators equipped with organic vapor cartridges for employees working in environments containing up to 10 ppm BD.

In the final rule, OSHA has used the APFs for the various respirator classes contained in the NIOSH Respirator Decision Logic. (Ex. 32–25) The ANSI Z88.2–1992 APF values have not been adopted, although they were relied on in the recommended standard from the joint labor/industry agreement. As discussed earlier in this section of the preamble, OSHA is currently engaged in evaluating extensive data and evidence on APFs as part of its 29 CFR 1910.134 revision. However, in the case of the BD standard, OSHA's decision to rely on the more protective NIOSH APFs is based on evidence showing that organic-vapor cartridges and canisters have limited capacity for adsorbing BD and may have too short a service life when used in environments containing greater than 50 ppm BD. This evidence (discussed in detail in the section below entitled *Service Life of Organic Vapor Cartridges and Canisters*) consists of laboratory test data showing that organic vapor cartridges and canisters have a useful service life of no more than about 1.5 hours when challenged with air containing greater than 50 ppm BD, and that, at these concentrations, service life declines rapidly with increasing BD concentration. Allowing for a reasonable margin of protection, and given that test data were available only for a few makes of cartridges and canisters, OSHA believes that air-purifying devices should not be used for protection against BD present in concentrations greater than 50 ppm, or 50 times the 1 ppm PEL. Thus, OSHA finds that the ANSI APFs of 100 for full-facepiece, air-purifying respirators and 1,000 for PAPRs equipped with tight-fitting facepieces are inappropriate for selecting respirators for BD.

The proposal contained a provision (g)(2)(iii) requiring employers to provide employees with the option of using a positive-pressure respirator if the employee is unable to use a negative-pressure device. John Hale of Respirator Support Services objected to this provision since it would take respirator selection, the most critical aspect of a respirator program, out of the hands of the program administrator who is most knowledgeable about respirators and put it into the hands of the worker. (Ex. 32–3) Hale questioned whether the provision's language implied that the individual's medical condition would preclude the wearing of any respirator, since the breathing resistance of a modern negative pressure respirator is not a concern for a healthy worker. Mr. Hale also questioned the additional cost of supplying these alternative respirators. The International Institute of Synthetic Rubber Producers (IISRP) stated that, ''this provision is unwarranted because employees who are not medically fit should not be assigned to a job where respiratory protection is required.'' (Ex. 34–4)

OSHA has similar provisions requiring that the employer supply alternative respirators, either upon employee request or if the employee has difficulty wearing a negative-pressure device, in other substance specific standards such as inorganic arsenic (1910.1018), lead (1010.1025), cadmium (1910.1027), benzene (1910.1028), formaldehyde (1910.1048), and MDA (1910.1050). It has been OSHA's experience that this requirement has not proven to be a burden to implement and has proved to be a way to improve worker acceptance of respirator use. The language used in the BD proposal was the same as the language used in the benzene standard, 1910.1028 (g)(2)(iii). However, commenters felt the language in question implied that medically unfit workers would be allowed to wear PAPRs or supplied air respirators in place of a negative pressure respirator. (Ex. 32–3; 34–4) This is not the intent of this provision. The final provision (h)(2)(iii) has been modified to clarify that employers must determine that employees are able to use positive-pressure respiratory devices before upgrading an employee's respirator from a negative-pressure device. OSHA believes that this change in language better reflects the Agency's intent that employees who are unable to wear negative-pressure respirators be permitted to wear positive-pressure devices only after the employer takes appropriate steps to ensure the employee's ability to do so safely.

Some commenters pointed out that Table 1 of the proposal contained an error in that it would have permitted the use of PAPRs and self-contained breathing apparatus operated in a negative-pressure demand mode at any BD concentrations exceeding 50 ppm, which could result in a potentially dangerous situation since no maximum use concentration for these types of respirators was specified. (Ex. 32–28; 32–25; 32–3; 32–14) OSHA agrees that its proposed respiratory selection table was in error and has revised Table 1 of the final rule to reflect the appropriate maximum use concentration for PAPRs. OSHA deleted SCBA operated in negative-pressure demand mode from Table 1 since this type of respirator is not typically used in industrial settings.

Respirator Program. The proposal required (paragraph (g)(3)) that employers institute a respirator program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f). It was pointed out by one commenter that since 29 CFR 1910.134 is under revision, these references to specific paragraphs may change. (Ex. 32–3) The language of this provision has been revised to eliminate any reference to specific paragraphs in 29 CFR 1910.134, but still retains the requirement that a respirator program in accordance with the respiratory protection standard be implemented that contains the basic requirements for proper selection, fit, use, training of employees, cleaning, and maintenance of respirators. For employers to ensure that employees use respirators properly, OSHA has found that the employees need to understand the respirator's limits and the hazard it is protecting against in order to appreciate why specific requirements must be followed when respirators are used.

Service Life of Organic Vapor Cartridges and Canisters

The proposal in paragraph (g)(4)(i) required that the air purifying filters be replaced at 90% of the expiration of service life. The service life of organic vapor cartridges and canisters relates to the amount of time that the charcoal filter effectively purifies the breathing air before contaminants break through the filter and enter the facepiece. In laboratory testing for service life, air containing a known concentration of contaminant is passed through a cartridge or canister at a predetermined flow rate. The concentration of contaminant is measured in the air exiting the filter element on the other side. The time required for the contaminant concentration to reach a target level after passing through the filter element is known as the breakthrough time, and represents a measure of the service life of the filter element when used in atmospheres containing concentrations of the contaminant near the challenge concentration.

OSHA received comments on the proposed provision that would require replacement of organic vapor filters at 90% of the service life. The joint labor/industry agreement supported the proposed provision and recommended its inclusion in the final rule. (Ex. 118–12) However, John Hale of Respirator Support Services questioned how anyone could be expected to know when an element had reached 90% of its service life, or even come close to guessing it, since service life is dependent on the filter's inherent capacity (sorbent efficiency, bed depth, and other design factors) and even more so on respirator use conditions. (Ex. 32–3) Mr. Hale recommended that OSHA simply require filter elements to be replaced at the end of each shift.

In contrast, Tom Nelson, testifying for CMA (Ex. 32–28 C; 107–22), recommended that service life be taken into account to permit the use of organic vapor cartridges against BD, pointing out that there were test data contained in the BD record that would permit employers to establish cartridge change schedules suitable for their individual workplaces (these test data are discussed below). Specifically, Mr. Nelson suggested modifying paragraph (g)(4)(iii) of the proposal to permit the use of cartridge style respirators, provided that the cartridges have a minimum service life of at least 110% the anticipated duration of respirator use. Mr. Nelson also recommended that service life be tested under worst-case conditions of use, i.e., at a flow rate of 64 lpm at 25°C and at a relative humidity of 85%.

OSHA agrees with Mr. Nelson that adequate service life data are currently available both to support the use of organic vapor cartridges for BD and to establish schedules for changing filter elements. For example, NIOSH has performed respirator cartridge breakthrough testing at various exposure levels. (Ex. 23–83; 90) The BD record also contains other reports of service life testing of organic vapor filters, one a published report by Mr. Mark Ackley (Chemical cartridge respirator performance: 1,3-butadiene. *Am. Ind. Hyg. Assoc. J.* 48:447–453 in Ex. 32–28, Vol. II, App. B), and the other an unpublished report prepared by Mr. William Myles of Dow Chemical (Ex. 32–28, Vol. II, App.C). A summary of service life test data from these reports is presented in Table 2. Most of the breakthrough tests conducted for BD used high challenge concentrations relative to the PEL (most exceeding 50 ppm). In addition, the data from Myles and those from Ackley measured breakthrough times for a target concentration of 10 ppm, which was the ACGIH TLV at the time testing was conducted. However, after the informal hearing, NIOSH conducted breakthrough tests at lower challenge (10 to 50 ppm) and target (2 to 10 ppm) concentrations; some of these data are also summarized in Table X–1. (Ex. 90)

TABLE X–1. SUMMARY OF BREAKTHROUGH TEST DATA FOR RESPIRATOR CARTRIDGES AND CANISTERS CHALLENGED AGAINST BUTADIENE

Upstream Concentration (ppm)	Breakthrough Concentration (ppm)	Temperature, Relative Humidity (RH), Flow Rate (lpm)	Breakthrough Time (min)	Reference
CARTRIDGES				
500	10	27°C, 85% RH, 64 lpm	36	Myles (Ex. 32–28C).
100	10	25°C, 50% RH, 64 lpm	132.8, 142.0	Ackley (Ex. 32–28C).
100	10	25°C, 50% RH, 32 lpm	240.7, 245.1, 260.0	Ackley (Ex. 32–28C).
100	10	27°C, 85% RH, 64 lpm	108	Myles (Ex. 32–28C).
100	10	27°C, 85% RH, 32 lpm	174	Myles (Ex. 32–28C).
75	0.75	25°C, 85% RH, 64 lpm	55	NIOSH (Ex. 23–83).
93	0.93	25°C, 85% RH, 64 lpm	92	NIOSH (Ex. 23–83).
50	2	25°C, 85% RH, 64 lpm	159.1 [a]	NIOSH (Ex. 90).
20	2	25°C, 85% RH, 64 lpm	201.1 [a]	NIOSH (Ex. 90)
10	2	25°C, 85% RH, 64 lpm	217.3 [a]	NIOSH (Ex.90).
CANISTERS				
500	10	27°C, 85% RH, 64 lpm	42	Myles (Ex. 32–28C)
100	10	27°C, 85% RH, 64 lpm	102	Myles (Ex. 32–28C)

TABLE X–1. SUMMARY OF BREAKTHROUGH TEST DATA FOR RESPIRATOR CARTRIDGES AND CANISTERS CHALLENGED AGAINST BUTADIENE—Continued

Upstream Concentration (ppm)	Breakthrough Concentration (ppm)	Temperature, Relative Humidity (RH), Flow Rate (lpm)	Breakthrough Time (min)	Reference
100	10	27°C, 85% RH, 32 lpm	234	Myles (Ex. 32–28C).

[a] Mean values reported.

The more recent NIOSH data (Ex. 90) show that organic vapor cartridges, when tested in the range of 10 to 20 ppm, can provide about 3 to 3.5 hours of protection against BD under worst case test conditions (see Table X–1). However, at concentrations above 20 ppm, NIOSH test data (Ex. 23–83, see Table X–1) show that breakthrough time begins to decline rapidly; breakthrough times of about 2.5, 1, and 1.5 hours were obtained at test concentrations of 50, 75, and 93 ppm, respectively. More limited data on canister performance provided by Myles (see Table X–1) suggest that canisters will provide little gain in service life compared to cartridges. At a challenge concentration of 100 ppm and a target concentration of 10 ppm, breakthrough of organic vapor canisters occurred in 102 minutes under worst-case test conditions.

After reviewing the record evidence and comments on filter service life for BD, OSHA has modified its proposal to include a required schedule for the replacement of organic vapor cartridges and canisters (paragraph (h)(4)(i) and Table 1). Alternatively, employers may use other existing data or conduct additional tests to evaluate cartridge or canister service life in BD-contaminated atmospheres, and establish schedules for filter replacement based on 90% of the service life (paragraph ((h)(4)(ii)), as originally proposed. Employers may adopt the second approach, rather than use the default schedule in Table 1, so long as the written respirator program clearly describes the basis for the filter replacement schedule and demonstrates that employees will be adequately protected. In conducting this evaluation, employers should consider any workplace-specific factors that may affect filter service life, such as pattern and intensity of exposure to BD, temperature and humidity, and presence of other air contaminants that may shorten service life. In addition, where air-purifying respirators are used intermittently throughout the day, the filter replacement schedule developed by the employer must consider the effects of BD migration through the filter element during periods of non-use, and the impact of this effect on service life.

Under the default schedule in the final rule, cartridges and canisters for negative- pressure respirators must be replaced every 4 hours at BD concentrations less than or equal to 5 ppm, every 3 hours at concentrations between 5 and 10 ppm, every 2 hours at 10 to 25 ppm, and every hour at 25 to 50 ppm (see Table 1 of the final rule). The record contained no specific evidence on the performance of PAPR cartridges against BD. Therefore, the default change schedule for PAPR cartridges is based on that of negative-pressure devices, i.e., PAPR cartridges must be replaced every 2 hours or every 1 hour at BD concentrations less than or equal to 25 ppm or 50 ppm, respectively. Under the default replacement schedule, the maximum service time permitted in Table 1 begins from the time that the filter seal is broken, regardless of whether the respirator is actually put into immediate use, and runs continuously regardless of the pattern of respirator use. For example, if the seals of a pair of cartridges for a negative-pressure half mask respirator are broken at 8 am and the respirator is used in atmospheres not exceeding 5 ppm BD, the cartridges must be replaced no later than 12 pm, even if the respirator was only used intermittently for a few minutes. OSHA believes that it is necessary to define the replacement schedule requirement in this manner to account for BD migration throughout the cartridge during periods of non-use, and to ensure simplicity in administering the respirator program.

In setting the service lives of air purifying respirators for BD, OSHA has taken a conservative approach in evaluating the service life testing data. Temperature, humidity, air flow through the filter, the work rate, and the presence of other potential interfering chemicals in the workplace all can have a serious effect on the service life of an air purifying cartridge or canister. High temperature and humidity directly impact the performance of the activated carbon in air purifying filters. Humidities of 85% and temperatures of 25 °C or higher are commonly reached in the summer at BD polymer processing plants located on the Gulf Coast. An air flow rate of 64 liters per minute (lpm) used to test cartridges represents an air flow that may be achieved at a moderately high work rate. In addition, filter elements from different manufacturers may exhibit different service lives depending upon the types and amounts of charcoal used. OSHA realizes that lower humidity, temperature, and air flow through the filter would increase the estimates of service life. However, OSHA believes that, in establishing a default schedule for filter replacement that applies to all work situations involving exposure to BD, it is important to base the schedule on worst case conditions found in the workplace, since this will provide the greatest margin for safety in using air purifying respirators with BD. NIOSH in its comments (Ex. 32–25) stated that filters should be tested at worst case conditions of temperature, humidity, and BD concentration, and in combination with the other gases and vapors present in the workplace, since they may drastically affect service lives.

OSHA believes that specifying a schedule for filter changes based on service life data, or allowing employers to develop schedules based on BD-specific test data, is key to permitting the use of organic vapor cartridge respirators for protection against BD, since the service life data described above clearly demonstrate that organic vapor cartridges will not provide adequate protection if used over an entire work shift. In addition, OSHA believes that specifying a default filter change schedule for organic vapor cartridges will simplify compliance for those employers who do not have access to additional breakthrough data for BD.

Furthermore, OSHA finds that the odor warning properties of BD will provide an additional margin of protection in the event that the filter replacement schedule contained in Table 1 is not adequate for certain work situations. The regulatory text recommended by the joint labor/industry agreement suggested that OSHA add language in paragraph (h)(4) to require that employers replace air-purifying elements as soon as possible if an employee detects the odor of BD while using the respirator. OSHA agrees that this is an appropriate precaution,

and has included the language in the final rule.

Respirator Use. The proposal required (paragraph (g)(4)(i)) that canisters be labeled with the date they were put into service. A date alone was all that was needed since the proposal would have allowed for their use for a full work shift before replacement. However, in the final rule, OSHA will now be allowing the use of air purifying cartridges for BD exposures, and the service life of these cartridges is less than a full work shift. Therefore, the proposed provision has been modified in the final rule (paragraph (h)(4)(iii)) to require the labeling of air purifying filter elements with both the date and the time of the start of use to allow for their prompt replacement once the service life listed in Table 1 is reached.

The final standard (paragraph (h)(4)(v)) permits employees to leave the regulated area to readjust the respirator facepiece to their faces for proper fit. The respirator wearer who detects the odor of BD or who feels eye irritation should leave the area immediately and replace the air purifying elements before reentry. It also permits employees wearing respirators to leave the regulated area to wash their faces and respirator facepieces to avoid potential skin irritation associated with respirator use.

End-of-Service-Life Indicators. End-of-service-life indicators (ESLI) for BD do not now exist. The final standard contains a provision (paragraph (h)(4)(iv)) that would allow the use of such a NIOSH-approved ESLI. OSHA originally proposed permitting the use of a NIOSH-approved ELSI for BD, and inclusion of this requirement was supported by the joint labor/industry agreement. This provision is intended to encourage respirator manufacturers to develop a reliable ESLI for organic vapor cartridges and canisters used to protect against BD. Respirator manufacturers have been reluctant to develop filter elements with ESLI without an indication from OSHA that it would allow the use of an ESLI.

In its comments on the proposed standard, NIOSH stated that if OSHA chooses to allow air purifying respirators for BD, OSHA should require the use of an ESLI along with the requirement for doing a service life determination based on the worst case BD exposure level expected, at high humidity levels and high temperatures encountered at that plant location. (Ex. 32–25) Since a NIOSH approved ESLI for BD does not yet exist, OSHA cannot make their use a prerequisite for air purifying respirator use with BD, since by doing so OSHA would preclude the use of air purifying respirators. However, OSHA does encourage employers to use ESLIs when they are approved by NIOSH.

John Hale of Respirator Support Services objected to the practice of relying on mechanical end-of-service-life indicators, stating that since mechanical devices do fail, it is preferable instead to rely upon breakthrough to dictate when to replace air purifying elements. (Ex. 32–3) However, since the permissible exposure limits for chemicals such as BD are being lowered to levels almost at the odor threshold, a reliable ESLI would not replace breakthrough detection by the wearer, but would instead provide an additional means of ensuring that air purifying elements are replaced before their service life expires.

Air purifying filter elements with end of service life indicators (ESLI) may be used until the ESLI indicates that filter replacement is necessary. For cartridges and chin style canisters this may mean that their service lives with an ESLI would be longer than the conservative service lives listed in Table 1. However, the final rule includes a requirement to replace the cartridge or canister at the beginning of the next work shift, regardless of any residual service life left, due to the problem of BD migration through the filter element during the time the previously exposed filter element is not in use (e.g., overnight).

Fit Testing. Paragraph (h)(5) of the final BD rule requires employers to perform either qualitative (QLFT) or quantitative (QNFT) fit testing at the time a tight-fitting negative-pressure respirator is first assigned to an employee who is working in atmospheres containing 10 ppm or less of BD, and annually thereafter. At BD concentrations above 10 ppm, employers must use QNFT for full-facepiece, negative-pressure respirators. In the proposal, employers would have been required to perform either QNFT or QLFT on all tight-fitting respirator facepieces, including those used for positive-pressure devices. The final rule also adds a new paragraph (h)(5)(iii) that requires employers to ensure that employees perform a fit check of the respirator facepiece before each entry into a BD-contaminated atmosphere.

OSHA received many comments on the proposed fit test requirements for BD. The IISRP stated that OSHA should not require QNFT at exposure levels above 20 ppm (i.e., an APF of 10), because it is scientifically unnecessary and much more expensive than QLFT. (Ex. 34–4) In the preamble to the BD proposal (55 FR 32793), OSHA referred to the Agency's proposed revision to 29 CFR 1910.134, which in turn discussed evidence indicating that QLFT was not reliable in achieving APFs higher than 10. (55 FR at 32793) OSHA's standards for cadmium (29 CFR 1910.27) and asbestos (29 CFR 1910.1001) require QNFT of full facepiece respirators used at APFs higher than 10. Although the Agency will make a final determination on the effectiveness of QLFT for achieving APFs higher than 10 as part of its revision of 29 CFR 1910.134, OSHA is not aware of any data or evidence presented in the BD rulemaking that suggest that OSHA should depart from the position expressed in the proposal. Therefore, the final rule for BD will require QNFT when negative-pressure respirators are to be used in atmospheres containing more than 10 ppm BD.

