846-472

August 8, 1996

Docket Officer
NIOSH
M/S C34
4676 Columbia Parkway
Cincinnati, OH 45226

Dear Sir:

This is in response to the May 16, 1996 Federal Register notice for which NIOSH solicits comments on issues related to fees, privatization of certification, auditing of products, as well as setting priority for future modules.

I believe that privatization is not in the interest of the respirator users since NIOSH has performed an admirable job in getting respirators tested and approved. Since each testing method is critical to protect the health and safety of a specific group of workers, setting different revision times for different modules would discriminate against workers from different groups. All testing modules should be implemented at the same time. The privatization issue should only be considered when all testing methods have been revised and implemented. I am enclosing my comments on these issues.

I would like to thank you for the opportunity to comment and also to offer my assistance in developing the revised respirator testing and certification regulations.

Sincerely,

Ching-tsen Bien, PE, CIH

Enclosure

COMMENTS ON THE PART 84 RESPIRATOR CERTIFICATION

A. Priority of Technical Modules

Since each type of respirator provides protection for a specific group of workers, setting different revision times for different modules would discriminate against workers from different groups. NIOSH already completed a proposal in 1987 and a revision was made on that proposal. To avoid further delay, NIOSH should reintroduce the revised proposal with the following additions or modifications:

1. Simulated Workplace Testing

Since the fit testing requirement was deleted from the filter module, some approved filtering facepieces provide poor fit. To insure that approved respirators provide adequate faceseal especially under adverse environmental conditions, simulated workplace testing is the test of choice. Under the joint sponsorship of the Occupational Safety and Health Administration (OSHA) and the Nuclear Regulatory Commission (NRC), the Los Alamos National Laboratory (LANL) conducted a simulated workplace testing of various types of respirators under the extremes of temperature and humidity[1]. The results indicated that high temperature and humidity would reduce the effectiveness of tight fitting negative pressure air-purifying respirators. However, these test conditions have no effect on the continuous flow respirators, such as powered air-purifying respirators (PAPRs) and supplied air respirators (SARs). The controlled test conditions of simulated workplace testing would ensure that all respirators are tested under the same conditions. This test method is also able to correlate test results and set rankings of respirators in the same class as well as from different classes. NIOSH should adopt the LANL testing protocol for simulated workplace testing.

2. Minimum Acceptable Flow Rate for PAPRs and SARs

Another OSHA sponsored simulated workplace testing was conducted by the Lawrence Livermore National Laboratory (LLNL)[2]. In this study the performance of approved PAPRs was evaluated under a heavy work rate and at different air flow rates. The results indicated that the approved flow rate of 117 liters per minute (lpm) for the tight fitting PAPRs is inadequate to maintain a positive pressure inside the tight fitting PAPRs. An air flow of 170 lpm would maintain a positive pressure inside the tight fitting PAPRs. Based on this study, NIOSH should set the minimum air flow rate of 170 lpm for certifying tight fitting continuous flow respirators such as PAPRs or continuous flow supplies air respirators (CFSARs). By similar reasoning, a higher approval flow rate should be required for loose fitting continuous flow respirators. Alternatively, each continuous flow respirator should be required to carry out this test to determine the minimum flow rate that would achieve a positive pressure inside the respirator inlet covering.

3. Open-Circuit Self-Contained Breathing Apparatus

The test requirements for open-circuit self-contained breathing apparatus (SCBA) prescribed by the National Fire Protection Association (NFPA) standard 1981[3,4] is more stringent than NIOSH's testing criteria. The NFPA standard has been recognized by many states and many fire departments require the use of SCBAs meeting the testing requirements of the NFPA-1981. NIOSH should adopted this standard to ensure the safety and health of fire fighters.

4. Continuous Flow Escape SCBA

The continuous flow escape SCBA is widely used for escape from the immediately dangerous to life or health (IDLH) environments. However, there are no testing requirements established by NIOSH to evaluate the performance of these devices. There is a wide variation of air flow provided by these breathers. Some have a flow rate as low as 30 lpm for a service life of 5 minutes. Studies conducted by LLNL and OSHA[5,6] indicated that at a moderate work rate, the concentrations of oxygen and carbon dioxide inside the hood of the low air flow units reached IDLH conditions at three minutes after deployment. The LLNL and OSHA studies indicated that a minimum air flow of 70 lpm is needed to maintain the oxygen and carbon dioxide concentrations at a safe level. NIOSH should set test criteria for the continuous flow escape SCBAs based on these two studies.

5. Supplied Air Suit

The supplied air suit provides the whole body protection against hazardous materials as well as providing relief of heat stress. However, there is no suit testing criteria developed by NIOSH. Under the authorization of the Department of Energy, the LANL tests and approves supplied air suits. The LANL test criteria[7] should be adopted by NIOSH for suit testing.

