

Dated: May 7, 1996.
 Stephen L. Johnson,
 Director, Registration Division, Office of
 Pesticide Programs.

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:
 Authority: 21 U.S.C. 346a and 371.

adding alphabetically the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *
 (c) * * *

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

2. In § 180.1001 the tables in paragraphs (c) and (e) are amended by

Inert Ingredient	Limits	Uses
2-Propene-1-sulfonic acid, sodium salt, polymer with ethenol and ethenyl acetate, number average molecular weight (in amu) 6,000 - 12,000.		Binding Agent

(e) * * *

Inert Ingredient	Limits	Uses
2-Propene-1-sulfonic acid, sodium salt, polymer with ethenol and ethenyl acetate, number average molecular weight (in amu) 6,000 - 12,000.		Binding Agent

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 84

National Institute for Occupational Safety and Health (NIOSH); Meeting

AGENCY: National Institute for Occupational Safety and Health, CDC, HHS.

ACTION: Public meetings and request for comments.

SUMMARY: This document is to request public comments in preparation of rulemaking to revise current NIOSH procedures for certifying respiratory devices used to protect workers in hazardous environments. NIOSH is seeking public comments on issues of privatization and fees related to possible changes in its administration of respirator certification, and comments on establishing priorities for future rulemaking. NIOSH will hold three public meetings in June 1996 to discuss these issues and will consider all comments provided in response to this notice.

DATES: The meetings are scheduled as follows:

- June 6, 1996, 9:00 a.m. to 5:00 p.m., Washington, D.C.
- June 7, 1996, 9:00 a.m. to 5:00 p.m., Washington, D.C.
- June 8, 1996, 9:00 a.m. to 5:00 p.m., Northglenn, Colorado

ADDRESSES: The meetings will be held at the following locations:

- Washington—Holiday Inn Capitol (Columbia Room), 550 C Street SW., Washington, DC 20024
- Washington—Holiday Inn Capitol (Columbia Room), 550 C Street SW., Washington, DC 20024

[Open to the public, limited only by the space available.

The meeting room accomodates approximately 150 people.]

- Northglenn—Holiday Inn Denver Northglenn (Pikes Peak Room), 10 East 120th Avenue, Northglenn, Colorado 80233

[Open to the public, limited only by the space available.

The meeting room accomodates approximately 200 people.]

Comments should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533-8450, fax 513/533-8285. Comments may also be submitted by e-mail to:

DMM2@NIOSDT1.EM.CDC.GOV. E-mail

attachments should be formatted as WordPerfect 4.2, 5.0, 5.1/5.2, 6.0/6.1, or ASCII files. Requests to participate in the public meeting should be mailed to the NIOSH Docket Officer, at the same address.

FOR FURTHER INFORMATION CONTACT:

Richard W. Metzler or Roland Berry Ann, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888, telephone 304/285-5907.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Mine Safety and Health Act of 1977 (Pub. L. 95-173, as amended by Pub. L. 95-164), NIOSH and the Mine Safety and Health Administration are mandated to approve respirators used for worker protection. In June 1995, NIOSH published a final rule (42 CFR part 84), beginning a stepwise or "modular" approach to updating the respirator certification process and requirements. The 1995 final rule transferred the existing standards for respirator certification from the labor section to the health section of federal regulations to expedite NIOSH rulemaking to improve these standards. Concurrently, the final rule revised existing standards for certifying the most commonly used respirators, air-purifying respirators used to filter out toxic particulates. NIOSH had identified these revisions as

the highest priority for improving the protection of workers using respirators.

II. Public Meetings

NIOSH will convene two public meetings to obtain comments from interested parties on priorities for updating respirator certification standards and other issues addressed in this notice.

The tentative agenda of the meetings includes a brief summary by NIOSH of plans for rulemaking and a review of the issues outlined in this notice. This will be followed by presentations by the public. Participants will be given fifteen minutes to present comments. Participants may comment on the issues addressed by this notice as well as other concerns related to respirator certification.

Any interested person may, consistent with the orderly conduct of the meeting, record or otherwise make a transcript of the meeting. Each participant may submit relevant written information, data, or views for inclusion in the record of the meeting. Any person who desires to submit an advance written statement may file it with the NIOSH Docket Office. A participant may be accompanied by a reasonable number of additional persons, space permitting.

All interested persons are encouraged to submit written comments to assure receipt on or before the close of business August 16, 1996, and to advise the NIOSH Docket Office by close of business May 24, 1996, of their intent to participate in the informal public meeting. All requests to present at the informal public meeting should contain the name, address, and telephone number, relevant business affiliations of the presenter, a brief summary of the presentation, and the approximate time requested for the presentation. NIOSH requests that oral presentations be limited to 15 minutes.

