Ms. Diane M. Manning  
Docket Office Manager  
NIOSH Docket Office  
Robert A. Taft Laboratories  
Mail Stop C34  
4676 Columbia Parkway  
Cincinnati, OH 45226  

RE: Federal Register 59, No. 99, 05/24/94 (Certification for Respiratory Protective Devices)  

Dear Ms. Manning:  

The American Industrial Hygiene Association (AIHA) is pleased to have the opportunity to comment on the issue of certification for respiratory protective devices as requested by the National Institute for Occupational Safety and Health (NIOSH) in the 05/24/94 Federal Register 59, Number 99.  

AIHA is also pleased to have had the opportunity to present testimony at the recent public hearing on this issue held in Washington, DC on June 23-24. At this hearing, several questions were asked of AIHA regarding the issue. AIHA was requested to attach responses to these questions to the official comments we submit. Our responses are attached.  

AIHA is composed of nearly 12,000 members, mainly industrial hygienists, but also including a broad range of professionals in the industrial health and environmental areas. The enclosed comments are the effort of our Respiratory Protection Committee.  

If there is anything further our organization can do to assist in this worthwhile effort please contact me.  

Sincerely,  

Jeremiah Lynch, CIH, CSP, PE  
President  

Enclosures  

cc: Board of Directors  
Respiratory Protection Committee Chair  
O. Gordon Banks, Executive Director
AIHA COMMENTS TO THE
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

CERTIFICATION FOR RESPIRATORY PROTECTIVE DEVICES PROPOSED RULE

42 CFR Part 84 RIN 0905-AB58

The respiratory protection committee of The American Industrial Hygiene Association (AIHA) supports the development of updated standards for the testing and certification of respiratory protection devices used in the workplace. With the publication of the proposed rule 42 CFR Part 84, the committee is supportive of the efforts of NIOSH to move forward in this area, and is submitting the following comments in an effort to assist in the development of sound standards directed toward improved understanding, use and protection of respiratory wearers in the workplace.

Modular Approach

The modular approach to upgrading respirator certification standards should provide benefits in the development of respirator performance requirements that reflect advancements in technology as well as the changing requirements of the user community and workplace activity. However, there are many important aspects of this type of process that have not been addressed which may cause confusion and add cost in the workplace and difficulty in product development. These aspects of the modular approach are identified individually in the following seven paragraphs. The questions relative to each aspect reflect areas of needed definition in the proposed rule, and the suggestions reflect proposals by the AIHA Respiratory Protection Committee for support to effective rulemaking.

Module Interface: Many modules will have effects on each other. How will the interface be coordinated when a future module effects a previous module such as with assigned protection factors or combination respirators? What will be the grandfathering overlap? How will the consumer maintain an up-to-date respiratory protection program, and at what additional cost? What will be the effect on respiratory development when a future module may affect design requirements or earlier modules? Will this slow new product development or add cost to the user? These questions should be addressed by NIOSH.
Module development overlap: With the proposed schedule, there will be concurrent work on various modules at various times. Are there available resources within NIOSH to maintain progress and ensure timely completion?

Schedule: Has a formal schedule been developed with a committed completion date? The AIHA Respiratory Protection Committee suggests a five year schedule requirement for completion to ensure limited user confusion as modules take effect, enable completion prior to obsolescence, and limit the potential cost burden associated with updating respirators.

Development interface: As modules develop, will there be an opportunity for input prior to publication? AIHA and other organizations are a valuable source of information regarding user requirements and concerns, as well as workplace and laboratory studies. The AIHA Respiratory Protection Committee, for example, would be willing to provide support whenever possible. These resources may assist in expediting module development.

Additional modules: A new separate module, specifically for the testing and certification requirements of power air purifying respirators (PAPR) should be added to the schedule. PAPR’s are a specific class of respirators that have a broad base of styles for varied workplace requirements. Combination respirators, gas masks, and supplied air respirators also need to be identified in module schedule.

International integration: A plan should be outlined to reflect the goals of international integration as the modular program progresses. This plan should be included at the start of the program.

Phase-in period: A commitment should be made to put all manufacturers on equal footing as, for example, simultaneous issuance of all approvals of applications received within a specific time period after promulgation. This to limit confusion of the user, and avoid potential market monopolization periods.

Interagency Coordination

The AIHA Respiratory Protection Committee recommends that respiratory protections related rulemaking should be coordinated throughout the regulatory agencies of OSHA, MSHA, EPA, NRC and FDA. This to provide uniform understanding in the workplace specifically in the areas of selection, use limitations, assigned protection factors and fit testing.

