NIOSH Respirator User Notices

42 CFR Part 84 Respiratory Protective Devices

SUMMARY: This final rule was made available to the public at the Government Printing Office in Washington, DC, on June 2, 1995. It is scheduled for publication in the Federal Register on June 8, 1995, in Part II of that issue. This rule addresses NIOSH and the Department of Labor/Mine Safety and Health Administration (MSHA) certification requirements for respiratory protective devices. Specifically, the rule replaces MSHA regulations at 30 CFR part 11 with new public health regulations at 42 CFR part 84, while also upgrading testing requirements for particulate filters. Concurrently with publication by NIOSH of this new rule, MSHA published a final rule to remove existing regulations at 30 CFR part 11, which are made obsolete by this final rule. NIOSH will now have exclusive authority for testing and certification of respirators with the exception of certain mine emergency devices, which will continue to be jointly certified by NIOSH and MSHA.

The certification of air-purifying respirators under the final rule will enable respirator users to select from a broader range of certified respirators. All of these new respirators will meet the performance criteria recommended by CDC for respiratory devices used in health-care settings for protection against *Mycobacterium tuberculosis* (Mtb), the infectious agent that causes tuberculosis (TB). The CDC published "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994", in the Federal Register (59 FR 54242) and MMWR (Volume 43, No. RR-13) on October 28, 1994. All nine classes of air-purifying, particulate respirators to be certified under the provisions of the new particulate filter tests exceed the performance recommendations contained in the CDC Guidelines. Several of these new classes of air-purifying, particulate respirators are expected to be less expensive than respirators with HEPA filters.

This action is the first of a series of modules that will incrementally upgrade current respirator approval standards. This modular approach will allow improvements to be implemented on a safety and health priority basis as well as facilitate adaptation to new requirements by the manufacturers and users of respirators. It will also expedite the incorporation of technological advancements and will allow for expeditious response to emerging hazards.

Except for the particulate-filter standards, most of the existing regulations are incorporated into the new 42 CFR part 84 without change. The revised testing standards for particulate filters will significantly improve the effectiveness of air-purifying filters in removing toxic particulates from the ambient air. These changes are consistent with two decades of advances in respiratory protection technology.

Under the new particulate filter tests, NIOSH will certify three classes of filters, N-, R-, and P-series, with three levels of filter efficiency, 95%, 99%, and 99.97%, in each class. All filter tests will employ the most penetrating aerosol size, 0.3 µm aerodynamic mass median diameter. The N-series will be tested against a mildly degrading aerosol of sodium chloride (NaCl). The R- and P-series filters will be tested against a highly degrading aerosol of dioctylphthalate (DOP):

Filter Designation	Maximum Efficiency	Test Agent	Maximum Test Challenge Loading
N100	99.97%	NaC1	200 mg filter loading
N99	99%	NaC1	200 mg filter loading
N95	95%	NaC1	200 mg filter loading
R100	99.97%	DOP	200 mg filter loading
R99	99%	DOP	200 mg filter loading
P100	99.97%	DOP	Maximum filter degradation
P99	99%	DOP	Maximum filter degradation
P95	95%	DOP	Maximum filter degradation

Tested to a specified maximum loading level (200 mg), the N- and R-series will be certified with the recognition that in some settings time-use limitations will apply. A single shift time limitation, for example, may be appropriate. In addition to possible time-use restrictions, the N-series filters should be restricted to use in those workplaces free of oil or other severely degrading aerosols. The R-series filters would not have similar aerosol-use restrictions. The P-series filters will be tested with DOP until no further decrease in filter efficiency is observed. The P-series filters have neither aerosol-use nor time-use limitations. As for any filter, service time will be limited by considerations of hygiene and increased breathing resistance due to filter loading.

The final rule differs from the proposal (59 FR 26850) in eight ways. These changes are summarized as follows:

Proposal	Final Rule
2 categories of particulate filters (Solid; Solid and Liquid).	3 categories of particulate filters (N-, R-, and P-series).
Filter efficiency tests applied to all air-purifying particulate filters.	Filter efficiency tests apply only to air-purifying particulate filters for non-powered respirators. Filters for powered air-purifying respirators will be addressed in another module.
Inhalation resistance maximum at 30 mm; exhalation resistance maximum at 20 mm.	Inhalation resistance maximum at 35 mm; exhalation resistance maximum at 25 mm.
Isoamyl acetate tightness test for particulate respirators was included.	Isoamyl acetate tightness test was eliminated from the certification procedures.
Certification of filters was based on statistical evaluation of results form 30 filters tested.	Pass/Fail test based on results from 20 filters tested. All must pass.
Pending Part 11 applications would be processed for six months, and no new Part 11 applications accepted after the effective date of Part 84.	All pending Part 11 applications will be processed. All new applications received after the effective date of Part 84 will be considered applications for approval under Part 84.
Approval holders allowed to manufacture and sell Part 11 filters as approved devices for 2 years from the effective date of Part 84.	Approval holders allowed to manufacture and sell Part 11 filters as approved devices for 3 years from the effective date of Part 84.
No provisions were included for the continued issuance of extensions of existing 30 CFR Part 11 approvals.	A new subpart KK has been added for the issuance of extensions of existing 30 CFR Part 11 approvals to address respirator non-conformance when there is a demonstrated safety or health need during the 3-year transition period and for the approval of PAPRs until addressed in a later module.

EFFECTIVE DATE: This final rule is effective on July 10, 1995

FOR FURTHER INFORMATION CONTACT: Richard W. Metzler, Chief, Certification and Quality Assurance Branch, Division of Safety Research, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505-2888. The telephone number is (304) 285-5907. Copies of this final rule can be downloaded from the NIOSH World Wide Web page (http://www.cdc.gov/niosh/homepage.html) or may be obtained by calling the NIOSH toll-free information number (1-800-35-NIOSH, option 5, 9:00 am - 4:00 pm, ET). Arrangements have also been made for this final rule to be listed on the electronic bulletin boards of the Government Printing Office and of the Department of Labor; the telephone numbers are (202) 512-1387 and (202) 219-4784, respectively.

The HHS Press Release announcing the publication of the final rule is also available.

A current list of approved respirators under 42 CFR Part 84 is available.

The HHS Press Release announcing NIOSH certified respirators is also available.