DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

49-039

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Centers for Disease Control
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National Institute for Occupational
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1095 Willowdale Road
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September 27, 1999

Janice C. Bradley, CSP
Industrial Safety Equipment Association
Technical Director
1901 North Moore Street
Arlington, Virginia 22209-1762

Dear Ms. Bradley:

Thank you for your letter of August 19, 1999, expressing concern about the inclusion of fit test requirements for respirators in an Administrative and Quality Assurance module. In the letter, you convey your perspective that properly designed fit test protocols have not been validated for use in product certification, and that there is significant controversy surrounding the meaning of such testing.

The National Institute for Occupational Safety and Health (NIOSH) published a Notice for priority rulemaking in the Federal Register on August 24, 1999 (64 FR 53998). That Notice listed areas for potential modification in the Administrative/Quality Assurance module to include: upgrade of quality assurance requirements; ability to use private sector quality auditors and private sector testing laboratories in the approval program; revised approval label requirements; validated approval fit tests; updated and restructured fee schedule; and fee retention in the respirator program. NIOSH is aware that some parties may question the appropriateness of inclusion of fit testing in an Administrative/Quality Assurance module. We believe NIOSH must fulfill the commitment made in the 1995 publication of 42 CFR Part 84 to propose fit testing for the approval process when research is completed. Your comments on this subject are appreciated and we welcome additional comments detailing your concerns on our published research.

By continuing to work together with the respirator community, we believe we will provide a better service that meets everyone's needs. We hope to use a number of forums. such as scientific conferences and meetings of health professionals, to present and discuss the scientific issues in the area. In that vein, we would welcome an opportunity to address the members of your Respirator Committee at one of their meetings. Please notify Richard Metzler or Paul Jensen if this is of interest to your Committee Members. We recognize and appreciate the support the Industrial Safety Equipment Association has provided for the modular approach to rulemaking and look forward to your continued support and participation in the NIOSH rulemaking process.

Sincerely yours,

Gregory R. Wagner, M.D.
Director
Division of Respiratory Disease Studies

CDC:NIOSH:DRDS:RB:PDT:Berry Ann:dkb
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