Test Protocol

With particulate respiratory protection affecting the largest number of respirator wearers, and the growing concerns in the healthcare industry, enhancements in the area of filter testing and requirements are needed. However, the protocol identified in the publication of the proposed rule presents many concerns. Specifically, the following sections need to be addressed:
* Paragraph 84.184(i). Is the penetration measured by what the photometer sees, or by the particle number ratio? The particle size distribution will change some as it goes through the filter.

* Filter tests with DOP or equivalent oil. These test materials offer an opportunity to test electrostatic filters to assure that the electrostatic charge is dependable over the life of the filter. The residue these substances leave in the filter being tested often gradually discharge the electrostatic charge. A requirement for retesting each filter after an inactive interval, of 30 minutes for example, should be included in the protocol.

* Paragraph 84.63(c). With regard to the specific subsection, when NIOSH prescribes a new test, or modifies an existing test, it should be required to publish that test in the Federal Register with a statement as to the circumstances in which the test will be required. The concern is, should the public allow NIOSH to prescribe tests and revise those tests at will without review as required by the Administrative Procedures Act?

* With regard to hot and cold generated DOP, are independent studies available to show a correlation between these aerosol tests?

* Does the new test protocol establish a requirement for new equipment for the manufacturing community? Is this equipment readily and immediately available, and from more than one manufacturer? What additional cost will this requirement add to the user community?

* What is the protocol for gas mask filter performance?

**Carbon Tetrachloride**

Carbon tetrachloride now has limits in availability and for use in testing and is an animal carcinogen that poses a hazard to laboratory personnel, yet continues to be referenced in the proposal of 42 CFR 84. Pentane, or correlated equivalents should be specified as currently acceptable.

**Powered Air Purifying Respirators (PAPR)**

PAPR testing requirements are ambiguous and difficult to follow.

**Recommendation:** This module of 42 CFR 84 should only address the filtration requirements of PAPR system filters. PAPR system requirements should be addressed in a separate additional module specifically for PAPR performance testing and certification where all system elements and requirements are included. What follows are some of the concerns relative to PAPR filter testing in support of the recommendation for a separate PAPR module:
* A definition of loose-fitting and tight-fitting inlet coverings is supported, but a requirement for multiple categories should be included. This is to avoid a potential restriction limiting design advancement and user benefit. For example, hoods with bibs, hoods with suit tops, and hoods without bibs. When all designs are lumped together, they all receive the lowest assigned protection factor. ANSI Z88.2 1992 recognizes four types of PAPR’S, half mask, full facepiece, loose fitting facepiece and hoods/helmets. This is supported by the result of workplace protection factor studies that have found differing levels of protection for these types of PAPR’S. NIOSH should add the ANSI definition of loose fitting facepieces to the proposed rule, and include loose fitting facepieces as a separate category of PAPR’s. Paragraphs 84.171(a)(1), 84.175, 84.176, 84.179, 84.183(a) and 84.183(a) should be changed to reflect this requirement.

* Breathing machine requirements for PAPR filter performance testing should not be required in this module as the emphasis should be on filter performance not system performance. Constant flow filter performance testing, with specific minimum air flow requirements would be more appropriate, efficient and less costly.

* Air flow rate should be addressed. Most PAPR’S with tight-fitting facepieces operate at a steady flow rate of about 4 cfm. At moderate to high workrates, the worker can overbreathe and create a negative pressure inside the facepiece during inhalation. Tests should be carried out at a higher work rate equivalent, or a minimum flow rate of 6 cfm should be required. Similarly, the flow rate or work rate should be higher than 6 cfm or a minute volume of 40 liters for loose-fitting head covers.

**Replaceable Straps**

Paragraph 84.178 in the proposed rule does not recognize that not all respirator head harnesses may need to be replaced as in the example of maintenance-free half mask respirators.

**Recommendation:** This paragraph should be changed to state an exception in the cases of single use respirators, or respirators designed not to be maintained by the user.

**Applications**

As written, the proposed rule would permit NIOSH, at will, to issue approval based solely on the representation of the applicant.

**Recommendation:** A requirement should be included in the proposed rule for NIOSH to verify the submitted data within a specified, reasonable amount of time such as 90 days. As a public agency, NIOSH holds equal responsibility to all applicants and users. Users should have the confidence that all applicants are treated in the same manner, and certified respirators come from uniformed procedures.
Filter Classification

To provide uniformity, and reduce user confusion, filter classification should follow the existing structure of the European classification format. As opposed to classifying filter by A, B, and C, the classification should be 1, 2 and 3, with 3 being the highest efficiency in an effort toward global harmonization, and in the spirit of NAFTA and GATT.