When tight fitting respirators are used, OSHA requires respirator fit testing because proper fit is critical to the performance of tight fitting negative pressure, air-purifying respirators. With tight fitting air-purifying respirators, a negative pressure is created within the facepiece of a properly fitted respirator when the wearer inhales. A poorly fitted respirator allows contaminated workplace air to enter the facepiece through gaps and leaks in the seal between the face and the facepiece instead of passing through the sorbent material.

The fit testing of positive pressure respirators, both half masks and full facepieces, was part of the respirator fit testing provisions in the proposal (paragraph (g)(5)(i)), based on a concern that employees may ''overbreathe'' while wearing the respirator, thus creating a temporary negative pressure within the facepiece and increasing the likelihood for leakage. Tom Nelson, testifying for CMA, questioned this requirement since the requirement had never appeared in previous OSHA standards. (Ex. 112) Mr. Nelson also claimed that requiring fit testing of positive-pressure respirators due to the potential for ''overbreathing'' was unwarranted for BD since this was likely to occur only at extremely high work rates. (Ex. 112) In addition, Mr. Nelson stated that, if OSHA does require fit testing of positive pressure respirators, then it should adopt the ANSI approach.

OSHA has previously required fit testing for positive pressure respirators in the recent cadmium standard, 29 CFR 1910.1027(g)(4) (ii), (iii), and (iv). However, OSHA is currently conducting a comprehensive evaluation of the need to require fit testing of positive-pressure facepieces as part of its rulemaking to revise 29 CFR 1910.134. Until this

evaluation is complete and OSHA has made a final determination, OSHA is not including the proposed requirement to fit test positive-pressure devices in the final rule for BD.

Some commenters objected to the requirement contained in Appendix E that employers conduct at least three separate quantitative fit tests to obtain a fit factor for a respirator, questioning the basis for the requirement and arguing that it was too costly. (Exs. 32–3, 32–28, 112, 118–6) For example, John Hale of Respirator Support Services provided the following comment in his pre-hearing submission:

> On what technical basis does OSHA impose this requirement? It is widely accepted among the health and safety professionals * * * that there is no more confidence gained from three fit test results than from one. Indeed, it would take many more than three to provide any level of statistical confidence in the actual value arrived at for a fit factor. The burden of time and expense imposed by this requirement is completely unjustified.* * * (and) there is no benefit to the respirator wearer. (Ex. 32–3)

As with other respirator issues raised in the BD record, OSHA is currently revising its required protocols for fit testing as part of the revision of 29 CFR 1910.134. At this time, OSHA has modified Appendix E in the final rule for BD to require a single test when QNFT is performed, pending OSHA's final determination for the revised 29 CFR 1910.134 standard.

Several commenters stated that the BD standard fit testing requirements did not allow the use of the Portacount fit testing device since there is no protocol for that method contained in Appendix E. (Ex. 32–3; 32–4; 32–8; 32–11; 32–27; 32–28; 112; 118–16) In 1988 OSHA issued a compliance memorandum classifying the use of the Portacount fit test as a de minimis violation for those OSHA standards that contain a mandatory appendix listing quantitative fit test protocols and instrumentation. The validation of fit testing methods such as the Portacount and appropriate protocols for such methods are to be addressed fully in the fit testing section of the 29 CFR 1910.134 respiratory protection standard revision. Shell Oil Company, in a pre-hearing submission to the BD record stated:

> In a new standard, it would seem reasonable for OSHA to recognize the Portacount system. It is improper for OSHA arbitrarily to exclude a proven fit-test system from a standard, but to encourage a technical violation by advising industry that it would consider Portacount [a de minimis violation] * * * (Ex. 32–27, p. 3)

CMA asked that OSHA allow use of ''any QNFT equipment such as the Portacount that can reliably measure a test challenge.'' (Ex. 32–28, p. 131)

TSI, Inc. (Ex. 32–11, Att. 1–3) submitted three technical papers to the BD record reporting the results of studies comparing the ''Portacount,'' condensation nuclei counting (CNC) respirator fit-test method with the aerosol/photometer method. The first, published in the Journal of the International Society for Respiratory Protection, described a U.S. Army study comparing fit factors determined by CNC and the more traditional corn oil aerosol/photometer determinations. Initial tests did not employ human subjects, but rather they used a mask/headform assembly enclosed in a plastic hood. Numerous conditions of heat and humidity were tested repeatedly.

The correlation coefficient was calculated to determine the strength of the relationship between measurements made in applying the two methods.[11] The correlation coefficients calculated in this study ranged from 0.953 to 0.996.

The Army study also fit-tested human subjects using both methods. Subjects were tested by each method sequentially and the pass-fail agreement/disagreements determined for 100 comparison tests. Agreement exceeded 95%. The author concluded that ''(CNC) was a suitable alternative to conventional photo-meter quantitative fit testing systems.'' (Ex. 32–11, Att. 1, p. 8)

The second study, performed at Shell Oil Company, described sequential fit tests of approximately 50 test subjects at each of two chemical plants. (Ex. 32–11, Att. 2) Again Portacount/CNC methodology was compared with the corn oil aerosol/photometric method. This researcher also compared fit test outcomes as pass-fail agreement/disagreement. The differences in the results obtained from the Portacount/CNC method and aerosol/photometric method shoed less than a 10% discordance and were not statistically distinguishable. The author concluded that ''the Portacount would appear to be an acceptable system for quantitative fit testing.'' (Ex. 32–11, Att. 2, p. 6)

The final submission was a paper by Rose et al. that appeared in the Journal of Applied Occupational and Environmental Hygiene in 1990. (Ex. 32–11, Att. 3) Again, sequential fit-factor measurements using both the aerosol/photometer test system and CNC (Portacount) methods were compared. They were tested at the same fitting of the respirator for each subject. The study involved 24 test subjects. It was found that fit factors determined by photometer were lower than the CNC determinations in 14 of 24 pairs. However, the correlation coefficient was over 0.85, indicating that the two sets of measurements were highly correlated. Other statistical tests were applied and no differences between the two methods were demonstrated. When pairwise comparisons of pass-fail agreement/disagreements were made, the authors concluded ''there was only one discordant pair in the 48 comparisons at the two critical fit factors.'' In reviewing the then-current literature, Rose et al. noted that several other studies had shown good agreement between the results of the 2 fit factor measurement methods also.

These findings affirm OSHA's earlier determination based on a study by Lawrence Livermore National Laboratory (as described in the above-mentioned compliance directive) that the CNC/Portacount method of fit factor determination is acceptable. Rather than continue to consider use of the CNC/Portacount method as a de minimis violation, OSHA is in this final rule accepting its use for fit testing for BD exposure and has included instructions for performing this fit test in Appendix E. These instructions are essentially the same as those of the manufacturer.

In Appendix E of the proposal, the QNFT protocol in section C(4)(xi) required that half masks and full facepiece respirators obtain a minimum fit factor of 100 during QNFT fit testing. John Hale stated that a minimum fit factor of 10 times the APF for that class of respirator is needed. (Ex. 32–3) James Kline of Wilson Safety Products pointed out that the preamble stated that a minimum fit factor of 100 for half masks and 500 for full facepieces should be obtained during fit testing, while Appendix E mentioned only a fit factor of 100. (Ex. 32–14) Mr. Kline recommended that the minimum fit factor should be ten times the applicable APF or the protection factor needed for the application, whichever is lower. NIOSH also recognized the difference in fit factor requirements between the preamble of the proposal and Appendix E and recommended a fit factor of 100 be used for quarter and half mask and that a fit factor of 500 be used for full facepieces. (Ex. 32–25) OSHA agrees that the language in the proposed Appendix E was in error, and has corrected it in the final rule to require that a minimum fit factor of 100 for half

[11] The correlation coefficient is the proportion of the total sum of the squares variation that is explained by the linear relationship. Thus, a correlation coefficient of zero indicates the two are not related, while a value close to 1 indicates a high positive correlation.

masks and 500 for full facepieces be obtained during QNFT testing.

Obtaining a proper fit for each employee may require that the employer provide two to three different sizes and types of masks so that an employee can select the most comfortable respirator that has a facepiece with the least leakage around the face seal. In past rulemaking efforts, OSHA has consistently found that this is a necessary requirement for fit testing of negative-pressure devices since the configuration of each manufacturer's facepiece varies, and it is highly unlikely that all employees will be comfortably fitted with the facepiece of a single manufacturer, even if different sizes are provided.

However, the requirement in Appendix E to use respirators from multiple manufacturers for the fit testing of positive-pressure respirators was questioned by CMA since, unlike the case for negative-pressure facepieces, most people can be adequately fitted with a single manufacturer's positive-pressure equipment. (Ex. 112) CMA was also concerned that, if employees were assigned different makes and models of positive-pressure facepieces, confusion would arise in the workplace with the use of different types of hoses specific to each manufacturer, increasing the likelihood that incompatible respirator hardware would be used, increasing risks to workers. However, as discussed above, OSHA is not now requiring fit testing of positive-pressure devices in the final rule for BD, deferring judgement until the issue is resolved in the rulemaking for 29 CFR 1910.134.

The CMA submission addressed two additional fit test issues, recommending that OSHA delete the protocol for the irritant smoke QLFT in Appendix E, due to health concerns, and that the grimace exercise be deleted from the QNFT protocols because it tends to yield an artificially low fit factor. (Ex. 32–28, Ex. 112) OSHA is evaluating both of these issues in the context of the rulemaking for 29 CFR 1910.134. At the present time, OSHA is retaining in Appendix E the irritant smoke QLFT, should employers wish to continue using it. Should OSHA determine upon promulgation of a final revision of 29 CFR 1910.134 that use of irritant smoke QLFT poses excessive risks to employees, OSHA will make appropriate changes to its final rule for BD.

Regarding the issue of the grimace test, this exercise is to determine whether the facepiece being tested will reseat itself on the face after the respirator seal is broken. In quantitative fit testing, the test instrument should show a rise in challenge agent concentration within the mask during the grimace exercise, followed by a drop once the respirator reseats itself. If the respirator fails to reseat, subsequent test exercises will show excessive leakage, resulting in a failed test. Since even a properly fitting mask may show increased penetration during the grimace exercise, the penetration observed during the exercise is not to be used in calculating the overall fit factor. OSHA has revised Appendix E in the final rule to clarify this aspect of determining fit factors for respirator facepieces.

The preamble to the proposal contained a discussion of the need to perform a facepiece fit check prior to entry into a BD exposed work area. (55 FR 32736 at 32793) The purpose of performing such a negative pressure or positive pressure fit check is to meet the objective of demonstrating that a proper facepiece seal is being obtained each time the respirator is donned. Appendix E, Section II contains descriptions of the recommended positive and negative fit check methods. This test can be either a positive pressure fit check, in which the exhalation valve is closed and the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure fit check, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Not all tight fitting respirators can be fit checked by using one or the other of these methods, since the wearer must be able to block off either the inlet or exhalation valves. Where the fit cannot be checked using one of the above methods, the wearer shall use the fit check method recommended by the manufacturer of the respirator being used. Language has been added to the respirator fit testing section of the final BD standard at paragraph (h)(5)(iii) that contains this requirement.

I. Personal Protective Equipment

This paragraph, which in the proposed rule was included in the Respiratory Protection paragraph, has been separated into a separate paragraph to facilitate compliance. Paragraph (i)(6) (paragraph (g)(6) of the proposed rule) requires that personal protective equipment must be worn where appropriate to prevent eye contact and limit dermal exposure to liquefied BD and solutions containing BD. Furthermore, it must be provided by the employer at no cost to the employee and the employer shall ensure its use where appropriate. OSHA believes that this performance oriented approach affords employers the flexibility to provide in a given situation only the protective clothing and equipment necessary to protect employees without specifying the exact nature of protective equipment to be used. This paragraph is sufficiently performance-oriented to allow the employer adequate flexibility to provide only the personal protective equipment necessary to protect employees in each particular work operation from the BD exposure encountered. Therefore, compliance can be tailored to fit the hazards posed on a day-to-day basis.

OSHA further notes that the generic requirements for Personal Protective Equipment (PPE) (Part 1910, Subpart I) apply for BD except where a specific provisions of the BD standard would provide otherwise.

J. Emergency Situations

Under paragraph (b) of this section, OSHA defines an emergency situation to be any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of BD.

Paragraph (j) requires that employers develop new written plans for emergency situations or modify an existing plan to contain applicable elements of 29 CFR 1910.38, Employee Emergency Plans and Fire Prevention Plans, and of 29 CFR 1910.120, Hazardous Waste Operations and Emergency Responses and how the cause of the emergency is to addressed.

Both the above-mentioned standards require written plans for emergency responses and set out their content and use; however, it is noted that paragraph (q)(1) of 1910.120 states the following:

> An emergency response plan shall be developed and implemented to handle anticipated emergencies prior to the commencement of emergency response operations. The plan shall be in writing and available for inspection and copying by employees, their representatives and OSHA personnel. Employers who will evacuate their employees from the danger area when an emergency occurs, and who do not permit any of their employees to assist in handling the emergency, are exempt from the requirements of this paragraph is they provide an emergency action plan in accordance with (29 CFR) 1910.38(a) of this part.

Thus, only one of the two standards, either 1910.38 or 1910.120, would likely apply in a single facility. OSHA believes that it is likely that smaller facilities will comply with the provisions of 29 CFR 1910.38, while employers whose facilities are large enough to have specific emergency response personnel available will comply with 29 CFR 1910.120.

OSHA recognizes that all sudden releases of BD do not constitute an emergency. For example, the accidental breaking of a sampling syringe containing a minute amount of BD would not normally constitute an emergency. On the other hand, failure of a valve on a reaction vessel, a flange, or a safety relief valve would likely constitute an emergency. OSHA believes that compliance with these requirements will ensure that affected employees are effectively protected during a BD emergency.

In the limited reopening of the BD record in March 1996, OSHA stated that it proposed to define ''Emergency'' as:

> * * * any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an unexpected significant release of BD.

The agency said that it was considering limiting the emergency releases to those that are uncontrolled, so that the last phrase of the definition would read: ''* * * that may or does result in an uncontrolled significant release of BD.'' It then asked whether this addition adequately clarifies what situations OSHA considers to be emergencies, and whether the term ''significant release'' gives adequate guidance to employers as to how much BD must be released in order to constitute an emergency?

Some comment was received on this issue and it is discussed in the paragraph dealing with the definition of the term emergency situation in the definition section (b) of the Summary and Explanation.

OSHA has chosen to use the term uncontrolled occurrence because it is more descriptive and is consistent with the Hazard Communication Standard (29 CFR 1910.1200) and Hazardous Waste Operations and Emergency Response Standard (29 CFR 1920.120).

In the proposed rule, OSHA included provisions for respiratory use and for alerting employees during emergencies. These have been omitted from this section as redundant. Paragraph (j)(1)(iv) sets out the requirement for respirator use during emergencies. Paragraph (k)(4)(ii) sets out medical screening requirements for those exposed to significant releases of BD.

K. Medical Screening and Surveillance

Where appropriate, medical screening and surveillance programs are required by section 6(b)(7) of the OSH Act to be included in OSHA health standards to aid in determining whether the health of workers is adversely affected by exposure to toxic substances. The relationship between medical screening and medical surveillance was clarified in posthearing comments by Dr. William Halperin, NIOSH. (Ex. 90, p.4) According to Dr. Halperin:

> The term ''medical'' surveillance is often used to encompass two distinct activities: (1) Medical screening: the search for early disease and (2) medical surveillance: the ongoing collection, analysis and dissemination of health related information that can be applied to the promotion of health and the prevention of adverse health effects (Ex. 90, p. 4).

Paragraph (k) of this rule clarifies OSHA's intention to include both activities in a program to identify and prevent BD-related disease.[12]

Health hazards that have been shown to be associated with occupational exposure to BD include leukemia, non-Hodgkins lymphoma, and anemia. Additionally, adverse reproductive and developmental outcomes have been observed in toxicologic studies of male and female mice. The medical screening and surveillance program specified in paragraph (k) has the following goals:

1. To prevent occupational diseases related to BD exposure;
2. To detect and treat BD-related disease before a worker would routinely seek medical care; and
3. To provide information on the adequacy of the PELs for BD.

Although most of the medical screening and surveillance provisions remain the same as in the proposal, several changes have been made. These changes include:

(1) Physical examinations are required once every three years, rather than annually;

(2) An annual health questionnaire for workers exposed to BD has been added;

(3) An annual complete blood count including differential and platelet count (CBC) is required;

(4) Medical evaluation of employees required to wear respirators, including assessment of cardiopulmonary function, is no longer required in this rule, and employers are referred to 29 CFR 1910.134;

(5) Employees with past BD exposures that meet specific criteria must be offered continued participation in medical screening and surveillance programs;

(6) Activities pertaining to medical screening and medical surveillance have been more clearly delineated; and

(7) Responsibility for the program has been expanded to include other licensed health care professionals, as well as physicians.

[12] Nothing in this standards changes the meaning of the term ''medical surveillance'' as it has been used in previous standards, such as the asbestos standards, 29 CFR 1910.1001 and 1926.110.

Paragraph (k)(1) specifies the circumstances under which employers must provide medical screening and surveillance for employees exposed to BD. Under paragraph (k)(1)(i) this program must be offered to each employee with exposure to BD at concentrations at or above the action level on at least 30 days a year. Additionally, it must be made available to those employees who have or may have exposure to BD at or above the PELs on at least 10 days per year.

This provision remains the same as that contained in the proposed rule. An alternative set of criteria for employee coverage was suggested in the joint labor-management agreement submitted to OSHA by the USWA and the IISRP. (Exs. 118–12; 119) This agreement would have raised the threshold of employee exposure to BD concentrations at or above the action level for at least 60 days per year, and at or above the PELs for at least 30 days per year. OSHA's review of the record did not produce evidence of controversy for the trigger levels as originally proposed. In fact, Shell Oil Company provided written comments which stated in part,

> This is a reasonable definition of who should be covered, with a time factor (30 days a year) for exposures at or above the action level * * * and a shorter time factor (10 days a year) for exposures at or above the PEL * * * or STEL * * * (Ex. 32–27)

Additionally, designation of trigger levels for medical screening and surveillance at or above the action level for 30 days and at or above the PELs for 10 days per year is consistent with past OSHA policy. For example, in the rulemaking for occupational exposure to coke oven emissions OSHA determined that a specific time period is the most effective and administratively feasible method to adopt in order to exclude workers with very limited exposures, e.g., temporary assignments during vacation periods. (41 FR 46777) At the same time, OSHA was concerned that the selected time period be sufficiently inclusive, and chose a cut-off point of 30 days. (41 FR 46777) The rulemaking for occupational exposure to inorganic arsenic followed the same policy. (43 FR 19620) Subsequently, the health standard for occupational exposure to benzene and the proposed rule for methylene chloride used the 30/10 triggers for inclusion in the medical surveillance program. (29 CFR 1910.1028; 56 FR 57036)

This overall approach to employee selection for coverage by the medical screening and surveillance program is based, in part, on the theory that cancers

associated with BD exposure are likely to be dose-related. Thus, employees exposed for only a few days a year may be at lower risk of developing BD-related disease. This approach allows employers to concentrate valuable medical screening and surveillance resources on higher risk employees.

