



18 DEC 1987

Dr. J. Donald Millar  
Director  
National Institute for  
Occupational Safety and Health  
1600 Clifton Road, N.E.  
Atlanta, Georgia 30333

Dear Dr. Millar:

In response to the notice published in the Federal Register (52 FR 32401) on August 27, 1987, proposing a "Revision of Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices used in Mines and Mining" (42 CFR part 84), the attached comments are submitted by the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA).

The comments represent serious concerns which OSHA and MSHA share regarding key provisions of the proposed regulation which are perceived to have potentially adverse effects on the regulatory programs of the two agencies and, in some cases, on the health of workers affected. Therefore, we will appreciate your giving the issues raised your most serious consideration.

Sincerely,

A handwritten signature in blue ink, appearing to read "David C. O'Neal".

David C. O'Neal  
Deputy Assistant Secretary for  
Mine Safety and Health

A handwritten signature in blue ink, appearing to read "John A. Pendergrass".

John A. Pendergrass  
Assistant Secretary  
Occupational Safety and Health

cc: NIOSH Docket Office  
Mail Stop E-23  
1600 Clifton Road, N.E.  
Atlanta, Georgia 30333

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Comments from the Department of Labor  
on the proposed NIOSH 42 CFR Part 84

The proposed regulation for certification of respirators represents a serious effort to approach a very difficult problem. However, we believe that the proposal in its present form presents difficulties which would make the program difficult to carry out and to coordinate with regulatory actions likely to be taken by OSHA and MSHA. Our primary comment involves the proposed actual workplace testing. MSHA and OSHA do not believe that there is sufficient evidence that workplace testing is repeatable and reliable. The methodology involved in workplace testing is currently in the research stage, and therefore is not appropriate for regulatory action. It is the opinion of OSHA and MSHA that simulated workplace testing conducted under laboratory conditions is more appropriate. The second major comment is that respirator use limitations are not appropriate for this proposal. Limitations on the use of respirators should be addressed by OSHA or MSHA regulation since other activities such as training, fit testing, and the overall respiratory protection program affect the protection offered by respirators. Therefore items such as protection factors and respirator use limitations should be determined as part of a comprehensive regulation promulgated by MSHA or OSHA. The third major comment is that certification of respiratory protection devices should not be limited to mining and mine environments, but should include general industry as well.



- §84.31 Guidelines for workplace or simulated workplace testing
- §84.32 Workplace or simulated workplace testing by applicant; certification of minimum performance level.
- §84.33 Workplace or simulated workplace testing by applicant; certification of higher performance level.

These three paragraphs present the most serious difficulty with the proposal in our judgment. We will first describe the problems with the three paragraphs and will then present a suggestion for restructuring the proposal to overcome these problems.

The problems inherent in the proposed general guidelines can be summarized as follows:

- a) There presently exists no satisfactory validated protocol for workplace testing which could be widely applied.
- b) According to the proposal, either testing in one workplace would certify a respirator for all workplaces or, alternatively, testing would need to be done in every type of workplace. The proposal does not state which it requires, but neither situation could be made workable.

The following remarks will amplify these points:

The preamble to the NPRM says that model workplace testing protocols would be too voluminous for publishing in the Federal Register. They would be developed and given to the respirator manufacturers later as non-mandatory guidelines. It has been the experience of both OSHA and MSHA that a protocol which is not mandatory is unenforceable.



The manufacturers won't know what is required of them, and it is unreasonable to expect them to second guess NIOSH on the criteria for workplace testing. There must be a clear, universally applicable statement as to what is acceptable and what is not.

NIOSH must specify detailed unambiguous test protocols for each type of device so that all respirators are tested under the same conditions. However, workplace testing studies done to date show that it is very difficult to perform valid workplace tests. Nobody, including NIOSH, has yet developed a workplace protocol that doesn't produce results with wide variations. Moreover, the proposal gives equal credence to workplace testing and to simulated workplace testing, even though there are vast inconsistencies between the results of such studies. NIOSH proposes to supply a workplace test protocol at a later time. However, in the time suggested it would be impossible to adequately validate such a protocol and even then, there will have been no opportunity for public comment on it.

The results of workplace testing are dependent on the specific contaminant present, particle size, concentration, and on the working conditions in the workplace and workload performed during testing. The environmental conditions during testing can also affect test results. These variables must be controlled so that comparable test results can be obtained.



