840-458

ISEA Industrial Safety Equipment Association

August 16, 1996

NIOSH Docket Office
Robert A. Taft Laboratories
M/S C34
4676 Columbia Parkway
Cincinnati, OH 45226

RE: NIOSH Request for Public Comments: Changes to Administration of Respirator Certification and Establishing Priorities to Future Rulemaking.

Dear Sir/Madam,

The Industrial Safety Equipment Association (ISEA) is the leading national organization representing manufacturers of personal protective equipment and clothing. ISEA is dedicated to protecting the health and safety of all workers, including those at factories, construction sites, farms, and health care facilities. Collectively, ISEA respirator manufacturers hold 88% of all NIOSH certifications.

The following are comments of the ISEA in response to the notice published in the May 16, 1996 *Federal Register* (61 FR 24740) by the National Institute for Occupational Safety and Health (NIOSH). ISEA provided oral comments at NIOSH's June 6, 1996 public meeting in Washington, DC. These comments expand upon that oral presentation and address the questions raised by the NIOSH panel at the public meeting.

Technical Amendments to First Module

ISEA believes that before NIOSH releases subsequent modules of 42 CFR 84, it should publish technical amendments to the first module, which revised performance criteria for non-powered air-purifying negative pressure respirators. In particular, NIOSH must clarify that the preloading requirement of the first module is 200 mg per respirator unit, not per filter. If this requirement is not clarified, all approvals issued under Part 84 for dual filter respirators challenged with 200 mg per respirator could theoretically be challenged as invalid. This would create unnecessary problems for both manufacturers and NIOSH and should be amended.

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Priority of Technical Modules

Issue 1

In the *Federal Register* notice, NIOSH correctly identifies the three main considerations to be used to prioritize the schedule of remaining Part 84 technical modules: standard public health criteria, opportunity for cost savings and expediency by which a change can be implemented.

Protection of public health is NIOSH's foremost priority and is part of the agency's charter. Protection of public health is also the objective of respirator manufacturers and should continue to be NIOSH's top consideration when prioritizing the schedule of remaining modules. Next, NIOSH should consider any opportunity for cost savings. Such savings will benefit manufacturers by reducing production and distribution costs. These savings, in turn, will be passed on to the end-users, making respiratory protection more readily available to workers. Finally, expediency by which change can be implemented should be considered to the degree that it will give end-users access to better products more quickly.

ISEA has consistently supported NIOSH's efforts to revise existing respirator performance criteria, both in principle and by providing technical and other relevant information. ISEA believes these contributions have shortened the time needed to develop well-supported and documented changes to the regulations. The contributions also have lessened the likelihood of successful legal challenges and resulting delay by ensuring end-users have access to new, top-quality respiratory protection products. ISEA is committed to continuing to assist NIOSH in developing technically supportable improvements in its respirator certification program.

Issue 2:

In applying the criteria identified above, ISEA members believe that the modules on Administrative and Quality Assurance and Powered Air Purifying Respirators (PAPRs) should be given equal priority and should be revised simultaneously. Each of these modules is critically important to the development of new, improved respiratory protection products. Protection of public health demands that the best possible products be made available to end users, and revised certification criteria would encourage development of new, more user-friendly PAPRs. By simultaneously updating the administrative aspects of certification, NIOSH would ensure that manufacturers were meeting the highest standards for quality assurance, which also serves the interests of public health.

Simultaneous development of these modules also would effect cost savings and could be implemented quickly. Administrative costs presumably would be reduced as greater efficiencies are built into the current system and new less expensive PAPRs are developed on the basis of filter technologies developed for other Part 84 modules. Because of manufacturers' internal quality assurance standards and ISO certifications, changes to NIOSH administrative procedures could be implemented quickly with little disruption of

the current application process. Similarly, development of new PAPR systems would be facilitated by new Part 84 particulate filters. Changes in certification requirements for many other PAPR product features -- such as battery life and low flow indication-- could be implemented almost immediately.

