DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 84

RIN 0905-AB58

Respiratory Protective Devices

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Public Health Service, HHS.

ACTION: Final rule.

SUMMARY: This final 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 with new public health regulations, while also upgrading testing requirements for particulate filters.

This action is the first of a series of modules that will incrementally upgrade current respirator approval requirements. 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 the expeditious response to emerging hazards.

Except for the particulate-filter requirements, most requirements of the existing regulations are incorporated into the new regulations without change. The revised testing requirements for particulate filters significantly improve the effectiveness of evaluating air-purifying filters to remove toxic particulates from the ambient air. These requirements are consistent with two decades of advances in respiratory protection technology.

The certification of air-purifying respirators under the final rule will also enable respirator users to select from a broader range of certified respirators that 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).

Elsewhere in this separate part of the **Federal Register**, MSHA is publishing a final rule to remove existing regulations which are made obsolete by this final rule.

EFFECTIVE DATES: This final rule is effective on July 10, 1995. The incorporation by reference of certain publications used in the regulations is approved by the Director of the Federal Register as of July 10, 1995.

FOR FURTHER INFORMATION CONTACT: Richard W. Metzler, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888. The telephone number is (304) 285–5907.

SUPPLEMENTARY INFORMATION:

I. Availability of Copies and Access to Final Rule

Additional copies of this final rule can 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. This final rule may also be obtained from the NIOSH Home Page on the World-Wide Web. The location for the NIOSH Home Page is http://www.cdc.gov/niosh/ homepage.html.

II. Paperwork Reduction Act

This final rule contains information collections that have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980 and assigned control Number 0920–0109. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Respiratory Protective Devices.

Description: This rule prescribes requirements and procedures which must be met in filing applications for approval by NIOSH of respirators and modifications of respirators.

Description of Respondents: Businesses and other for-profits.

Estimated Annual Reporting and Recordkeeping Burden:

Section	Annual number of respondents	Annual fre- quency	Average burden per response	Annual bur- den hours
84.35 84.41 84.43	56 56 56	10.5 10.5 10.5	22.70 hr	46,716 hr. 13,347 hr. 33,369 hr.
Total				130,805 hr.

The above citations are currently cleared under 30 CFR Part 11 as OMB control Number 0920–0109.

A Paperwork Reduction package is being submitted to OMB, requesting approval of the requirement for labeling to be effected by §84.33. A document will be published in the **Federal Register** when such approval has been obtained.

III. Background

NIOSH published a proposed rule (59 FR 26850) to establish a new 42 CFR part 84, on May 24, 1994. On May 26, 1994, NIOSH published a notice in the **Federal Register** (59 FR 27257) for an extension of the public comment period and a rescheduling of a public meeting. A public meeting was held to obtain comments on the proposal in Washington, D.C. on June 23–24, 1994.

The proposal and public meeting received response from the full complement of affected parties in the public. Commenters included safety professionals, respirator manufacturers, representatives of industrial and healthcare facilities, and workers' associations. Three hundred and three commenters responded to the proposed rule. One hundred twenty six commenters represented health-care workers. Ninety six commenters represented health-care facilities. Fifteen commenters represented associations of health-care professionals. Fifteen commenters represented associations of health-care facilities. Seventeen commenters represented respirator manufacturers. Eight commenters represented trade or manufacturers' associations. Eight individuals commented as private citizens. Six commenters represented regulatory agencies (federal, state,