

Update on NIOSH Respirator Standards Affecting Healthcare

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NIOSH PPT Healthcare Stakeholder Meeting

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Presentation Outline

- **Background**
- **Standard Challenges**
- **Current NIOSH Respirator Standards Development**

Pertinent Regulatory Respiratory Protection Standards

- **OSHA Regulatory Standards - 29 CFR 1910 PART 1910 -- OCCUPATIONAL SAFETY AND HEALTH STANDARDS**
 - [Respiratory Protection](#) – 1910.134
 - [Hazardous Waste Operations and Emergency Response](#) – 1910.120
 - [Personal Protective Equipment](#) – 1910.132
- **NIOSH Regulatory Standards – 42 CFR Part 84 Respiratory Protective Devices**
- **FDA – 21 CFR 820 Medical Devices**

Respiratory Protective Devices Regulatory Authority

- **The regulatory authority for the NIOSH certification program for respiratory protective devices is found in the Mine Safety and Health Amendments Act of 1977 (30 U.S.C. 577a, 651 et seq., and 657(g)) and the Occupational Safety and Health Act of 1970 (30 U.S.C. 3, 5, 7, 811, 842(h), 844)**
- **These regulations have as their basis the performance tests and criteria for approval of respirators used by millions of American workers**

IOM Respirator Standards Related Recommendations (2010 update)

- **Finish development of the TIL certification requirements for half-mask air-purifying respirators**
- **NPPTL should develop certification requirements for a low-noise, loose-fitting PAPR for healthcare personnel**

Standards Challenges

- **Changes to Federal Regulations require rulemaking processes**
 - Rulemaking process does not lend itself to rapid change
 - Concerns over market disruptions and cost impacts
 - Agreement/Disagreement over the performance requirements
 - Industry concerns over certification and enforcement
- **Adoption of a consensus standard respiratory protection performance requirements into the federal regulations requires a process:**
 - The standard addresses the needs of the worker
 - Technical and Administrative issues
 - Checks and Balances of the consensus standards process
 - Government Agency involvement in the consensus standard development

Standards Coordination Challenges

- **Public Law(s) and Executive Order(s) define the Federal Perspective**
- **Federal movement to use National and International Consensus standards**
- **NIOSH needs to define the content of the respirator regulation through:**
 - The definition of performance standards necessary to provide respiratory protection
 - Transparent rulemaking process

Inward Leakage for half-mask air-purifying particulate respirators

- **Proposed Requirements identified in 2009 NPRM being revised based upon Public Comments**
- **Scientific Workshops with stakeholders in July and August to discuss findings**
- **Public meeting to discuss Technical Requirements being planned for September**
- **Initiate staffing of revised proposed rule later this calendar year**

Powered Air-Purifying Respirators

- **Inclusion of CBRN requirements**
- **Opportunity to incorporate requirements for a broader range of PAPR relevant to a greater range of stakeholders**

Requirement	Current 42 CFR 84	Proposed
Noise level	80dBA measured at ear for hoods and helmets only	80dBA measured at ear for all classes at maximum work rate for which approval is sought
Loose fitting – nominal air flow	170Lpm	115Lpm – Low work rate 170Lpm – Moderate work rate 235Lpm – High work rate

- **Request for Information 4Q FY 13**

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