84-137

→ Dr. Leidel - These comments will take about 20-25 minutes to read.
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Good morning.

My name is James Spool and I am General Counsel of Siebe North, Inc., a major manufacturer of respirators certified by NIOSH under 30 CFR Part 11 for use in all applicable industries in accordance with OSHA, MSHA, EPA and NRC regulations. Accordingly, Siebe North will be subject to the regulation of proposed Rule 42 CFR Part 84, if it is ever promulgated. We have already filed a detailed written commentary on the Proposed Rule, and I wish to thank NIOSH for the opportunity to present this oral testimony at this hearing as well.

The first point I want to make this morning is an amplification of our written comments on Section 84.40 - The Certification Label.

Specifically, we recommend that NIOSH mandate the use of specific certification label language by manufacturers with respect to at least 4 generic restrictions on respirator use, when such use restrictions are applicable. [redacted]. The 4 generic use restrictions are:

1. The prohibition against use for protection against contaminants which do not have adequate warning properties.

2. The prohibition against use for protection against IDLH atmospheres.

3. A requirement for all respirators that they be used only in accordance with a complete respirator program, such as required under 29 CFR 1910.134 or which encompasses all of the aspects of respirator use identified in Assumption (i) of Appendix A of Part 84.

4. A requirement for all negative pressure respirators which notifies the user that no negative pressure respirator excludes 100% of contaminant from the breathing zone, and that positive pressure respirators permit less breathing zone contaminant that do negative pressure respirators.

These generic limitations are some of the least understood aspects of respirator use, and they apply to the products of all manufacturers. We recognize that these limitations must be taught as part of a user's training, but as a practical matter they frequently are not. The current practice by some manufacturers who voluntarily include in their instructional materials warnings covering some of these topics, is ineffective and counterproductive overall because the variations in text result in confusing variations in meaning, and because not all manufacturers promulgate these warnings. The Department of Labor recommendation to NIOSH, that such use restrictions be left to OSHA and MSHA regulation only, is unworkable, because the OSHA and MSHA regulations do not deal with respirator labeling.

While OSHA, MSHA, EPA and NRC could designate, by regulation, when these use restrictions are applicable, placing the

Warnings when they apply on the NIOSH certification label will give the greatest assurance that the warnings will most likely reach and be read by the workers who wear the respirators. We strongly recommend that NIOSH include this mandatory labeling proposal in any Rule which replaces 30 CFR Part 11.

Next, I would like to focus on some of the points raised by NIOSH in its statement for record which was read this morning.

The decision to designate Part 84 as a major rule under Executive Order 12291 is welcome news. I trust that the requirement to make a thorough regulatory impact analysis will provide the basis for greater participation by the respirator industry in the further development of Part 84. A more cooperative interface between NIOSH and the respirator industry is badly needed. Indeed, I strongly urge NIOSH to take a bold step and convert this proceeding into a negotiated rulemaking. The industry has much to contribute to the creation of an effective certification regulation, and a negotiated rulemaking is the fastest way for NIOSH to take advantage of the industry's expertise. This is not a new recommendation, but NIOSH's continued refusal to consider it in the development of Part 84 is inexplicable.

The decision to reopen the record of this rulemaking to permit comments on the so-called "performance-based guidance document for field testing" (whatever that is) is also good news, of sorts. However, it would have been much better news had NIOSH announced

this morning that it had taken the advice of the Department of Labor, the respirator industry, and virtually everyone else who has contributed to the docket in this proceeding, and was deleting workplace testing altogether. Workplace testing is an idea whose time has not yet come, and NIOSH's (literally blind) insistance to the contrary will succeed only in delaying promulgation of the needed replacement for Part 11 for another 10 years.

The section in this morning's NIOSH statement entitled "The Focus on 'Mines' and 'Mining'" deserves further comment. The references in Part 84 to "mining" and "mines" appear in the statement of purpose in Section 84.2 and in the definitions of "respirator", "workplace" and "simulated workplace" in Section 84.3. By contrast, neither "mines" nor "mining" appears anywhere in 30 CFR Part 11.

The question must be asked - and has been asked - why does NIOSH feel that Part 84 must be explicitly limited to the certification of respirators for mines and mining only, when it omitted that explicit limitation from Part 11 back in 1972? This morning's statement fails to answer this question.

That statement, and the preamble to Part 84, refer repeatedly to the Mine Safety and Health Act of 1977, implying that this legislation somehow mandates this change. We all know, however, that this is not the case - the sentences in Sections

842(h), 844 and 957 of Title 30 of the US Code, originally enacted in 1969, were unchanged by the 1977 Act. Therefore, I put the question again to NIOSH, why have you changed the coverage of the respirator certification regulation?

If, as this morning's statement appears to suggest, NIOSH does not consider the limitation to mines and mining to be a significant factor in the certification process, then why was the limitation put into Part 84 in the first place? It certainly wasn't in the earlier drafts of the Proposed Rule which appeared before May, 1986.