Revisions to the Administrative and Quality Assurance module are essential for both manufacturers and NIOSH in addressing the factors driving the current peak workload at the Morgantown respirator testing facility. These revisions are discussed further in Issues 2 and 3 of the Administrative and Quality Assurance module comments. According to recent NIOSH records, the Morgantown facility averaged 52 certifications and 67 applications per month with a working inventory of 183 applications from July 1995 to March 1996. From January to May 1996, NIOSH averaged 70.4 certifications and 80.4 applications with a working inventory of 201.6. May 1996 set a record for applications received at 119. Revamping the Administrative and Quality Assurance procedures will streamline application processing, reduce approval turnaround time to under 90 days (ISEA's recommended target turnaround time for a respirator certification), and facilitate revisions of future respirator performance modules.

The revised administrative procedures module should establish criteria for design review and quality assurance. Appropriate revisions to this module would permit the development and manufacture of new products without the delays imposed by NIOSH's existing system of reviewing all manufacturing procedures, drawings, and quality plans. Adoption of ISO 9000 design documentation would make NIOSH review of design documentation unnecessary and save NIOSH significant application review time.

In addition, implementing ISO 9001 procedures in place of the existing 42 CFR Part 84 design and quality assurance criteria requirement would eliminate the need for NIOSH audits of manufacturing sites. According to comments made by consultant Tom Radtliff at the public meeting, the cost to become ISO certified is approximately $20,000-$25,000 for manufacturing sites of approximately 300 employees. Many large respirator users are requiring their suppliers to be ISO certified. At present, 75% of ISEA respirator manufacturers are ISO certified or in the process of becoming ISO certified and acknowledge this as a cost of doing business in the international marketplace. Should NIOSH adopt ISO procedures, we recommend that a grandfather period be instituted to allow manufacturers time to attain ISO certification.

We also recognize that no national or international standards exist that can completely substitute for the Administrative and Quality Assurance module. Nonetheless, conformity with ISO 9001, insofar as possible, should be a NIOSH objective.

Economic gains to any administrative changes made to streamline the application process, including the elimination of unnecessary paperwork requirements and testing and adopting alternative auditing processes, would result in reduced costs to manufacturers and end users.

A PAPR performance module is essential because the testing requirements for PAPRs are the only particulate respirator criteria that were not revised under the first module of 42 CFR 84. The current regulation imposes somewhat antiquated testing requirements and procedures that hinder the development of new products. By aligning PAPRs with N-R-P classes of negative pressure respirators, a PAPR module would enable manufacturers to develop the next generation of products and further enhance worker protection. The existing PAPR requirements, therefore, should be updated to reflect the changes to the certification criteria for other particulate respirators. Due to the extensive needs of this issue, the ISEA has formed a subcommittee to draft additional detailed comments regarding the PAPR modular revision and will provide NIOSH with its version of a revised PAPR module in 1997.

NIOSH also should develop a module for Respiratory Protective Escape Devices (RPED), or smoke hoods. This should follow the Administrative/Quality Assurance and PAPR modules. The ISEA RPED Group is working on a final draft of an American National Standard for Respiratory Protective Escape Devices. The ISEA will submit a proposal for the RPED module for non-traditional respiratory protection devices following approval of the ANSI standard.

After RPED, NIOSH should address supplied air respirators (SARs). New criteria and test methods are needed because the present requirements for SARs do not adequately assess performance.

ISEA believes that NIOSH should revise the man tests for SCBAs, particularly the tests for self-contained, self rescuers (SCSR). This portion of the standard needs to be revised because of the reliance of the underground mining industry on SCSRs. Current testing uses antiquated "man-tests" as the methodology for evaluating the performance of these devices. Man-tests are very subjective in terms of duration measurement. Test subject performance varies greatly from test to test, introducing variables in the evaluation that impact the duration of each test, rendering results statistically invalid. A metabolic simulator protocol should be developed to eliminate subjectivity in the approval process. Optimization of device designs cannot be achieved without a common duration assessment process. The existing duration assessment regulations promote "over-design" of SCSRs at a time when the mining industry is looking for a lightweight, compact design, permitting SCSRs to be used as individual escape devices.

