

PROMULGATION OF TITLE 42, PART 84 CODE OF FEDERAL REGULATIONS
RESPIRATOR CERTIFICATION REGULATIONS

I am pleased to welcome you here today to discuss improved respirator certification standards and the Institute's new process for proposing them. This will be the first of many meetings to welcome and solicit public involvement in updating certification programs and standards.

The regulations that implement the Occupational Safety and Health and the Mine Safety and Health Acts require the use of NIOSH certified respirators. Respirators are currently certified jointly by NIOSH and MSHA in accordance with the Code of Federal Regulations Title 30, Part 11. These regulations are largely based on criteria developed by the U.S. Bureau of Mines between 1919 and 1969. They were last promulgated in 1972. They need to be updated to include contemporary performance, reliability and quality assurance standards, as well as, state-of-the-art test methodology to address emerging hazards and incorporate new technologies. This need for change was recognized in two concurrently published proposals in the Federal Register by MSHA and NIOSH in 1987. Consummation of this regulatory reform has been difficult because of the extensive scope and complexity of the reforms proposed. Revising the standards for all respirator types simultaneously proved to be a formidable task. Many difficulties were encountered that prolonged the process. The process was not equipped to meet this need in a timely way and limited our ability to respond to emerging hazards and to replace technically obsolete standards. This is evidenced by the age of the current filter penetration test that will be 60 years old this August. It delayed even those standards that were generally acceptable to all parties. NIOSH developed a new process. One that will propose revisions in a series of smaller steps or incremental improvements; thus adopting a continuous improvement strategy. This proposal signals the closure of earlier regulatory reform efforts and the beginning of a new process. It is consistent with reinventing government strategies, while meeting global challenges and making the most of the opportunities that they present.

The new process is referred to as a modular approach. It introduces standards incrementally rather than simultaneously revising the entire 30 CFR 11 certification standards. We are very excited about the possibilities for accelerating the incorporation of new technologies and improving our ability to timely address emerging hazards.

The proposed modular approach has many potential advantages:

1. Institute scientific talents and resources can be focused at developing improved standards needed to address the most pressing worker safety and health issues. This will facilitate the Institutes ability to

address emerging hazards such as that faced by HCW with the threat of MDR-TB and/or incorporate new technologies offering important health and safety benefits for workers.

2. Public participation in the rule making process will be facilitated by proposing important regulatory changes in segments of limited scope. Public attention can be focussed on a single topic rather than being divided among many technically diverse standards. A greater number of public meetings are anticipated in preparing proposals as we strengthen our partnerships. Other forums for public involvement will be explored.
3. With this modular approach the Institute has the opportunity to integrate both national or international standards which are not in the 1987 comprehensive proposal. This affords the Institute an opportunity to upgrade those standards to the most contemporary available anywhere.
4. Incremental promulgation of improvements should facilitate adaptation to new requirements by the respirator manufacturer and user communities. It will also minimize the potential for any disruption in the supply of certified respirators.
5. The modular approach allows the Institute to implement new standards most efficiently by focusing its scientific staff and resources in limited improvement areas.

This proposal introduces another important administrative revision. The Institutes approval responsibility is modified so that it is the sole certifying agency for the majority of respirators. MSHA will retain its role in the approval of respirators designed for mine rescue or other mine emergency use. This is a modification from the 1987 proposal. This provision recognizes MSHA's unique expertise in identifying the special needs and applications for respirators used in the mining environment. This joint review and certification would include associated reliability assurance service-life plans, use restrictions, user manuals, and other supporting documentation related to mine safety and health as a condition of certification. NIOSH and MSHA would also jointly address product and manufacturing-site audits, and recall and retrofit matters arising from field complaints or identified deficiencies concerning any respirators used in the mining environment. These joint certification activities are consistent the current practice between the agencies.

NIOSH is also proposing a limited revision to the existing technical standards of 30 CFR part 11 in this first module, requiring the improved filter standards that were initially

introduced in Subpart U of the 1987 proposal. These new standards would replace those of Part 11 that were developed in 1934. These proposed changes would produce significant improvements in the level of protection provided to the wearers of the respiratory protective devices. Users will be able to easily discern the level of protection that can be expected when using a particular respirator. These new filter standards provide a particulate efficiency classification system consistent with advances in respiratory protection technology. The new testing methodology is intended to demonstrate the filter's efficiency level against particulate of the most penetrating particle size range throughout the test period. The proposed test is also more stringent than Part 11 test requirements because the filter efficiency will be continuously monitored throughout the test, not just initially or averaged.

