8NB-476

E.D. Bullard Company
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August 16, 1996

[VIA Facsimile 513 533-8285]

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

Re: Comments on May 16, 1996 FR Notice on NIOSH Procedures for Certifying Respirators

E.D. Bullard Co. is a manufacturer of NIOSH-approved respirators, particularly of the atmosphere-supplying variety. At the NIOSH public meeting on June 5 and 6, we presented our oral comments concerning the May 16, 1996 notice on future rulemaking priorities for 42 CFR 84 and possible changes in the administration of respirator certification. The following written comments expand upon our oral presentation and address the questions asked by NIOSH during the meeting.

We think the following criteria should be used to rank the priority of each future module of 42 CFR 84, in order of importance:

Improving protection,
Number of workers affected,
Seriousness of hazards addressed,
Cost savings,
Expediency by which a change can be implemented,
Ability to use existing standards
and Encouraging new product development.

There are subject areas for improving current certification requirements that are not identified in the May 16 notice and that should be considered in the prioritizing process. Supplied air respirators such as airline respirators are a category that needs to be examined. The certification

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requirements for the performance of this category of respirators need to be upgraded. We believe that testing should be conducted using a breathing machine. The performance criteria should be that the pressure inside the respiratory inlet covering must remain positive. The respirators could be classified according to the work rate at which they are tested. Breathing machines are available that will enable testing of respirators in this fashion and these machines offer more strenuous work rates than the breathing machine and the minimum flow tests currently specified by NIOSH to evaluate SARs.

The NIOSH breathing machine has a minute volume of 40 liters and current NIOSH requirements for minimum flow are 115 liters per minute for tight fitting Type C and CE respirators, 170 liters per minute for loose-fitting Type C and CE respirators and 200 liters per minute for open circuit SCBA and combination Airline/SCBA. Currently available breathing machines can produce minute volumes of 40 liters, 70 liters and 100 liters. This corresponds to approximate maximum inspiratory flow rates of 120, 210 and 300 liters per minute, respectively.

The NFPA 1981 standard utilizes the 100 liter minute volume rate to evaluate SCBAs. Studies have been performed before the emergence of the NFPA standard, such as by B.J. Held, L.G. Myre, R.A. Da Roza, J.W. Stengel and G.O. Dahlback, that show some SCBAs can be over-breathed by test subjects under certain conditions. Firefighters are also capable of work rates corresponding to a minute volume of 100 liters per minute, according to the researchers. Man tests currently used to evaluate SCBA's should be replaced by metabolic simulator testing.

Also in NIOSH's supplied air section, we recommend incorporation of the NFPA 1981 standard's requirements into the NIOSH standards for SCBA which will be used for firefighting. Some NFPA requirements, higher air flow rates, lens abrasion resistance, etc. make sense for all wearers, 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 SAR's 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 American workers.

Another area that should be addressed is a device known as a "smoke hood" or respiratory protective escape device (RPED). There is an increased interest in these devices and standards do exist in Europe for testing and certifying these "smoke hoods." NIOSH should create a new module to add test requirements for these devices.

We believe that the administrative and quality assurance module as well as the technical module for PAPR's should be of the highest priority. The administrative and quality assurance module should be of the highest priority because improvements need to be made in the way respirator applications are submitted and processed to streamline the approval process. As NIOSH states in the notice of this meeting, it is being overwhelmed with the increased volume of applications and there is (apparently) no end in sight. As additional modules are promulgated, there will be further increases in the volume of applications received.

Therefore, administrative and quality assurance changes should be made early on to enable the future modules to be implemented with the minimum amount of delays and confusion.

Powered air purifying respirators should be of the next highest priority because of the fact that PAPR's are the only particulate removing respirators that are not covered by the first module of 42 CFR 84. PAPR's are now in limbo and should be brought into the same new filter categories as negative pressure air purifying respirators. Unfortunately, there have been many difficulties in developing new test methods for PAPRs using the same new filter testing technology that has been used in 42 CFR 84.

At a later date, after opportunity to research and investigate PAPR testing further, E. D. Bullard Company will be pleased to share with NIOSH its specific recommendations for PAPR testing in

alignment with the new N, P, and R classes of particulate respirators. including our concepts as to how this testing might be performed.

There would seem to be the possibility that NIOSH could promulgate both the administrative and quality assurance module and the PAPR technical module simultaneously because the administrative/QA module does not involve performance testing requirements or development of new testing protocols.

After PAPR's, the next technical module should be supplied air. The present requirements are in need of revision to improve the way that supplied air respirators are tested, such as the addition of the breathing machine test I mentioned before.

Next in priority should be positive pressure self-contained breathing apparatus. The requirements for SCBA should be upgraded to conform to the current criteria of the National Fire Protection Association (NFPA) 1981 standard, with modifications and additions to cover non-firefighting applications.

Next in priority should be the simulated workplace protection factor testing module. Simulated workplace protection factor testing for all respirators is a desirable addition to certification testing. However, further research needs to be done to understand exactly what we are measuring and its applicability to estimating performance in the workplace. Such testing could conceivably replace fit testing for certification. Simulated workplace protection factor testing would enable NIOSH to confirm the capability of a respirator to achieve the assigned protection factor of its class or type.