Moreover, it is not clear in the workplace testing requirements how the results of the workplace testing would be used. There are two possible interpretations:

- (a) certification of a particular respirator for all workplaces and all contaminants is based on the workplace conditions and the contaminant levels found in one workplace, or
- (b) testing is to be performed on every type respirator in every kind of workplace and for every level of contaminant for which it would be certified.

The first interpretation is clearly inappropriate because it would permit grossly inadequate protection in many circumstances. The second is also inappropriate since it would be impossible to test every respirator in every environment in which it would be used. Therefore the entire concept of workplace testing as described in the proposal seems unworkable.

The Department of Labor does believe that continued research involving workplace testing is extremely important because it can both provide vital information on the overall profile of respirator effectiveness and can occupy a useful developmental role in the generating of new fit test methods and new respirators. We strongly encourage NIOSH to continue with its program for these reasons. However, we do not believe that the certification program is the place to utilize it.



With respect to the paragraphs on certification of performance level, we believe that the purpose of respirator certification should be to assure users that the respirator is well made, reasonably reliable and has been shown under certain test conditions to achieve a certain level of performance. However, certification can not guarantee that the respirator will always achieve that performance level. To assign a protection factor to it on the basis of certification testing could imply to a user that it can.

With these considerations in mind, we recommend that NIOSH modify its proposal as follows:

1. Certification should be based on a simulated workplace test in an environmental chamber that can be performed by the manufacturer at his own establishment. It is our firm conviction that a certification program must be based on consistency and reproducibility and that the only way these can be achieved is through a well-defined set of tests that are applied exactly the same way to every respirator candidate of the same type. It should be a completely controlled test and should be performed under a detailed protocol supplied by NIOSH and made mandatory in the standard. The protocol should specify instrumental parameters, environmental conditions, activities to be performed by the subjects and whatever other elements are necessary to provide for reliability and repeatability.



2. To earn certification a minimal level of performance must be demonstrated in terms of penetration. The purpose of the certification test is to show that the respirator has been able to achieve at least that performance level and the certification should say that. No protection factor should be assigned as such because the assignment of a protection factor can only be part of an overall respiratory protection program. To avoid confusion of intent, the term "protection factor" should not be used. The certification documentation should state only that NIOSH certifies that the respirator has allowed no more than a certain penetration in controlled testing and that it is manufactured under an acceptable level of quality control.

Protection factors, as such, should be prescribed by the regulatory agencies which write standards for respirator use. However, the assignment of such protection factors by the regulatory agencies must always take into account the work that NIOSH has done and is doing and the resulting recommendations, such as in the NIOSH Decision Logic.

In light of the OSHA and MSHA comments on protection factors, the proposed section on certification of higher performance levels should become irrelevant. The proposed respirator certification standard should not be determining any protection factors, including higher performance levels, since protection factors are affected by other factors besides penetration levels. The present provision is



particularly dangerous. Given the variation in test results, and if the certification program were to include assigned protection factors, such assignments should be made on the basis of worst case results, not best case results. Once again, OSHA and MSHA believe that this problem is best addressed by not assigning protection factors as part of the certification procedure.

Since the definitions of simulated workplace and workplace are keyed to mining work sites and certification is based on workplace testing, then according to the proposal all respirators must be tested at mine sites and no other workplace tests would be acceptable. This makes the certification program irrelevant to any workplace except mines. The limitation on the certification of respiratory protection devices to mines and the mining environment could deny the benefits of respirator certification to respirator wearers in general industry. The definitions for "simulated workplace" and "workplace" in the proposal both specifically limit coverage to mines and mining work sites and illustrate part of the problem in requiring workplace testing. A mine work environment is not necessarily the same as the types of general industry work environments under OSHA jurisdiction where the vast majority of respirators are worn. Revision of the NIOSH certification program provides an ideal opportunity to establish a much needed update, but one which would require a soundly based certification procedure which would apply to every respirator independent of workplace.



In addition to the major comments given above, our other technical coments on the respirator certification proposal follow below.

