Dragon, Karen E. (CDC/NIOSH/EID)

From: Weed, Jeff [jeff.weed@tsi.com]
Sent: Friday, August 31, 2007 6:55 PM
To: NIOSH Docket Office (CDC)
Subject: TSI Comments on NIOSH TIL Proposal: Docket NIOSH 036
Attachments: TSI Comments on NIOSH NPPTL TIL Proposal- Aug 29-2007.pdf

Dear Docket officer,

Please accept the attached comments from TSI. The docket number is NIOSH # 036.

This message was sent on Friday August 29, 2007.

Thank you,

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TSI Comments on NIOSH NPPTL Total Inward Leakage (TIL) Proposal
Docket # NIOSH 036
August 29, 2007

Submitted by Jeff Weed, Product Specialist, TSI Incorporated

Comments on the Overall TIL Concept

TSI believes that the premise currently underlying 42CFR84 remains sound. Specifically, that the certification process does not need to include fit testing because employers are required by OSHA to fit test respirator wearers. Respirator manufacturers have ample incentive to design good fitting respirators because if they do not, workers will have difficulty passing the fit test, and employers will not buy their respirators.

The real problem is that only about half of respirator wearers who should be fit tested actually are. It is not clear how the proposed TIL program will address the real problem. NIOSH states that the TIL proposal will not in any way eliminate the need for, or requirement to do fit testing. That means that the TIL program will only benefit those who do not comply with fit testing requirements. There is no benefit whatsoever to the other 50% who comply with the regulations. If the TIL program goes into effect, 50% of respirator wears will remain un-fit tested. It's difficult to see what improvement the TIL program would deliver to respirator wearers. In fact, we think the expensive TIL proposal will have a minimal impact on worker health. If NIOSH really wants to protect respirator wearers it should develop a program to get annual fit test compliance up to 95%.

In our experience, those who are not fit tested are often not properly trained to use the respirator either, and the TIL proposal does not address user training at all. NIOSH should work on ways to promote annual respirator training with subsequent fit testing as inseparable procedures, and also develop faster fit test protocols that reduce the burden on employers. A direct approach that addresses the root of the problem is the right way to protect American workers.

A case in point is the recent NIOSH study* showing that workers who are fit tested achieve significantly higher protection levels than those who are not fit tested. The increase in protection experienced by those who were fit tested was enormous. Simply changing respirator design to marginally increase the likelihood of a good fit for un-fit tested workers will not produce anywhere near as much improvement as fit testing alone can.

* Duling, M.G., Lawrence, L.B., Slaven, J.E., Coffey, C.C., [HHS/PHS/CDC/NIOSH], **Simulated Workplace Protection Factors for Half-Facepiece Respiratory Protective Devices**. *Journal of Occupational and Environmental Hygiene*, Vol. 4, No. 6, pp. 420-431, June, 2007.

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If fit testing must be added to the NIOSH certification process, there are better ways to do it. The intent of the TIL program can be accomplished much more easily and much less expensively. The way to do it is to have the respirator manufacturers self-certify. Require them to submit fit test data to NIOSH that is obtained using an agreed upon test panel and protocol. Review the data and accept or reject it. There is no need for NIOSH to duplicate the testing.

Comments on Instrumentation

The N95-Companion (TSI Model 8095) accessory for the PortaCount Plus TSI Model 8020) was not designed or intended for laboratory or respirator certification purposes. We see no reason for NIOSH to specify the use of the N95-Companion for respirator certification purposes since instrumentation with higher precision is readily available. Examples include the PortaCount alone, or photometer based instrumentation like NIOSH currently uses for CBRN respirator certification. Indeed, oil-mist/photometer fit test systems are widely considered to be the "Gold Standard." TSI is flattered by NIOSH's selection of the PortaCount/N95-Companion for the TIL program, but we think that the Gold Standard would prove to be a superior choice.

We also question the use of the N95-Companion for series-99 and series-100 respirators. The higher efficiency media prevents significant penetration, so the N95-Companion test will be a fit test, not a TIL test. There is no need to accept the limitations inherent to the N95-Companion when the PortaCount alone can be used instead. For example, when the N95-Companion is used, fit factors are limited to 200. The instrument will not output a higher value. At NIOSH request, TSI has provided a means for NPPTL to bypass the 200 limit during respirator research; however, we have no intention of offering that option to other organizations on a widespread basis. If NIOSH goes ahead with the TIL program as proposed, it must be done with the understanding that the N95-Companion's fit factor limit of 200 will be in effect.

