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July 21, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C-34
4676 Columbia Parkway
Cincinnati, Ohio 45226

In Re:

Notice of Proposed Rulemaking,
Respiratory Protective Devices,
Tuesday May 24, 1994, 59 FR
26850

Dear Sir or Madam:

Organization Resources Counselors Inc., (ORC) appreciates the opportunity to submit comments on the National Institute for Occupational Safety and Health's Notice of Proposed Rulemaking on Respiratory Protective Devices.

ORC sponsors an Occupational Safety and Health Group which comprises more than 120 companies from a wide range of industries and with employment size ranging from medium to large. All of these companies have a strong commitment to employee safety and health. The members of this group work with ORC on OSHA rulemaking activities and other aspects of employee safety and health. This statement, and the comments which follow, are solely the responsibility of ORC and may differ from comments submitted by member companies.

ORC supports NIOSH's efforts to complete the revision of 30 CFR Part 11 and assure that the approval process selects respirators that are both effective and safe. As NIOSH undertakes this project, it should focus its attention on the ultimate end users of this product. The only purpose of a respirator is to protect its wearer against exposure to harmful or toxic substances. If it fails to supply that protection for any reason, it fails completely, as a unit, not as individual parts. To be effective, a respirator must fit properly and comfortably, it must

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supply appropriate levels of protection, and it must be affordable. If any one of these requirements is not met, the usability and effectiveness of the complete unit is sharply degraded.

It is crucial that respirators used to protect employees against exposure to potentially toxic substances be capable of operational performance that at a minimum, meets NIOSH requirements. ORC supports NIOSH's efforts to assure that all respirators available to employers meet certain minimum standards of performance, and looks forward to working with NIOSH on the development of those standards.

Sincerely,

Donell K. Mattheis
for

Richard F. Boggs, Ph.D.
Vice President

7-21-94

ORGANIZATION RESOURCES COUNSELORS, INC.
COMMENTS ON THE NIOSH 42 CFR PART 84
PROPOSED RULEMAKING ON
RESPIRATORY PROTECTIVE DEVICES
MAY 24, 1994, 59 FR, 26850

INTRODUCTION

In this first module, NIOSH has proposed many far reaching changes that would sharply increase the efficiency of particulate filters. Better particulate filters have long been needed, and ORC welcomes and commends NIOSH's proposal for improved filters. A respirator is more than a filter however, and the filter should not receive disproportionate attention. NIOSH should focus its attention on the over-all functional effectiveness of a complete respirator; the whole is greater than the sum of its parts.

NIOSH has stated that one of its goals for an improved respirator approval process is that it, "...Produce significant improvements in the level of protection provided to wearers of respirators." One of the best ways to achieve this goal is to require that all respirators approved by NIOSH be capable of being fit-tested on the wearer, and that the wearer be able to perform a fit-check each time the respirator is donned. A respirator that cannot be fit-checked each time it is worn is significantly less likely to achieve the level of protection expected by the user.

Improved communications between users, manufacturers and NIOSH must be a key element in the development of more effective respirators. Respirator manufacturers and NIOSH must both make renewed efforts to determine the needs of the user community, and cooperate to speed the development of respiratory protective equipment that is both more effective and economical to purchase. It is evident that NIOSH understands this, and its efforts to facilitate communications with both the user community and respirator manufacturers are to be commended!

PROFESSIONAL JUDGEMENT

For many employers, respirators provide an important means to protect employees against exposures to toxic substances, especially where effective engineering controls are not feasible. To supply effective protection however, the correct equipment must be selected and used properly. To accomplish this end, employers must have access to accurate, up-to-date information on the performance of respirators meeting their needs. If an inadequate respirator is selected for a particular job, it doesn't matter how "good" the filter is, it may not adequately protect the employee.

Some employers lack information about the nature of the hazards in their workplaces, and respirators may be purchased more on their price than their ability to protect their wearers.

NIOSH has attempted to remedy this problem by simplifying the selection of respirators, and upgrading the protection offered by even the least effective. This is important, but there is no substitute for knowledge and judgement in the selection of an appropriate respirator.

