

July 29, 2010

**Comments of the International Safety Equipment Association (ISEA)
National Institute for Occupational Safety and Health (NIOSH)
Second Public Meeting on Notice of Proposed Rulemaking: Total Inward Leakage
Requirements for Respirators, 42 CFR Part 84, RIN 0920-AA33**

ISEA is the trade association for personal protective equipment, including all kinds of respiratory protection for workers certified by NIOSH under 42 CFR Part 84. Member companies in the ISEA Respiratory Protection Group are knowledgeable in the design, manufacture, approval, selection, fit testing and use of respirators in occupational settings.

ISEA appreciates the extension of time given for consideration of the Total Inward Leakage proposal, and the opportunity to express our views at this public meeting. As you know, the association has been an active participant in the discussion of this proposed rule since the concept was first presented.

Last December, at the first public meeting, some ISEA members began to discuss how we could evaluate the proposal with real world testing. That discussion led to the study that will be presented later this morning by Jeff Weed, a member of the research team, and which ISEA made a part of the comments we submitted in March.

ISEA members have discussed and debated this proposal at great length, seeking a way to modify the rule that would make it workable for manufacturers, employers and users. Various approaches have been discussed, but at the end of the day, the consensus position of the group is that ISEA's position should question whether the tests envisioned by this proposal will enhance worker health, and if not whether NIOSH should continue to pursue it.

ISEA understands the concept of incorporating fit into the certification of respirators. We acknowledge that in a perfect world, any half mask respirator would provide an adequate seal on any face, every time. Manufacturers invest a great deal of R&D in the development of respirators that will not only pass the stringent filtration efficiency testing necessary for NIOSH certification, but that will also fit the greatest number of faces. Failure to do this will doom a product in the marketplace, and it should.

But we also know from experience that this perfect, universal respirator doesn't exist, because of the variability of face shapes and sizes, coupled with training and user experience in donning and using respiratory protection. In other words, nothing is going to take the place of fit testing each user as the only way to ensure that the respirator will provide the desired degree of protection. If we acknowledge that the need to fit a respirator to the user is not going to change, then we have to question the purpose behind the NIOSH TIL proposal, the methodology proposed to reduce total inward leakage by respirator design decisions, and whether the changes proposed to the certification process enhance worker protection.

In benchmark testing of 101 respirator models, NIOSH found that 30 percent of respirators did not provide a fit factor of 100 "for substantial numbers of human subjects." Using this data, NIOSH cites three justifications for the proposed rule. First, NIOSH states that when an employer buys one of these poor-fitting respirators, "fit-testing of the employees should reveal that a substantial proportion of the employees do not achieve an adequate fit. This presumably compels the employer to purchase other respirators and conduct additional fit-testing on

employees, continuing such purchases and fit testing until respirators are identified, through trial and error, that provide all employees with adequately fitting respirators.” 74 FR 56143

NIOSH writes the proposal as if this would be an ongoing process, with the employer buying more respirators and fit testing them until all workers are supplied with adequately fitting respirators. ISEA asks if this is as burdensome as it sounds. Putting yourself in the position of an employer, if you buy a supply of respirators and find that they don't provide a good fit to most of your workers, you're not going to buy any more of them. Nor is anyone else. Why would there be a market for such an ill-fitting product, unless employers are buying them and providing them to workers without fit testing, in clear violation of their legal obligations under OSHA regulations?

Now consider the process with respirators approved under the proposed TIL regulation. The employer will have to evaluate the intended users by facial characteristics, take measurements, and find a respirator identified by a manufacturer as suitable for those characteristics. If everyone in the facility has the same face, the employer may get lucky. But in the real world, it is still likely that one model of respirator will not adequately fit all workers. To use a phrase from the NIOSH proposal: This presumably compels the employer to purchase other respirators and conduct additional fit-testing on employees. But by mandating that a high percentage of respirators achieve a fit factor of 100 in certification testing, the employer's choices would be far more limited than they are today.

The second benefit NIOSH finds in its proposed TIL test is that it will provide better protection for users who are not fit tested. It cites a statistic that 40 percent of employers don't fit test workers, and that self-employed workers are even less likely to fit test. ISEA asks NIOSH what in its proposal would force these non-compliant employers to meet their obligation to fit test workers, especially if they are being told that the respirators tested under the new scheme are more likely to fit?

The third justification for the rule is that stockpiled respirators, deployed in the event of a pandemic or other emergency, might be given to workers without a respirator program or fit testing. In this case, the employer and worker are presumably not involved in the selection process, and the hazard may be something like a virus for which there is no PEL or well-defined risk, so fit testing is even more important to assure adequate protection. Handing out respirators for use in hazardous environments with the hope that they will fit most users is like playing Russian roulette with a worker's health.

After all this, NIOSH acknowledges that certification incorporating the TIL test will not substitute for individual fit testing, respirator training and other components of a complete respiratory protection program critical to worker protection (74 FR 56143). NIOSH claims that TIL will substantially improve the current circumstances by approving only respirators that demonstrate the ability to meet minimum specified performance requirements. We believe that NIOSH already does this, by testing and certifying respirators under 42 CFR Part 84. If NIOSH believes, as we do, that fit testing, training and other elements of a respirator program are critical to worker protection, ISEA is hard pressed to understand why NIOSH is proposing to add a component to respirator testing and certification that appears to be designed to allow employers and users to bypass these critical safeguards.

Ever since NIOSH first proposed incorporating fit testing into respirator certification, ISEA has questioned the wisdom of this approach. After the current proposal was introduced, we commissioned an independent evaluation, testing respirators using the NIOSH protocol. You

will hear a report on the result of that study, detailing the shortcomings of the proposed methodology and intended results. As the report indicates, there are things that could be done to improve the way the tests are conducted, and the way respirator performance is evaluated.

But even if the test protocols are improved, and the pass-fail criteria are modified to reflect the realities of respirator design and performance, will they replace the necessity of individual fit testing to determine whether or not a respirator will protect the wearer? ISEA believes the answer is no.

Given that reality, is it a better use of NIOSH resources to continue to refine the certification fit test, with its inherent flaws, or to redirect its efforts toward enhancing respirator fit at the user level? ISEA believes the Institute should focus its research on improving user fit testing, developing better field fit tests that are simple to administer and produce the most repeatable and reliable results.

Concurrently, NIOSH could direct its energy to working with OSHA, MSHA and employers to educate workers and employers about the reasons why respirators have to be fit tested, clearly explaining the function of a respirator in reducing exposure to airborne contaminants to acceptable levels, illustrating the risks of misuse, and encouraging rigorous enforcement of respiratory protection standards and regulations. Such an approach would do far more to enhance worker protection than adding a complex and unproven set of requirements to certification testing of half-mask respirators. ISEA and its member manufacturers stand ready to assist in this effort, to achieve our common goal of protecting the health and lives of workers everywhere.