We understand that one reason for the use of the PortaCount/N95-Companion is because the equipment is lower cost than the Gold Standard. However, looking at the costs that will be incurred by respirator manufacturers and NPPTL for the entire TIL proposal; the instrument costs pale in comparison to the costs of performing the thousands of fit tests that will be mandated. And many respirator manufacturers will want to duplicate the NIOSH CBRN testing that currently uses the Gold Standard anyway. Specifying the best test instrumentation available will better serve all involved over the long run.

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Comments Regarding Particle Size Issues:

If NIOSH really wants to do TIL testing on series-95 respirators, it would make more sense to use the PortaCount by itself, because that way a very broad range of particle sizes that likely includes the most penetrating particle size (MPPS) would be employed. This would also make sense because there is no assurance that all future respirator media will be electret. Respirator manufacturers can submit mechanical media for series-95 certification that has a much different MPPS. It would be a mistake to assume that future filter media will always be electret.

Total Inward Leakage means nothing unless the particle size (or distribution) is specified. It's just like filter efficiency. For example, a HEPA filter is at least 99.97 % efficient *at 0.3 microns*. Likewise, TIL values must specify a size. NIOSH appears to be doing this by proposing the use of the N95-Companion with its inherent 40nm focus. But is 40nm an appropriate size to use for TIL testing? Is there any location in the USA where respirators are used to protect workers from 40nm aerosol?

If 40nm aerosol is not representative of any workplace hazard, what size particle is appropriate? There is no correct answer to that question, because all workplaces are different. This is why TIL testing is inappropriate for respirator certification. NIOSH should be proposing fit testing, because eliminating particle penetration is the only way to isolate respirator face seal leakage.

In fact, NIOSH does not know what the MPPS is during a human subject TIL test. It will certainly never be the same as the MPPS during the constant flow (85 lpm) NIOSH filter certification test. The MPPS will vary with the person's breathing, which is always well below 85 lpm. The lower/variable flow rate will cause the MPPS to dynamically shift to larger/variable diameters.

It's easy to forget that the TIL proposal is not just about series-95 respirators. However, the proposed test method can only be termed TIL with respect to series-95 respirators. It's fit testing with respect to higher efficiency respirators because filter penetration is virtually zero. In fact, the NIOSH proposal for TIL testing is really identical to the fit testing done by employers who use the same equipment. How can the same exact test be a TIL test when NIOSH does it, and a fit test when an employer does it?

Also, it has long been our understanding that TIL measurements are meant to determine total human dosage. As such, TIL must be a mass-based measurement made with a mass-based instrument such as a photometer. It can be argued that a particle count-based instrument cannot meaningfully measure TIL since there is no accurate way to relate particle concentration to mass concentration.

One important aspect of the TIL program is going to be the ability of respirator manufacturers to perform the exact same TIL measurement in their own laboratory as NPPTL does during certification testing. For TIL measurements to be reproducible

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between locations, the challenge aerosol will also have to be reproducible. This may be a problem for the TSI Model 8026 Particle Generator currently specified in the proposal. The 8026 was developed as an inexpensive means for employers to augment ambient aerosol levels for the PortaCount alone, as well as when coupled with the N95-Companion. It produces a wide range of particle sizes, not just the 40nm particles used by the N95-Companion. It was not developed as a precision particle generator suitable for duplicating challenge aerosols in diverse locations. Local conditions such as humidity levels and the purity of the water used to make the salt solution affect the particle size and concentration output. Also, the total challenge aerosol that exists during fit testing is comprised of whatever particles exist naturally, mixed with the generator output. The bottom line is that use of the Model 8026 is unlikely to accomplish the location-independent challenge aerosol reproducibility that NIOSH desires. This represents another argument for NIOSH to use an oil-mist/photometer system like that currently used for CBRN certification where the challenge aerosol is well characterized and repeatable.

The Gold Standard is the instrumentation package NIOSH should be specifying for TIL measurements. It's a proven, repeatable, well-accepted, mass-based measurement made using a tightly controlled challenge aerosol. These qualities are exactly what are required for certification level testing.