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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 84**

**[Docket No. HHS-OS-2009-0019; NIOSH-0137]**

**RIN 0920-AA33**

**Total Inward Leakage Requirements for Respirators**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of proposed rulemaking; withdrawal.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces the withdrawal of its 2009 notice of proposed rulemaking (NPRM). The 2009 NPRM proposed to establish total inward leakage requirements for half-mask, air-purifying particulate respirators approved by NIOSH.

**DATES:** As of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], the proposed rule published on October 30, 2009, at 74 FR 56141, is withdrawn.

**FOR FURTHER INFORMATION CONTACT:** Rachel Weiss, Office of the Director, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS-C46, Cincinnati, OH 45226. Telephone: (855) 818-1629 (this is a toll-free number); email: NIOSHregs@cdc.gov.

**SUPPLEMENTARY INFORMATION:** On October 30, 2009, HHS published an NPRM (74 FR 56141) that proposed to establish total inward leakage requirements for half-mask, air-purifying particulate respirators approved by NIOSH under regulations found in 42 CFR part 84. The NPRM included a 60-day comment period closing on December 29, 2009, which was eventually extended to September 30, 2010 (April 20, 2010, 75 FR 20546).

In response to the proposed rule, HHS received comments from five respirator manufacturers, one manufacturer of laboratory test equipment, two labor unions, one trade organization, one state's departments of public health and occupational safety and health, three consulting firms, and three private individuals in the

field of respiratory protection. Stakeholders presented evidence that the approval decision outcomes could vary significantly between human subject panels that would be constituted according to the proposed test protocol, and expressed concern that the proposed approval requirements would not improve the performance of NIOSH-approved respirators on the market and might eliminate good-performing respirators from the market. Stakeholders also expressed concern that the cost of conducting inward leakage testing using the protocol proposed by NIOSH would be prohibitive and that costs would likely outweigh benefits.

As a result of the stakeholder input submitted to the docket and during public meetings, NIOSH decided instead to pursue improved inward leakage performance of this class of respirators through participation in national and international consensus standard development efforts, rather than rulemaking. Thus, HHS finds that the public interest is best served by withdrawing the 2009 total inward leakage NPRM. The withdrawal of the 2009 total inward leakage NPRM does not preclude HHS from initiating future rulemaking concerning total inward leakage requirements for half-mask, air-purifying particulate respirators.

The NPRM published on October 30, 2009 (74 FR 56141)  
is hereby withdrawn.

Dated: November 13, 2017.

Eric D. Hargan

Acting Secretary

Department of Health and Human Services

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