Revisions to the NIOSH supplied air section should incorporate NFPA 1981 standard's requirements for SCBA used for firefighting. Some NFPA requirements (higher air flow rates, lens abrasion resistance, etc.) are applicable for all users, not just firefighters.

For all these reasons, NIOSH should revise the test requirements for SARs to improve the flow performance and man testing assessment. Many SARs have already been designed to meet the more stringent NFPA requirements. The addition of new breathing machine tests, flow requirements and metabolic tests will significantly upgrade 42 CFR 84 and will lead to increased protection for workers.

ISEA does not believe that there has been a need identified to justify the changing of the present requirements for gas/vapor respirators, nor to include fit testing requirements within 42 CFR Part 84. Gas/vapor respirators have not been problematic for end users and there is no need to alter the current certification requirements. Fit testing requirements should be part of a comprehensive respiratory protection program for the user and do not belong in product certification rulemaking. We would therefore not include either as future modules.

ISEA believes that all the recommended changes identified in this summary are feasible and welcomes the opportunity to assist NIOSH in developing these modules with appropriate provisions from the ISO and NFPA standards included in future proposed rules.

Issue 3:
ISEA can assist NIOSH in disseminating information to respirator users by supplementing NIOSH's traditional information distribution channels. Because ISEA member companies hold 88% of NIOSH certifications, these manufacturers can help ensure that customers are informed of changes that affect respirator producers, distributors and users.

Administrative and Quality Assurance Module

ISEA believes that NIOSH plays a vital role in providing in-house testing and administrative review of respiratory products submitted for approval. We recognize manufacturers have responded to the new 42 CFR 84 certification criteria with new product submittals, which now are taxing NIOSH's ability to process these applications. We urge NIOSH to provide sufficient resources to accommodate the increasing respiratory certification and testing workload.

Issue 1:
ISEA believes laboratory tests carried over from 30 CFR Part 11 and currently being conducted by NIOSH to certify respirators are neither well defined nor reproducible. Presently, only NIOSH and most manufacturers have the facilities and expertise to conduct certification testing to existing regulations.

Issue 2:
The NIOSH approval label has become a symbol of integrity to end users, who have come to believe in its value. To uphold this reputation, ISEA believes that NIOSH should become ISO/IEC Guide 25 and ANSI Z34.1-1992 certified as a qualifying body for third party certification.

Respirator manufacturers should be ISO 9001 certified before applying to NIOSH for product certification. Manufacturing sites should at a minimum be ISO 9001 or 9002 certified and be audited before manufacturing begins. There are currently many manufacturing and quality assurance design documents that are developed by manufacturers for NIOSH only and have no other purpose in the manufacturing process.

Utilizing some of the existing ISO requirements would save manufacturers valuable document preparation time and NIOSH review time. ISO audits are based on the content of manufacturers' quality plans. NIOSH can require that specific design and quality assurance information be incorporated into the quality plans required for ISO registration. ISO certification would then reflect the auditing of NIOSH requirements. In addition, ISO designations would provide end-users with further assurance regarding the use of equipment designed to protect their health.

Issue 3:

NIOSH fees for testing and certification should reasonably relate to the task and should include both certification and audit costs. As ISEA members stated in their revised comments to NIOSH on proposed 42 CFR 84 in December 1987, NIOSH should compute the costs of testing and certifying respirators based on the actual cost to conduct such tests and publish a fee schedule for public comment. For tests that lack enough information to calculate an appropriate fee, NIOSH should charge a flat or hourly rate based on actual technical and support staff time and testing supply costs.