Another change in the coverage of the medical screening and surveillance program is the elimination of coverage based only on required respirator use. The proposal specified that each employee whose exposure to BD requires the use of a respirator, regardless of the duration of exposure, be covered by the program. In the final rule, employees using respirators will be part of the medical screening program if they are over the action level or PELs for the amount of time stated in the medical screening provisions (on least 30 or more days for the action level and on 10 or more days for the PELs). This change is consistent with the recommendations contained in the labor-management agreement, and with OSHA's intention to clearly delineate medical screening requirements for employees with chemical specific exposures and those who must wear respirators, irrespective of the specific hazard. (Ex. 118–12; 29 CFR 1910.134) OSHA believes that the medical screening requirements for respirator users must be consistent with the provisions contained in 29 CFR 1910.134. Support for this approach was received from several industry representatives. (Exs. 118–11; 118–13; 118–14)

The proposed rule also included a provision for medical evaluation of cardiopulmonary function for all employees whose exposures require them to use respirators. This evaluation was supported by Dr. Philip Landrigan of the Mount Sinai Medical Center. He stated that,

> * * * the cardiorespiratory testing for people that are going to be wearing respirators is very much indicated, that wearing a respirator increases the work of breathing. It is important to know that a person has sufficient cardiorespiratory capacity to be able safely and healthfully to be able to work with the respirator on. (Tr.1/15/91, p. 200)

However OSHA received several comments, including ones from Shell, CMA, and Dr. James A. Saunders, that disagreed with this provision. (Exs. 32–27; 112; Tr. 1/18/91, p. 1213–1214) According to CMA,

> All employees who wear respirators should not receive an evaluation of cardiopulmonary function. As in the benzene standard, a pulmonary function test should be performed every three years on employees who wear respirators for at least 30 days per year. The cardiopulmonary function of these employees should also be evaluated but no specific test should be required except as directed by the examining physician. (Ex. 112, pp. 127–128)

The testimony of Dr. Saunders, who testified on behalf of the CMA BD panel, supported the CMA position on this issue. (Tr. 1/18/91, pp. 1213–1214) Shell offered the following opinion,

> This is *not* a reasonable definition of who should be evaluated. * * * To promulgate slightly different requirements for respirator user evaluation in different individual chemical exposure standards only creates confusion and nonuniformity. OSHA needs to finalize a respirator standard rather than putting different details in each standard. * * * (Ex. 32–27, attachment II, p. 3)

In the final rule, OSHA has clarified its position on medical screening and surveillance for employees whose exposure to BD requires them to use a respirator. Determinations regarding an employee's physical ability to perform the work and use the equipment should be made pursuant to 29 CFR 1910.134. Accordingly, paragraph (k)(4)(iii) has been added to refer employers to the standard on respiratory protection, and the requirement for evaluation of cardiopulmonary function has been deleted from this standard. Comments that support these changes have also been received from labor and industry representatives in response to the limited reopening of the rulemaking record. (Exs. 118–11; 118–13; 118–14; 118–16)

The concept for paragraph (k)(1)(ii) was recommended in the labor-management agreement submitted to OSHA by the USWA and the IISRP. It requires that employers continue medical screening and surveillance for employees after they have transferred to a job without potential exposure to BD when their work histories meet specified criteria. (Ex. 118–12) These criteria are: (1) Exposure at or above the 8-hour TWA limit or STEL on 30 or more days a year for 10 or more years; (2) exposure at or above the Action level on 60 days a year for 10 or more years; or (3) exposure above 10 ppm for 30 days in any past year. (Ex. 118–12) This would also include employees who transfer to low exposure BD jobs, provided that their work histories meet the specified criteria. OSHA welcomes this new provision to the final rule because of the additional protection it affords to workers with a history of occupational exposure to BD. The relatively short latency periods associated with BD-related diseases, which range from 4–9 years to 15–20 years, provide supporting rationale for this provision.

Objections to this provision were made by Texas Petrochemicals Corporation and Hampshire Chemical Corporation on the grounds of unreliable past exposure measurements and recordkeeping. (Exs. 118–6; 118–8) The Air Transport Association objected to this provision on the grounds that including ''employees whose past exposure was over a period of 10 years seems extreme.'' (Ex. 118–18B) Instead, they suggested a ''period of 5 or 3 years'' as a selection criterion. In response to these concerns, OSHA believes that the epidemiologic evidence suggests that these workers may be at increased risk of BD-related disease. This provision narrows the coverage of previously exposed workers to those with the greatest risk. It is OSHA's opinion that this approach errs on the side of caution for this group of workers. Support for this requirement, together with the provisions of paragraph (k)(1)(i), was offered by CMA in their statement that, ''this eligibility standard is appropriate for the medical surveillance program and will effectively protect employees most at risk.'' (Ex. 118–13) OSHA is of the opinion that, when taken in conjunction with the entire labor-management agreement, the requirement to include employees with historical BD exposure will be protective for high risk employees and provide valuable data for the medical surveillance portion of this section, paragraph (k)(8)(i).

Paragraph (k)(1)(iii) requires that coverage in the medical screening and surveillance program must be extended to each employee exposed to BD following an emergency situation regardless of the airborne concentrations of BD normally present in the workplace. Where very large amounts of BD are maintained in a sealed system, routine exposure may be essentially zero. However, system failure might result in catastrophic exposures. Thus, employers who have identified operations where there is potential for an emergency involving BD must take the necessary action to implement an emergency plan, as required in 29 CFR 1910.38. Additionally, employers must ensure that emergency medical care is available to exposed employees, and that such care is rendered by physicians or other licensed health care professionals with knowledge of the acute and chronic toxicity of BD.

Paragraph (k)(2) addresses program administration. Specifically, this provision requires that the medical screening and surveillance program be provided without cost to the employee, without loss of pay, and at a reasonable time and place. It is OSHA's opinion

that this provision is necessary to encourage employee participation. This same requirement was contained in the proposal. Furthermore, it is consistent with other OSHA health standards as well as with provisions contained in the OSH Act.

Additionally, paragraph (k)(2)(ii) requires that all physical examinations, medical procedures, and health questionnaires be administered by a ''physician or other licensed health care professional,'' defined as an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (k) of this section. The proposal required that all medical procedures be performed by or under the supervision of a licensed physician.

However, OSHA has long been considering the issue of whether and how to specify the particular professionals who are to perform medical surveillance in all of its standards. The Agency has determined that other professionals who are licensed under state laws to provide medical screening and surveillance services would also be appropriate providers of such services for the purposes of the BD standard. The Agency recognizes that the personnel able to provide the required medical screening and surveillance may vary from state-to-state depending on the state's licensing laws. Under the final rule, an employer, after becoming familiar with state laws delineating scope of practice for various licensed health care professionals, has the flexibility to retain the services of a range of qualified licensed health care professionals, thus potentially reducing cost and inconvenience for employers, and easing compliance burdens.

In the future, OSHA may attempt, with the cooperation of interested stakeholders, to specify which health care professionals are the most appropriate to perform each of a variety of diagnostic, therapeutic, medical management and other services. The more generic approach contained in this standard does, however, signal OSHA's belief that employees should have access to, and that employers should retain, when feasible, those professionals with the greatest level of expertise in discriminating between medical problems associated with occupational or environmental exposures and those associated with organic conditions unrelated to exposure. While the limited numbers of occupational physicians and occupational health nurses available to perform these services is increasing, such expertise does not necessarily correlate with any particular credential.

The final program administration requirement, paragraph (k)(2)(iii), is for all laboratory tests to be conducted by an accredited laboratory. This provision is consistent with other health standards, including benzene (29 CFR 1910.1028), bloodborne pathogens (29 CFR 1910. 1030), and lead (29 CFR 1910.1025). Furthermore, OSHA believes that this requirement is a necessary element for quality control in the medical screening and surveillance program.

The required frequency of medical screening activities is shown in paragraph (k)(3). For each employee covered under paragraphs (k)(1)(i)-(ii), a health questionnaire and CBC are required every year. Additionally, physical examinations must be provided at specified intervals: (1) An initial physical examination if twelve months or more have elapsed since the last physical examination conducted as part of a medical screening program for BD exposure; (2) a preplacement examination before assumption of duties by the employee in a job with BD exposure; (3) every three years after the initial or preplacement physical examination; (4) at the discretion of the physician or other licensed health care professional; (5) a termination of exposure examination at the time of employee reassignment to an area where exposure to BD is below the Action level, if the employee's past exposure history does not meet the criteria of paragraph (k)(1)(ii) for continued participation in the program, and if twelve months or more have elapsed since the last physical examination; and (6) at termination of employment, if twelve months or more have elapsed since the last physical examination.

There are several differences between the proposed and final rules regarding the type and frequency of medical screening activities. First, the initial physical examination provided under this section must be provided only ''if twelve months or more have elapsed since the last physical examination conducted as part of a medical screening program for BD exposure.'' This addition to the proposal language was made to prevent unnecessary extra physical examinations when the medical screening and surveillance portion of the final rule becomes effective. It is OSHA's opinion that, if an employee has received a physical examination as part of a medical screening program for BD within the past year, a repeated physical examination conducted just to coincide with the promulgation of this rule would be unnecessary and costly to the employer and burdensome for the employee. However, evaluation of the data for the entire group of BD exposed workers would still need to be done to comply with the surveillance portion of this paragraph.

Second, the requirement for preplacement evaluations has been changed from ''before the time of initial assignment of the employee'' to ''before assumption of duties by the employee.'' This change reflects comments received from Shell, which stated,

> * * * before the time of initial assignment of the employee is not effective. OSHA should make clear that what is meant is at the time of initial assignment or transfer into a job meeting the entry criteria, and preferable before assumption of duties in such an assignment. (Ex. 32–27, attachment II, p. 4)

OSHA agrees that this wording more clearly reflects the intention behind this requirement for preplacement examinations. Such examinations are intended to evaluate an employee's ability to work in a safe and healthful manner in a specific work environment. Additionally, they establish a baseline of information against which future health status changes can be compared.

Third, the frequency of physical examinations has been changed from once a year to every three years following the initial or preplacement examination. Several comments were received that addressed the frequency of these examinations. For example, CMA offered the opinion that, ''requiring a complete physical examination each year is unreasonable and excessively burdensome.'' (Ex. 112, p. 131) Dr. Saunders, testifying on behalf of the CMA BD panel, also objected to annual physical examinations, stating that they are ''unreasonable and wasteful of limited medical resources.'' (Tr. 1/18/91, p. 1210) OSHA agrees that an annual physical examination is not the most effective medical screening activity to detect BD-related disease, and thus has changed this requirement. However, OSHA does not agree with CMA that physical examinations should only be provided ''where warranted by symptoms of adverse health effects that might be related to butadiene exposure.'' (Ex. 112, p. 127) Such an approach would ignore principles of medical screening and surveillance, i.e., early identification of disease before medical care would routinely be sought. Most recently, support has been expressed by both labor and industry representatives for this frequency schedule. (Exs. 118–12; 118–13)

Fourth, under the final rule employees covered by the medical screening and surveillance program must be offered an annual health questionnaire and a CBC. It is OSHA's opinion that these medical evaluation activities will be effective in detecting signs and symptoms of BD-related disease that occur in the interval between physical examinations. Furthermore, they allow for greater efficiency of medical resource utilization. Support for this approach to medical screening has been shown in the labor-management agreement submitted to OSHA. (Ex. 118–12; 118–13)

Fifth, to allow for the application of professional judgement in the care of employees exposed to BD, physical examinations are to be provided at the discretion of the physician or other licensed health care professional reviewing the annual health questionnaire and blood test results. This provision not only creates a mechanism for immediate response to abnormal questionnaire responses or laboratory results, but provides flexibility by eliminating the requirement for unnecessary physical examinations and requiring physical examinations when they are indicated.

The sixth difference between the NPRM and the final rule pertaining to the frequency of physical examinations concerns those that occur at termination of employment or at the time of employee reassignment to an area where exposure to BD is below the action level, if the employee has not been exposed over the action level or the PELs for the requisite period of time and if twelve months or more have elapsed since the last physical examination. The NPRM required a termination physical examination ''if three months or more have elapsed since (the) last annual medical examination.'' The final rule extends this time interval to a lapse of one year or more.

The frequency of medical evaluations for employees exposed to BD following an emergency situation is specified in paragraph (k)(3)(ii). Medical screening in this situation is required to be conducted as quickly as possible, but no later than 48 hours after the event. This requirement is supported in part by the labor-management agreement that recommended these medical evaluations to ''be performed as quickly as possible.'' (Ex. 118–12, p.16) OSHA has added the stipulation ''but not later than 48 hours after the exposure'' to ensure that a baseline CBC is obtained within that time period. An accurate CBC baseline reading is vital for comparison with subsequent CBC values in order to detect significant deviations from normal.

Finally, paragraph (k)(3)(iii) addresses medical evaluations for employees who must wear a respirator by referring employers to 29 CFR 1910.134. This change from the NPRM is consistent with comments received from Shell,

> * * * Respirator user medical evaluation should have some uniformity, regardless of the exposure. To promulgate slightly different requirements for respirator user evaluation in different individual chemical exposure standards only creates confusion and nonuniformity. OSHA needs to finalize a respirator standard rather than putting different details in each standard. * * * (Ex. 32–27, attachment II, p. 3)

This approach further clarifies OSHA's intention to distinguish between health-related issues of employees who wear respirators and those who are exposed to BD. Support for the separation of these issues was provided by both labor and industry representatives. (Ex. 118–12; 118–13; 118–11; 118–14; 119)

Paragraph (k)(4) covers the required content of medical screening. One of the required components is a comprehensive occupational and health history that is updated annually. This history must place particular emphasis on the hematopoietic and reticuloendothelial systems, including exposure to chemicals, in addition to BD, that may have an adverse effect on these systems, the presence of signs and symptoms that might be related to disorders of these systems, and any other information determined by the physician or other licensed health care professional to be necessary. OSHA has restated the intended focus of the occupational and health history to more clearly reflect current knowledge of BD epidemiology. While OSHA is not specifying the format of the questionnaire, samples provided in Appendix F indicate the minimum information that must be obtained through the use of any questionnaire to comply with the requirements of this paragraph.

A complete occupational and health history is one part of a thorough medical evaluation. More specifically, however, for workers who are exposed to BD this history has several focused goals. First, the initial history may identify workers who are potentially at increased risk of adverse health effects from exposure to BD. For example, as suggested by Dr. William Halperin of NIOSH on cross examination, ''[i]t may be reasonable to advise workers with a previous history of leukemia or lymphoma to avoid exposure to [BD] * * *'' (Tr. 1/17/91, p. 705) Personal risk factors, such as existing hematologic abnormalities, that also place a worker at increased risk of BD-related disease, may also be identified through the health history. Additionally, predisposition to lymphomas is associated with immune deficiency syndromes.

Second, the initial and updated occupational and health history will have a training effect on workers by educating them about the potential adverse health effects from exposure to BD. Over time OSHA believes that informed workers will be more likely to seek medial attention for signs and symptoms that may be associated with BD exposure. Third, the initial history will provide a critical baseline of health status against which any changes can be compared. Finally, the health questionnaire might also suggest to the physician or other licensed health care professional additional medical tests or procedures that would be prudent to offer to the employee.

Another required component of medical screening for BD is a complete physical examination, with special emphasis on the spleen, liver, lymph nodes and skin. The physical examination for BD exposed employees provides an opportunity for direct observation and palpation of target organs such as the lymph nodes, liver, and spleen. Specifically, the physician or other licensed health care professional would be looking for signs of lymphadenopathy (enlarged lymph nodes), splenomegaly (enlarged spleen), or hepatomegaly (enlarged liver). Although lymphadenopathy is not specific for either lymphoma or leukemia, the physical examination provides an opportunity to detect this finding before symptoms develop. This rationale was rejected by Dr. Saunders in his testimony. (Tr. 1/18/91, p. 1211–1212) However, according to Dr. Halperin of NIOSH, ''[s]ome individuals may benefit by receiving treatment at this earlier point in the course of their disease.'' (Ex. 90, p. 5) Dr. Dennis D. Weisenburger, an expert witness for OSHA, also offered testimony that supported this basis for periodic physical examination of BD exposed employees. (Tr. 1/16/91, pp. 275–276)

The final required medical screening activity is a complete blood count (CBC). A CBC consists of a white blood cell (WBC) count, hematocrit, hemoglobin, differential WBC count, platelet count, red blood cell (RBC) count, and WBC and RBC morphology. (Ex. 23–55) It is an important component of the medical screening program because acute leukemia may, in some cases, be diagnosed with the aid of a CBC prior to the onset of symptoms. Additionally, the CBC is an effective test

for the detection of anemia, which may result from BD exposure. (Tr. 1/17/91, p. 784)

Animal evidence suggests that BD affects the bone marrow, resulting in anemia. In mice, inhalation of BD at 1,250 ppm resulted in a decrease in circulating erythrocytes, total hemoglobin and hematocrit, an increase in mean corpuscular volume, and leukopenia (a decrease in the WBC count), due mainly to a decrease in segmented neutrophils. (Ex. 23–12) These findings are consistent with a diagnosis of macrocytic megaloblastic anemia, suggesting that a CBC with a leukocyte count might yield information on overexposure to BD.

Additionally, changes in hemoglobin level, thrombocyte (platelet) count, and leukocyte count occur in the presence of leukemia. However, the detection of leukemia at a pre-clinical phase, i.e., prior to onset of symptoms, may not lead to improved treatment outcomes. The value of early disease detection, in this case, is that it provides an opportunity to terminate further potential exposure to BD. An employee who already has hematologic abnormalities due to leukemia should avoid exposure to BD and any other chemicals that could accelerate or worsen cytopenias and blood cell dysfunction.

Abnormality in blood counts is found in only 37 percent of patients with bone marrow infiltration. The correlation between peripheral blood counts and marrow involvement by lymphoma is poor. However, examination of the peripheral smear in patients with non-Hodgkins lymphoma may yield evidence of malignant cells in about 15 percent of patients. (Ex. 23–52, p. 1,357)

A CBC would also be a valuable screening tool for disorders other than leukemia and lymphoma. According to testimony offered by OSHA's expert witness Dr. Dennis D. Weisenburger,

> * * * the occurrence of other diseases of the blood and blood forming organs should also be critically examined in workers with BD exposure, particularly blood cytopenias, bone marrow failure, aplastic anemia, and the myelodysplastic (pre-leukemic) syndromes, which have also been associated with other chemical agents. (Ex. 39, p. 11)

Because the latency period for development of lymphohematopoietic disorders and cancers is relatively short, e.g., death from leukemia may occur in as little as 3–4 years after initial exposure, a CBC performed annually is reasonable and prudent. (Ex. 39, p. 9)

The combination of an annual CBC and a physical examination every three years balances both the need to diagnose leukemias (CBC) and lymphomas (physical examination) at an early stage, and the limited number of cases likely to be identified through the screening program. OSHA believes that waiting for sentinel cases to be identified would place other employees at risk of chronic BD-related illnesses, such as leukemias and lymphomas. The more quickly such illnesses are recognized, the sooner workplace modifications may be instituted to protect the health of other employees. An annual CBC, in addition to a health questionnaire, is an efficient means of using medical screening resources to detect early leukemia or anemia in individuals, while simultaneously providing data that can be used to protect the whole population of exposed employees. A medical screening strategy that includes an annual CBC and health questionnaire with physical examinations provided every three years has received support from both labor and industry representatives. (Exs. 118–12; 118–13)

To allow for individual differences among covered employees, as well as professional judgement, provision is made for inclusion of any other test which the examining physician or other licensed health care professional deems necessary. This requirement is provided to ensure that adequate flexibility is incorporated into the standard, so that any occupational diseases due to BD exposure are adequately diagnosed and treated. Furthermore, this provision is consistent with previously promulgated health standards.

Medical screening requirements for employees exposed to BD in an emergency situation focus on the acute effects of BD exposure. These effects include: Irritation of the eyes, nose, throat, lungs, or skin; blurred vision; coughing; drowsiness; nausea; and headache. At a minimum, the required medical screening components include: A CBC within 48 hours of the exposure and then monthly for three months; and a physical examination if the employee reports symptoms related to any of the acute effects. Employee participation in the medical screening and surveillance program, subsequent to a BD exposure from an emergency situation, need not continue for the duration of employment. This limitation on employee inclusion after emergency exposure is supported in comments received from Shell. (Ex. 32–27, Att. II, pp. 3–4) However, to accommodate management of individual cases, continued employee participation in the medical screening and surveillance program, beyond the minimum requirements, is left to the discretion of the physician or other health care professional.