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The certification of respirators under 42 CFR Part 84 is performed by NIOSH and the label should so state. The words "Certified by the U.S. Government" are inappropriate. There may be many instances where other agencies of the U.S. Government may modify or set



different limits on the use of NIOSH certified respirators. NIOSH can only certify in the name of NIOSH unless all government agencies which use or regulate the use of respirators are willing to specify officially that they relinquish their authority to NIOSH.

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The proposal does not allow respirators to be used in the presence of a contaminant with poor warning properties. However, there is no definition for poor odor warning properties in the proposal. If this use restriction were to remain, it would be incumbent upon NIOSH to define "poor warning properties". However, since use restrictions such as this one should be left up to OSHA and MSHA to regulate, the restriction on the use of respirators in the presence of a contaminant with poor warning properties should be removed, in which case no definition of poor warning properties need be added to the proposal.

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the final rule, emphasize that, any other document notwithstanding, the definition, as stated in the proposal, is the only definition relevant to certification. However, OSHA and MSHA believe that the definition for IDLH is a matter for regulations which apply to workplace exposures and practices. Thus it is best left to regulatory agencies which write such regulations to define IDLH.

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The maximum allowed face seal leakages permitted in order to pass the laboratory tests do not provide a sufficient margin of protection. For example, a full facepiece particulate respirator with high efficiency filter is allowed a facesal leakage rate that corresponds to a fit factor of only 100. This means that to achieve a target protection factor of 50, a safety factor of only 2 is provided. The assigned protection factors OSHA and MSHA establish must be based on the worst penetration performance of the respirators in each class, as well as on other factors which influence respirator effectiveness. By acting on NIOSH' certification of respirators with



such high penetration levels, MSHA and OSHA would logically establish correspondingly lower protection factors. OSHA and MSHA consider a safety factor of 10 to be appropriately applied to fit test results, requiring that fit factors achieved during fit testing be at least 10 times any assigned protection factor. Approving respirators with face seal leakage rates as high as NIOSH proposes means that some of the wearers will not be achieving minimal protection factors in the workplace. It should also be noted that NIOSH certification of respirators with a penetration level corresponding to a fit factor of 50 for negative pressure halfmask respirators would logically imply that OSHA or MSHA should, in keeping with the accepted industrial hygiene practice of using a safety factor of 10, establish an assigned protection factor of 5 for all such respirators.

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This section does not cover one type of air-line respirator, the supplied air suit. These respirators are currently being used in industry, and their increased use in areas such as hazardous waste disposal operations can be anticipated. NIOSH should specify whether it intends to certify supplied air suits and if so what the requirements will be. It is not clear how NIOSH will handle certification of respirators such as the supplied air suit which do not fit into one of the existing respirator certification classifications. The proposal does not contain provisions for certifying new respiratory protection technology or to allow



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A testing scheme similar to that developed by Nelson and Harder - Respirator Cartridge Efficiency Studies v. Effect of Solvents (AIHA Journal - July, 1974) should be developed. Their scheme divided solvents by chemical family and boiling points into 13 groups. Utilizing the developed scheme, the manufacturer would list the category of organic chemicals against which the cartridge was effective.

If a cartridge or canister is to be approved for protection against multiple contaminants, that cartridge should be tested simultaneously for those contaminants. For example, a cartridge respirator seeking approval for both acid gasses and organic vapors should be tested simultaneously to ensure that the cartridge will act appropriately under those conditions.



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The test requirements for ESLIs should be specifically set by NIOSH with clear testing criteria. It is unclear what NIOSH is requiring with testing at high and low temperatures, humidities, and contaminant concentrations, since none of these test parameters are given.

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Appendix A - Assumed Conditions of Use

These assumed conditions of use for respirators are more appropriately set by a regulatory agency such as OSHA or MSHA. The use of respirators with substances that have poor warning properties, in oxygen deficient or IDLH atmospheres, or which type respirator to wear for a carcinogen exposure are subjects best addressed by the regulatory agencies and are inappropriate as part of the respirator certification requirements.



Comments from the Department of Labor  
on the proposed NIOSH 42 CFR Part 84

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Appendix A - Assumed Conditions of Use

These assumed conditions of use for respirators are more appropriately set by a regulatory agency such as OSHA or MSHA. The use of respirators with substances that have poor warning properties, in oxygen deficient or IDLH atmospheres, or which type respirator to wear for a carcinogen exposure are subjects best addressed by the regulatory agencies and are inappropriate as part of the respirator certification requirements.