PLAINTIFF'S
EXHIBIT
GF-2202

BEFORE THE

UNITED STATES DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

WASHINGTON, D.C. 20210

In Re: The Proposed Regulations of the United States Occupational Safety and Health Administration for the Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk To Humans	OSHA Docket No. 090

Statement
of
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April 4, 1978

This Statement Was Requested
By The United States Occupational
Safety and Health Administration

GAF 15821

A commentary on the US Department of Labor's Occupational Safety and Health Administration Proposal published, October 4, 1977, to adopt regulations concerning, "Identification, Classfication and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk."

by

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I am a Registered Professional Engineer and am Certified in the Comprehensive Practice of Industrial Hygiene. I have been employed in industrial hygiene for 22 years by both private industry and governmental agencies. For over half that period I was Chief Industrial Hygiene Engineer and Director of Occupational Health for the State of Oregon. Presently I am employed by the Los Alamos Scientific Laboratory (LASL) as Leader, Respirator Research and Development Section.

My commentary is made at the request of the United States Department of Labor (DOL) as a private consultant and the views I express do not necessarily represent those of the LASL.

INTRODUCTION

According to the preamble of this document, there should be no exposure to carcinogen a goal not always possible to achieve. Since a basic premise of this document is that risk increases as the intensity of exposure rises withoutaa no effect threshold, it is necessary to keep the exposure level to the lowest feasible concentration.

My concern is the use of respirators for protection from carcinogens. It is stated in this document that respirators are a secondary means of exposure control. They are to be used only while engineering controls are being installed; to supplement engineering controls when they are not adequate; and for maintenance and repair operations. Their use is restricted because of the effort necessary to be expended by both employer and employee to insure that the protection sought is received. It is necessary for the employer to analyze the exposure, choose the proper respirator, train the employee, insure that the respirator is used correctly on the job, and be watchful that the conditions of use do not change significantly. The employee must continue in his everyday assignments while wearing a device which affects his ease of breathing, impairs his vision and reduces his efficiency.

It is important to emphasize that respirators generally remain the secondary means of control for chemical carcinogens and toxic chemicals generally. Respirators are not as satisfactory a method of control as engineering and work practice controls for most employees. However it must be remembered that for some segments of the workforce, especially maintenance employees, engineering controls may not be effective and respirators will have to be the primary means of protection.

For many types of respirators face fit is crucial to their effective use. It is difficult to get a good face fit because of the variation in the shape of the human face. Also the shape changes when people make facial movements such as when talking, smiling or frowning. Facial hair interferes with proper fit. Presently face fit also presents a major problem for women. Most respirators currently in use have been designed to fit the male facial configuration.

Respirators also may create safety problems. They make communications difficult, reduce vision and sometimes reduce employee efficiency. Some respirators make hearing difficult and all make speach more difficult.

Where communications are important, special microphones inside the respirators need to be considered. Persons wearing glasses may also have difficulties with both half-face and full-face respirators. If prescription glasses are needed, then special lenses must be installed in full face piece respirators. Most respirators are uncomfortable and facial irritation can be associated with their use.

To overcome these and other difficulties associated with respirator use, requires an excellent respirator program. Such a program places substantial burdens on both employers and employees. If just one element of the program is neglected, the protection given by the respirators, will be substantially reduced.

A first class respirator program is neither inexpensive nor easy to carryout. Less than an excellent program, or a respirator program which is written but not carried out will not provide adequate protection to the employees. The respirators will not be worn because they are unconfortable, of it worn they will leak because they will not have been properly fitted or maintained.

It is also advantageous for the best health protection, to utilize engineering controls to the lowest level feasible even if supplementary respirator use is needed for some employees, to provide appropriate exposure reductions. The engineering controls will reduce the number of employees on respirators. The lower exposure levels resulting from the engineering controls will permit the use of simple less confining and easier to use respirators. Finally, lower background levels will reduce the potential exposure for those employees who have not been properly fitted to their respirator or who do not wear them conscientiously.

A litany of the problems of respirator use as a means of control does not eliminate their use. Supplementing engineering controls and maintenance operations may require the use of respirators for an indefinite period in order to give needed health protection. Properly selected and fitted respirators, backed up with an excellent respirator program can reduce employee exposures to carcinogens to very low levels indeed. It should be remembered that the protection afforded to employees by engineering controls may end with the control operator or assembly line employee. The maintenance staff which works different hours from those of the production employees can be exposed to hazardous concentration of toxic materials during their routine maintenance operations and may require respirators. It is important that precautions in the use of respirators be carefully delineated.