ORC strongly recommends that knowledgeable, qualified health and safety professionals be actively involved in the selection of appropriate respirators. ORC would like to suggest that NIOSH work with the American Industrial Hygiene Association and the American Society of Safety Engineers and other associations to establish education and training programs targeting employers who may need assistance in dealing with a variety of workplace hazards.

NEW TECHNOLOGY

For too many years the constraints of 30 CFR Part 11 have discouraged research on new and improved respirators. As NIOSH undertakes the revision of its testing and approval requirements, it should make every effort to encourage substantive research into all aspects of respiratory protection technology. Our growing capabilities in materials science should make possible the development of respirators that fit better, have better filters, make use of sophisticated end of cartridge life warnings, and are affordable.

TIME ALLOWED FOR COMMENTS

ORC recognizes that NIOSH accelerated the time schedule for hearings and comments to assure the earliest possible availability of improved respirators for the medical community. However, ORC suggests that in the future a minimum of 60-90 days be allowed for the development of comments and to prepare for hearings.

SCHEDULING OF PUBLIC HEARINGS

NIOSH's decision to schedule the public hearing for the first module prior to the final due date for comments is to be commended! For those of us in the user community who are not intimately familiar with all of the major issues of concern in the testing and approval process, it was a valuable educational session. The opportunity to hear representatives of all interested parties discuss key issues was extremely useful and should result in better informed comments. For the remaining six modules, NIOSH should continue to schedule public hearings prior to the due date for comments.



ORDER IN WHICH MODULES ARE TO BE CONSIDERED

In the May 24, 1994 Notice of Proposed Rulemaking (59 FR 26850) NIOSH indicated that the next module to be considered would be Assigned Protection Factors (APF). ORC would like to suggest that the third module should be the Simulated Workplace Protection Factor Test, rather than Administrative Programs.

The relationship, for a given piece of equipment, between the APF for its class, and the PF factor consistently achievable in simulated workplace conditions is important. Placing the two modules in close proximity would serve to focus needed attention on that relationship. ORC believes that there should be a closer relationship between the protection factor that is assigned a particular class of respirator, and the proven capability of that piece of equipment to reliably provide a given level of protection under worst case conditions in the workplace.

REALISTIC TESTING

This module is directed toward modifying the procedures used to test the performance of respirator filters, and proposes significant increases in the levels of performance required for all classes of air-purifying respirators. This is an important step forward for all respirator users, but an effective filter does not guarantee an effective respirator. In the last analysis, the only tests that matter to the user are those that evaluate the performance of the complete respirator under conditions which accurately simulate workplace conditions.

NIOSH should require that every respirator submitted for approval be quantitatively tested in a simulated workplace environment, against the most penetrating particle, "hot" dioctyl phthalate (DOP) while performing realistic work under conditions of elevated heat and humidity for 2-3 hours continuously. Equipment that fails to consistently achieve at least the minimum protection factor for which it is rated, should not receive approval.(1)

TESTING FILTERS WITH THE MOST PENETRATING PARTICLE

NIOSH in its proposal for 42 CFR Part 84, stated that one of its goals with this rulemaking is to "enable classification of filters on their ability to inhibit penetration of particulates of the most penetrating size." The current respirator certification, 30 CFR 11, requires the use of mono-dispersed, thermally generated dioctyl phthalate (DOP) as the test agent. NIOSH's proposed 42 CFR part 84 however, requires a poly-dispersed and neutralized, cold-nebulized, DOP challenge aerosol. During the June 14-15, 1994 public meeting, testimony was presented by several speakers showing that cold-nebulized DOP was significantly less effective at penetrating filters depending on

electrostatic or electret media. During their testimony, representatives from Mine Safety Appliances Company, presented graphs showing that "hot" DOP was significantly more penetrating against electrostatic Type A, Type B and Type C filters. Since electrostatic media is used in many of the most popular respirators, ORC believes that in the interest of testing filter media with the most penetrating particle, NIOSH should continue to require that all such testing be performed using mono-dispersed, "hot" DOP.