Last in priority should be changes to the requirements for powered air purifying gas and vapor removing respirators. Changes should be made to the requirements involving the equilibration or pre-conditioning of these filter elements. The current regulation requires pre-conditioning for 6 hours at the minimum required flow rate for PAPR's. This presents an undue burden on

performance and requires the manufacturers to provide one or more large canisters to meet this requirement. The users are being done a disservice by this rule since smaller canisters would provide adequate service life and save weight and bulk. After further investigation and research, E.D. Bullard Company will address this issue at a later date by providing NIOSH with specific recommendations on changes to testing procedures for gas and vapor PAPRs.

No module is needed for negative pressure chemical cartridge gas and vapor respirators because no need has been demonstrated that would require changes to the tests, unlike with particulates.

We are not aware of any national or international standards that can be used in their entirety to replace existing sections of 42 CFR 84. However, as previously indicated, the NFPA 1981 standard on SCBA may be used by NIOSH as a guide for modifications to the SCBA section. In addition, the ISO 9000 standards and certification could be used by NIOSH in place of the design and quality assurance criteria currently in place. ISO 9001 covers design review and compliance to this standard would relieve NIOSH of the requirement to review all of the manufacturing procedures, drawings and individual product quality plans. Because of the frequent auditing that also occurs with ISO registration, NIOSH could accept such audits as part of the acceptance and recognition of the ISO 9000 certification. Manufacturing facilities that are not involved in design functions should be, as a minimum, ISO 9002 certified. This will enable such facilities to be audited to the necessary requirements. As a matter of information, E. D. Bullard Company was certified to ISO 9001 in March, 1995

Concerning the issue of notifying respirator purchasers and users of revised priorities, NIOSH can utilize its "Respirator Users Notice," which NIOSH can disseminate through its usual channels. Additionally, NIOSH can put the word out on its web site on the Internet. Another way to publicize the impending changes is to work with newspapers and magazines used in the safety industry and other newsletters that serve our industry, such as the BNA Occupational Safety and Health Reporter. Respirator manufacturers can also be a valuable resource in helping NIOSH to disseminate information.

Today, NIOSH plays an extremely important role in respirator testing and certification and we believe that the integrity and credibility of this process must be preserved. In the future, private sector resources might be an acceptable alternative or adjunct to NIOSH services. This should be explored by NIOSH, perhaps in co-operation with the respirator industry. However, we do not believe that the testing procedures are today well defined enough to enable third party testing for certification of respirators.

NIOSH is the only laboratory that we are aware of that is capable of performing certification testing today. However, resources could be freed at NIOSH if the quality assurance, design and auditing requirements of 42 CFR 84 were changed to incorporate the ISO 9000 standards and requiring certification to same. The ISO 9000 audit process occurs every 6 months to 1 year, which is a very acceptable frequency and exceeds NIOSH's current audit frequency rate. Audits are required of manufacturing sites certified to ISO 9000 prior to the ISO registration.

The certification fees charged by NIOSH should include the cost of site and product audits in the original fee, as long as NIOSH is performing such activities. The fees should go directly to NIOSH to support the testing and certification program rather than into the general treasury fund as is done today.

NIOSH could select product for testing from the manufacturer's warehouse during the post-certification audit , as is done in other certification programs, such as the Safety Equipment Institute program for eye and face protective devices and head protection. This would defray the cost of the products to NIOSH.

NIOSH should not collect fees for respirator complaint investigations because the manufacturer is not necessarily at fault, and this is a responsibility of NIOSH beyond testing and certification. NIOSH should not allow replacement parts from other manufacturers to be used on approved respirators. There is no way to ensure that interchangeable components from various manufacturers will perform according to the original manufacturer's specifications and

accompanying certifications. In Europe, there is interchangeability but only of certain components, such as threaded filters, where specifications for the interfaces involved are both feasible and extant. Even in Europe, all replacement parts are not interchangeable, no doubt for the same reasons adopted by NIOSH in its current regulations.

NIOSH could still consider certifying respirator components in addition to or instead of complete respirators. This would allow a "family" type approval of a respirator series in which all approved components (supplied by the certified manufacturer) are certified under a single approval number. This would expedite certification processing and be less confusing to the end users. In Europe, components such as filters are approved separately from facepieces and user instructions define allowable configurations of use.

A NIOSH certification should not be time-limited. Previous experience with approvals that have expired, such as the Bureau of Mines approvals, indicate that problems and confusion can be created by such expirations. For example, confusion was created by the availability of different approved particulate -removing respirators for the same application, one approved under 30 CFR 11 and the other approved under the Bureau of Mines.

Today we have co-existing new and different particulate filter respirator approvals under 42 CFR 84 and the unexpired approvals under 30 CFR 11 that are still both certified for use. This situation is causing some confusion.

With each module of 42 CFR 84, it is anticipated that the approvals granted under the "old" regulation will be given expiration dates. That in itself will create problems without any other expiring approvals further contributing to this. The distribution chain for respiratory protective equipment has many channels and creating large numbers of respirators with expiring approvals in these channels will unnecessary troubles for the user community.

Product changes such as the temporary or permanent removal from production of any individual respirator should be required to be communicated to NIOSH by the manufacturer. NIOSH could then indicate the status of respirators in the Certified Equipment List as active, inactive, or obsolete. At the same time, we do not see the necessity for NIOSH to require information on the number of produced units as we cannot see why this information would be of value to users or the government.

Thank you very much for the opportunity to express our views. We are looking forward to working with NIOSH for the common goal of providing American workers with state-of-the-art personal protective equipment, including respirators.

Very truly yours,

Jay A. Parker

Laboratory Manager

cc: John King, Rick Miller, Jed Bullard, Janice Bradley (ISEA)