6. Powered air-purifying respirators (PAPR)

a. Low Air Flow or Negative Facepiece Pressure Warning Device

A low air flow or facepiece pressure warning device should be required for all PAPRs to ensure that workers are protected, since workers are not able to detect whether the PAPR provides adequate air flow. Several manufacturers have marketed PAPRs with a low air flow warning device. Due to the higher manufacturing cost, the demand is low. Many manufacturers have discontinued the warning device. NIOSH should study this problem and develop air flow and facepiece pressure warning device testing criteria for PAPRs.

b. Pressure Demand PAPR

A testing criteria should be developed for approving pressure demand (PD) PAPRs. A PDPAPR would increase the service life of sorbent and battery packs. If there is no testing method, the manufacturer would not be interested in developing this device.

c. PAPR for the Health-Care Industry

The work environment for the health-care industry is quite different from that of the general industry. A hospital is very clean and usually workers may not need the high air flow rate, heavy battery pack, and other requirements which are designed for general industry use. If the air flow or other requirements which are applicable to the industry setting are modified, a light weight hood type PAPR could be developed. A hood type PAPR which weighs less than 1 kilogram and uses D-size batteries was developed in the U.K. for protecting civilians during the Israeli-Iraq conflict. A light-weight PAPR with a flow rate of 70 lpm could be designed and provide adequate protection without bulk for health-care workers.

B. **Administration and Quality Control**

Issue 1. Independent Laboratory to Conduct Certification Test

The major responsibility of the respiratory protection certification program is to ensure that certified respirators provide adequate protection to workers. The NIOSH staff has performed an admirable job in getting respirators tested and approved. The current program on respirator testing is not deficient and should not be changed. The question is that NIOSH lacks the funds to perform other functions which are critical to the certification program, such as product audits and complaint investigations. There is no cost saving to the respirator manufacturers whether NIOSH or an independent laboratory conducts the test. The issue is that all the funds NIOSH collects for certification testing must be returned to the Treasury. In order to make the certification program self-supporting, NIOSH should request authorization that would allow NIOSH to collect fees and make frequent adjustments to make the program self-supporting. NIOSH could also charge each manufacturer a certification maintenance fee based on the units of respirators produced by the manufacturer. If annual respiratory sales is $ 200,000,000 per year, a two percent maintenance fee would be $ 4,000,000, which should be adequate for NIOSH staff to conduct more frequent quality control audits, complaint investigation and perform additional tests to evaluate the performance of respirators during use.

In order to accept independent testing laboratories, NIOSH must develop certification and auditing criteria that may take time to develop. Furthermore, more NIOSH staff would be needed to conduct frequent visits to the laboratories, consuming the scarce resources at NIOSH.

Issue 2. Use of Internationally Certified Auditors

Integrity and user confidence are the major emphasis of the audit program. The public may not have trust in the private auditors and laboratories. Any consensus standard is a compromise which may not be in the interest to the users. For example, the original CEN draft standard on chemical cartridges testing requires an equilibration test since moisture has a detrimental effect on the service life of cartridges. However, this proposal was deleted in

the final standard. Has NIOSH reviewed the ISO auditor certification program to ensure that the program has no compromise on the integrity of the auditor? Has the ISO-9000 auditor program specifically addressed to respiratory protective equipment audits? How are the qualifications of auditors determined? Has NIOSH communicated with European countries that accept the use of independent auditors to determine how the integrity and effectiveness of independent auditors are monitored by these countries? Since the quality of the respirator would affect the health and well being of workers, severe criminal sanctions should be imposed upon independent test laboratories and auditors for failing to fulfill their responsibilities.

If NIOSH has sufficient funds to carry out this program as suggested in Issue 1, there is no need to use independent auditors.

Issue 3. Fees for Conducting Certification

Please refer to Issue 1

Issue 4. Certification of components

The major issue confronting respirator manufacturers is product liability. Respirator manufacturers are often being sued, even when due to the negligence of the employer. NIOSH should not certify the component alone because of the liability concern. Furthermore, component manufacturers are generally smaller in size than the respirator manufacturers, and they may not have sufficient insurance to cover liabilities. To increase competition among manufacturers, NIOSH should only allow the interchange of atmospheric supplying respirator components among approved assemblies. The OSHA standard on Fire Brigade, 29 CFR 1910.156, permits the interchange of air cylinders among different makes of self-contained breathing apparatus. However, due to differences in design, each brand has a different flow rate and alarm triggering time, making air cylinders non-interchangeable even when the same air cylinder is used by these manufacturers. NIOSH should set uniform design requirements for respirators to make them functionally interchangeable.

If NIOSH decides to certify components, an insurance fund of manufacturer contributions should be established to compensate injured users in case the manufacturer ceases operation.

5. Products Auditing

NIOSH should set a requirement that respirator manufacturers supply NIOSH with free product coupons so that NIOSH could use these coupons to obtain samples from distributors or users for quality control audits or problem investigations. The number of coupons should be based on the units produced. The distributors or users can use these coupons to obtain products or receive credits from the manufacturer. NIOSH should return non-consumable respirator components to the manufacturers after testing. In order to ensure random selection of products, NIOSH could ask OSHA compliance officers to collect samples at different

locations in the country.

Issue 6. Life of Certification

Most national consensus standards organizations, such as the American National Standards Institute, update their standards periodically. NIOSH should set a time interval, e.g. every 5 years, to review the standards. In addition, NIOSH should require manufacturers to issue an annual report which lists the number of respirators produced for each model and the certification number for each model. If the manufacturer is only a distributor, the source of the manufacturer should be identified. If a new standard is needed, a grandfather clause, similar to the one used for the transition between respirators approved under provisions of 30 CFR 11 and 42 CFR 84, can be used to allow for a smooth transition while the new regulation is phased in.

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