TESTING ELECTROSTATIC FILTER MEDIA

A number of studies have shown that many common industrial aerosols are capable of neutralizing the charges built up on the electret type filters.(2),(4), Once the filter is neutralized, there is a significant reduction in filter efficiency. Examples of agents that have been demonstrated to neutralize the charge on electrostatic filters include, but are not limited to, silkstone, coal dust, foundry burning fume, carbon brick dust, lead smelting fume, lead battery dust, and ammonium chloride.(3)

As part of its certification testing, NIOSH should consider including tests on electrostatic media in a discharged state as part of realistic worst-case testing. Many respirator users are unaware of the potential for a respirator, that depends on an electrostatic filter, to lose an unknown but potentially significant, part of its filtration efficiency.

ISOAMYL ACETATE TESTING

Section 84.181, "Isoamyl Acetate Tightness Test; Particulate Respirators With Filters Not Intended To Be Replaced" requires that filtering facepiece respirators pass an isoamyl acetate (IAA) test. To conduct this test, the respirator must be extensively modified so that it is substantially different from similarly designated respirators sold to the public. Because of the extensive modifications required, the respirator actually used in workplaces is not tested.

Since the purpose of the pressure-tightness fit check is only to assess the clarity of the manufacturer's user instructions, and since it is not used to assess the protection offered by a particular respirator, ORC recommends that the isoamyl acetate tightness test be eliminated.

SOLID OR LIQUID FILTER DESIGNATION

In Section 84.170 "Particulate Respirators; Description" NIOSH has proposed that, for each of the three types of respirator listed, "The respirator could be designed to remove contaminants,

either solid or both liquid and solid, from the wearer's breathing air." In practice this means there would be six classes of respirators, not just three, and also a high probability that some users would employ a solid only respirator against liquid aerosols.

In the interests of simplicity, and safe practice, ORC suggests that NIOSH require that all filters approved be capable of protecting against both liquids and solids. An additional benefit from approving only liquid and solid filters would be the cost savings to manufacturers who would not be required to purchase the very expensive equipment required to generate the sodium chloride aerosol mandated for testing filter leakage of solid particulate aerosols, but could continue to use "hot" DOP.

FILTER CLASSIFICATIONS

ORC suggests that NIOSH consider changing the requirements of the three classes of filters to add a fourth classification, 90% efficiency (L & S). This would give us: (A) with a filter efficiency of 99.97% (L & S), (B) with a filter efficiency of 99% (L & S), (C) with a filter efficiency of 95% (L & S), and (D) 90% (L & S). This change in classification would give a meaningful, practical differentiation between the four classes.

The differences between NIOSH's currently proposed Type (A) filters, 99.97% efficiency, and Type (B) filters, 99.0% efficiency, are small enough to make the practical utility of NIOSH's proposed Type (B) filters somewhat marginal, but it does allow a non-HEPA filter respirator to be used with a full facepiece and achieve an APF of 50-100, which is desirable. ORC believes that it is important to have low cost respirators available to users where HEPA-level protection is not needed.

The efficiency requirements of NIOSH's proposed Type (C) filter (95%) will give the respirator user community, particularly the health care community, a piece of equipment that it needs, and will give users who need something better than 90% efficiency, a choice other than the 99.97% efficient Type (A), or 99% efficient Type (B), both of which will have a significant pressure drop.

Adding the Type (D) filter, at 90% efficiency when tested against the most penetrating particle, will give users a better filter than many currently existing, while not increasing their costs to undesirable levels. Respirator manufacturers may be able to use currently available materials for production of this type of filter. A 90% efficient Type (D) respirator would also be valuable in situations where a respirator is not mandatory, as exposure limits are not exceeded, but where its use is desirable to avoid unnecessary exposure and for comfort.

ORC believes that if a 95% efficient Type (C) is the least efficient filter, it will significantly increase the costs for many users of respirators. This cost increase would be especially hard on users of single-use disposables, where most of the facepiece is constructed of the filtering media.

Increased costs may also lead to reduced use of respirators where they are desirable but not mandatory, and could lead to respirators being used for longer periods of time rather than being discarded when they have become soiled with sweat and dirt. The improved filter material necessary to achieve 95% efficiency will mean increased resistance to breathing, increased leakage around the face seal, decreased worker acceptance, and probably less use.