Given its acknowledgement in this morning's statement that more than 95% of all respirators sold are not used in mines and mining, NIOSH owes that vast community of respirator users, respirator regulating agencies and respirator manufacturers, some forthright answers to this question.

Moving now to the question of economic impact, it is obvious that the economic study on which NIOSH relied had at least one failing - it was based on too few responses - and it probably had other failings as well. However, NIOSH's criticism of the ISEA study is wholly wrong. Since ISEA's testimony later in this hearing will explain this NIOSH error in great detail, I am constrained by time to only point out that NIOSH's suggestion, that workplace testing Sections 84.31, .32 and .33 do not limit workplace testing to mines and mining sites only, turns the English language on its head.

The Section 84.3 definitions of "workplace", "simulated workplace" and "respirator" all limit these terms to mines, mining worksites and mining. Thus, the use of these specially defined words in the workplace testing Sections 84.31, .32 and .33 incorporates the definitional references to mines, mining worksites and mining into these sections. To say otherwise is pure, unadulterated doublespeak.

Time does not permit a detailed critique of the NIOSH statements included under the heading "The Workplace Testing Protocol". However, Siebe North would like to point out that, even if NIOSH were to take the DOL's advice, and limit performance testing to simulated work environments in laboratory test chambers, the flexibility in testing protocols which NIOSH plans to allow is highly likely to be counterproductive. Rather than permitting and encouraging innovation in product design, this regulatory flexibility is more likely to encourage innovation in the design of test protocols intended to permit lower quality or poorer product to compete against products of higher quality and better design. Quite frankly, the respirator user will be much better served if NIOSH uses the same measuring stick to measure all manufacturers who seek certification of the same class of respirator. NIOSH should leave the marketing incentives where they belong - in the market - and not in the hands of a government bureaucracy.

This morning's NIOSH statement also makes reference to the appeal procedure contained in Section 84.80. As we said in our

It literally makes no sense for NIOSH to allow 22 respirator manufacturers to certify 22 different dust respirators using 22 different test protocols.

written comments, while a procedure including a hearing before an administrative law judge is better than nothing, it is worth little more than nothing, if, as in this case, the recommendations of the ALJ are not binding on the Director of NIOSH, and the right to an appeal to the courts from the Director's decision is not available. Section 84.80 provides neither and is therefore of little benefit to manufacturers.

In its statements under heading 5 "Organic Vapor Cartridges", NIOSH has completely failed to tell us why the new OV cartridge criteria are required. These new criteria have only one benefit - they increase service life. But neither the workers who use these cartridges, nor their employers who buy them, are complaining to us or anyone else that current service life is too short.

If the market is providing no incentive to increase OV cartridge service life, then why is NIOSH tampering with the market by mandating an increase? The NIOSH response to this question is "public health considerations". Of course, that's an answer NIOSH frequently gives to tough questions. It signals the fact that NIOSH doesn't have a sound technical basis to support an arbitrary decision.

Our advice to NIOSH is to look for a better answer. Otherwise, if it ain't broke, don't fix it.

We do have another question about NIOSH's remarks on the organic vapor cartridge issue. The NIOSH statement says, and I quote - "More and more frequently these cartridges and canisters are being used against organic vapors having poor warning properties". End of quote.

Even if this were true, what has this to do with organic vapor cartridge performance criteria, particularly service life? Since such uses violate OSHA and MSHA regulations, is NIOSH intending to use its regulatory powers to force the manufacturers to design their OV cartridges to facilitate their misuse? Certainly NIOSH owes us a better explanation on this point.

Considering, next, NIOSH's statements under heading 6 - "Filter Technology", NIOSH again fails to provide any rational explanation for its arbitrary decision that a particulate filter meet both liquid and solid aerosol tests. If anything will inhibit innovation, it is this new NIOSH requirement for a universal particulate filter. Most particulate filter applications are notin atmospheres containing both solid and liquid contaminants. Since there is a market demand for dust filters for atmospheres having no oil mist, why require an oil mist capability? It makes as much sense as requiring chlorine cartridges to have an ammonia capability. Here again, NIOSH is tampering with the market.

Mr. Chairman, in closing, I want to make it clear that Siebe North recognizes full well that 30 CFR Part 11 requires wholesale

revision. However, our conclusion is that 42 CFR Part 84, as it currently stands, is not an adequate substitute for the existing regulation. Accordinlgy, we recommend that NIOSH withdraw 42 CFR Part 84 as it currently stands, and convert the proceeding into a negotiated rulemaking. Next, NIOSH should eliminate the express limitation to respirators used in mines and mining, as well as the requirement for workplace testing. If any performance testing is to be prescribed, it should be limited to tests which can be performed in an environmental chamber.

Third, NIOSH should assure that the revised regulation prescribes all tests and test criteria, so that the same measuring stick is used for all manufacturers seeking certification of respirators of the same class.

And finally, NIOSH should specify that its certification labels include prescribed expressions for generic use limtiations.

Thank you very much, Mr. Chairman.

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I have one fenial request, Mr. Chairman, and that is that NIOSH extend the post-hearing comment period from to 60 days to allow a full critique of NIOSH's statement of this morning.