After reviewing the requests for presentations, NIOSH will notify each presenter by mail or telephone of the approximate time that their oral presentation is scheduled to begin. If a participant is not present when his or her presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meeting, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make presentations may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

The record of the informal public meetings will consist of the meeting

schedule and any written comments submitted at the meetings or in response to the meetings. The meetings will be video taped for the record. In addition, an administrative record will be established including a record of the informal public meetings and all comments received in response to this notice. The administrative record will be made available for viewing and copying in the NIOSH Docket Office. All requests for any portion of the administrative record must be submitted in writing.

III. Matters To Be Discussed

A. Priority of Technical Modules

1. Background

On May 24, 1994, NIOSH published a Notice of Proposed Rulemaking (50 FR 26580) which led to promulgation of the current respirator certification standards at 42 CFR Part 84. This proposal introduced the modular approach to rulemaking NIOSH has adopted and listed anticipated subjects and a sequence for future rulemaking. These subjects (in proposed priority order) were: assigned protection factors, administrative program (application submittal and processing, fee structure, etc.), quality assurance requirements, gas and vapor requirements (including maximum use concentrations), positive pressure self contained breathing apparatus requirements, and simulated workplace protection factor test. In response to that notice, NIOSH received numerous suggestions for additional module subjects, such as powered air-purifying respirators, smoke masks, fit testing, supplied air respirators, gas masks, and combination respirators. Many commenters also recommended a priority order for the sequence of rulemaking. However, opinions on priorities were diverse and few commenters included a rationale to support their suggested priorities.

None of the commenters indicated specific changes needed to improve current standards. One commonality among suggestions was that they all referred to the need to improve individual respirator classes (e.g., gas and vapor, powered air purifying, self contained, etc.). However, component specific upgrades that are applicable across respirator classes (e.g., head harness, facepiece, breathing hose, etc.) are also possible in the modular approach.

2. Issues for Comment

Specifically, NIOSH is seeking comments on the following issues for prioritizing the development of modules:

Issue 1. Diverse criteria may be considered to establish priorities for improving respirator certification standards.

These include standard public health criteria such as the number of persons (workers) affected, the seriousness of hazards or problems that would be addressed, and the extent to which changes would improve protection. Other criteria that also may have an important influence on worker protection include, opportunity for cost savings (reducing costs for manufacturers and purchasers of respirators) and the expediency by which a change can be implemented (e.g., the existence of adoptable consensus standards).

(1) What criteria should be used to rank the priority of each module?

Issue 2. NIOSH will be developing a complete, ranked listing of priorities for rulemaking, including justification for the ranking.

(1) In general terms, what changes to current respirator certification requirements are needed in the modules identified in this notice?

(2) Are there any subject areas for improving current certification requirements that are not identified in this notice that should be considered in the prioritizing process? If so, please include an explanation of the importance of the subject and describe in general terms the changes needed in current requirements.

(3) How should the modules be ranked, and why? Please provide criteria and data or reasoning used to determine ranking.

(2) Are there existing national or international standards that could be adopted by NIOSH to replace current certification requirements pertaining to a given module? Please provide a rationale and indicate any inadequacies of the suggested standard.

(3) How would potential changes to current requirements achieved through a proposed module affect public health?

(4) Which industries and how many workers would be affected by potential changes achieved through a proposed module?

(5) What would be the technical feasibility of suggested changes?

(6) What would be the economic impact to respirator manufacturers, purchasers, and users resulting from the suggested changes?

(7) What other factors relate to the priority ranking of the proposed module?

Issue 3. NIOSH will inform the respirator community of regulatory priorities to allow research and planning to be coordinated with the

development of new standards. However, these priorities may change as new needs are identified. NIOSH can readily notify respirator manufacturers directly about these changes.

(1) How should NIOSH notify respirator purchasers and users of revised priorities?

B. Administrative/Quality Assurance Module

1. Background

NIOSH certification requirements (42 CFR Part 84) contain application procedures and technical requirements for respirators. NIOSH currently tests and evaluates a product for a fee paid by the applicant. Pretesting is required by the manufacturers. Drawings and specifications submitted with the application are evaluated to ensure that applicable technical requirements of 42 CFR Part 84 are met. This includes evaluation of the manufacturer's quality control plan.