Additionally, the time frame for the collection of the blood specimen has been extended from immediately after the emergency to ''within 48 hours of the exposure and then monthly for three months.'' Again, support for this approach was provided by Shell,

> ''Immediately'' after every emergency may not be possible or even reasonable. We suggest ''as soon as possible'' after a *significant exposure* from an emergency event and at least within 48 hours. * * * (Ex. 32–27, attachment II, p.4)

Further support for this medical screening strategy following an emergency situation was provided by Dr. William Halperin, NIOSH,

> The life span of a red blood cell is approximately 120 days. Thus, the results of a medical examination shortly after a high exposure may be normal despite severely compromised blood-producing capacity. If an exposure is high enough to warrant a medical examination, then it would be reasonable to obtain a baseline hematologic examination at the time of exposure, followed by reexaminations at 30, 60, and 90 days. (Ex. 90)

A physical examination is required only if the employee reports symptoms related to the acute effects after exposure to BD in an emergency situation. Comments submitted by Shell support the idea that not every exposure in an emergency situation necessitates a physical examination. (Ex. 32–27, attachment II, p. 4) It is OSHA's opinion that this approach provides flexibility, as suggested by Dr. Saunders. (Tr. 1/18/91, p. 1214–1213) Contrary to the suggestion by CMA, it does not leave the need and frequency for medical examinations following an emergency situation completely to the judgement of the physician. (Ex. 112, p. 128) Thus, OSHA believes the final rule adopts a moderate, yet protective, approach for medical evaluation requirements for employees exposed to BD in an emergency situation.

Paragraph (k)(5) addresses additional medical evaluations and referrals. Whenever the results of medical screening indicate abnormalities of the hematopoietic or reticuloendothelial systems, for which a non-occupational cause is not readily apparent to the health care professional, the employee shall be referred to an appropriate specialist, e.g., hematologist, for further evaluation. The content of the evaluation is left to the professional judgement of the specialist to whom the employee is referred. This provision is essential to ensure that employees receive prompt diagnosis at the earliest stage possible, when treatment is most likely to be effective.

In the NPRM, the paragraph on additional examinations and referrals contained a provision for the content of the medical examinations or consultations to include, ''evaluation of fertility and other tests, if requested by the employee and deemed appropriate by the physician.'' (55 FR 32736 at 32806) After evaluation of all factors presented in the rulemaking, the Agency has deleted the provision for fertility testing from the final rule. However, given the observations in experimental animals, the medical screening and surveillance program provided by the employer should address the potential reproductive and developmental problems of workers exposed to BD. (The reader is referred to the Health Effects section of this preamble.) The sample health questionnaires provided in Appendix F include examples of questions that address reproductive and developmental health concerns.

Information that the employer must provide to the examining physician or other licensed health care provider is listed in paragraph (k)(6). Specifically, that information includes: (1) A copy of the BD standard; (2) a description of the employee's duties as they relate to BD exposure; (3) the employee's actual or representative BD exposure level; (4) a description of required pertinent personal protective equipment; and (5) information from previous employment-related medical evaluations which the physician or other licensed health care professional may not otherwise have available. The purpose of this requirement is to provide information necessary for the physician or other licensed health care professional to make an informed determination regarding whether the employee may be at increased risk from exposure to BD.

Paragraph (k)(7) requires employers to ensure that the physician or other licensed health care professional produces a written opinion of the evaluation results and provides a copy to the employer and employee within 15 business days of the medical evaluation. OSHA rejected Shell's suggestion of extending the time frame for provision of the written opinion to the employee from 15 to 30 days. (Ex. 32–27) In OSHA's opinion 30 days is too long to wait to inform employees of the results of the medical evaluation. However, OSHA agrees with the recommendation made in the labor-management agreement to specify ''business days.'' (Ex. 118–12, p.18) It is OSHA's opinion that this recommendation does not adversely impact the health of employees in the medical screening and surveillance program and, yet, it provides a more practical time frame for the communication of this information.

The written opinion must contain the results of the medical evaluation that are pertinent to BD exposure, an opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to BD, and any recommended limitations on the employee's exposure to BD. This opinion must be developed with consideration given to a comparison of all available medical evaluation results for occupational exposure to BD. OSHA recommends that the physician or other licensed health care professional use a flow sheet to chart temporal changes in the CBC. The occurrence of temporal changes in the CBC indices, even if the actual results remain within normal limits, should be considered when evaluating risk of material impairment to health, as well as the overall medical opinion.

Additionally, the written opinion must include a statement that the employee has been informed of the medical evaluation results and any conditions resulting from BD exposure that require further explanation or treatment. This written opinion shall not contain any information that is not related to the employee's ability to work with BD. In rendering this opinion, the physician or other licensed health care professional must rely on the results obtained from the medical evaluation. This provision does not negate the ethical obligation of the physician or other health care professional to transmit any other adverse findings directly to the employee.

Medical surveillance requirements are specified in paragraph (k)(8). This provision requires the employer to ensure periodic review of information obtained from the medical screening program activities to determine whether the health of the employee population of that employer is adversely affected by exposure to BD. This requirement is meant to clarify OSHA's longstanding policy that individual data collected during medical screening activities should be examined in the aggregate, with personal identifiers removed, so that population trends or patterns can be observed and appropriately managed. This medical surveillance provision does not require employers to conduct epidemiologic or any other type of research studies, although such studies are certainly not precluded.

It is OSHA's opinion that this information review will provide employers with supplemental evidence of the effectiveness of their exposure control strategies. The employer's obligations regarding medical surveillance may be limited to a determination that all medical evaluation results are within normal limits and temporal changes in these results have not occurred. However, should a pattern of abnormal findings be identified, the employer may have an opportunity for primary prevention of BD-related disease. Information learned from medical surveillance activities must be disseminated to employees covered by the medical screening and surveillance program provision, as defined in paragraph (k)(1).

L. Hazard Communication

The requirements for hazard communication have been moved from proposed paragraph (j), redesignated and promulgated as paragraph (l) of the final rule. The paragraph addressing hazard communication in the final BD rule is consistent with the requirements of OSHA's Hazard Communication Standard (HCS). The HCS requires all employers to provide information concerning the hazards of workplace chemicals to their employees. The transmittal of hazard information to employees is to be accomplished by such means as container labeling and other forms of warning, material safety data sheets, and employee training.

Signs and Labels

Since the HCS is ''intended to address comprehensively the issue of evaluating the potential hazard of chemicals and communicating information concerning hazards and appropriate protective measures to employees,'' OSHA is including paragraph (l)(1) only to reference HCS requirements for labels and material safety data sheets. Employers who have already met their longstanding requirements to comply with the HCS will have no additional duties with regard to labels and MSDSs under the BD rule.

The warning sign and labels for BD which OSHA proposed in 1990 have been deleted from the final rule in response to the recommendation of various commenters, including the labor/industry group, who suggested that no requirements were needed beyond those already listed in the HCS. (Tr. 1/18/91, p. 1169; Tr. 1/22/91, pp. 1348–1249; Ex. 112, 32–17, 32–19, 32–22, 32–27, 108, 118–12A) Therefore, the final rule now references the HCS.

Employee Information and Training

OSHA is also referencing the HCS for employee information and training, but is specifying additional provisions applicable when employee exposures

are likely to exceed the action level or STEL. Paragraph (l)(2) reiterates that training must be afforded employees in accordance with the HCS and contains various provisions which apply when exposure limits are exceeded. The first of these is the requirement that a training program be instituted and that employee participation in it be assured by the employer (paragraph (l)(2)(i)).

OSHA believes that training is not a passive process. The information provided employees in training requires their comprehension of the material and subsequent use of what they have learned while performing their duties in the workplace. There are many different ways to accomplish training effectively, but it cannot be a mechanical transfer of information such as giving someone a written document. OSHA's voluntary guidelines, which are found in OSHA publication No. 2252, are available to provide employers with additional guidance in setting up and implementing an appropriate employee training program. An effective training program is a critical component of any safety and health program in the workplace. Workers who are fully informed and engaged in the protective measures established by the employer will play a significant role in the prevention of adverse health effects. Ineffective training will not serve the purpose of making workers full participants in the program, and the likelihood of a successful program for safety and health in the absence of an effectively-trained workforce is remote.

OSHA expects that employers will ensure that the information and training is effective. Although not specifically required in the standard, any good training program should include an evaluation component to help ensure effectiveness. The voluntary training guidelines previously recommended can provide additional guidance in this respect.

Paragraph (l)(2)(ii) requires employers to provide the required information and training prior to or at the time of initial assignment to work with BD. This paragraph also requires that such training be repeated annually when employees are exposed over the action level or STEL ((l)(2)(iii)). OSHA notes that annual training for workers exposed above an action level is also required in other standards e.g., benzene (29 CFR 1910.1028), asbestos (29 CFR 1910.1001), cadmium (29 CFR 1910.1027), formaldehyde (29 CFR 1910.1048).

CMA requested that OSHA correct the final rule to require annual training only when the employee is assigned to a job where the potential exposure is above the action level or STEL. OSHA has included this provision in paragraph (l)(2)(iii). (Ex. 112, p. 116) OSHA notes, however that all employees potentially exposed to BD must receive training at least once as provided by the HCS. Those employees whose tasks place them at risk of higher exposure (above the action level or STEL) need training at least annually to review the nature of the hazards of BD exposure and the methods to be used to minimize exposure and to maintain a continuing awareness of the potential dangers associated with exposure.

In its submission, CMA also requested that OSHA specify in the final rule that where the BD standard does not apply because objective data are used to exempt a material or process from the standard, the hazard communication requirements would come from the HCS. (Ex. 112, p. 178) OSHA does not believe this is necessary and that it might lead to greater confusion. Clearly, exemption from the BD standard does not imply exemption from the HCS.

OSHA notes that materials containing less than 0.1% BD are exempt from the BD standard unless there is evidence which indicates that the action level or STEL can reasonably be expected to be exceeded during the job. On the other hand, the HCS contains no exemption from employee information and training provisions for materials containing less than 0.1% of a carcinogen (BD).

Paragraph (l)(2)(iv) indicates that employers must ensure that the information and training is presented in a manner that is understandable to employees, and lists topics which must be included in the training program.

The labor/industry agreement recommended deletion of the proposed requirement that: ''The training program shall be conducted in a manner that the employee is able to understand.'' (Ex. 118–12A) No explanation for this suggestion was offered in submissions to the record. OSHA believes that it is essential that training be understood by the employee. Thus, OSHA has not deleted the requirement from the standard.

Paragraph (l)(2)(iv) also addresses the items upon which employees are to be trained and includes training regarding specific measures employees can take to protect themselves from the effects of BD exposure. Paragraphs (l)(2)(iv)(A) through (F) set forth the basic topics to be covered during the requisite training program. CMA asked that OSHA delete most of this list of training topics. (Ex. 112, p. 177) CMA felt that the HCS provisions were adequate. However, the labor/industry group did not make a similar recommendation, and the final rule contains basic guidance to employers establishing an employee training program as to what subjects must be included. OSHA believes that these requirements build upon the HCS and provide BD-specific information needed by the employee to reduce exposure to BD, and therefore prevent adverse health effects from occurring.

Upon recommendation of the labor/industry group, OSHA has consolidated some of the training topics and made them more concise and clearer. (Ex. 118–12A) The labor/industry group recommended deletion of proposed paragraph (k)(4)(iii)(D), which stated that the training must cover

> The measure employees can take to protect themselves from exposure to BD, including a review of their habits, such as smoking and personal hygiene; and specific procedures the employer has implemented to protect employees from exposure to BD, such as appropriate work practices, emergency procedures, and personal protective equipment. (55 FR 32736 at 32807)

OSHA agrees that most of this material is to be covered under the other topics listed in the final rule, but has determined that the training must include information regarding what employees themselves can do to assist in protecting themselves from exposure to BD. Additionally, as recommended in the labor/industry agreement, reference to personal habits and hygiene has been deleted. (Ex. 118–12A) OSHA has concluded that there is little data regarding the relationship of personal habits to the hazards associated with BD exposure to justify the inclusion of this provision in the final rule. Therefore this subject is not included among those required in the training program.

Paragraph (l)(3)(i) requires the employer to give copies of the BD standard in its entirety, including all appendices, to employees. In response to the labor/industry group recommendation, OSHA has included in the provision that the standard must also be provided by the employer to persons designated as employee representative(s). (Ex. 118–12A) Further, the copy must be provided at no cost to the employee.

In paragraph (l)(3)(ii) OSHA has indicated that the Assistant Secretary or the Director may access all materials relating to employee information and training in the workplace. This would be done in conjunction with an inspection to ascertain compliance with the rule, or in the event of a NIOSH health hazard evaluation. Review of the available materials regarding information and training will help evaluate whether the program has been properly conducted, as well as ascertain

what could be improved if employees do not appear to be effectively trained. As in previous paragraph (l)(3)(i), and at the suggestion of the labor/industry group, designated employee representatives are to be provided all materials relating to information and training. (Ex. 118–12A) This will be useful to them in helping to assure that their members are benefitting from all the protection the BD standard affords.

The training provisions of this final rule are performance-oriented because employees may be exposed to BD in a variety of circumstances. Thus, the standard lists the topics of information to be transmitted to the employees, but does not specify the ways in which it is to be transmitted.

M. Recordkeeping

Section 8(c)(3) of the Act provides for the promulgation of ''regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6.'' All employers with BD in their workplace must do initial monitoring or reasonably rely on objective data that show that workplace exposures to BD are at or below the action level. Paragraph (m)(1) of the final rule requires employers who are relying on objective data (under paragraph (d)(2)) to avoid the initial monitoring requirements of the final rule, to maintain records that show the basis for their reliance and the reasoning used in reaching the conclusion that such monitoring is not necessary.

The objective data must provide the same degree of assurance that employees are not being significantly exposed to butadiene as monitoring would. Thus, such data should include information about the materials, product, activity, or process tested and found to qualify for exemptions; the source (e.g., manufacturer, testing laboratory, research study) of the objective data; the protocol used to obtain the results; a description of the product(s), materials(s), activities, or processes to which the relied upon data applies and an explanation of why such data are worthy of being relied upon; and any other data the employer believes are relevant to the exemption. This documentation is intended to demonstrate the appropriateness of the employer's reliance on objective data in lieu of the initial monitoring of employee exposure to BD.

The Agency has made a determination that significant employee exposures to BD should be closely monitored. Therefore it is appropriate to require the employer to carefully document and keep records of the data that are being relied upon in lieu of actual monitoring.

At the suggestion of the labor/industry group and for consistency with other provisions of the standard, the word ''streams'' has been included in paragraph (m)(1), since it is part of the exemptions in paragraph (a)(2) of this section.[13] (Ex. 118–12A)

Paragraph (m)(1)(iii) requires the employer to keep records of the objective data relied upon for as long as the employer continues to rely on such data.

Paragraph (m)(2) requires that employers keep records of all exposure monitoring required by the final rule. The provisions in this paragraph are consistent with those of 29 CFR 1910.1020, OSHA's Access to Employee Exposure and Medical Records standard. Paragraph (m)(2) specifies what information related to employee exposure monitoring must be kept. For example, it requires retention of information on the sampling and analytical methods, as well as information about the employee(s) sampled and their use of protective equipment. At the recommendation of the labor/industry group, records must also be maintained on written corrective action to be taken when monitoring indicates exposures over the PEL. (Ex. 118–12A) In addition, OSHA has also included a requirement that the schedule for completing the corrective action also be maintained.

A new paragraph, (m)(3), has been added to the final rule, which requires that records of respirator fit tests be maintained by the employer until the next fit test is administered to the employee. In the proposal, this provision was included in the mandatory appendix for respirator fit testing. OSHA believes that it will be more convenient for those using the standard to have all recordkeeping provisions together in the standard. Therefore recordkeeping provisions from other parts of the standard are being moved to paragraph (m) of the final rule.

Paragraph (m)(4) requires that the employer keep accurate medical records for each employee subject to medical screening and surveillance under the standard. Section 8(c) of the Act authorizes the promulgation of regulations requiring an employer to keep necessary and appropriate records regarding activities to permit the enforcement of the Act or to develop information regarding the causes and prevention of occupational illnesses. OSHA has determined that, in this context, requiring employers to maintain both medical and exposure measurement records is necessary and appropriate, and paragraph (m)(3) simply details what information must be kept.

Paragraph (m)(5)(i) states that all records required to be maintained by the standard must be made available to the Assistant Secretary and Director of NIOSH for examination and copying if such records are requested in writing. Access to these records is necessary for compliance monitoring. These records also contain information that the agencies may need to carry out other statutory responsibilities.

Paragraph (m)(5)(ii) provides that employees, former employees, and their designated representatives have access upon request to all exposure and medical records required by the standard. This provision is consistent with 29 CFR 1910.1020 (e). Section 8(c)(3) and other provisions of the Act make clear that employees and their representatives are expected to have an active and meaningful role in workplace safety and health. Employees and their representatives need information about employee exposures to toxic substances and their potential effects on health and safety if they are to benefit fully from these statutorily created rights.

OSHA's generic rule (29 CFR 1910.1020) permitting access to employee exposure and medical records was issued on May 23, 1980. (45 FR 35212) This rule applies to records created pursuant to specific standards and to records that are voluntarily created by employers. OSHA retains unrestricted access to medical and exposure records, but the Agency's access to personally identifiable records is subject to the Agency's rules of practice and procedure concerning OSHA access to employee medical records, which are codified at 29 CFR 1913.10.

Paragraph (m)(6) of the final rule addresses transfer of records. Under paragraph (m)(6)(i), when an employer ceases to do business, the employer must transfer records required by this section to the successor employer, who shall receive and maintain such records. If there is no successor employer, the employer shall notify the Director of NIOSH at least three months prior to anticipated disposal of the records, and shall transmit the records to the Director, if so requested. Under paragraph (m)(6)(ii), the employer is required to transfer medical and exposure records in accordance with

[13] Paragraph (m)(1)(i) now reads in pertinent part: ''Where the processing, use, or handling of products *or streams* made from or containing BD * * *

requirements set forth in 29 CFR 1910.1020(h).

The Agency believes it is necessary to keep certain records for extended periods of time because of the long latency periods commonly observed for the induction of cancer caused by exposures to carcinogens. Cancer often is not detected until 20 or more years after onset of exposure. The extended record retention period required by 29 CFR 1910.1020 therefore is needed for two purposes. First, possession of past and present exposure data and medical records aids in the diagnosis of workers' disease and determination of work-relatedness. In addition, retaining records for extended periods make possible future review to determine the effectiveness and adequacy of OSHA's final rules.

The time periods required for retention of exposure records and medical records are thirty years and the period of employment plus thirty years, respectively. These retention requirements are consistent with those in the OSHA exposure and medical records access standard.

N. Dates

This paragraph establishes the effective date of the final rule for butadiene and sets out start-up dates for various provisions of the standard. The final rule becomes effective 90 days following publication in the Federal Register. This period enables employers to familiarize themselves with the final rule. In addition, individual provisions, where appropriate, have delayed start-up dates. In addition, the Agency has established delayed start-up dates for several provisions of the final rule, based on evidence submitted to the record demonstrating that compliance with some provisions may require longer times than compliance with other provisions. These dates are based on the record in this rulemaking and on the Agency's experience with other standards concerning the amount of time required for employers to perform initial employee monitoring, institute medical surveillance programs, implement emergency procedures, etc.