RESPIRATOR SELECTION

Proposed Section 6(c) Model Standard for a Category I Toxic Substance as outlined in 1990.150 (Emergency Tempoary Standard) and 1990.160 (Final Standard) requires that the Permissible Exposure Limit (PEL) be set at the lowest feasible level see 1910.0000(c). 1910.0000(h) which permits the use of respirators also specifies that the employee's exposure must be reduced within the PEL. In addition, the respirator program must meet the requirements of 1910.134 and states that a respirator selection table is to be provided.

Respirators under 1910.150, the emergency standard, may be used more liberally than is the case for the permanent standard, 1910.160. Immediate respirator use would be sanctioned during the period of determing and installing engineering controls. When the permanent standard is in effect respirators may be used only during the installation of engineering controls; during maintenance and to supplement engineering controls in case they are not adequate to reduce the contaminant concentration below the PEL. There should be no difference in the respirators provided for either category.

A respirator selection table is required to be published with each standard. Considering the statement that a no effect threshold does not exist for carcinogenic materials, it is prudent that the efficiency of the respirator used be known. The ratio of the PEL to the actual contaminant concentration will influence the choice of respirator. Respirator efficiency is measured by the respirator Protection Factor (PF) and defined as:

$$PF = \frac{\text{Contaminant concentration outside repirator}}{\text{Contaminant concentration inside respirator}}$$

A PF of 50 indicates that the leakage inside the respirator is 2% of the outside concentration. A PF of 100 indicates that the leakage inside the respirator is 1% of the outside concentration. This concept has been widely publicized by E.C. Hyatt in his publication "Respirator Protection Factors." Mr. Hyatt quantitatively assessed the efficiency of various types of respirators, determined their effectiveness, and summarized the results. His summary table from the publication is shown in Table I. [1]

TABLE I
RESPIRATOR PROTECTION FACTORS[a]

Type Respirator	Facepiece[b] Pressure	Protection Factor
I. Air-Purifying		
A. Particulate[c] removing		
Single-use,[d] dust[e]	-	5
Quarter-mask, dust[f]	-	5
Half-mask, dust[f]	-	10
Half- or Quarter-mask, fume[g]	-	10
Half- or Quarter-mask, High-Efficiency[h]	-	10
Full-Facepiece, High-Efficiency	-	50
Powered, High-Efficiency, all enclosures	+	1000
Powered, dust or fume, all enclosures	+	X[i]
B. Gas-and Vapor-Removing[j]		
Half-Mask	-	10
Full-Facepiece	-	50
II. Atmosphere-Supplying		
A. Supplied-Air		
Demand, Half-mask	-	10
Demand, Full-Facepiece	-	50
Hose Mask Without Blower, Full-Facepiece	-	50
Pressure-Demand, Half-Mask[k]	+	1000
Pressure-Demand, Full-Facepiece[l]	+	2000
Hose Mask With Blower, Full-Facepiece	-	50
Continuous-Flow, Half-Mask[k]	+	1000
Continuous-Flow, Full-Facepiece[l]	+	2000
Continuous-Flow, Hood, Helmet, or Suit[m]	+	2000
B. Self-Contained Breathing Apparatus (SCBA)		
Open-Circuit, Demand, Full-Facepiece	-	50
Open-Circuit, Pressure-demand Full-Facepiece	+	10 000[n]
Closed-Circuit, Oxygen Tank-type, Full-Facepiece	-	50
III. Combination Respirator		
A. Any combination of air-purifying and atmosphere-supplying respirator.	Use minimum protection factor listed above for type of mode of operation.	
B. Any combination of supplied-air respirator and an SCBA.		

Exception: Combination supplied-air respirators, in pressure-demand or other positive pressure mode, with an auxiliary self-contained air supply, and a full facepiece, should use the PF for pressure-demand SCBA.

Note: Table I is not to be reproduced without the accompanying footnotes.

Footnotes for Respirator Protection Factor Table I

[a]The overall protection afforded by a given respirator design (and mode of operation) may be defined in terms of its protection factor (PF). The PF is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of contaminant in the ambient atmosphere to that inside the enclosure (usually inside the facepiece) under conditions of use. Respirators should be selected so that the concentration inhaled by the wearer will not exceed the appropriate limit. The recommended respirator PF's are selection and use guides, and should only be used when the employer has established a minimal acceptable respirator program as defined in Section 3 of the ANSI Z88.2-1969 Standard.

[b]In addition to facepieces, this includes any type of enclosure or covering of the wearer's breathing zone, such as supplied-air hoods, helmets or suits.

