Miller, Diane M. (CDC/NIOSH/EID)

From: Larry Green [lgreen@bio-md.com]
Sent: Thursday, July 29, 2010 4:40 PM
To: NIOSH Docket Office (CDC)
Subject: TIL Testing NIOSH docket # 137

Listening to the comments on 7/29/10 it appears that most concerns are associated with 84.175(i)(4)(i), the requirement for 35 subjects for the one size "fits" all. Obviously we all know it doesn't. Why spend so much time and money proving it?

Very little emphasis was placed on 84.175(i)(4)(ii), the acknowledgment of the fallacy of "one size fits all." I believe this and 84.175(h)(2), appropriate user instructions, to be the most relevant.

84.175(i)(4)(ii) lowers the number of test subject to 15 for sized respirators. I believe most respirators are available in multiple sizes. The representative from Moldex indicated they had one with 5 sizes. Thus the test requirement is not in fact 35, it is 15. A manufacturer of an current respirator would only need to prove that it worked for 12 of 15 subjects meeting a size or characteristic profile that they may determine (see 84.175(h)(2)) to continue producing their product ... without modification. "Prove it fits somebody" is a pretty minimal requirement to place on a manufacturer.

84.175(h)(2) requires appropriate user instructions. There were hints that end users would follow the sizing guidance to avoid fit testing. I feel the opposite. Confronted with the facts, "this respirator fits ..., that respirator fits ..., etc., the users will be more aware of the fit problems and be more diligent.

I note a significant increase in sophistication and knowledge with respect to respirators of the safety personnel at our customer base. And with their representatives that they sent to NIOSH sponsored meetings. They usually want more, relevant, data versus less. With more information on facial characteristics they can get multiple makes of respirators with the manufacturers guidance respective of their employee profile. This would make performing the required fit test less onerous as they should have less first round failures.

Other issues, noses in ethnic populations, etc. and how the panel didn't screen this feature, I believe are covered in 84.175(h)(2) which clearly states that the standard panel needn't be the only selection guideline. The only problem is that the guidelines are presented clearly to the users and NIOSH. Having written user instructions, I fully understand the challenge in conveying information fast and clear enough that it will be followed. The challenge does not excuse us from doing it. As the users get used to having the information, they will be able to assist in refining its clarity.

The avoidance of mentioning a test chamber allows the test to be followed by both end users, who will almost never have a chamber, and manufactures who probably will because the more stable concentrations will benefit them and others trying to perform repeatable tests. By default, NIOSH will probably need to use a chamber also because 84.175(i)(10) states that they discriminate to NaCl. As any ambient (non controlled) challenge will/may consist of mostly other particles, a chamber or other closed room becomes desirable.

The end users will have a less controlled environment. Thus, their results will potentially be slightly different than in a controlled test environment. If the respirator design is marginal enough that it cannot afford this slight deviation from ideal, it probably shouldn't be on the market.

Smaller companies will probably rent the required equipment for the test. At approximately $100/day, not having good guidance in selecting an appropriate field of respirators to fit test can be very expensive if they

have to retain the equipment while they purchase additional models. They now have performing the required testing costing 10's of times as much as they will spend on respirators for the year. A major disincentive to doing testing. Maybe the next year they will have less problems, but the dis-service will already have been done.

As a designer and manufacturer of PAPR respirators my primary interest in this standard is how it may effect future regulations for PAPRs. As a purchaser of several million difficult to fit filtering face piece respirators (by proxy as a citizen of California) I hope better guidance from manufacturers will allow better purchase decisions.

The fact that the VA has sponsored development of respirators that are easier to fit (project BREATH) is testament to the failings of these products. Industry shirks their duty, the government bails them out. We all pay.

It is easy to ignore the obvious (black stripe down the side of your nose) and say "its approved, it says it fits everybody, it must be OK." Hopefully, soon those days will be gone.

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