As filtering facepiece respirators increase in price to where they are no longer cost efficient, it will make sense to switch to reusable respirators which require greatly increased levels of care, cleaning, maintenance and storage. All of this will sharply increase the cost of using respirators, leading to a probable decreased use of respiratory protection where it is not mandatory.

LABELING FILTERS AND RESPIRATORS

Section 84.180, "Particulate Respirators; Filter Type Identification" proposes a new classification system for identifying the efficiency of filters for particulate respirators. NIOSH has indicated that information it proposes to include on the filter label "...would be necessary to allow the user to make an informed decision on selecting the appropriate respiratory protection."

ORC agrees with NIOSH that it is important to provide users with information on the performance of a piece of respiratory protective equipment. ORC would like to suggest that in addition to requiring that the filter assembly be labeled with the efficiency it is capable of, that the complete respirator be labeled with the protection factor it achieved in realistic testing. APFs should be established in a closer range than currently exists. For example:

5, 10, 25, 50, 100, 250, 500, 1000, 2500, 5000, 10,000,
>10,000

Devices which exceed the APF in NIOSH certification tests would be assigned an APF which is statistically justifiable. For example: A half-facepiece Type (B) 99% efficient filter media which performs well under simulated workplace testing could receive an APF of 50, while the same filter media in a worse performing facepiece could receive an APF of 10. Certain minimum

criteria could be established to insure that inferior equipment is kept out of the workplace, and to encourage better devices and innovation. For instance, minimum APFs of 5 could be established for single-use devices, 10 for half-facepieces, and 50 for full facepieces.

Higher APFs would be allowed for better devices in a class all the way to the IDLH for a contaminant. A high-performing half-facepiece with a Type (A) filter might get an APF of 1000. This would allow better performing respirators a significant distinction from less efficient devices, and encourage the manufacturers of superior equipment. Such information would allow a user to select a respirator with a significantly greater margin of safety.

42 CFR part 84, Subpart J, Table 8.-"Air-Supply-Line Requirements and Tests" (p. 26881 in NIOSH's NPR) lists Type A, Type B, and Type C respirators, but these are supplied air respirators! To avoid confusion with other similarly labeled, currently available respiratory protective equipment, NIOSH should devise a filter labeling system different from its proposed (A),(B),(C).

FACEPIECE TESTING

Section 84.205 "Facepiece test; minimum requirements." requires that a complete chemical cartridge respirator be fitted to the faces of persons having varying facial shapes and sizes. Given the increasing diversity of the modern workplace, ORC believes that NIOSH should assure that the panel of individual testers includes both males and females from diverse ethnic backgrounds.

There should however, be no need for a separate facepiece test. This test could be combined with simulated workplace testing, using a diverse test panel as here suggested. If an individual must wear a respirator to protect against exposure to potentially toxic substances, it is imperative that the respirator be properly fitted, that it be reasonably comfortable, and that the wearer have confidence that it will supply the necessary protection. The growing diversity of the workforce found in modern workplaces makes it increasingly important that respirator facepieces be available that are capable of fitting all individuals who may be required to wear them.

FOOTNOTES

(1) B.J. Skaggs, J.M. Loibl, K.D. Carter, E.C. Hyatt: *Effects of Temperature and Humidity on Respirator Fit Under Simulated Work Conditions*, Los Alamos National Laboratory, NUREG/CR-5090, LA-11236, (1988).

(2) C.C. Chen, M. Lehtimaki, and K. Willeke: *Loading and Filtration Characteristics of Filtering Facepieces*. Am. Ind. Hyg. Assoc. J. 54:51-60 (1993).

(3) D.B. Blackford, G.J. Bostock, R.C. Brown, R. Loxley & D. Wake: *Alterations in the Performance of Electrostatic Filters Caused by Exposures to Aerosols*. Proc. fourth World Filtration Congress, Ostende, Belgium: 1986. pp. 7.27-7.33.

(4) R.C. Brown, D. Wake, R. Gray, D.B. Blackford and G.J. Bostock. *Effect Of Industrial Aerosols On The Performance Of Electrically Charged Filter Material*. Ann. Occup. Hyg., Vol. 32, No. 3. pp 271-294, (1988).