[c]Includes dusts, mists, and fumes only. Does not apply when gases or vapors are absorbed on particulates and may be volatilized or for particulates volatile at room temperature. Example: Coke oven emissions.

[d]Any single-use dust respirator (with or without valve) not specifically tested against a specified contaminant.

[e]Single-use dust respirators have been tested against asbestos and cotton dust and could be assigned a PF of 10 for these particulates.

[f]Dust filter refers to a dust respirator approved by the silica dust test and includes all types of media, that is, both nondegradable mechanical type media and degradable resin-impregnated wool felt or combination wool-synthetic felt media.

[g]Fume filter refers to a fume respirator approved by the lead fume test. All types of media are included.

[h]High-efficiency filter refers to a high-efficiency particulate respirator. The filter must be at least 99.97% efficiency against 0.3-μm DOP to be approved.

[i]To be assigned, based on dust or fume filter efficiency for specific contaminant.

[j]For gases and vapors, a PF should only be assigned when published test data indicate the cartridge or canister has adequate ambient efficiency and service life for a specific gas or vapor. In addition, the PF should not be applied in gas or vapor concentrations that are: (1) immediately dangerous to life, (2) above the lower explosive limit, and (3) cause eye irritation when using a half-mask.

[k]A positive pressure supplied-air respirator equipped with a half-mask facepiece may not be as stable on the face as a full facepiece. Therefore, the PF recommended is half that for a similar device equipped with a full facepiece.

[l]A positive pressure supplied-air respirator equipped with a full facepiece provides eye protection but is not approved for use in atmospheres immediately dangerous to life. It is recognized that the facepiece leakage, when a positive pressure is maintained, should be the same as an SCBA operated in the positive pressure mode. However, to emphasize that it basically is not for emergency use, the PF is limited to 2000.

[m]The design of the supplied-air hood, suit, or helmet (with a minimum of 170 liters/min of air) may determine its overall efficiency and protection. For example, when working with the arms over the head, some hoods draw the contaminant into the usual breathing zone. This may be overcome by wearing a short hood under a coat or overalls. Other limitations specified by the approval agency must be considered before using in certain types of atmospheres.

[n]The SCBA operated in the positive pressure mode has been tested on a selected 31-man panel and the facepiece leakage recorded as <0.01% penetration. Therefore, a PF of 10 000+ is recommended. At this time, the lower limit of detection 0.01% does not warrant listing a higher number. A positive pressure SCBA for an unknown concentration is recommended. This is consistent with the 10 000+ that is listed. It is essential to have an emergency device for use in unknown concentrations. A combination supplied-air respirator in pressure-demand or other positive pressure mode, with auxiliary self-contained air supply, is also recommended for use in unknown concentrations of contaminants immediately dangerous to life. Other limitations, such as skin absorption of HCN or tritium, must be considered.

The Respirator Selection Table, if OSHA follows its past practice, will be constructed using the NIOSH/OSHA Respirator Decision Logic which incorporates the Protection Factor (PF) concept and table proposed by Hyatt. Since the publication of the PF document in 1975, further research in the area of respirator PFs has been carried on, principally at LASL. A review of this later data indicates a need to revise some aspects of Mr. Hyatt's PF Table. For example, some of Hyatt's recommendations were analogies based on test data for devices which were assumed to act in a similar way. Hyatt stressed that when additional data becomes available his PF table should be modified.

A summary of the modifications proposed are given in Table II.

Table II

PROTECTION FACTORS FOR RESPIRATORS

For Routine Use

	Respirator Fit Testing	
Air Purifying Respirators	Qualitative	Quantitative
For Particulates		
Half Mask Use High Efficiency Filters only	10	50
Full Facepiece Use High Efficienty Filters only	50	500
For Gases anf Vapors Lifetime of the cartridge or canister must be specified.		
Half Mask	10	50
Full Facepiece	50	500
Powered Air Purifying	2000	
Atmosphere-Supplying Respirators		
Continuous Flow, Half or Full Facepiece with belt mounted regulator valve, minimum air flow of 4 CFM	1000	
Continuous Flow, Hood or Helmet with belt mounted regulator valve, minimum air flow of 6 CFM	1000	
Pressure-demand, Half or Full Facepiece	2000	
Self-Contained Breathing Apparatus Pressure-Demand Mode	10000	

A comparison of Tables I and II reveals several differences:

1. All Hyatt's PF data was obtained using male subjects. Later PF test data from LASL using both female and male subjects reveals some differences from Hyatt's recommendations. The results are in reasonable agreement with Hyatts PFs for larger faces (predominately male test subjects). Lower PFs were obtained for the smaller faces (predominately female test subjects). Careful fitting is required to enable women to achieve the PFs given.