The effective date, in conjunction with the start-up dates, will allow sufficient time for employers to achieve compliance with the substantive requirements of the final rule.

Paragraph (n)(2)(i) requires that initial monitoring shall be completed within sixty days of the effective date of the standard or within 60 days of the introduction of BD into the workplace. In the proposed rule, this paragraph was designated as paragraph (d)(2)(ii); it has been moved to paragraph (n) in the final rule to consolidate all effective date information in one section.

Dow Chemical Company objected to the 60 day start-up date for initial monitoring as being inadequate to set up such a program. (Ex. 118–16) OSHA believes that 60 days after the effective date of the standard is sufficient time to carry out initial monitoring. OSHA believes that much of the required monitoring may have already been performed by employers.

Final rule paragraph (n)(2)(iii) requires that the feasible engineering controls required by paragraph (f)(1) be implemented within two years after the effective date of the standard. This represents an extension of 12 months beyond that proposed for engineering controls. In testimony, the CMA Panel Chair, Dr. Norman Morrow, said that it was necessary to extend the one year start-up date to two years because of the time needed to identify those areas needing control, to determine the appropriate control measure to use, and to procure and install the equipment. (Tr. 1/18/91, p. 1168)

Other submissions contained similar requests for extension of the period to comply with controls. (Ex. 28–32; 112) OSHA agrees that additional time may be needed to come into full compliance and thus the final rule permits a full 24 months for compliance with the engineering controls provision of the final rule. During the period in which employers are implementing these controls, additional respirator use may be required to comply with the new exposure limits.

Paragraph (n)(2)(iii) also has a start-up date of within three years of the effective date of the standard to implement the exposure goal program (paragraph (g)). This is the length of time agreed upon by the labor/industry group who developed the provisions for the exposure goal program and submitted them to OSHA. (Ex. 118–12A) OSHA believes that this will provide ample time for employers to install or otherwise comply with the provisions in the program.

Final rule paragraph (n)(2)(ii), which covers start-up dates for paragraphs (c) through (m), including those for feasible work practice controls but not for the engineering controls specified in the paragraph (f)(1), requires that employers attain compliance within 180 days of the effective date of the BD standard. This provision is identical to proposed paragraph (n)(2)(i).

The rest of the provisions of the standard must be implemented within 180 days of the effective date.

O. Appendices

Six appendices have been included at the end of this standard. Appendices A, B, C, D, and F are included primarily for purposes of information and compliance assistance and should not be construed as establishing a mandatory requirement not otherwise imposed by the standard, or as detracting from an obligation which the standard does impose. However, the protocols for respiratory fit testing in Appendix E are binding.

The appendices have been updated from the proposal to reflect the final rule. Additionally, a number of technical and typographical corrections have been made in them. Appendix A contains information briefly describing the properties of BD and its hazards, and describes in general terms the provisions of the standard. Further, it contains the procedures to be used during emergencies, fires, and other situations in which there is potential for BD exposure.

Appendix B describes more fully the chemical and physical properties of BD and gives procedures to use when leaks or spills occur. Correct disposal is also outlined. Additional information is given on ways to safely handle BD.

Appendix C provides medical screening and surveillance guidelines for BD. The appendix describes the effects of BD exposure on the body and gives an overview of the medical screening and surveillance provisions of the standard. In general terms, it provides the physician or other licensed healthcare professional with an outline of the requirements of the rule.

Appendix D contains the sampling method developed and validated by the OSHA laboratory for use with BD. This is a non-mandatory appendix—the use of other measurement methods is allowed when accuracy levels required in the standard are met. Paragraph (d)(6) states that monitoring shall be accurate, at a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of BD at or above the 1 ppm TWA limit and to within plus or minus 35 percent for airborne concentrations of BD at or above the action level of 0.5 ppm and below the 1 ppm TWA limit. In addition, paragraph (m)(2)(ii)(C) requires that the exposure measurement record include sampling and analytical methods used and evidence of their accuracy.

Supplementary data used by the OSHA laboratory in developing the analytical method were included in the proposal, but have been deleted from the final rule. (55 FR 32736 at 32814.)

Basically, the OSHA method is a charcoal tube (CT)-gas chromatography (GC)-mass spectrometry (MS) (CT–GC–MS) method. It involves the use of charcoal tubes and sampling pumps, followed by analysis of the samples by gas chromatography and a confirmation of GC peak by MS when it is necessary. The charcoal is coated with 4-tert-butylcatechol to inhibit the polymerization of BD, in order to increase the stability of the sample. (Ex. 118–9) Since BD often is present in a complex mixture which may make it difficult to adequately evaluate due to interferences, MS is used in GC–MS combination to identify the GC chemical peak and to make sure that there is no interferences and to identify any interferences that occur.

OSHA agrees with API that no single CT–GC–MS method can be used as a ''cookbook'' for all situations. (Ex. 118–11) The American Petroleum Institute (API) developed a method to ''resolve interferences for complex mixtures found in the petroleum industry'' in 1991 and refined the method in 1996. (Exs. 108 and 118–11) The API method uses a long length of capillary column with different configurations for a greater separation ability from other isomers/interferences found in the petroleum industry. API asked OSHA's acceptance of the API BD monitoring method. (Ex. 118–11) OSHA believes that the API method, as well as other methods which may be developed that accurately measure BD levels in the breathing zone of exposed workers, are acceptable.

Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers must assure that the evaluation of employee exposure is performed by a technically qualified person.

Appendix E is the only mandatory appendix to the BD rule. This appendix has been revised somewhat from the proposal throughout, primarily for clarity. However, it now contains a protocol for using ambient aerosol condensation nuclei counter (CNC) quantitative fit testing, which was not included in the proposal.

Appendix F contains sample questionnaires for use in medical screening and surveillance. The appendix contains two sample questionnaires, one for the initial medical evaluation and the other for the annual updating of the medical evaluations. These are included to provide medical personnel information to assist them in complying with the standard.

Authority and Signature

This document was prepared under the direction of Joseph A. Dear, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210

Pursuant to sections 4, 6(b), 8(c) and 8(g) of the Occupational Safety and Health Action (29 U.S.C. 653, 655, 657), section 107 of the Contract Work Hours and Safety Standards Act (the Construction Safety Act) (40 U.S.C. 333); the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 941); the Secretary of Labor's Order No. 1–90 (55 FR 9033); and 29 CFR part 1911; 29 CFR parts 1910, 1915 and 1926 are amended as set forth below.

List of Subjects in 29 CFR Parts 1910, 1915 and 1926

1,3–Butadiene, Cancer, Chemicals, Health risk-assessment, Occupational safety and health.

Signed at Washington, DC, this 24th day of October 1996.

Joseph A. Dear,

Assistant Secretary of Labor.

PART 1910—[AMENDED]

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended as follows:

Subpart B—[Amended]

1. The authority citation for subpart B of Part 1910 is revised to read as follows:

Authority: Secs. 4, 6 and 8 of the Occupational Safety and Health Act, 29 U.S.C. 653, 655; 657; Walsh-Healey Act, 41 U.S.C. 35 *et seq;* Service Contract Act of 1965, 41 U.S.C. 351 *et seq;* sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act), 40 U.S.C. 333; sec. 41, Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 941; National Foundation of Arts and Humanities Act, 20 U.S.C. 951 et seq.; Secretary of Labor's Order No. 12–71 (36 FR 8754); 8–76 (41 FR 25059); 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable; and 29 CFR part 1911.

2. A new paragraph (l) is added to § 1910.19 to read as follows:

§ 1910.19 Special provisions for air contaminants.

* * * * *

(l) 1,3-Butadiene (BD): Section 1910.1051 shall apply to the exposure of every employee to BD in every employment and place of employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or § 1910.16, in lieu of any different standard on exposure to BD which would otherwise be applicable by virtue of those sections.

Subpart Z—Toxic and Hazardous Substances—[Amended]

3. The authority citation for subpart Z of part 1910 continues to read as follows:

Authority: Secs. 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, and 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736), of 1–90 (55 FR 9033) as applicable; and 29 CFR part 1911.

Section 1910.1000, Tables Z–1, Z–2, and Z–3 also issued under 5 U.S.C. 553. Section 1910.1000, Tables Z–1, Z–2, and Z–3 not issued under 29 CFR Part 1911 except for the arsenic (organic compounds), benzene, cotton dust, and 1,3-butadiene listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and 5 U.S.C. 553.

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR 1911; also issued under 5 U.S.C. 553.

Section 1910.1200 also issued under 5 U.S.C. 553.

§ 1910.1000 [Amended]

4. The entry in Table Z–1 of § 1910.1000, ''Butadiene (1,3-Butadiene)'' is amended as follows: remove the ''1000'' and ''2200'' from the columns entitled ppm(a)[1] and mg/m^3 (b)[1] respectively, add ''1 ppm/5 ppm STEL'' in the ppm (a)[1] column; and add the following to the butadiene entry ''; See 29 CFR 1910.1051; 29 CFR 1910.19(l)'' so that the entry reads as follows: ''Butadiene (1,3-Butadiene); See 29 CFR 1910.1051; 29 CFR 1910.19(l).''

5. A new 1910.1051 is added to read as follows:

§ 1910.1051 1,3-Butadiene.

(a) *Scope and application.* (1) This section applies to all occupational exposures to 1,3-Butadiene (BD), Chemical Abstracts Service Registry No. 106–99–0, except as provided in paragraph (a)(2) of this section.

(2)(i) Except for the recordkeeping provisions in paragraph (m)(1) of this section, this section does not apply to the processing, use, or handling of products containing BD or to other work operations and streams in which BD is present where objective data are reasonably relied upon that demonstrate the work operation or the product or the group of products or operations to which it belongs may not reasonably be foreseen to release BD in airborne concentrations at or above the action level or in excess of the STEL under the expected conditions of processing, use, or handling that will cause the greatest possible release or in any plausible accident.

(ii) This section also does not apply to work operations, products or streams where the only exposure to BD is from liquid mixtures containing 0.1% or less of BD by volume or the vapors released from such liquids, unless objective data become available that show that airborne concentrations generated by such mixtures can exceed the action level or STEL under reasonably predictable conditions of processing, use or handling that will cause the greatest possible release.

(iii) Except for labeling requirements and requirements for emergency response, this section does not apply to the storage, transportation, distribution or sale of BD or liquid mixtures in intact containers or in transportation pipelines sealed in such a manner as to fully contain BD vapors or liquid.

(3) Where products or processes containing BD are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (m)(1) of this section.

(b) *Definitions:* For the purpose of this section, the following definitions shall apply:

Action level means a concentration of airborne BD of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

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

Authorized person means any person specifically designated by the employer, whose duties require entrance into a regulated area, or a person entering such an area as a designated representative of employees to exercise the right to observe monitoring and measuring procedures under paragraph (d)(8) of this section, or a person designated under the Act or regulations issued under the Act to enter a regulated area.

1,3–Butadiene means an organic compound with chemical formula $CH_2{=}CH{-}CH{=}CH_2$ that has a molecular weight of approximately 54.15 gm/mole.

Business day means any Monday through Friday, except those days designated as federal, state, local or company specific holidays.

Complete Blood Count (CBC) means laboratory tests performed on whole blood specimens and includes the following: White blood cell count (WBC), hematocrit (Hct), red blood cell count (RBC), hemoglobin (Hgb), differential count of white blood cells, red blood cell morphology, red blood cell indices, and platelet count.

Day means any part of a calendar day.

Director means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

Emergency situation means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that may or does result in an uncontrolled significant release of BD.

Employee exposure means exposure of a worker to airborne concentrations of BD which would occur if the employee were not using respiratory protective equipment.

Objective data means monitoring data, or mathematical modelling or calculations based on composition, chemical and physical properties of a material, stream or product.

Permissible Exposure Limits, PELs means either the 8 hour Time Weighted Average (8-hr TWA) exposure or the Short-Term Exposure Limit (STEL).

Physician or other licensed health care professional is an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide one or more of the specific health care services required by paragraph (k) of this section.

Regulated area means any area where airborne concentrations of BD exceed or can reasonably be expected to exceed the 8-hour time weighted average (8-hr TWA) exposure of 1 ppm or the short-term exposure limit (STEL) of 5 ppm for 15 minutes.

This section means this 1,3-butadiene standard.

(c) *Permissible exposure limits (PELs).*—(1) *Time-weighted average (TWA) limit.* The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of one (1) part BD per million parts of air (ppm) measured as an eight (8)-hour time-weighted average.

(2) *Short-term exposure limit (STEL).* The employer shall ensure that no employee is exposed to an airborne concentration of BD in excess of five parts of BD per million parts of air (5 ppm) as determined over a sampling period of fifteen (15) minutes.

(d) *Exposure monitoring*—(1) *General.* (i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift and for each job classification in each work area.

(iii) Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the STEL for each shift and for each job classification in each work area.

(iv) Except for the initial monitoring required under paragraph (d)(2) of this section, where the employer can document that exposure levels are equivalent for similar operations on different work shifts, the employer need only determine representative employee exposure for that operation from the shift during which the highest exposure is expected.

(2) *Initial monitoring.* (i) Each employer who has a workplace or work operation covered by this section, shall perform initial monitoring to determine accurately the airborne concentrations of BD to which employees may be exposed, or shall rely on objective data pursuant to paragraph (a)(2)(i) of this section to fulfill this requirement.

(ii) Where the employer has monitored within two years prior to the effective date of this section and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section, provided that the conditions under which the initial monitoring was conducted have not changed in a manner that may result in new or additional exposures.

(3) *Periodic monitoring and its frequency.* (i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be at or above the action level but at or below both the 8-hour TWA limit and the STEL, the employer shall repeat the representative monitoring required by paragraph (d)(1) of this section every twelve months.

(ii) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the 8-hour TWA limit, the employer shall repeat the representative monitoring required by paragraph (d)(1)(ii) of this section at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period, after which such monitoring must occur at least every six months.

(iii) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be above the STEL, the employer shall repeat the

representative monitoring required by paragraph (d)(1)(iii) of this section at least every three months until the employer has collected two samples per quarter (each at least 7 days apart) within a two-year period, after which such monitoring must occur at least every six months.

(iv) The employer may alter the monitoring schedule from every six months to annually for any required representative monitoring for which two consecutive measurements taken at least 7 days apart indicate that employee exposure has decreased to or below the 8-hour TWA, but is at or above the action level.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (d)(2) of this section reveals employee exposure to be below the action level and at or below the STEL, the employer may discontinue the monitoring for employees whose exposures are represented by the initial monitoring.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level and at or below the STEL, the employer may discontinue the monitoring for those employees who are represented by such monitoring.

(5) *Additional monitoring.* (i) The employer shall institute the exposure monitoring required under paragraph (d) of this section whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to BD or when the employer has any reason to suspect that a change may result in new or additional exposures.

(ii) Whenever spills, leaks, ruptures or other breakdowns occur that may lead to employee exposure above the 8-hr TWA limit or above the STEL, the employer shall monitor [using leak source, such as direct reading instruments, area or personal monitoring], after the cleanup of the spill or repair of the leak, rupture or other breakdown, to ensure that exposures have returned to the level that existed prior to the incident.

(6) *Accuracy of monitoring.* Monitoring shall be accurate, at a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of BD at or above the 1 ppm TWA limit and to within plus or minus 35 percent for airborne concentrations of BD at or above the action level of 0.5 ppm and below the 1 ppm TWA limit.

(7) *Employee notification of monitoring results.* (i) The employer shall, within 5 business days after the receipt of the results of any monitoring performed under this section, notify the affected employees of these results in writing either individually or by posting of results in an appropriate location that is accessible to affected employees.

(ii) The employer shall, within 15 business days after receipt of any monitoring performed under this section indicating the 8-hour TWA or STEL has been exceeded, provide the affected employees, in writing, with information on the corrective action being taken by the employer to reduce employee exposure to or below the 8-hour TWA or STEL and the schedule for completion of this action.

(8) *Observation of monitoring.*—(i) *Employee observation.* The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to BD conducted in accordance with paragraph (d) of this section.

(ii) *Observation procedures.* When observation of the monitoring of employee exposure to BD requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer at no cost with protective clothing and equipment, and shall ensure that the observer uses this equipment and complies with all other applicable safety and health procedures.

(e) *Regulated areas.* (1) The employer shall establish a regulated area wherever occupational exposures to airborne concentrations of BD exceed or can reasonably be expected to exceed the permissible exposure limits, either the 8-hr TWA or the STEL.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated from the rest of the workplace in any manner that minimizes the number of employees exposed to BD within the regulated area.

(4) An employer at a multi-employer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite whose employees may have access to these areas.

(f) *Methods of compliance.*—(1) *Engineering controls and work practices.* (i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the PELs, except to the extent that the employer can establish that these controls are not feasible or where paragraph (h)(1)(i) of this section applies.

(ii) Wherever the feasible engineering controls and work practices which can be instituted are not sufficient to reduce employee exposure to or below the 8-hour TWA or STEL, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (h) of this section.

(2) *Compliance plan.* (i) Where any exposures are over the PELs, the employer shall establish and implement a written plan to reduce employee exposure to or below the PELs primarily by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section. No compliance plan is required if all exposures are under the PELs.

(ii) The written compliance plan shall include a schedule for the development and implementation of the engineering controls and work practice controls including periodic leak detection surveys.

(iii) Copies of the compliance plan required in paragraph (f)(2) of this section shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the PELs.

(g) *Exposure Goal Program.* (1) For those operations and job classifications where employee exposures are greater than the action level, in addition to compliance with the PELs, the employer shall have an exposure goal program that is intended to limit employee exposures to below the action level during normal operations.

(2) Written plans for the exposure goal program shall be furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives.

(3) Such plans shall be updated as necessary to reflect significant changes in the status of the exposure goal program.

(4) Respirator use is not required in the exposure goal program.

(5) The exposure goal program shall include the following items unless the employer can demonstrate that the item is not feasible, will have no significant effect in reducing employee exposures, or is not necessary to achieve exposures below the action level:

(i) A leak prevention, detection, and repair program.

(ii) A program for maintaining the effectiveness of local exhaust ventilation systems.

(iii) The use of pump exposure control technology such as, but not limited to, mechanical double-sealed or seal-less pumps.

(iv) Gauging devices designed to limit employee exposure, such as magnetic gauges on rail cars.

(v) Unloading devices designed to limit employee exposure, such as a vapor return system.

(vi) A program to maintain BD concentration below the action level in control rooms by use of engineering controls.

(h) *Respiratory protection.*—(1) *General.* The employer shall provide respirators that comply with the requirements of this paragraph, at no cost to each affected employee, and ensure that each affected employee uses such respirator where required by this section. Respirators shall be used in the following circumstances:

(i) During the time interval necessary to install or implement feasible engineering and work practice controls;

(ii) In non-routine work operations which are performed infrequently and in which exposures are limited in duration.

(iii) In work situations where feasible engineering controls and work practice controls are not yet sufficient to reduce exposures to or below the PELs; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required, the employer shall select and provide the appropriate respirator as specified in Table 1 in paragraph (h)(5)(ii) of this section, and ensure its use.

(ii) The employer shall select respirators from among those approved by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 42 CFR Part 84, ''Respiratory Protective Devices.'' Air purifying respirators shall have filter element(s) approved by NIOSH for organic vapors or BD.

(iii) If an employee whose job requires the use of a respirator cannot use a negative pressure respirator, the employee must be provided with a respirator having less breathing resistance, such as a powered air-purifying respirator or supplied air respirator, if the employee is able to use it and if it will provide adequate protection.

(3) *Respirator program.* Where respiratory protection is required, the employer shall institute a respirator program in accordance with 29 CFR 1910.134.

