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Dräger

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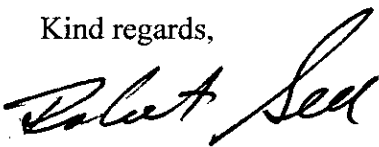
Subject: 42 CFR, Part 84; Proposed Rules

To whom it may concern:

In accordance with the Federal Register dated May 16, 1996 concerning requests for public comments in preparation of rulemaking to revise current NIOSH procedures for certifying respiratory devices used to protect workers in hazardous environments the attached response is being provided. If there should be any questions or clarifications required please do not hesitate to contact me. I can be reached in any of the following manners:

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Kind regards,



Robert Sell
Senior Mechanical Designer

attachements

R E C E I V E D

AUG 15 1996

NIOSH DOCKET OFFICE

A. Priority of Technical Modules

Issue 2 (2):

- Are there any subject areas for improving current certification requirements that are not in this notice that should be considered in the prioritization process? If so, please include an explanation of the importance of the subject and describe in general terms the changes needed in current requirements.
 - Various test protocol for SCBA/SAR certification utilizes test equipment specific to the NIOSH certifications process. Some of this equipment reflects obsolete technology and needs to be updated. Revising the test protocols and updating the equipment would assist the manufacturer's, independent test labs, and NIOSH in achieving consistent pre-certification and certification test data.
 - Revision of the SCBA standard to separate the requirements for Open-Circuit SCBA from the requirements for Closed-Circuit SCBA.
 - 42 CFR, Part 84, Section 84.89 identifies the maximum weight requirement for SCBA as 35 pounds. The standard does provide for a maximum weight of 40 pounds as long as the additional equipment significantly contributes to the wearers comfort. Also, it is our understanding that the weight of the accessory items are not included in this calculation. Therefore, we are recommending the following:
 - * A definition be added to the standard for "Accessory." A possible definition could be: "An item, provided by the SCBA manufacturer for use with their SCBA, which is attached to the SCBA and is not a critical component required for the SCBA to function in accordance with this standard."
 - * NIOSH should also consider revising their position concerning the 40 pound weight limit to not only include wearer comfort but to also consider safety and function. A typical fire fighter often carries 60 pounds or more of protective clothing and equipment. This includes such items as a PASS, helmet, communication systems, lamps/strobes, etc. In order to develop a lower total ensemble weight and improve firefighter protection, design technology is moving toward integrated equipment designs such as the integrated helmet and PASS devices. The present NIOSH practice concerning the weight requirement is design restrictive and prevents the development of safer equipment with a lower net ensemble weight and reduced heat-stress health hazard to the fire fighter.
 - At a minimum, if the weight requirement is to remain the same, revise the maximum weight requirement from 16 Kg (35 pounds) to 16 Kg. (35.3 pounds) in order to maintain the proper conversion.

Issue 3 (1)

- How should NIOSH notify respirator purchasers and users of revised priorities?
 - Currently, any changes to the standard have been published in the Federal Register. This practice should be maintained.
 - Through the NIOSH Homepage on the Internet. To assist NIOSH in getting their Internet address out to the public, they could request that each manufacturer voluntarily add it to the operation instructions that accompanies each respirator.

B. Administrative/Quality Assurance Module

Issue 1 (1)

- Are private sector testing laboratories capable of conducting respirator testing currently performed by NIOSH?
 - To our knowledge, there are not many independent testing labs that can perform NIOSH testing as the equipment exists today. Changes to the equipment and test protocols would be required before the independent testing labs could evaluate the process. Once this has been accomplished and the test labs have evaluated the process, in conjunction with NIOSH, there would be independent testing facilities with the abilities to perform the required tests. This would aid in expediting the approval process and in making the latest and safest technology available to the public.

Issue 1 (2)

- What qualification requirements (e.g., certification by National Voluntary Lab Accreditation Program (NVLAP), American National Standards Institute (ANSI, NRTL, etc.) should NIOSH require of private labs who perform certification and product audit testing under NIOSH guidance?
 - There are many qualification requirements that exist and many of the test labs meet the requirements of several of the agencies listed. NIOSH will need to evaluate each of the major agencies to determine which one(s) meet the NIOSH goals for public safety and health.
 - Ensure that the independent test labs do not have any vested interest in the certification of products or with manufacturers.

Issue 1 (3)

- Should NIOSH assign the testing of a manufacturer's respirators to laboratories approved by NIOSH or should the manufacturer be permitted to use the laboratory of choice among approved laboratories?
 - The manufacturer should be permitted to choose the testing laboratory from a list of approved testing facilities. We have worked with several independent testing labs and found differences in the services that they provide (e.g.: lead times, fees). We would prefer to have the choice.