2. Table II specifies only high efficiency filters for air-purifying respirators. Some dust filters use a resin felt which degrades when exposed the high temperature and/or heat. Considering the need for assured protection from carcinogens, the use of such dust filters is not recommended.

3. A serious problem with the use of odor as a warning property is the dependance upon the human nose, which is highly variable in its ability to detect odors. A brief exposure to a high concentration of some materials may anesthetize the olfactory bulbs for a period of time. This reduces the chances of detecting the concentration coming through the cartrida. It is recommended that finite use times be established for all serption cartridges and canisters instead of relying on the sense of small as the end of life indicator.

4. Under Atmosphere-Supplying Respirators the Demand Mode category has been omitted. Recent data published by Hack[2] indicates that the protection provided by these devices is poor. Since both Contineous-Flow and Pressure-Demand Respirators are available as replacements, the omission of these devices should not be missed.

5. The PFs for Continuous-Flow Respirators, both tight fitting and loose fitting has been reduced from 2000 to 1000. Data published by Hack[2] and Douglas[3] indicates the need for this reduction.

6. The PF for Atmosphere-Supplying Pressure-Demand Half Mask Respirator has been raised from 1000 to 2000 based on Hack's[3] data.

7. The category of Atmosphere-Supplying Continuous-Flow Suit has been omitted. The present design of two piece suits provides poor protection under common conditions of use. Such a suit should not be used without prior quantatitive fit testing.

8. The category of Demand Mode Self Contained Breathing Apparatus (SCBA) has been omitted. Based on the data obtained by Hack[3] when testing Atmosphere-Supplying Respirators, the poor PF provided by Demand Mode SCBA should not be high enough to warrant their use.

9. A column designating PFs for Half and Full Facepiece Respirators when quantitative fit testing is carried out has been added. They are identical with the PFs advocated by Hyatt for quantitative fit testing. A procedure to be followed for quantitative fit testing is now being prepared by Dr. John O'Neill, OSHA.

The NIOSH/OSHA Respirator Decision Logic provides a good basis for devising respirator selection tables for specific chemicals. The above suggestions will improve that process. I would recommend, if it has not already been done so, that the Decision Logic be made part of the record of this hearing.

Respirator Fitting

Changes affecting the respirator selection have been suggested above. After the respirator has been selected, 1910.134 specifies a series of steps to be taken to insure that the respirator user is familiar with the respirator and that it will be used properly. The series of steps is sparsely outlined and needs some additions to insure that the employee who is to be exposed to carcinogen will have the protection necessary.

1910.134 (e)(5) specifies: "Training shall provide the men an opportunity to handle the respirator, have it fitted properly, test its face-piece-to-face seal, wear it in normal air for a long familiarity period, and finally to wear it in a test atmosphere."

Of importance to the protection provided the user is the test of the respirator faceseal. PF data refered to previously shows that smaller faces, primarily female, have a more difficult time obtaining a good seal than do larger faces. The qualitative tests usually prescribe for this purpose is an isoamyl acetate or irritant fume test whidh consists of

holding a isoamyl acetate saturated cloth close to the face-seal or blowing irritant fume near the faceseal. The importance of obtaining protection when exposed to carcinogen makes it necessary to improve the isoamyl acetate test that is used. This test should be done only after the subjects ability to detect isoamyl acetate at a level of 2 parts per million (ppm) has been determined. The isoamyl acetate test should be done in a hood or room into which sufficient isoamyl acetate to produce a concentration of 100 ppm. A series of exercises which stretch the head and neck up, down and sideways should be performed while in the isoamyl atmosphere. The fit test is not satisfactory if the subject detects isoamyl acetate.

Respirator Programs

Respirator programs require a continual committment in management time and money to be successful. The necessity of cleaning and maintaining respirators requires an estimated addition of 2 employees for every 100 employees using respirators. This does not include the manpower necessary to insure that the user is initially trained and fitted with a respirator. Additional demands upon management include the necessity of frequent review of the workplace.

If atmosphere-supplying respirators are used, monitoring the air supplied to the user is necessary. As the PEL decreases the problems arising from contamination of the air will be necessary prior to delivery to the user of the air-line respirator. This can be a costly process.

The obligation of supplying, fitting, maintaining and cleaning respirators should be on the employer. The average employee does not have the training or facilities to properly carryout these tasks. To provide guidance on these matters and a good respirator program generally, OSHA should consider publishing model programs for employers of various sizes.

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Curriculum Vitae

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