Manufacturers must assure that approved respirators continue to conform to the specifications and design approved by NIOSH. Any proposed change to the documentation must be submitted prior to implementation of the change. If NIOSH approves the change, it issues an extension of certification for the modified product. Manufacturers are authorized to mark the product to identify its certification status. The introduction of new performance standards for particulate filters in the NIOSH certification requirements promulgated in June 1995 increased competition, caused the development of new technologies, and resulted in new uses for respirators. All of these factors have resulted in a dramatic increase in the volume of respirator certification applications submitted to NIOSH. This increased volume of application continues unabated eight months later and is overwhelming NIOSH resources to process applications. The number of applications awaiting processing (the working inventory), and the length of processing time are both increasing, despite an accelerated rate of processing.

All of the manufacturers who hold NIOSH certifications under Part 11 will apply for certification under Part 84. To date, approximately one-third of these manufacturers have applied for certification under Part 84. In addition, many manufacturers that have already received certifications under Part 84 have informed NIOSH that their volume of applications will continue at an increased level for the next 18 to 24 months. NIOSH anticipates similar

increases in the volume of applications with the promulgation of additional modules to improve certification requirements.

The long-term prospect of high demand for processing applications is leading NIOSH to investigate alternatives to expedite certification. The current application process, which is largely based on practices established in the early 1900's by the U.S. Bureau of Mines, cannot expeditiously respond to the volume of applications associated with periodic improvements to the standards.

In response to this situation, NIOSH is considering adopting new administrative and quality assurance procedures that will enable the Institute to use private sector resources. A primary concern in investigating this option is safeguarding the integrity and public credibility of the certification process. NIOSH may consider adopting national and international standards (e.g., ISO-9000, Nationally Recognized Testing Laboratories (NRTL), etc.) where feasible, to provide oversight for the certification process.

2. Issues for Comment

Specifically, NIOSH is seeking comments on the following issues for the development of this module:

Issue 1. Independent laboratories should be capable of performing routine testing required for respirator certification. Transferring this testing to private laboratories would enable NIOSH to focus on aspects of the certification program other than pre-certification evaluation. Newly available resources could be used for investigation of complaints about certified respirators and development of testing procedures and new standards for improving the certification standards. However, NIOSH must ultimately be able to ensure the integrity of the program.

(1) Are private sector testing laboratories capable of conducting the respirator testing currently performed by NIOSH?

(2) What qualification requirements (e.g., certification by National Voluntary Lab Accreditation Program (NVLAP), American National Standards Institute (ANSI), NRTL, etc.) should NIOSH require of private laboratories who perform certification and product audit testing under NIOSH guidance?

(3) Should NIOSH assign the testing of a manufacturer's respirators to laboratories approved by NIOSH or should the manufacturer be permitted to use the laboratory of choice among approved laboratories?

(4) What type of monitoring should NIOSH perform to assure that private sector laboratories continue to provide quality service?

Issue 2. Quality auditors with international certification are authorized to conduct audits for International Organization of Standardization (ISO) certification. The auditors could conduct audits of manufacturers for NIOSH concurrently with audits required for ISO. Combining these audits could result in fewer interruptions for the manufacturer and lower inspector costs. NIOSH oversight of these auditors can ensure that audit quality is comparable to that which has been provided by NIOSH employees.

By primarily examining auditors, rather than manufacturing sites and processes, NIOSH would be able to enhance worker protection. Use of private sector quality auditors to perform routine manufacturing site audits would allow manufacturing sites to be audited more frequently; NIOSH audits each manufacturer on the average of once every four years, while ISO audits are conducted twice a year. Use of ISO auditors would also free up NIOSH resources to evaluate a potential certification holder's quality control system prior to the production of any certified respirators. This type of audit could be advantageous to both the manufacturer and respirator users, reducing the potential for manufacture and distribution of deficient respirators.

(1) What qualification requirements (e.g., certification by ANSI-Registrar Accreditation Board, United Kingdom Accreditation Service, International Auditor and Training Certification Association, etc.) should NIOSH require for the acceptance of independent quality auditors to perform manufacturing site audits under NIOSH guidance?

(2) What measures should NIOSH use to ensure the integrity of the program using private quality auditors?

(3) What frequency of audits would be considered a minimum to provide assurance that only quality products are distributed?

(4) Should manufacturing sites be audited prior to the issuance of a NIOSH certification?

Issue 3. The fees and free structure for activities conducted in the certification program are based on the fee schedule contained in 42 CFR Part 84. This fee schedule has not been updated since 1972, and applies to only one of the five primary functions of the NIOSH certification program. The fees are assessed only for pre-certification technical evaluations and tests. The costs of conducting a certification

program have risen over the years, but these increased costs have not been reflected in certification charges. The fees charged for NIOSH services do not recover the costs to maintain the program. NIOSH will be updating the fee schedule to reflect the actual costs to maintain the program.

(1) How should certification fees be structured and calculated to recoup the cost of the certification process?