(4) *Respirator use.* (i) Where air-purifying respirators are used, the employer shall replace the air purifying filter element(s) according to the replacement life interval set for the class of respirator listed in Table 1 in paragraph (h)(5) of this section and at the beginning of each work shift.

(ii) In lieu of the replacement intervals listed in Table 1, the employer may replace cartridges or canisters at 90% of the expiration of service life, provided the employer can demonstrate that employees will be adequately protected. BD breakthrough data relied upon by the employer must derive from tests conducted under worst case conditions of humidity, temperature, and air flow rate through the filter element. The employer shall describe the data supporting the cartridge/canister change schedule and the basis for reliance on the data in the employer's respirator program.

(iii) A label shall be attached to the filter element(s) to indicate the date and time it is first installed on the respirator. If an employee detects the odor of BD, the employer shall replace the air-purifying element(s) immediately.

(iv) If a NIOSH-approved end of service life indicator (ESLI) for BD becomes available for an air-purifying filter element, the element may be used until such time as the indicator shows no further useful service life or until replaced at the beginning of the next work shift, whichever comes first. If an employee detects the odor of BD, the employer shall replace the air-purifying element(s) immediately.

(v) The employer shall permit employees who wear respirators to leave the regulated area to wash their faces and respirator facepieces as necessary in order to prevent skin irritation associated with respirator use or to change the filter elements of air-purifying respirators whenever they detect a change in breathing resistance or whenever the odor of BD is detected.

(5) *Respirator fit testing.* (i) The employer shall perform either qualitative fit testing (QLFT) or quantitative fit testing (QNFT), as required in Appendix E to this section, at the time of initial fitting and at least annually thereafter for employees who wear tight-fitting negative pressure respirators. Fit testing shall be used to select a respirator facepiece which exhibits minimum leakage and provides the required protection as prescribed in Table 1 in paragraph (h)(5)(ii) of this section.

(ii) For each employee wearing a tight-fitting full facepiece negative pressure respirator who is exposed to airborne concentrations of BD that exceed 10 times the TWA PEL (10 ppm), the employer shall perform quantitative fit testing as required in Appendix E to this section, at the time of initial fitting and at least annually thereafter.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE BD

Concentration of airborne BD (ppm) or condition of use	Minimum required respirator
Less than or equal to 5 ppm (5 times PEL).	(a) Air-purifying half mask or full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 4 hours.
Less than or equal to 10 ppm (10 times PEL).	(a) Air-purifying half mask or full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 3 hours.
Less than or equal to 25 ppm (25 times PEL).	(a) Air-purifying full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every 2 hours.
	(b) Any powered air-purifying respirator equipped with approved BD or organic vapor cartridges. PAPR cartridges shall be replaced every 2 hours.
	(c) Continuous flow supplied air respirator equipped with a hood or helmet.
Less than or equal to 50 ppm (50 times PEL).	(a) Air-purifying full facepiece respirator equipped with approved BD or organic vapor cartridges or canisters. Cartridges or canisters shall be replaced every (1) hour.
	(b) Powered air-purifying respirator equipped with a tight-fitting facepiece and an approved BD or organic vapor cartridges. PAPR cartridges shall be replaced every (1) hour.

TABLE 1.—MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE BD—Continued

Concentration of airborne BD (ppm) or condition of use	Minimum required respirator
Less than or equal to 1,000 ppm (1,000 times PEL).	(a) Supplied air respirator equipped with a half mask of full facepiece and operated in a pressure demand or other positive pressure mode.
Greater than 1000 ppm	(a) Self-contained breathing unknown concentration, or apparatus equipped with a firefighting full facepiece and operated in a pressure demand or other positive pressure mode. (b) Any supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode in combination with an auxiliary self-contained breathing apparatus operated in a pressure demand or other positive pressure mode.
Escape from IDLH conditions	(a) Any positive pressure self-contained breathing apparatus with an appropriate service life. (b) A air-purifying full facepiece respirator equipped with a front or back mounted BD or organic vapor canister.

Notes: Respirators approved for use in higher concentrations are permitted to be used in lower concentrations. Full facepiece is required when eye irritation is anticipated.

(iii) The employer shall ensure that employees wearing tight fitting respirators perform a facepiece seal fit check to ensure that a proper facepiece seal is obtained prior to entry into a BD atmosphere. The recommended positive or negative pressure fit check procedures listed in Appendix E to this section or the respirator manufacturer's recommended fit check procedure shall be used.

(i) *Protective clothing and equipment.* Where appropriate to prevent eye contact and limit dermal exposure to BD, the employer shall provide protective clothing and equipment at no cost to the employee and shall ensure its use. Eye and face protection shall meet the requirements of 29 CFR 1910.133.

(j) *Emergency situations. Written plan.* A written plan for emergency situations shall be developed, or an existing plan shall be modified, to contain the applicable elements specified in 29 CFR 1910.38, ''Employee Emergency Plans and Fire Prevention Plans,'' and in 29 CFR 1910.120 ''Hazardous Waste Operations and Emergency Responses,'' for each workplace where there is a possibility of an emergency.

(k) *Medical screening and surveillance.*—(1) *Employees covered.* The employer shall institute a medical screening and surveillance program as specified in this paragraph for:

(i) Each employee with exposure to BD at concentrations at or above the action level on 30 or more days or for employees who have or may have exposure to BD at or above the PELs on 10 or more days a year;

(ii) Employers (including successor owners) shall continue to provide medical screening and surveillance for employees, even after transfer to a non-BD exposed job and regardless of when the employee is transferred, whose work histories suggest exposure to BD:

(A) At or above the PELs on 30 or more days a year for 10 or more years;

(B) At or above the action level on 60 or more days a year for 10 or more years; or

(C) Above 10 ppm on 30 or more days in any past year; and

(iii) Each employee exposed to BD following an emergency situation.

(2) *Program administration.* (i) The employer shall ensure that the health questionnaire, physical examination and medical procedures are provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(ii) Physical examinations, health questionnaires, and medical procedures shall be performed or administered by a physician or other licensed health care professional.

(iii) Laboratory tests shall be conducted by an accredited laboratory.

(3) *Frequency of medical screening activities.* The employer shall make medical screening available on the following schedule:

(i) For each employee covered under paragraphs (j)(1) (i)–(ii) of this section, a health questionnaire and complete blood count with differential and platelet count (CBC) every year, and a physical examination as specified below:

(A) An initial physical examination that meets the requirements of this rule, if twelve months or more have elapsed since the last physical examination conducted as part of a medical screening program for BD exposure;

(B) Before assumption of duties by the employee in a job with BD exposure;

(C) Every 3 years after the initial physical examination;

(D) At the discretion of the physician or other licensed health care professional reviewing the annual health questionnaire and CBC;

(E) At the time of employee reassignment to an area where exposure to BD is below the action level, if the employee's past exposure history does not meet the criteria of paragraph (j)(1)(ii) of this section for continued coverage in the screening and surveillance program, and if twelve months or more have elapsed since the last physical examination; and

(F) At termination of employment if twelve months or more have elapsed since the last physical examination.

(ii) Following an emergency situation, medical screening shall be conducted as quickly as possible, but not later than 48 hours after the exposure.

(iii) For each employee who must wear a respirator, physical ability to perform the work and use the respirator must be determined as required by 29 CFR 1910.134.

(4) *Content of medical screening.* (i) Medical screening for employees covered by paragraphs (j)(1) (i)–(ii) of this section shall include:

(A) A baseline health questionnaire that includes a comprehensive occupational and health history and is updated annually. Particular emphasis shall be placed on the hematopoietic and reticuloendothelial systems, including exposure to chemicals, in addition to BD, that may have an adverse effect on these systems, the presence of signs and symptoms that might be related to disorders of these systems, and any other information determined by the examining physician or other licensed health care professional to be necessary to evaluate whether the employee is at increased risk of material impairment of health from BD exposure. Health questionnaires shall consist of the sample forms in Appendix C to this section, or be equivalent to those samples;

(B) A complete physical examination, with special emphasis on the liver, spleen, lymph nodes, and skin;

(C) A CBC; and

(D) Any other test which the examining physician or other licensed health care professional deems necessary to evaluate whether the

employee may be at increased risk from exposure to BD.

(ii) Medical screening for employees exposed to BD in an emergency situation shall focus on the acute effects of BD exposure and at a minimum include: A CBC within 48 hours of the exposure and then monthly for three months; and a physical examination if the employee reports irritation of the eyes, nose throat, lungs, or skin, blurred vision, coughing, drowsiness, nausea, or headache. Continued employee participation in the medical screening and surveillance program, beyond these minimum requirements, shall be at the discretion of the physician or other licensed health care professional.

(5) *Additional medical evaluations and referrals.* (i) Where the results of medical screening indicate abnormalities of the hematopoietic or reticuloendothelial systems, for which a non-occupational cause is not readily apparent, the examining physician or other licensed health care professional shall refer the employee to an appropriate specialist for further evaluation and shall make available to the specialist the results of the medical screening.

(ii) The specialist to whom the employee is referred under this paragraph shall determine the appropriate content for the medical evaluation, e.g., examinations, diagnostic tests and procedures, etc.

(6) *Information provided to the physician or other licensed health care professional.* The employer shall provide the following information to the examining physician or other licensed health care professional involved in the evaluation:

(i) A copy of this section including its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's BD exposure;

(iii) The employee's actual or representative BD exposure level during employment tenure, including exposure incurred in an emergency situation;

(iv) A description of pertinent personal protective equipment used or to be used; and

(v) Information, when available, from previous employment-related medical evaluations of the affected employee which is not otherwise available to the physician or other licensed health care professional or the specialist.

(7) *The written medical opinion.* (i) For each medical evaluation required by this section, the employer shall ensure that the physician or other licensed health care professional produces a written opinion and provides a copy to the employer and the employee within 15 business days of the evaluation. The written opinion shall be limited to the following information:

(A) The occupationally pertinent results of the medical evaluation;

(B) A medical opinion concerning whether the employee has any detected medical conditions which would place the employee's health at increased risk of material impairment from exposure to BD;

(C) Any recommended limitations upon the employee's exposure to BD; and

(D) A statement that the employee has been informed of the results of the medical evaluation and any medical conditions resulting from BD exposure that require further explanation or treatment.

(ii) The written medical opinion provided to the employer shall not reveal specific records, findings, and diagnoses that have no bearing on the employee's ability to work with BD.

Note: However, this provision does not negate the ethical obligation of the physician or other licensed health care professional to transmit any other adverse findings directly to the employee.

(8) *Medical surveillance.* (i) The employer shall ensure that information obtained from the medical screening program activities is aggregated (with all personal identifiers removed) and periodically reviewed, to ascertain whether the health of the employee population of that employer is adversely affected by exposure to BD.

(ii) Information learned from medical surveillance activities must be disseminated to covered employees, as defined in paragraph (k)(1) of this section, in a manner that ensures the confidentiality of individual medical information.

(l) *Communication of BD hazards to employees.*—(1) *Hazard communication.* The employer shall communicate the hazards associated with BD exposure in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, and 29 CFR 1926.59.

(2) *Employee information and training.* (i) The employer shall provide all employees exposed to BD with information and training in accordance with the requirements of the Hazard Communication Standard, 29 CFR 1910.1200, 29 CFR 1915.1200, and 29 CFR 1926.59.

(ii) The employer shall institute a training program for all employees who are potentially exposed to BD at or above the action level or the STEL, ensure employee participation in the program and maintain a record of the contents of such program.

(iii) Training shall be provided prior to or at the time of initial assignment to a job potentially involving exposure to BD at or above the action level or STEL and at least annually thereafter.

(iv) The training program shall be conducted in a manner that the employee is able to understand. The employee shall ensure that each employee exposed to BD over the action level or STEL is informed of the following:

(A) The health hazards associated with BD exposure, and the purpose and a description of the medical screening and surveillance program required by this section;

(B) The quantity, location, manner of use, release, and storage of BD and the specific operations that could result in exposure to BD, especially exposures above the PEL or STEL;

(C) The engineering controls and work practices associated with the employee's job assignment, and emergency procedures and personal protective equipment;

(D) The measures employees can take to protect themselves from exposure to BD.

(E) The contents of this standard and its appendices, and

(F) The right of each employee exposed to BD at or above the action level or STEL to obtain:

(*1*) medical examinations as required by paragraph (j) of this section at no cost to the employee;

(*2*) the employee's medical records required to be maintained by paragraph (m)(4) of this section; and

(*3*) all air monitoring results representing the employee's exposure to BD and required to be kept by paragraph (m)(2) of this section.

(3) *Access to information and training materials.* (i) The employer shall make a copy of this standard and its appendices readily available without cost to all affected employees and their designated representatives and shall provide a copy if requested.

(ii) The employer shall provide to the Assistant Secretary or the Director, or the designated employee representatives, upon request, all materials relating to the employee information and the training program.

(m) *Recordkeeping.*—(1) *Objective data for exemption from initial monitoring.* (i) Where the processing, use, or handling of products or streams made from or containing BD are exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial

monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish and maintain a record of the objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The product or activity qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and analysis of the material for the release of BD;

(D) A description of the operation exempted and how the data support the exemption; and

(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) *Exposure measurements.* (i) The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to BD as prescribed in paragraph (d) of this section.

(ii) The record shall include at least the following information:

(A) The date of measurement;

(B) The operation involving exposure to BD which is being monitored;

(C) Sampling and analytical methods used and evidence of their accuracy;

(D) Number, duration, and results of samples taken;

(E) Type of protective devices worn, if any; and

(F) Name, social security number and exposure of the employees whose exposures are represented.

(G) The written corrective action and the schedule for completion of this action required by paragraph (d)(7)(ii) of this section.

(iii) The employer shall maintain this record for at least 30 years in accordance with 29 CFR 1910.20.

(3) *Respirator Fit-test.* (i) The employer shall establish a record of the fit tests administered to an employee including:

(A) The name of the employee,

(B) Type of respirator,

(C) Brand and size of respirator,

(D) Date of test, and

(E) Where QNFT is used, the fit factor, strip chart recording or other recording of the results of the test.

(ii) Fit test records shall be maintained for respirator users until the next fit test is administered.

(4) *Medical screening and surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical screening and surveillance under this section.

(ii) The record shall include at least the following information:

(A) The name and social security number of the employee;

(B) Physician's or other licensed health care professional's written opinions as described in paragraph (k)(7) of this section;

(C) A copy of the information provided to the physician or other licensed health care professional as required by paragraphs (k)(7)(ii)–(iv) of this section.

(iii) Medical screening and surveillance records shall be maintained for each employee for the duration of employment plus 30 years, in accordance with 29 CFR 1910.20.

(5) *Availability.* (i) The employer, upon written request, shall make all records required to be maintained by this section available for examination and copying to the Assistant Secretary and the Director.

(ii) Access to records required to be maintained by paragraphs (l)(1)–(3) of this section shall be granted in accordance with 29 CFR 1910.20(e).

(6) *Transfer of records.* (i) Whenever the employer ceases to do business, the employer shall transfer records required by this section to the successor employer. The successor employer shall receive and maintain these records. If there is no successor employer, the employer shall notify the Director, at least three (3) months prior to disposal, and transmit them to the Director if requested by the Director within that period.

(ii) The employer shall transfer medical and exposure records as set forth in 29 CFR 1910.20(h).

(n) *Dates.*—(1) *Effective date.* This section shall become effective ninety (90) days after the date of publication in the Federal Register.

(2) *Start-up dates.* (i) The initial monitoring required under paragraph (d)(2) of this section shall be completed within sixty (60) days of the effective date of this standard or the introduction of BD into the workplace.

(ii) The requirements of paragraphs (c) through (m) of this section, including feasible work practice controls but not including engineering controls specified in paragraph (f)(1) of this section, shall be complied with within one-hundred and eighty (180) days after the effective date of this section.

(iii) Engineering controls specified by paragraph (f)(1) of this section shall be implemented within two (2) years after the effective date of this section, and the exposure goal program specified in paragraph (g) of this section shall be implemented within three (3) years after the effective date of this section.

(o) *Appendices.* (1) Appendix E to this section is mandatory.

(2) Appendices A, B, C, D, and F to this section are informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations.

Appendix A. Substance Safety Data Sheet For 1,3-Butadiene (Non-Mandatory)

I. Substance Identification

A. Substance: 1,3-Butadiene (CH_2=CH-CH=CH_2).

B. Synonyms: 1,3-Butadiene (BD); butadiene; biethylene; bi-vinyl; divinyl; butadiene-1,3; buta-1,3-diene; erythrene; NCI–C50602; CAS–106–99–0.

C. BD can be found as a gas or liquid.

D. BD is used in production of styrene-butadiene rubber and polybutadiene rubber for the tire industry. Other uses include copolymer latexes for carpet backing and paper coating, as well as resins and polymers for pipes and automobile and appliance parts. It is also used as an intermediate in the production of such chemicals as fungicides.

E. Appearance and odor: BD is a colorless, non-corrosive, flammable gas with a mild aromatic odor at standard ambient temperature and pressure.

F. Permissible exposure: Exposure may not exceed 1 part BD per million parts of air averaged over the 8-hour workday, nor may short-term exposure exceed 5 parts of BD per million parts of air averaged over any 15-minute period in the 8-hour workday.

II. Health Hazard Data

A. BD can affect the body if the gas is inhaled or if the liquid form, which is very cold (cryogenic), comes in contact with the eyes or skin.

B. Effects of overexposure: Breathing very high levels of BD for a short time can cause central nervous system effects, blurred vision, nausea, fatigue, headache, decreased blood pressure and pulse rate, and unconsciousness. There are no recorded cases of accidental exposures at high levels that have caused death in humans, but this could occur. Breathing lower levels of BD may cause irritation of the eyes, nose, and throat. Skin contact with liquefied BD can cause irritation and frostbite.

C. Long-term (chronic) exposure: BD has been found to be a potent carcinogen in rodents, inducing neoplastic lesions at multiple target sites in mice and rats. A recent study of BD-exposed workers showed that exposed workers have an increased risk of developing leukemia. The risk of leukemia increases with increased exposure to BD. OSHA has concluded that there is strong evidence that workplace exposure to BD poses an increased risk of death from cancers of the lymphohematopoietic system.

D. Reporting signs and symptoms: You should inform your supervisor if you develop any of these signs or symptoms and suspect that they are caused by exposure to BD.

III. Emergency First Aid Procedures

In the event of an emergency, follow the emergency plan and procedures designated for your work area. If you have been trained

in first aid procedures, provide the necessary first aid measures. If necessary, call for additional assistance from co-workers and emergency medical personnel.

A. Eye and Skin Exposures: If there is a potential that liquefied BD can come in contact with eye or skin, face shields and skin protective equipment must be provided and used. If liquefied BD comes in contact with the eye, immediately flush the eyes with large amounts of water, occasionally lifting the lower and the upper lids. Flush repeatedly. Get medical attention immediately. Contact lenses should not be worn when working with this chemical. In the event of skin contact, which can cause frostbite, remove any contaminated clothing and flush the affected area repeatedly with large amounts of tepid water.

B. Breathing: If a person breathes in large amounts of BD, move the exposed person to fresh air at once. If breathing has stopped, begin cardiopulmonary resuscitation (CPR) if you have been trained in this procedure. Keep the affected person warm and at rest. Get medical attention immediately.

C. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, call for help and begin emergency rescue procedures. Use extreme caution so that you do not become a casualty. Understand the plant's emergency rescue procedures and know the locations of rescue equipment before the need arises.

