94-366

Industrial Safety Equipment Association

August 12, 1994

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

NIOSH Notice of Proposed Rulemaking on Respiratory Protective Devices, 42 CFR Part 84 (59 FR 26850)

Dear Sir or Madam:

The Industrial Safety Equipment Association (ISEA) is pleased to submit the following comments on behalf of its Respiratory Protection Group.

ISEA previously submitted its position regarding the NIOSH proposed test criteria for certification of Respiratory Protective Devices and has reviewed all public comments received at the docket. ISEA would like to present the following additional comments as a result of our review of the public comment.

Simulated Workplace Testing

Two commentors, Organization Resources Counselors ORC (94-307) and Mark Nicas (94-349), suggest the use of Simulated Workplace Protection Factors under laboratory conditions to evaluate the efficiency of respiratory protective devices. These commenters suggested that the manufacturers perform these tests on each of their products submitted for certification.

In 1987, NIOSH proposed such testing. At that time, ISEA provided comments and provides similar comments today.

Much is discussed about the need to correlate the results of simulated workplace testing or various laboratory testing with workplace testing before the proper confidence can be placed on non-workplace testing. While this is understandable, it is apparent that a point has not been reached in the development of workplace testing or simulated workplace testing where this would be possible. This was true in 1987 and still holds true today.

Correlation is only possible when all the variables affecting the results are known, controlled, or accounted for in a predictive equation. Today, the level of knowledge still has not progressed to the extent where all the information necessary for this understanding

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is available. It is not known whether one workplace study will correlate with another, let alone if any study will correlate to any testing conducted in a laboratory. Until such data is available, understood, and validated, simulated workplace testing and its generated protection factors will provide little meaning or confidence as to the efficacy of respiratory protection. For this reason, ISEA has suggested removing fit-testing from the proposed regulation. Fit-testing should be a requirement of use.

Respiratory User's Notice

Many of the comments address the confusion that will occur in the workplace with the nomenclature proposed for filter types and the information that will be available to use those filters in the current application. For example, Neoterik (94-290) and ORC (94-307) asked what would be put on the approval label. Presently, the approval label states limitations in terms of TWA's not less than or greater than .05 mg/m^3. What, if any, limitations will be placed on the new labels?

At least ten comments addressed the need for better guidance on the use of "solid" (S) and "solid/liquid" (S/L) filters. Several others addressed the need to have guidance in selecting filters for paints, fumes, or other particulates for which specific approvals are granted under 30 CFR 11. For the reasons above, in addition to the preponderance of comments about the efficacy of any of the filter respirators proposed in 42 CFR 84 for use in protection against infectious disease, ISEA would like to reemphasize the need for a comprehensive use document developed in conjunction with other agencies, including OSHA, DOE, MSHA, NRC, user groups, and respirator manufacturers and, in particular, the ISEA.

The TB Issue

While ISEA acknowledges the concerns of the health care industry and commends NIOSH for its attempts to address this concern within the first module of 42 CFR 84, ISEA is concerned that a precedent is being set by respirator certification rulemaking focused on the requrements of a small segment of the respirator-use community.

ISEA members manufacture a broad range of respiratory protection devices intended to protect workers in a vast array of hazardous work environments. In the case of particulate respirators, the health care community represents a small percentage of workers requiring respiratory protection. By developing respirator certification performance requirements with a focus on the health care worker, the potential for underemphasizing the protection requirements of the remaining millions of industrial workers exists. The result is an unnecessary burden on the vast majority of particulate respirator wearers, by virtue of an unnecessary added cost and decreased comfort and use, which may lead to less effective protection. There are still unknown factors related to respiratory exposure to TB. Threshold limit values and permissible exposure limits have

not been established. In addition, two studies submitted to the docket from the New England Journal of Medicine and the Annals of Internal Medicine support the use of administrative and engineering controls over respiratory protection for protection against TB in the health care setting. Specific selection information, such as in the case of TB protection, should be addressed in a users notice when pertinent application and limitation information is available.

ISEA recommends that NIOSH establish particulate respirator certification performance requirements that address the protection requirements of the majority of workplace settings. This is supported by ISEA's recommendation to expand the efficiency range to include 99.97%, 96%, and 90% classifications.

Sincerely,

Daniel K. Shipp
President

cc: Richard Metzler, Chief, NIOSH-CQAB