ISEA believes these fees should go directly to NIOSH to support the certification program. Currently several Federal agencies receive public funding to conduct review or certification programs for private industry. The "Prescription Drug User Fee Act of 1992" requires members of the pharmaceutical and biological prescription drug industries to pay a fee to the Food & Drug Administration (FDA) to "assist in funding the application review activities of the FDA Center for Drug Evaluation and Research." The program was originally initiated to "eliminate the overdue backlog of NDAs (new drug applications) within 24 months of initiation of user fee payments.[1]

In addition, the President's 1997 budget proposal recommends implementing dozens of new user fees. Specifically, the Department of Agriculture's Animal and Plant Health Inspection Service, with fees covering the costs associated with insurance of biotechnology permits will charge fees to firms that manufacture chemically engineered fruit and vegetable commodities. Another example is the Department of Energy's decontamination and decommissioning fee, which will be charged to U.S. and foreign companies and deposited in a fund to carry out environmental clean up of the government's uranium enrichment plants. The Department of Transportation's aviation-related user fees are charged to the airlines for the cost of supporting the operation and maintenance of a continued safe and efficient National Space System. Currently, there is a bill before Congress which would reform the FDA's medical device certification procedures, creating an approval program funded by the users of the certification. Not

[1]Public Law 102-571, October 29, 1992, 102nd Congress states in part: "the Congress finds that prompt approval of safe and effective new drugs is critical to the improvement of the public health...the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process of the review of human drug applications... the fees authorized by this title that are dedicated toward expediting the review of human drug applications..."

only is the fee system put into place under the 1992 FDA Prescription Drug User Fee Act identical to what is suggested for NIOSH, the impetus for doing so is the same as well.

If NIOSH audits are replaced by ISO audits, the number and cost of audits will be kept to a minimum. Any cost savings resulting from the consolidated audit process can be passed on to manufacturers and end users.

Issue 4:
ISEA has consistently opposed the certification of components, including a statement on September 13, 1982 to the OSHA Docket. ISEA members maintain the position expressed then, that we favor certification of complete devices. We would only be in favor of individual respirator component certification if the same manufacturer who has been granted approval for a complete respirator submits the components, and they are certified only for that manufacturer's products. We would not support the certification of interchangeability of components among manufacturers. It must be clear to users that NIOSH only issues certifications for products containing a single manufacturer's components. A respirator manufacturer cannot assure the overall performance of its device if other manufacturers' components are interchangeable with those of the original manufacturer. Components from different manufacturers will not provide the same level of protection originally designed into the respirator, which is certified as a complete device. In countries where individual components are certified, component interchangeability has been strictly limited to specific designs and to specific products.

Issue 5:
NIOSH (or ISO) auditors should randomly select enough devices from a manufacturer's production line or inventory to adequately evaluate the manufacturer's quality assurance program. At the time of the audit, a device can be selected from either the manufacturer's most recent supply of equipment or from the assembly line. Selection of the device at this time eliminates the existing voucher system. The manufacturer's audit fee should be part of an all-inclusive certification fee. The fee should represent the total cost to NIOSH of certification and associated testing.

Issue 6:
As long as NIOSH requires notice of product modifications, NIOSH certification should not expire. Manufacturers are already required to notify NIOSH of any changes to products; therefore, renewal applications for products that are unchanged would only worsen the current certification backlog with no benefit to the end user. We believe that implementing and imposing expiration dates on certified products would be counter productive to efforts to streamline the application process and to keep costs to end users low. To address NIOSH's interest in keeping the public informed, respirator manufacturers can periodically notify NIOSH and identify their products as Active, Inactive or Obsolete. Information regarding changes in the production status or the number of respirators produced is inconsequential to the end user and may only lead to confusion.

Conclusion

ISEA appreciates the opportunity to work with NIOSH as the Institute proceeds through the module prioritization process. We believe that the Administrative and Quality Assurance and PAPRs modules should have the highest priority and we recommend that NIOSH pursue their revisions in parallel. Since NIOSH's requirements for manufacturers should be the equivalent of ISO 9002 requirements, we urge the use of ISO certification in place of current NIOSH design and quality assurance requirements. ISEA will continue to support NIOSH efforts to identify ways to provide the greatest number of workers with the state-of-the-art in respiratory protection and will work with NIOSH to achieve these common objectives.

Respectfully submitted,

Daniel K. Shipp
President