IV. Respirators and Protective Clothing

A. Respirators: Good industrial hygiene practices recommend that engineering and work practice controls be used to reduce environmental concentrations to the permissible exposure level. However, there are some exceptions where respirators may be used to control exposure. Respirators may be used when engineering and work practice controls are not technically feasible, when such controls are in the process of being installed, or when these controls fail and need to be supplemented or during brief, non-routine, intermittent exposure. Respirators may also be used in situations involving non-routine work operations which are performed infrequently and in which exposures are limited in duration, and in emergency situations. In some instances cartridge respirator use is allowed, but only with strict time constraints. For example, at exposure below 5 ppm BD, a cartridge (or canister) respirator, either full or half face, may be used, but the cartridge must be replaced at least every 4 hours, and it must be replaced every 3 hours when the exposure is between 5 and 10 ppm. If the use of respirators is necessary, the only respirators permitted are those that have been approved by the National Institute for Occupational Safety and Health (NIOSH). In addition to respirator selection, a complete respiratory protection program must be instituted which includes regular training, maintenance, fit testing, inspection, cleaning, and evaluation of respirators. If you can smell BD while wearing a respirator, proceed immediately to fresh air, and change cartridge (or canister) before re-entering an area where there is BD exposure. If you experience difficulty in breathing while wearing a respirator, tell your supervisor.

B. Protective Clothing: Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen by contact with liquefied BD (or a vessel containing liquid BD).

Employees should be provided with and required to use splash-proof safety goggles where liquefied BD may contact the eyes.

V. Precautions for Safe Use, Handling, and Storage

A. Fire and Explosion Hazards: BD is a flammable gas and can easily form explosive mixtures in air. It has a lower explosive limit of 2%, and an upper explosive limit of 11.5%. It has an autoignition temperature of 420° C (788° F). Its vapor is heavier than air (vapor density, 1.9) and may travel a considerable distance to a source of ignition and flash back. Usually it contains inhibitors to prevent self-polymerization (which is accompanied by evolution of heat) and to prevent formation of explosive peroxides. At elevated temperatures, such as in fire conditions, polymerization may take place. If the polymerization takes place in a container, there is a possibility of violent rupture of the container.

B. Hazard: Slightly toxic. Slight respiratory irritant. Direct contact of liquefied BD on skin may cause freeze burns and frostbite.

C. Storage: Protect against physical damage to BD containers. Outside or detached storage of BD containers is preferred. Inside storage should be in a cool, dry, well-ventilated, noncombustible location, away from all possible sources of ignition. Store cylinders vertically and do not stack. Do not store with oxidizing material.

D. Usual Shipping Containers: Liquefied BD is contained in steel pressure apparatus.

E. Electrical Equipment: Electrical installations in Class I hazardous locations, as defined in Article 500 of the National Electrical Code, should be in accordance with Article 501 of the Code. If explosion-proof electrical equipment is necessary, it shall be suitable for use in Group B. Group D equipment may be used if such equipment is isolated in accordance with Section 501–5(a) by sealing all conduit ½- inch size or larger. See Venting of Deflagrations (NFPA No. 68, 1994), National Electrical Code (NFPA No. 70, 1996), Static Electricity (NFPA No. 77, 1993), Lightning Protection Systems (NFPA No. 780, 1995), and Fire Hazard Properties of Flammable Liquids, Gases and Volatile Solids (NFPA No. 325, 1994).

F. Fire Fighting: Stop flow of gas. Use water to keep fire-exposed containers cool. Fire extinguishers and quick drenching facilities must be readily available, and you should know where they are and how to operate them.

G. Spill and Leak: Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until clean-up has been completed. If BD is spilled or leaked, the following steps should be taken:

1. Eliminate all ignition sources.
2. Ventilate area of spill or leak.
3. If in liquid form, for small quantities, allow to evaporate in a safe manner.
4. Stop or control the leak if this can be done without risk. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place and repair the leak or allow the cylinder to empty.

H. Disposal: This substance, when discarded or disposed of, is a hazardous waste according to Federal regulations (40 CFR part 261). It is listed as hazardous waste number D001 due to its ignitability. The transportation, storage, treatment, and disposal of this waste material must be conducted in compliance with 40 CFR parts 262, 263, 264, 268 and 270. Disposal can occur only in properly permitted facilities. Check state and local regulation of any additional requirements as these may be more restrictive than federal laws and regulation.

I. You should not keep food, beverages, or smoking materials in areas where there is BD exposure, nor should you eat or drink in such areas.

J. Ask your supervisor where BD is used in your work area and ask for any additional plant safety and health rules.

VI. Medical Requirements

Your employer is required to offer you the opportunity to participate in a medical screening and surveillance program if you are exposed to BD at concentrations exceeding the action level (0.5 ppm BD as an 8-hour TWA) on 30 days or more a year, or at or above the 8 hr TWA (1 ppm) or STEL (5 ppm for 15 minutes) on 10 days or more a year. Exposure for any part of a day counts. If you have had exposure to BD in the past, but have been transferred to another job, you may still be eligible to participate in the medical screening and surveillance program. The OSHA rule specifies the past exposures that would qualify you for participation in the program. These past exposure are work histories that suggest the following: (1) That you have been exposed at or above the PELs on 30 days a year for 10 or more years; (2) that you have been exposed at or above the action level on 60 days a year for 10 or more years; or (3) that you have been exposed above 10 ppm on 30 days in any past year. Additionally, if you are exposed to BD in an emergency situation, you are eligible for a medical examination within 48 hours. The basic medical screening program includes a health questionnaire, physical examination, and blood test. These medical evaluations must be offered to you at a reasonable time and place, and without cost or loss of pay.

VII. Observation of Monitoring

Your employer is required to perform measurements that are representative of your exposure to BD and you or your designated representative are entitled to observe the monitoring procedure. You are entitled to observe the steps taken in the measurement procedure, and to record the results obtained. When the monitoring procedure is taking place in an area where respirators or personal protective clothing and equipment are required to be worn, you or your representative must also be provided with,

and must wear, the protective clothing and equipment.

VIII. Access to Information

A. Each year, your employer is required to inform you of the information contained in this appendix. In addition, your employer must instruct you in the proper work practices for using BD, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to BD. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits and of the schedule to implement these actions.

C. Your employer is required to keep records of your exposures and medical examinations. These records must be kept by the employer for at least thirty (30) years.

D. Your employer is required to release your exposure and medical records to you or your representative upon your request.

Appendix B. Substance Technical Guidelines for 1,3-Butadiene (Non-Mandatory)

I. Physical and Chemical Data

A. Substance identification:

1. Synonyms: 1,3-Butadiene (BD); butadiene; biethylene; bivinyl; divinyl; butadiene-1,3; buta-1,3-diene; erythrene; NCI-C50620; CAS–106–99–0.

2. Formula: CH_2=CH-CH=CH_2.

3. Molecular weight: 54.1.

B. Physical data:

1. Boiling point (760 mm Hg): −4.7 °C (23.5 °F).

2. Specific gravity (water=1): 0.62 at 20 °C (68 °F).

3. Vapor density (air=1 at boiling point of BD): 1.87.

4. Vapor pressure at 20 °C (68 °F): 910 mm Hg.

5. Solubility in water, g/100 g water at 20 °C (68 °F): 0.05.

6. Appearance and odor: Colorless, flammable gas with a mildly aromatic odor. Liquefied BD is a colorless liquid with a mildly aromatic odor.

II. Fire, Explosion, and Reactivity Hazard Data

A. Fire:

1. Flash point: −76 °C (−105 °F) for take out; liquefied BD; Not applicable to BD gas.

2. Stability: A stabilizer is added to the monomer to inhibit formation of polymer during storage. Forms explosive peroxides in air in absence of inhibitor.

3. Flammable limits in air, percent by volume: Lower: 2.0; Upper: 11.5.

4. Extinguishing media: Carbon dioxide for small fires, polymer or alcohol foams for large fires.

5. Special fire fighting procedures: Fight fire from protected location or maximum possible distance. Stop flow of gas before extinguishing fire. Use water spray to keep fire-exposed cylinders cool.

6. Unusual fire and explosion hazards: BD vapors are heavier than air and may travel to a source of ignition and flash back. Closed containers may rupture violently when heated.

7. For purposes of compliance with the requirements of 29 CFR 1910.106, BD is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.

8. For purposes of compliance with 29 CFR 1910.155, BD is classified as a Class B fire hazard.

9. For purposes of compliance with 29 CFR 1910.307, locations classified as hazardous due to the presence of BD shall be Class I.

B. Reactivity:

1. Conditions contributing to instability: Heat. Peroxides are formed when inhibitor concentration is not maintained at proper level. At elevated temperatures, such as in fire conditions, polymerization may take place.

2. Incompatibilities: Contact with strong oxidizing agents may cause fires and explosions. The contacting of crude BD (not BD monomer) with copper and copper alloys may cause formations of explosive copper compounds.

3. Hazardous decomposition products: Toxic gases (such as carbon monoxide) may be released in a fire involving BD.

4. Special precautions: BD will attack some forms of plastics, rubber, and coatings. BD in storage should be checked for proper inhibitor content, for self-polymerization, and for formation of peroxides when in contact with air and iron. Piping carrying BD may become plugged by formation of rubbery polymer.

C. Warning Properties:

1. Odor Threshold: An odor threshold of 0.45 ppm has been reported in The American Industrial Hygiene Association (AIHA) Report, *Odor Thresholds for Chemicals with Established Occupational Health Standards.* (Ex. 32–28C)

2. Eye Irritation Level: Workers exposed to vapors of BD (concentration or purity unspecified) have complained of irritation of eyes, nasal passages, throat, and lungs. Dogs and rabbits exposed experimentally to as much as 6700 ppm for 7½ hours a day for 8 months have developed no histologically demonstrable abnormality of the eyes.

3. Evaluation of Warning Properties: Since the mean odor threshold is about half of the 1 ppm PEL, and more than 10-fold below the 5 ppm STEL, most wearers of air purifying respirators should still be able to detect breakthrough before a significant overexposure to BD occurs.

III. Spill, Leak, and Disposal Procedures

A. Persons not wearing protective equipment and clothing should be restricted from areas of spills or leaks until cleanup has been completed. If BD is spilled or leaked, the following steps should be taken:

1. Eliminate all ignition sources.

2. Ventilate areas of spill or leak.

3. If in liquid form, for small quantities, allow to evaporate in a safe manner.

4. Stop or control the leak if this can be done without risk. If source of leak is a cylinder and the leak cannot be stopped in place, remove the leaking cylinder to a safe place and repair the leak or allow the cylinder to empty.

B. Disposal: This substance, when discarded or disposed of, is a hazardous waste according to Federal regulations (40 CFR part 261). It is listed by the EPA as hazardous waste number D001 due to its ignitability. The transportation, storage, treatment, and disposal of this waste material must be conducted in compliance with 40 CFR parts 262, 263, 264, 268 and 270. Disposal can occur only in properly permitted facilities. Check state and local regulations for any additional requirements because these may be more restrictive than federal laws and regulations.

IV. Monitoring and Measurement Procedures

A. Exposure above the Permissible Exposure Limit (8-hr TWA) or Short-Term Exposure Limit (STEL):

1. 8-hr TWA exposure evaluation: Measurements taken for the purpose of determining employee exposure under this standard are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2. STEL exposure evaluation: Measurements must represent 15 minute exposures associated with operations most likely to exceed the STEL in each job and on each shift.

3. Monitoring frequencies: Table 1 gives various exposure scenarios and their required monitoring frequencies, as required by the final standard for occupational exposure to butadiene.

TABLE 1.—FIVE EXPOSURE SCENARIOS AND THEIR ASSOCIATED MONITORING FREQUENCIES

Action level	8-hr TWA	STEL	Required monitoring activity
−*	−	−	No 8-hr TWA or STEL monitoring required.
+*	−	−	No STEL monitoring required. Monitor 8-hr TWA annually.
+	+	−	No STEL monitoring required. Periodic monitoring 8-hr TWA, in accordance with (d)(3)(ii).**
+	+	+	Periodic monitoring 8-hr TWA, in accordance with (d)(3)(ii)**. Periodic monitoring STEL, in accordance with (d)(3)(iii).

TABLE 1.—FIVE EXPOSURE SCENARIOS AND THEIR ASSOCIATED MONITORING FREQUENCIES—Continued

Action level	8-hr TWA	STEL	Required monitoring activity
+	–	+	Periodic monitoring STEL, in accordance with (d)(3)(iii). Monitor 8-hr TWA, annually.

*Exposure Scenario, Limit Exceeded: + = Yes, – = No.

**The employer may decrease the frequency of exposure monitoring to annually when at least 2 consecutive measurements taken at least 7 days apart show exposures to be below the 8 hr TWA, but at or above the action level.

4. Monitoring techniques: Appendix D describes the validated method of sampling and analysis which has been tested by OSHA for use with BD. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his or her unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of BD at or above 1 ppm, and to plus or minus 35 percent for concentrations below 1 ppm.

V. Personal Protective Equipment

A. Employees should be provided with and required to use impervious clothing, gloves, face shields (eight-inch minimum), and other appropriate protective clothing necessary to prevent the skin from becoming frozen from contact with liquid BD.

B. Any clothing which becomes wet with liquid BD should be removed immediately and not re-worn until the butadiene has evaporated.

C. Employees should be provided with and required to use splash proof safety goggles where liquid BD may contact the eyes.

VI. Housekeeping and Hygiene Facilities

For purposes of complying with 29 CFR 1910.141, the following items should be emphasized:

A. The workplace should be kept clean, orderly, and in a sanitary condition.

B. Adequate washing facilities with hot and cold water are to be provided and maintained in a sanitary condition.

VII. Additional Precautions

A. Store BD in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.

B. Non-sparking tools must be used to open and close metal containers. These containers must be effectively grounded.

C. Do not incinerate BD cartridges, tanks or other containers.

D. Employers must advise employees of all areas and operations where exposure to BD might occur.

Appendix C. Medical Screening and Surveillance for 1,3-Butadiene (Non-Mandatory)

I. Basis for Medical Screening and Surveillance Requirements

A. Route of Entry Inhalation

B. Toxicology

Inhalation of BD has been linked to an increased risk of cancer, damage to the reproductive organs, and fetotoxicity. Butadiene can be converted via oxidation to epoxybutene and diepoxybutane, two genotoxic metabolites that may play a role in the expression of BD's toxic effects.

BD has been tested for carcinogenicity in mice and rats. Both species responded to BD exposure by developing cancer at multiple primary organ sites. Early deaths in mice were caused by malignant lymphomas, primarily lymphocytic type, originating in the thymus.

Mice exposed to BD have developed ovarian or testicular atrophy. Sperm head morphology tests also revealed abnormal sperm in mice exposed to BD; lethal mutations were found in a dominant lethal test. In light of these results in animals, the possibility that BD may adversely affect the reproductive systems of male and female workers must be considered.

Additionally, anemia has been observed in animals exposed to butadiene. In some cases, this anemia appeared to be a primary response to exposure; in other cases, it may have been secondary to a neoplastic response.

C. Epidemiology

Epidemiologic evidence demonstrates that BD exposure poses an increased risk of leukemia. Mild alterations of hematologic parameters have also been observed in synthetic rubber workers exposed to BD.

II. Potential Adverse Health Effects

A. Acute

Skin contact with liquid BD causes characteristic burns or frostbite. BD is gaseous form can irritate the eyes, nasal passages, throat, and lungs. Blurred vision, coughing, and drowsiness may also occur. Effects are mild at 2,000 ppm and pronounced at 8,000 ppm for exposures occurring over the full workshift.

At very high concentrations in air, BD is an anesthetic, causing narcosis, respiratory paralysis, unconsciousness, and death. Such concentrations are unlikely, however, except in an extreme emergency because BD poses an explosion hazard at these levels.

B. Chronic

The principal adverse health effects of concern are BD-induced lymphoma, leukemia and potential reproductive toxicity. Anemia and other changes in the peripheral blood cells may be indicators of excessive exposure to BD.

C. Reproductive

Workers may be concerned about the possibility that their BD exposure may be affecting their ability to procreate a healthy child. For workers with high exposures to BD, especially those who have experienced difficulties in conceiving, miscarriages, or stillbirths, appropriate medical and laboratory evaluation of fertility may be necessary to determine if BD is having any adverse effect on the reproductive system or on the health of the fetus.

III. Medical Screening Components At-A–Glance

A. Health Questionnaire

The most important goal of the health questionnaire is to elicit information from the worker regarding potential signs or symptoms generally related to leukemia or other blood abnormalities. Therefore, physicians or other licensed health care professionals should be aware of the presenting symptoms and signs of lymphohematopoietic disorders and cancers, as well as the procedures necessary to confirm or exclude such diagnoses. Additionally, the health questionnaire will assist with the identification of workers at greatest risk of developing leukemia or adverse reproductive effects from their exposures to BD.

Workers with a history of reproductive difficulties or a personal or family history of immune deficiency syndromes, blood dyscrasias, lymphoma, or leukemia, and those who are or have been exposed to medicinal drugs or chemicals known to affect the hematopoietic or lymphatic systems may be at higher risk from their exposure to BD. After the initial administration, the health questionnaire must be updated annually.

B. Complete Blood Count (CBC)

The medical screening and surveillance program requires an annual CBC, with differential and platelet count, to be provided for each employee with BD exposure. This test is to be performed on a blood sample obtained by phlebotomy of the venous system or, if technically feasible, from a fingerstick sample of capillary blood. The sample is to be analyzed by an accredited laboratory.

Abnormalities in a CBC may be due to a number of different etiologies. The concern for workers exposed to BD includes, but is not limited to, timely identification of lymphohematopoietic cancers, such as leukemia and non-Hodgkin's lymphoma. Abnormalities of portions of the CBC are identified by comparing an individual's results to those of an established range of normal values for males and females. A substantial change in any individual employee's CBC may also be viewed as ''abnormal'' for that individual even if all measurements fall within the population-based range of normal values. It is suggested that a flowsheet for laboratory values be included in each employee's medical record so that comparisons and trends in annual CBCs can be easily made.

A determination of the clinical significance of an abnormal CBC shall be the responsibility of the examining physician, other licensed health care professional, or medical specialist to whom the employee is referred. Ideally, an abnormal CBC should be compared to previous CBC measurements for the same employee, when available. Clinical common sense may dictate that a CBC value

that is very slightly outside the normal range does not warrant medical concern. A CBC abnormality may also be the result of a temporary physical stressor, such as a transient viral illness, blood donation, or menorrhagia, or laboratory error. In these cases, the CBC should be repeated in a timely fashion, i.e., within 6 weeks, to verify that return to the normal range has occurred. A clinically significant abnormal CBC should result in removal of the employee from further exposure to BD. Transfer of the employee to other work duties in a BD-free environment would be the preferred recommendation.

C. Physical Examination

The medical screening and surveillance program requires an initial physical examination for workers exposed to BD; this examination is repeated once every three years. The initial physical examination should assess each worker's baseline general health and rule out clinical signs of medical conditions that may be caused by or aggravated by occupational BD exposure. The physical examination should be directed at identification of signs of lymphohematopoietic disorders, including lymph node enlargement, splenomegaly, and hepatomegaly.

Repeated physical examinations should update objective clinical findings that could be indicative of interim development of a lymphohematopoietic disorder, such as lymphoma, leukemia, or other blood abnormality. Physical examinations may also be provided on an as needed basis in order to follow up on a positive answer on the health questionnaire, or in response to an abnormal CBC. Physical examination of workers who will no longer be working in jobs with BD exposure are intended to rule out lymphohematopoietic disorders.

The need for physical examinations for workers concerned about adverse reproductive effects from their exposure to BD should be identified by the physician or other licensed health care professional and provided accordingly. For these workers, such consultations and examinations may relate to developmental toxicity and reproductive capacity.

Physical examination of workers acutely exposed to significant levels of BD should be especially directed at the respiratory system, eyes, sinuses, skin, nervous system, and any region associated with particular complaints. If the worker has received a severe acute exposure, hospitalization may be required to assure proper medical management. Since this type of exposure may place workers at greater risk of blood abnormalities, a CBC must be obtained within 48 hours and repeated at one, two, and three months.

