

subject areas and timetable, NIOSH will conduct a public meeting to further develop the schedule with input from all interested parties. The location and date for this meeting will be announced in the **Federal Register**, Morbidity and Mortality Weekly Report (MMWR), and other media.

The Institute coordinated the development and implementation of the modular approach with OSHA and MSHA. The specific requirements of this first module were reviewed and accepted by both agencies to ensure that 42 CFR part 84 properly links with OSHA and MSHA respirator use regulations. Both agencies will participate in the development by NIOSH of appropriate user guidelines. NIOSH and MSHA developed a Memorandum of Understanding to delineate roles for the continuing joint approval under 42 CFR part 84 of respirators used for mine emergencies and mine rescue. The Institute will continue to collaborate with MSHA and OSHA as future modules are developed.

B. User's Guide

The proposal stated the intent to develop a user's notice or guide to explain the use of respirators certified for protection against particulate exposures under the new 42 CFR part 84 that would replace the existing filter respirators certified under 30 CFR part 11 subparts K and M. Commenters indicated that this user's guide should be developed in a public forum with public involvement. One commenter stated that the user's guide should be issued prior to the finalization of part 84. Another believed that its availability should coincide with the publication of the final rule. Constraints on releasing specific information as to the contents of the final rule prior to its publication limits the availability of information needed for development of a user's guide, thus making its development with public input prior to or concurrent with this rule impossible. NIOSH agrees with the commenters that public input into the user's guide will result in a better product. An informational respirator user's guide for part 84 respirators will be developed with public involvement.

The user's guide will address both the use of part 11 and part 84 respirators during the transition period. Assigned Protection Factor (APF) values are used in the respirator selection process to indicate the expected protection level for the respirator wearer. NIOSH recommends APFs for respirators certified under 30 CFR part 11 in its Guide to Industrial Respiratory Protection and in the Respirator

Decision Logic. The future user's guide will recommend APFs appropriate for use with the part 84 particulate respirators until APFs can be addressed through future rulemaking. It will also provide information and recommendations on a variety of other respirator use issues associated with this current rulemaking.

During review of this rule, both OSHA and MSHA expressed strong interest in the APF values for the new part 84 particulate filter classifications. Both agencies agreed with NIOSH that APFs could not be addressed properly in this first module. They therefore urged NIOSH to develop a subsequent module defining APFs for all respirators. In the interim, OSHA regulations under Title 29 and the MSHA regulations under Title 30 will allow the use of the new part 84 particulate classifications with the APFs to be established by NIOSH in the users' guide. OSHA is in the process of updating its respirator use regulations, and the current proposal specifies acceptance of APFs developed and promulgated under part 84.

C. Use of Particulate Respirators for Protection Against TB

While the requirements in this final rule were not developed specifically to certify respirators against biological agents, this rule will address the important public health need to control the transmission of *Mycobacterium tuberculosis*, the causative agent of TB, in health-care and other facilities through the use of respiratory protective devices.

In response to the recognized risk of TB transmission in health-care facilities, increases in TB in many areas, and recent outbreaks of multidrug-resistant TB, 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. These guidelines enumerate four performance criteria that CDC has determined are necessary for respiratory protective devices used in health-care settings for protection against TB. The only currently certified air-purifying respirator class that meets all the respiratory protection performance criteria in the CDC Guidelines is a respirator with a high efficiency (HEPA) filter. Many comments were received from the health-care community supporting the positive impact of the proposed rule on compliance with the CDC Guidelines.

All nine classes of air-purifying, particulate respirators to be certified under the provisions of the new

particulate filter tests (filter efficiency) in part 84 meet or 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. Consequently, implementation of the modifications included in this rule should promote a substantial increase in respiratory protection provided to health-care and other workers potentially exposed to the *M. tuberculosis* droplet nuclei in health-care and other occupational settings.

D. Conversion From 30 CFR Part 11 to 42 CFR Part 84

Since 1974, the Mine Enforcement and Safety Administration (MESA), MSHA, and the Occupational Safety and Health Administration (OSHA) have regulated the selection, use, and maintenance of respirators in the workplace under their respective enforcement authorities. NIOSH is not including the requirements of §§ 11.2 and 11.2-1 with this redesignation to 42 CFR part 84. Sections 11.2(a) and 11.2-1 refer to respirator use and selection criteria that since have been superseded by OSHA and MSHA respirator regulations.

Section 11.2(b) allows for the continued manufacture and sale of gas masks approved under the former U.S. Bureau of Mines (BOM) Schedule 14F (dated April 23, 1955). This Schedule was replaced by the requirements in Subpart I of 30 CFR part 11 in 1972. Gas masks approved under Subpart I of 30 CFR part 11 (14G canisters) are widely available and only a limited number of types of 14F canisters are marketed. MSHA experience indicates that few of the 14F respirators are currently sold or used. MSHA also indicated that removal of the provisions in § 11.2(b) would remove the authority to market these respirators as approved devices.

NIOSH is not transferring the requirements of § 11.2(b) to 42 CFR Part 84 since NIOSH does not have the capability to process applications for these respirators. The approval records on these BOM-approved respirators no longer exist and therefore NIOSH has no way of monitoring the production of these respirators to assure that they continue to meet the approved design. Thus, NIOSH will not authorize the sale and shipment of the Schedule 14F respirators under this part 84.

In addition, the codification of the redesignated sections into a non-hyphenated numbering system results in several general heading sections that contained no substantive requirements