Issue 1 (4)

- What type of monitoring should NIOSH perform to assure that private sector laboratories continue to provide quality service?
 - NIOSH should audit these facilities to ensure that the goals concerning public safety and health are adhered to.
 - NIOSH should develop a customer complaint and arbitration system in which the manufacturer and testing facility could utilize in order to resolve any problems.

Issue 2 (1)

- What qualification requirements should NIOSH require for the acceptance of independent quality auditors to perform manufacturing site audits under NIOSH guidance?
 - With many qualification requirements available, NIOSH needs to determine which ones are appropriate and consistent with the goals concerning public safety and health.

Issue 2 (3)

- What frequency of audits would be considered a minimum to provide assurance that only quality products are distributed?
 - The minimum of QA audits should kept to a minimum of one per year. Currently SEI/NFPA are performed twice a year for SCBA under their program and in these and similar situations NIOSH could require a copy of the audit report be provided by each manufacturer.

Issue 2 (4)

- Should manufacturing sites be audited prior to the issuance of a NIOSH certification?
 - Only new manufacturer's applying for certification should have their sites audited prior to issuance of the first NIOSH certification.
 - Existing manufacturer's already have a track record concerning audits that can be reviewed to determine if a site audit is required before issuing a certification. NIOSH should do more product audits on new respirators by existing manufacturer's.

Issue 3 (1)

- How should certification costs be structured and calculated to recoup the cost of the certification process?
 - Fees should be restructured in order to recoup the costs. Some suggestions are:
 1. For new certifications, the costs of performing all of the tests and the administrative costs should be factored in. This should also include the payments made to test subjects for the various man tests. The certification fee for a new respirator would be based upon that calculation.
 2. For extensions of approvals, the fee should be calculated upon the tests performed and the administrative costs involved in issuing the certification.
 3. For those applications that require no testing, the administrative costs should be used to determine the fee required.

These fees could be recalculated each year and manufacturer's notified through the Federal Register in a similar manner that MSHA has used.

Issue 3 (2)

- Should manufacturer's be required to pay for manufacturing site and product audits?
 - Yes, manufacturer's should pay for the site and product audits only to recoup the costs. This is standard practice used by other certification agencies.

Issue 3 (3)

- Should fees be collected by NIOSH for respirator complaint investigations?
 - Fees should only be collected by NIOSH for complaint investigations in which the manufacturer is found guilty of violation or non-conformance.

Issue 4 (1)

- Should NIOSH allow replacement parts for respirators by manufacturer's other than the original manufacturer of the respirator?
 - Only OEM parts are to be used for replacements. With product liability being a major concern only the manufacturer can ensure the quality, proper assembly, and maintenance.
 - If a manufacturer wishes to utilize another manufacturer's component then the normal submittal process should be used to determine the safety of the respirator.

Issue 4 (4)

- Should NIOSH consider certifying respirator components in addition to, or instead of, complete respirator?
 - NIOSH should not consider certifying respirator components.

Issue 5 (1)

- What would be the maximum number of respirator per year, aside from problem investigations, that NIOSH should request from a manufacturer, at no charge to NIOSH?
 - A maximum of two units per respirator type should be requested.

Issue 5 (2)

- How should NIOSH acquire products for audit (i.e.: by voucher, reimbursement, random selection by NIOSH at the manufacturer or distributor)?
 - Units could be obtained for product audit at the same time the QA audit is performed at the manufacturer's facility. Reasonable notice should be given to ensure that the product is available because some manufacturer's use a "Make to Order" system.
 - Units could be obtained from distributors to ensure production units are procured.

Issue 5 (3)

- Should manufacturer's be charged for these product audits, since they are a condition of certification?
 - Yes, manufacturer's should pay for product audits. This is standard procedures for other certification agencies. The fee for this audit can be calculated as outlined in Issue 3 (1) above.

Issue 6 (1)

- Should the NIOSH certification be valid for a limited time?
 - NIOSH certification should be valid for a limited time. The half life of respirator design technology is approximately 3 or 4 years. That means that any approved design with no up-dates is about 75% obsolete in 6-8 years. NIOSH should require complete resubmittal in the ninth year or automatically expire in ten years. This would have no affect on product already in the field; it would only affect sales and manufacturing.

Issue 6 (4)

- Should certification holders be required to notify NIOSH of changes in the production status and the number of produced units when production is halted?
 - Certification holders should be required to notify NIOSH of the production status. The number of units produced is not relevant and does not need to be identified.

Issue 6 (5)

- How would purchasers and users be affected if the certification of their respirator expires?
 - The only affect of a discontinued product on purchasers/users would be that they would not be able to obtain complete respirator assemblies. Many manufacturer's have provisions to support spare parts for a period of time.