(2) Should manufacturers be required to pay for manufacturing site and product audits?

(3) Should fees be collected by NIOSH for respirator complaint investigations?

Issue 4. The certifications standards currently limit NIOSH to certify only complete respirators. Standards are not provided to evaluate component parts independently. There are not provisions in the current addressing standardization and interchangeability of components. Any change to a component part, or a replacement part that differs from the original, can change the effectiveness of a respirator, and decreased effectiveness normally cannot be detected by the user. To ensure that respirators perform effectively, they must be maintained as approved. Replacement parts are limited to those specified in the certification for the manufacturer's assembly of the respirator. These are the only components that have been evaluated for effectiveness. As a result, a respirator user must obtain replacement parts and service from the respirator's original manufacturer.

(1) Should NIOSH allow replacement parts for respirators by manufacturers other than the original manufacturer of the respirator?

(2) How should the effectiveness of replacement parts be assured?

(3) Would NIOSH need to adopt or develop component-specific certification requirements to allow alternate suppliers for replacement parts?

(4) Should NIOSH consider certifying respirator components in addition to, or instead of, complete respirator?

(5) Do other certifying agencies or standards organizations allow suppliers other than the original manufacturer to provide replacement parts for certified units?

(6) If suppliers other than the original manufacturer were permitted to provide replacement parts, how should NIOSH monitor these alternate suppliers?

(7) If suppliers other than the original manufacturer were permitted to provide replacement parts, how should NIOSH monitor those parts?

(8) Would NIOSH need to adopt design specifications to ensure that interchangeability of parts is safe?

Issue 5. Products auditing is an ongoing NIOSH activity involving the acquisition of respirators to assure compliance with NIOSH certification requirements. These products are purchased from distributors, inspected, and tested to verify they continue to meet the NIOSH certification criteria. This activity provides a "snapshot" of the results of quality control, quality assurance, and manufacturing processes used to produce the certified respirator.

NIOSH currently procures approximately 64 respirators a year to perform product audits. With increasing budget constraints and the very small number of respirators that NIOSH can purchase each year, NIOSH may require manufacturers to supply respirators upon request for product audits.

(1) What would be the maximum number of respirator per year, aside from problem investigations, that NIOSH should request from a manufacturer, at no charge to NIOSH?

(2) How should NIOSH acquire products for audit (i.e., by voucher, reimbursement, random selection by NIOSH at the manufacturer or distributor)?

(3) Should manufacturer be charged for these product audits, since they are a condition of certification?

Issue 6. The NIOSH certification is issued for an unlimited number of units, without an expiration date. In the past, some certified respirators have been removed from production for a period of time, then returned to production. Some certification holders have even gone out of business. There is currently no provision for notification to be given to NIOSH of these events. Typically, NIOSH becomes aware of these events only when attempting to purchase the affected respirator for audit, or as a result of a field complaint.

Consequently, NIOSH has no information for most certified respirators on the number sold, or whether or not they are still in production.

The NIOSH certification is only removed in the event a certification rescission proceeding is invoked. Since 1919, only a couple of rescission proceedings have occurred. These proceedings are costly and time consuming to NIOSH, the manufacturers and users.

NIOSH is considering provisions that will inform the Institute on the production of respirators under a certification. These provisions could limit the time that a certification would

be valid or require notification of production status.

(1) Should the NIOSH certification be valid for a limited time?

(2) What conditions should be met for a time-limited NIOSH certification to be renewable?

(3) What time limits should be used for a NIOSH certification and renewal?

(4) Should certification holders be required to notify NIOSH of changes in production status and the number of produced units when production is halted?

(5) How would purchasers and users be affected if the certification of their respirator expires?

(6) Would an expired certification benefit purchasers and users by informing them that their respirator is no longer produced?

(7) Could information on the number of respirators produced under a certification be used to benefit purchasers and users?

Availability and Access of Copies: Additional copies of this document can be obtained by calling the NIOSH toll-free information number (1-800-35-NIOSH, option 5, 9 a.m.-4 p.m. ET); the electronic bulletin board of the Government Printing Office, 202/512-1387; and the NIOSH Home Page on the World-Wide Web (<http://www.cdc.gov/niosh/homepage.html>).

Dated: May 7, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[GC Docket No. 96-101, FCC 96-192]

In the Matter of Implementation of Section 34(a)(1) of the Public Utility Holding Company Act of 1935, as Added by the Telecommunications Act of 1996

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This notice of proposed rulemaking (NPRM) seeks comment on proposed regulations which implement new section 34(a)(1) of the Public Utility Holding Company Act of 1935 (PUHCA), as added by section 103 of the Telecommunications Act of 1996. Under new section 34, registered public utility