These filter performance standards will address the Institutes concern over the health risks to workers due to the inappropriate selection and use of dust/mist and dust/fume/mist respirators. Excessively high filter penetration can occur when these respirators are inappropriately used against aerosols less than 2 micrometers in diameter.

ADVANTAGES OF MODULAR APPROACH

Proactively addresses emerging hazards and new technology

Promotes and focuses public participation on a single topic for improvement

Provides an opportunity to integrate contemporary national and international standards

Facilitates transition to new requirements

Optimizes utilization of NIOSH staff and resources to develop and implement new standards and technology

MSHA ROLE

MSHA retains approval for respirators designed for mine rescue and emergency use

NIOSH will continue to recognize MSHA's unique expertise in identifying special needs for respiratory protection in the mining environment

Review and certification role includes:

- approval documentation
- reliability assurance service life plans
- use restrictions and users manuals
- field complaints, audits, recalls and retrofits

FILTER STANDARDS

Replace filter standards developed in 1934

Improve filter performance against sub-micron size particles

Produce a filter classification system consistent with current technology

Users can easily discern the level of protection of a particular respirator

Produce significant improvements in protection provided to the wearer

Presentation Draft and Key Points

RWM/RJB/HIL--6/14/94

PRESENTATION

I am fortunate and pleased to have joined NIOSH at a critical and exciting time. Government programs are being transformed across the entire Federal system. Like many government organizations, the Institute is undergoing substantial reform to improve its products and services. Dynamic changes in the Institute and the way we work are reflected in our commitment to quality and continuous improvement; to revitalizing existing, and initiating and nurturing new, partnerships; to the development of state-of-the-art laboratories and research programs in our new Morgantown facility; and to the creation and staffing of the new Institute Director's office right here in Washington, DC, just to mention a few.

These changes are not merely for the sake of change. There is truly a need for reform. We are embracing change because we want NIOSH to be less an autonomous bureaucracy, sometimes at odds with key sectors of society on issues of science and policy, and more a catalyst for effective social action that leads to improved worker safety and health.

The need for improvements in our respirator certification standards is evident. There have been no substantial regulatory changes for years. This has impaired our ability to incorporate technological

advances into our standards, and to respond in a timely way to emerging and resurfacing hazards.

Today's proposal is significant. It introduces a modular approach to regulatory improvement. The first module incorporates currently available technology that improves filter efficiency. At the same time, the provisions of this rule address an important public health need regarding the control of *Mycobacterium tuberculosis* in health care settings. Currently, air-purifying respirators with high efficiency (HEPA) filters are the only respirators that meet all of the proposed CDC respirator performance guidelines. However, all new classes of air-purifying, particulate respirators to be certified under the proposed Part 84 provisions would meet or exceed the CDC guidelines. These new respirators are expected to be markedly less expensive than respirators with HEPA filters. For these compelling reasons, NIOSH is planning to publish a final rule pertaining to particulate filters within this year.

Future modules will not only incorporate technological improvements in other respirator types, but will be developed with greater interaction with, and sensitivity to the needs of, our partners. Greater private sector participation will be encouraged by increasing the number of public meetings and other fora for public involvement in the process. The Institute has published a suggested schedule for additional modules as the first step in this process. We are open to hearing your priorities, suggestions, and comments.

We have the opportunity at hand to work together to replace the obsolete process of the past with a process that produces timely improvements, and ultimately, improved respirators, and reduced workplace exposures. I look forward to working with all of you in achieving the goal of enhanced worker safety and health through quality partnerships.

KEY POINTS

1. The Institute is undergoing a cultural transformation to improve its responsiveness in addressing worker safety and health needs and its partnerships. Many activities demonstrate change in the Institute--New Director, New Facilities in Morgantown, New HQ. in Wash, D.C, Partnership meetings, etc.
2. The past regulatory reform process has failed to produce a single (much needed) regulation improvement. Thus, limiting our ability to incorporate technological advancements into the certification standards and to timely address emerging hazards. The new modular process is being introduced in this Part 84 proposal greatly improves both.
3. The new filter performance standards incorporate the most contemporary filter technologies to improve protection for all workers. It also provides a greater number of respirators that meet the CDC respirator guidelines for protecting health care workers against MDR-TB. While meeting the CDC guidelines the new Part 84 respirators should cost substantially less than the current available choices.
4. The modular rule making process will encourage greater public participation. More public meetings are expected on narrowly

focused topics. New forums for public involvement will be explored. The emphasis is that a quality partnership among all members of the respirator community--labor, management, manufacturer and government --will enhance worker safety and health.