Recommendation: Filter classification should be 1, 2, and 3, with 3 representing the highest efficiency. This relates to the European sequence but doesn’t match it in that efficiencies are not identical to P1, P2, and P3.

Efficiency

There is a concern that NIOSH is testing filters with the worst case aerosol, using unnecessarily restrictive limits on the test and tight statistics. This may be done for simplicity, but may make the particulate respirator harder to use (breathing resistance) which, in turn, may potentially cause a lowering of protection in the workplace. In addition, these tight respirator requirements do not relate to all workplace requirements, possibly causing workers to pay higher prices for a respirator with greater performance characteristics than needed, or sourcing alternate respiratory protection to meet their needs that may not meet NIOSH certification requirements.

Current respirators provide adequate filter efficiency as evidenced by the number of workplace protection factor studies that have found average WPFs over 10. In changing the filter test, NIOSH is moving the least efficient respirator class from one that would test at 20 to 1% penetration depending on the exact manufacturer (Japuntich and Moyer references) to a class with no more than 5% would provide for improved respirators with less of a burden on the people who must use the respirators. To get higher filter efficiencies will require that filters will have more pressure drop that may increase leakage (Campbell reference), make them more uncomfortable and less likely to be used properly resulting in an overall decrease in protection.


A 10% filter penetration during testing is not an unreasonable limit for a respirator filter when the test aerosol is considered. For example, the sodium chloride aerosol is specified to have a count median diameter of between 0.06 and 0.11 micrometers, with a geometric standard deviation less than 1.86. It is highly unlikely that such an aerosol would occur outside the laboratory, so the field performance of a filter that passes at 90% will always be more efficient than 90%.

**Recommendation:** With published studies as support, and a relationship to the broad workplace requirements referenced, the filter efficiency range should follow 99.97% for high efficiency classification to 90% for the third classification, with a middle classification of 95%. This to provide an appropriate range and differentiation to meet the various needs of the workplace including the healthcare setting.

**Identification**

Limited information regarding filter identification was provided in the proposed rule.

**Recommendation:** To help simplify user selection and identification of the new classes of filters, plain language labeling should be included. Labeling should clearly state the certified efficiency rating numerically, and include "solids" and "solids or liquids" spelled out on the filter, filter package or respirator box. In addition, it is believed that ANSI K13.1 is no longer obtainable from ANSI, and this reference for color identification may need to be removed.

**Instructions**

Respirator instructions are an important requirement for the proper use and maintenance of respirators, and should be properly reviewed in a sound respiratory protection program. This area is not specifically defined in regard to respirator certification requirements.

**Recommendation:** It is strongly recommended that NIOSH include respirator instruction review and responsibility as part of the respirator certification process. A standard format should be established for ease of user understanding and effectiveness. This standardized, simplified format should also include certification labeling again aimed at simplifying user selections and use.

**Fit Testing**

Paragraphs 84.181 and 84.182 of the proposed rule proposes a tightness test using isoamyl acetate. The purpose of this test is not given, and it is believed to be unnecessary, not reproducible, provides no benefit and an additional cost burden to NIOSH. This requirement has prevented chemical filtration respirators from receiving particulate and chemical approval because sufficient carbon to pass the fit test would require face piece modifications, therefore restricting product development.
Respirator fit is an important factor in how a respirator fits an individual, so important that ANSI requires that each person who will use a tight fitting respirator be fit tested at least once a year. OSHA, in most of their substance specific standards, also requires that respirator users be fit tested. However, the tightness test required by NIOSH as part of the certification process does nothing to help assure an adequate fit. Fit testing must be included as part of a sound respiratory protection program, and must be done on an individual basis. Prior testing during certification will not assure that an individual receives an adequate fit, and may confuse the user into thinking they have a respirator that is certified to fit.

Ensuring that a face seal has an ability to conform to a range of facial structures is a critical aspect of respirator design, but requiring the use of isoamyl acetate may restrict technical innovation. Additionally, NIOSH, in this requirement, has not provided a test that can be reproduced by others. No descriptions of the face sizes and quantities for the test (as in OSHA’s lead standard), no provision is given to determine if a person participating in the test can sense the presence of isoamyl acetate that leaks into the respirator. The test conditions vary between the two tests for test time and test exercises.

**Recommendation:** With an understanding of respiratory protection program requirements, and the characteristics of various respirators relative to fit test agents, the isoamyl acetate test should be deleted from the filter respirator certification proposal or replaced with a more appropriate and scientifically supported test.

**Assigned Protection Factors**

Assigned protection factors are an important aspect regarding respirator selection. They also can be confusing to the user. A specific module addressing assigned protection factors as outlined in the modular schedule is needed.

**Recommendation:** It is highly recommended that assigned protection factors (APF) remain intact until the new procedures and soon-to-be proposed APF module is promulgated. This will minimize confusion and disruption of respirator practices that would have been placed on respirator wearers had temporary APF’s been adopted. In addition, it is highly recommended that outside resources be utilized when the APF module is developed. The AIHA Respiratory Protection Committee would welcome the opportunity to assist whenever possible. In addition, there are a great deal of independent workplace protection factor studies available for reference. Many of these were used by ANSI in the development of the protection factor table of the 1992 edition of Z88.2, American National Standard for Respiratory Protection.

**IDLH**

The definitions for "IDLH" and "not IDLH" in the proposed rule are not accurate and do not cover many exposures. For example, a nuisance dust exposure does not fit the definition of a "not IDLH" exposure since it does not cause immediate physical discomfort or long-term effects. The definition for IDLH includes "...conditions that...likely to have adverse effects." This is
a broad definition of health effects and could include exposures to many chemicals not considered IDLH such as toluene, where chronic exposures may result in nervous system damage. Additionally, allergens, regardless of how infrequently sensitization may occur, would fall under this definition of IDLH.

**Recommendation:** The ANSI definition of IDLH should be used, and the definition of not IDLH deleted. The ANSI definition of IDLH is: **Immediately dangerous to life or health.** Any atmosphere that poses an immediate hazard to life or poses immediate irreversible debilitating effect on health.

**HEPA filter requirements**

The change NIOSH has made in classifying filters as replaceable and non-replaceable is supported, thus eliminating the requirement that only high efficiency filters can be used for materials with exposure limits less than 0.05 mg/mv. Filters do not vary in filter efficiency based on toxicological properties or regulatory requirements for exposure limits.

**ANSI references**

It is recommended that whenever the ANSI Z88.2 document is referenced in the proposed rule that the 1992 edition is the edition of reference, not the 1969 document as proposed.

**NIOSH and MSHA Memorandum of Understanding**

The proposed rule references a memorandum of understanding that is being developed between NIOSH and MSHA that will affect administrative matters related to respirator approval. It is unclear if this memorandum will have an effect on this notice of public rulemaking.

**Recommendation:** The public should be permitted to review and comment on this memorandum of understanding during this comment period.

**User Notice**

The proposed rule states a respirator user’s notice will accompany the publication of this new rule. This user’s notice provides great concern due to its potential to be looked as as part of the rulemaking, therefore not subject to public review or comment. The potential for the notice to contain revised APF values and other selection criteria, which may greatly confuse the worker and disrupt existing workplace respiratory protection programs, would cause unnecessary cost and burden in the workplace when an APF module is scheduled for later this year.
**Recommendation:** It is highly recommended that if a respirator user’s notice is to be published, it is open for review and comment prior to publication. To best support the needs in the workplace, a user’s notice should be developed with input from the user, manufacturing and regulatory groups. The notice should be user friendly and assist in areas of selection not covered in the regulation, such as what class filter respirator to select for fibers such as asbestos, or hazards no longer identified such as paint spray and pesticides.

**Grandfathering**

Grandfathering is an important aspect of this regulation and leaves a great deal of concern. A two-year grandfathering provision and an immediate conversion to 42 CFR 84 filter performance test appears to be somewhat short-sighted. Following are the areas that must be addressed:

* Applications for filter respirator approval having a requirement to meet 42 CFR 84 performance testing 30 days from rule publication provides little or no time for product development activities, performance testing or user needs analysis, much less new testing equipment procurement, provided it is available. In addition, this immediately cuts out new respirators currently in the development pipeline that may provide a benefit to today’s worker.

* A two-year limit on the sale and distribution of currently certified respirators does not provide enough time for NIOSH to process the applications for certification it will receive based on the current time requirements for respirator certification. This potentially sets up an extreme limitation on respirator selection capability for the worker, compromising safety and adding burden and cost to respirator program administrators.

* Disallowing extensions of approval to 30 CFR 11 certified filter respirators will immediately eliminate enhancements in design of current respirators in the workplace, and potentially cut off the supply of respirators in the workplace if the respirator manufacturer experiences a change in components or obsolescence by a supplier. This may add cost and burden to the workplace or compromise safety and health protection.

* Limiting distribution in the grandfathering proposal may restrict the availability of respirators to the workplace as distribution; manufacturing and users will want to limit the cost impact of inventory becoming obsolete. This may cause a safety risk should a sufficient supply of new certified respirators not be available on storeroom shelves.

* No provision has been given to the grandfathering relationship with respirators affected by future modules that have already been redesigned to meet the earlier modules. This may limit the development of advanced respirator designs until later modules are published due to the risk of design change requirements.
**Recommendation:** Due to the range of unknowns, and the changes that must occur at the user, manufacturer and regulatory levels, along with the need to maintain user protection without undue burden, it is recommended that a four-year grandfathering provision for the sale of respirators by manufacturers, and a two-year limitation for extensions of approval for 30 CFR 11 filter respirators be incorporated into the regulation. A four-year grandfathering provision is shorter than previously accepted by NIOSH, follows examples set by the European regulatory community, and sets a standard for future modules that may be more complex such as self-contained breathing apparatus performance. A two-year limitation of extensions of approvals takes into account certification backlog, product upgrades and component changes, and broad based research and development work. Should the pipeline become filled with 42 CFR 84 certified respirators in a shorter period of time, user selection and manufacturer marketing will create swifter conversion.

**Cost**

When evaluating cost impact of the proposed rule, various areas must be addressed for impact analysis. With many potential variables remaining undefined, it is difficult to comment on specific aspects of a cost impact. From the users standpoint, if new testing procedures are going to cause a major change in respiratory protection programs, the benefits of the changes should be weighed against potential burdens on employers in terms of increased cost of respirators, and increased training requirements, etc. In regard to manufacturing, the cost of new equipment, additional R&D, supplier procurement and plant retooling must be evaluated to determine the cost impact on the price of new respirators made available. Additionally, the cost to the government should be evaluated including additional equipment, administrative requirements, testing requirements and resources.

**Recommendation:** NIOSH’s detailed cost impact analysis, utilized to arrive at the figures presented in the proposal, should be made public for review and comment.

**Third Party Certification**

It is recommended that NIOSH incorporate a third party respirator certification program as part of the modular development of 42 CFR 84. This would provide for an expedited respirator certification process enabling the swifter availability of enhanced respiratory protection devices to the user, and lessen the burden on government agencies allowing for increased administrative, enforcement, research and rulemaking activities, all of which would add benefits to the worker. This recommendation has been made previously (Corn and Brief and other), and can be shown to be effective by the example of the advancements in SCBA performance through the third party certification program of the National Fire Protection Agency (NFPA).

July 19, 1994
AIHA RESPONSE TO THE
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
PUBLIC HEARING ON JUNE 24, 1994 PERTAINING TO
CERTIFICATION FOR RESPIRATORY PROTECTIVE DEVICES PROPOSED RULE
42 CFR Part 84          RIN 0905-AB58

During the AIHA presentation of Mr. Thomas J. Nelson, CIH at the June 28, 1994 NIOSH hearing in Washington, DC, two specific requests were made of AIHA:

1) NIOSH requested a summary of workplace studies that includes particle size information. This summary is attached.

2) There were also questions raised about assigned protection factors and filter efficiency. In order to assure the panel is clear on the response provided by AIHA, the following comments are provided:

During the hearing, NIOSH asked questions regarding the assigned protection factor (APF) for half mask respirators with the various types of filters. Specifically, there was discussion regarding the APF for a 90% efficient filter. As stated during the hearing, the APF as calculated by NIOSH is a sum of face fit and filter efficiency. For this respirator NIOSH would calculate an APF of 5 (1/10 + 1/10). AIHA does not agree with NIOSH’s analysis.

First, the face fit factor includes filter efficiency for the current approved filters. The face fit value used by NIOSH is the assigned protection factor of ten for half masks. This value is derived from workplace protection factor studies. These studies measure performance of the respirator as it is used which includes filter leakage.

To use face fit in the equation requires that filter efficiency for the current filters be subtracted. AIHA suggests that a value of 0.01 be used, the minimum required fit factor for quantitative fit testing as defined by the ANSI Z88.2 (1992) standard and the assumed minimum fit factor for qualitative fit tests.

The second part of the equation is for filter efficiency; NIOSH uses a value of 0.1. AIHA does not agree that this is an appropriate value. As stated by NIOSH, the APF can never be greater than 10 since filter leakage will always be at least 10%. This is based on the worst case test used by NIOSH in the filter tests.

AIHA believes that the filter leakage will be less than 10% since the test aerosol and test conditions will likely never exist outside the laboratory. The monodisperse particle used in the test will not exist outside the laboratory, therefore filter efficiency will be greater than tested.
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