Appendix D: Sampling and Analytical Method for 1,3-Butadiene (Non-Mandatory)

OSHA Method No.: 56.

Matrix: Air.

Target concentration: 1 ppm (2.21 mg/m^3)

Procedure: Air samples are collected by drawing known volumes of air through sampling tubes containing charcoal adsorbent which has been coated with 4-tert-butylcatechol. The samples are desorbed with carbon disulfide and then analyzed by gas chromatography using a flame ionization detector.

Recommended sampling rate and air volume: 0.05 L/min and 3 L.

Detection limit of the overall procedure: 90 ppb (200 ug/m^3) (based on 3 L air volume).

Reliable quantitation limit: 155 ppb (343 ug/m^3) (based on 3 L air volume).

Standard error of estimate at the target concentration: 6.5%.

Special requirements: The sampling tubes must be coated with 4-tert-butylcatechol. Collected samples should be stored in a freezer.

Status of method: A sampling and analytical method has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch, OSHA Analytical Laboratory, Salt Lake City, Utah 84165.

1. Background

This work was undertaken to develop a sampling and analytical procedure for BD at 1 ppm. The current method recommended by OSHA for collecting BD uses activated coconut shell charcoal as the sampling medium (Ref. 5.2). This method was found to be inadequate for use at low BD levels because of sample instability.

The stability of samples has been significantly improved through the use of a specially cleaned charcoal which is coated with 4-tert-butylcatechol (TBC). TBC is a polymerization inhibitor for BD (Ref. 5.3).

1.1.1 Toxic effects

Symptoms of human exposure to BD include irritation of the eyes, nose and throat. It can also cause coughing, drowsiness and fatigue. Dermatitis and frostbite can result from skin exposure to liquid BD. (Ref. 5.1)

NIOSH recommends that BD be handled in the workplace as a potential occupational carcinogen. This recommendation is based on two inhalation studies that resulted in cancers at multiple sites in rats and in mice. BD has also demonstrated mutagenic activity in the presence of a liver microsomal activating system. It has also been reported to have adverse reproductive effects. (Ref. 5.1)

1.1.2. Potential workplace exposure

About 90% of the annual production of BD is used to manufacture styrene-butadiene rubber and Polybutadiene rubber. Other uses include: Polychloroprene rubber, acrylonitrile butadiene-stryene resins, nylon intermediates, styrene-butadiene latexes, butadiene polymers, thermoplastic elastomers, nitrile resins, methyl methacrylate-butadiene styrene resins and chemical intermediates. (Ref. 5.1)

1.1.3. Physical properties (Ref. 5.1)

CAS No.: 106–99–0

Molecular weight: 54.1

Appearance: Colorless gas

Boiling point: −4.41 °C (760 mm Hg)

Freezing point: −108.9 °C

Vapor pressure: 2 atm @ 15.3 °C; 5 atm @ 47 °C

Explosive limits: 2 to 11.5% (by volume in air)

Odor threshold: 0.45 ppm

Structural formula: $H_2C{:}CHCH{:}CH_2$

Synonyms: BD; biethylene; bivinyl; butadiene; divinyl; buta-1,3-diene; alpha-gamma-butadiene; erythrene; NCI–C50602; pyrrolylene; vinylethylene.

1.2. Limit defining parameters

The analyte air concentrations listed throughout this method are based on an air volume of 3 L and a desorption volume of 1 mL. Air concentrations listed in ppm are referenced to 25 °C and 760 mm Hg.

1.2.1. Detection limit of the analytical procedure

The detection limit of the analytical procedure was 304 pg per injection. This was the amount of BD which gave a response relative to the interferences present in a standard.

1.2.2. Detection limit of the overall procedure

The detection limit of the overall procedure was 0.60 µg per sample (90 ppb or 200 µg/m^3). This amount was determined graphically. It was the amount of analyte which, when spiked on the sampling device, would allow recovery approximately equal to the detection limit of the analytical procedure.

1.2.3. Reliable quantitation limit

The reliable quantitation limit was 1.03 µg per sample (155 ppb or 343 µg/m^3). This was the smallest amount of analyte which could be quantitated within the limits of a recovery of at least 75% and a precision (±1.96 SD) of ±25% or better.

1.2.4. Sensitivity [1]

The sensitivity of the analytical procedure over a concentration range representing 0.6 to 2 times the target concentration, based on the recommended air volume, was 387 area units per µg/mL. This value was determined from the slope of the calibration curve. The sensitivity may vary with the particular instrument used in the analysis.

1.2.5. Recovery

The recovery of BD from samples used in storage tests remained above 77% when the samples were stored at ambient temperature and above 94% when the samples were stored at refrigerated temperature. These values were determined from regression lines which were calculated from the storage data. The recovery of the analyte from the collection device must be at least 75% following storage.

1.2.6. Precision (analytical method only)

The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.6 to 2 times the target concentration was 0.011.

1.2.7. Precision (overall procedure)

The precision at the 95% confidence level for the refrigerated temperature storage test

[1] The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operation parameters.

was ±12.7%. This value includes an additional ±5% for sampling error. The overall procedure must provide results at the target concentrations that are ±25% at the 95% confidence level.

1.2.8. Reproducibility

Samples collected from a controlled test atmosphere and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The average recovery was 97.2% and the standard deviation was 6.2%.

2. Sampling procedure

2.1. Apparatus

2.1.1. Samples are collected by use of a personal sampling pump that can be calibrated to within ±5% of the recommended 0.05 L/min sampling rate with the sampling tube in line.

2.1.2. Samples are collected with laboratory prepared sampling tubes. The sampling tube is constructed of silane-treated glass and is about 5-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The opening in the tapered end of the sampling tube is at least one-half the ID of the tube (2 mm). The other end of the sampling tube is open to its full 4-mm ID to facilitate packing of the tube. Both ends of the tube are fire-polished for safety. The tube is packed with 2 sections of pretreated charcoal which has been coated with TBC. The tube is packed with a 50-mg backup section, located nearest the tapered end, and with a 100-mg sampling section of charcoal. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two 7⁄32 inch OD plastic end caps. Instructions for the pretreatment and coating of the charcoal are presented in Section 4.1 of this method.

2.2. Reagents

None required.

2.3. Technique

2.3.1. Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2. Attach the sampling tube to the pump using a section of flexible plastic tubing such that the larger front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3. After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps. Wrap the tube lengthwise.

2.3.4. Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5. List any potential interferences on the sample data sheet.

2.3.6. The samples require no special shipping precautions under normal conditions. The samples should be refrigerated if they are to be exposed to higher than normal ambient temperatures. If the samples are to be stored before they are shipped to the laboratory, they should be kept in a freezer. The samples should be placed in a freezer upon receipt at the laboratory.

2.4. Breakthrough

(Breakthrough was defined as the relative amount of analyte found on the backup section of the tube in relation to the total amount of analyte collected on the sampling tube. Five-percent breakthrough occurred after sampling a test atmosphere containing 2.0 ppm BD for 90 min at 0.05 L/min. At the end of this time 4.5 L of air had been sampled and 20.1 µg of the analyte was collected. The relative humidity of the sampled air was 80% at 23 °C.)

Breakthrough studies have shown that the recommended sampling procedure can be used at air concentrations higher than the target concentration. The sampling time, however, should be reduced to 45 min if both the expected BD level and the relative humidity of the sampled air are high.

2.5. Desorption efficiency

The average desorption efficiency for BD from TBC coated charcoal over the range from 0.6 to 2 times the target concentration was 96.4%. The efficiency was essentially constant over the range studied.

2.6. Recommended air volume and sampling rate

2.6.1. The recommended air volume is 3L.

2.6.2. The recommended sampling rate is 0.05 L/min for 1 hour.

2.7. Interferences

There are no known interferences to the sampling method.

2.8. Safety precautions

2.8.1. Attach the sampling equipment to the worker in such a manner that it will not interfere with work performance or safety.

2.8.2. Follow all safety practices that apply to the work area being sampled.

3. Analytical procedure

3.1. Apparatus

3.1.1. A gas chromatograph (GC), equipped with a flame ionization detector (FID).[2]

3.1.2. A GC column capable of resolving the analytes from any interference.[3]

3.1.3. Vials, glass 2-mL with Teflon-lined caps.

3.1.4. Disposable Pasteur-type pipets, volumetric flasks, pipets and syringes for preparing samples and standards, making dilutions and performing injections.

3.2. Reagents

3.2.1. Carbon disulfide.[4]

The benzene contaminant that was present in the carbon disulfide was used as an internal standard (ISTD) in this evaluation.

3.2.2. Nitrogen, hydrogen and air, GC grade.

3.2.3. BD of known high purity.[5]

3.3. Standard preparation

3.3.1. Prepare standards by diluting known volumes of BD gas with carbon disulfide. This can be accomplished by injecting the appropriate volume of BD into the headspace above the 1-mL of carbon disulfide contained in sealed 2-mL vial. Shake the vial after the needle is removed from the septum.[6]

3.3.2. The mass of BD gas used to prepare standards can be determined by use of the following equations:

MV=(760/BP)(273+t)/(273)(22.41)

Where:

MV=ambient molar volume
BP=ambient barometric pressure
T=ambient temperature
µg/µL=54.09/MV
µg/standard=(µg/µL)(µL) BD used to prepare the standard

3.4. Sample preparation

3.4.1. Transfer the 100-mg section of the sampling tube to a 2-mL vial. Place the 50-mg section in a separate vial. If the glass wool plugs contain a significant amount of charcoal, place them with the appropriate sampling tube section.

3.4.2. Add 1-mL of carbon disulfide to each vial.

3.4.3. Seal the vials with Teflon-lined caps and then allow them to desorb for one hour. Shake the vials by hand vigorously several times during the desorption period.

3.4.4. If it is not possible to analyze the samples within 4 hours, separate the carbon disulfide from the charcoal, using a disposable Pasteur-type pipet, following the one hour. This separation will improve the stability of desorbed samples.

3.4.5. Save the used sampling tubes to be cleaned and repacked with fresh adsorbent.

3.5. Analysis

3.5.1. GC Conditions
Column temperature: 95 °C
Injector temperature: 180 °C
Detector temperature: 275 °C
Carrier gas flow rate: 30 mL/min
Injection volume: 0.80 µL
GC column: 20-ft x ⅛-in OD stainless steel GC column containing 20%
FFAP on 80/100 Chromabsorb W–AW–DMCS.

3.5.2. Chromatogram. See Section 4.2.

3.5.3. Use a suitable method, such as electronic or peak heights, to measure detector response.

[2] A Hewlett-Packard Model 5840A GC was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

[3] A 20-ft x ⅛-inch OD stainless steel GC column containing 20% FFAP on 80/100 mesh Chromabsorb W–AW–DMCS was used for this evaluation.

[4] Fisher Scientific Company A.C.S. Reagent Grade solvent was used in this evaluation.

[5] Matheson Gas Products, CP Grade 1,3-butadiene was used in this study.

[6] A standard containing 7.71 µg/mL (at ambient temperature and pressure) was prepared by diluting 4 µL of the gas with 1-mL of carbon disulfide.

3.5.4. Prepare a calibration curve using several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report the results in µg/mL.

3.5.5. Bracket sample concentrations with standards.

3.6. Interferences (analytical)

3.6.1. Any compound with the same general retention time as the analyte and which also gives a detector response is a potential interference. Possible interferences should be reported by the industrial hygienist to the laboratory with submitted samples.

3.6.2. GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3. A useful means of structure designation is GC/MS. It is recommended that this procedure be used to confirm samples whenever possible.

3.7. Calculations

3.7.1. Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2. The concentration, in ug/mL, for a particular sample is determined by comparing its detector response to the calibration curve. If any analyte is found on the backup section, this amount is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3. The BD air concentration can be expressed using the following equation:

$mg/m^3=(A)(B)/(C)(D)$

Where:

A=µg/mL from Section 3.7.2
B=volume
C=L of air sampled
D=efficiency

3.7.4. The following equation can be used to convert results in mg/m^3 to ppm:

$ppm=(mg/m^3)(24.46)/54.09$

Where:

mg/m^3=result from Section 3.7.3.
24.46=molar volume of an ideal gas at 760 mm Hg and 25°C.

3.8. Safety precautions (analytical)

3.8.1. Avoid skin contact and inhalation of all chemicals.

3.8.2. Restrict the use of all chemicals to a fume hood whenever possible.

3.8.3. Wear safety glasses and a lab coat in all laboratory areas.

4. Additional Information

4.1. A procedure to prepare specially cleaned charcoal coated with TBC

4.1.1. Apparatus.

4.1.1.1. Magnetic stirrer and stir bar.

4.1.1.2. Tube furnace capable of maintaining a temperature of 700°C and equipped with a quartz tube that can hold 30 g of charcoal.[8]

4.1.1.3. A means to purge nitrogen gas through the charcoal inside the quartz tube.

4.1.1.4. Water bath capable of maintaining a temperature of 60°C.

4.1.1.5. Miscellaneous laboratory equipment: One-liter vacuum flask, 1–L Erlenmeyer flask, 350–M1 Buchner funnel with a coarse fitted disc, 4-oz brown bottle, rubber stopper, Teflon tape etc.

4.1.2. Reagents

4.1.2.1. Phosphoric acid, 10% by weight, in water.[9]

4.1.2.2. 4-tert-Butylcatechol (TBC).[10]

4.1.2.3. Specially cleaned coconut shell charcoal, 20/40 mesh.[11]

4.1.2.4. Nitrogen gas, GC grade.

4.1.3. Procedure.

Weigh 30g of charcoal into a 500-mL Erlenmeyer flask. Add about 250 mL of 10% phosphoric acid to the flask and then swirl the mixture. Stir the mixture for 1 hour using a magnetic stirrer. Filter the mixture using a fitted Buchner funnel. Wash the charcoal several times with 250-mL portions of deionized water to remove all traces of the acid. Transfer the washed charcoal to the tube furnace quartz tube. Place the quartz tube in the furnace and then connect the nitrogen gas purge to the tube. Fire the charcoal to 700 °C. Maintain that temperature for at least 1 hour. After the charcoal has cooled to room temperature, transfer it to a tared beaker. Determine the weight of the charcoal and then add an amount of TBC which is 10% of the charcoal, by weight.

CAUTION-TBC is toxic and should only be handled in a fume hood while wearing gloves.

Carefully mix the contents of the beaker and then transfer the mixture to a 4-oz bottle. Stopper the bottle with a clean rubber stopper which has been wrapped with Teflon tape. Clamp the bottle in a water bath so that the water level is above the charcoal level. Gently heat the bath to 60 °C and then maintain that temperature for 1 hour. Cool the charcoal to room temperature and then transfer the coated charcoal to a suitable container.

The coated charcoal is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number.

4.2 Chromatograms

The chromatograms were obtained using the recommended analytical method. The chart speed was set at 1 cm/min for the first three min and then at 0.2 cm/min for the time remaining in the analysis.

The peak which elutes just before BD is a reaction product between an impurity on the charcoal and TBC. This peak is always present, but it is easily resolved from the analyte. The peak which elutes immediately before benzene is an oxidation product of TBC.

5. References

5.1. ''Current Intelligence Bulletin 41, 1,3-Butadiene'', U.S. Dept. of Health and Human Services, Public Health Service, Center for Disease Control, NIOSH.

5.2. ''NIOSH Manual of Analytical Methods'', 2nd ed; U.S. Dept. of Health Education and Welfare, National Institute for Occupational Safety and Health: Cincinnati, OH. 1977, Vol. 2, Method No. S91 DHEW (NIOSH) Publ. (US), No. 77–157–B.

5.3. Hawley, G.C., Ed. ''The Condensed Chemical Dictionary'', 8th ed.; Van Nostrand Rienhold Company: New York, 1971; 139.5.4. *Chem. Eng. News* (June 10, 1985), (63), 22–66.

Appendix E: Respirator Fit Testing Procedures (Mandatory)

A. The Employer Shall Conduct Fit Testing Using the Following Procedures

These provisions apply to both QLFT and QNFT

1. The test subject shall be allowed to pick the most comfortable respirator from a selection of respirators of various sizes and models.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those which obviously do not give a comfortable fit.

5. The more comfortable facepieces are noted; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose.
(b) Room for eye protection.
(c) Room to talk.
(d) Position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;
(b) Adequate strap tension, not overly tightened;

[8] A Lindberg Type 55035 Tube furnace was used in this evaluation.

[9] Baker Analyzed'' Reagent grade was diluted with water for use in this evaluation.

[10] The Aldrich Chemical Company 99% grade was used in this evaluation.

[11] Specially cleaned charcoal was obtained from Supelco, Inc. for use in this evaluation. The cleaning process used by Supelco is proprietary.

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks using procedures in Appendix A or those recommended by the respirator manufacturer. Before conducting the negative or positive pressure fit checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. Test Exercises. The test subject shall perform exercises, in the test environment, while wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with fit, in the manner described below:

(a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(b) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(f) Grimace. The test subject shall grimace by smiling or frowning. (Only for QNFT testing, not performed for QLFT)

(g) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) Normal breathing. Same as exercise (a). Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become uncomfortable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

(a) Odor threshold screening.

The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): ''The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.''

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl acetate fit test

(1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test

exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When the subject wearing the respirator passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self sealing bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section (a) above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 13 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

4. Irritant Fume Protocol

(a) The respirator to be tested shall be equipped with high-efficiency particulate air (HEPA) filters.

(b) No form of test enclosure or hood for the test subject shall be used.

(c) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties.

(d) Break both ends of a ventilation smoke tube containing stannic chloride. Attach one end of the smoke tube to an aspirator squeeze bulb and cover the other end with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(d) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his/her eyes closed while the test is performed.

(e) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject. He/She shall begin at least 12 inches from the facepiece and gradually move to within one inch, moving around the whole perimeter of the mask.

(f) The exercises identified in section I. A. 13 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(g) Each test subject passing the smoke test without evidence of a response (involuntary cough) shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he/she reacts to the smoke. Failure to evoke a response shall void the fit test.

(h) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable.

(1) Quantitative fit testing using a non-hazardous challenge aerosol (such as corn oil or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator.

(2) Quantitative fit testing using ambient aerosol as the challenge agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit.

(3) Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean, maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated aerosol quantitative fit testing protocol

Apparatus

(a) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil or sodium chloride) or gases or vapors as test aerosols shall be used for quantitative fit testing.

(b) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(c) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate air (HEPA) filter supplied by the same manufacturer in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(d) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers which integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(e) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process based upon the length of the exposure and the exposure limit duration.

(f) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least ¼ inch.

(g) The test set up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(h) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent constant to within a 10 percent variation for the duration of the test.

(I) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(j) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(k) The exhaust flow from the test chamber shall pass through a high-efficiency filter before release.

(l) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(m) The limitations of instrument detection shall be taken into account when determining the fit factor.

(n) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

4. Procedural Requirements

(a) When performing the initial positive or negative pressure fit check the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these fit checks.

(b) The use of an abbreviated screening QLFT test is optional and may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to use to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(c) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(d) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(e) A stable challenge concentration shall be obtained prior to the actual start of testing.

(f) Respirator restraining straps shall not be over tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use.

(g) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(I) Calculation of fit factors.

(1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(2) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e. 8 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers which calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method. .

(ii) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(iii) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(iv) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_7 + 1/ff_8}$$

Where ff_1, ff_2, ff_3, etc. are the fit factors for exercise 1,2,3, etc. [Results of the grimace exercise (7) are not used in this calculation.]

(j) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(k) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced if there is any indication of breakthrough by a test agent.

2. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing