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Sent:	Monday, August 27, 2007 2:13 PM
To:	NIOSH Docket Office (CDC)
Cc:	Newcomb, William E. (CDC/NIOSH/NPPTL); Klaus-Michael.Rueck@ex2k3.corpmig.local; Wolfgang.Drews@ex2k3.corpmig.local
Subject:	TIL Comments - Docket #036
Attachments:	TIL Comments - NIOSH Docket No 036 - August 2007.doc

Attached please find Draeger Safety's comments for the Total Inward Leakage proposal - Docket No. 036

Regards

Bob Sell

Sr. Project Engineer - Protection

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August 24, 2007

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Reference: TIL - DOCKET NUMBER NIOSH 036
Total Inward Leakage Concept - May 2007

Dear Sir / Madam:

Draeger Safety manufactures respirators for various markets and applications therefore we offer the following comments in response to the NIOSH Concept Standard for Total Inward Leakage posted May 29, 2007 and from the information that was presented at the Public Meeting held on June 26, 2007.

The following Draeger Safety comments are being submitted for consideration:

Technical Concept for Half-Mask Respirator Total Inward Leakage Performance Requirements and Test Methods

1.1 Test Panel:

1. We are concerned that a panel which utilizes 35 test subjects with a requirement that 26 subjects must pass the test criteria will prolong the testing process for certification at NIOSH. Draeger's experience with the CBRN Laboratory Respirator Protection Level (LRPL) testing has shown that there are significant delays in getting these tests completed due to the availability of tests subjects required to meet the Los Alamos Fit Test Panel. Has an estimate be determined on the time involved in order to complete one test series for the possible respirator families that are anticipated?

2. It is our understanding that each half mask face piece size will be required to be tested with the 35 test subjects and each subject is to repeat the test three times which in turn triples the number of tests required for each respirator family for a three size half mask. Has an estimate of the overall timing from submission to approval for a respirator family, with 3 sizes of half masks have been determined? We suggest that only one TIL test consisting of 35 test subjects be used for a respirator family and not to test each size individually.

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3. It was estimated at the public meeting that the cost for TIL testing would be in the range of $8500 - $12,000 USD. This then becomes a very expensive test for a multiple size respirator family if each size is to be tested as currently stated. Again we suggest that only one TIL test consisting of 35 test subjects be used for a respirator family and not to test each size individually.

4. For the test panel, either the bivariate or the PCA panels, the verification of a mask size over the range of the wearer population should be achieved by an equal number of test subjects for each panel. If the center cells (#4 and #7) of the panel have more subjects than some of the outer cells (#1, #2, #5, #6, #9, and #10) those wearers are not being treated equally. This appears to discriminate the users for those cell extremes. Therefore, we propose that only two subjects be used per cell which doubles the number as compared to the current verification approach which is used in Europe.

Section 1.6:

5. It is identified in this section that the proposed requirements will be applicable to those respirators approved under 42 CFR, Part 84, Subpart K which results in a TC-84A-XXXX certification number. In addition to covering particulate respirators, this also would cover combination gas / vapor removing and particulate devices. It has not been identified how these respirator families would be chosen for testing. Would the lightest and heaviest combinations be evaluated or would only the heaviest be evaluated? Clarification needs to be provided in the proposal and in the Standard Test Procedure.

Total Inward Leakage Test for Half-mask Air-Purifying Particulate Respirators – RCT-APR-STP-0068

Section 3 Equipment / Materials:

6. The conditions of the test chamber need to be described accurately in the STP to ensure that the particle concentrations (cc) are being as evenly distributed as possible. We suggest that further details of the test chamber be included into the Standard Test Procedure.

7. In addition to the chamber conditions that were noted above, we also would like to see the details of the chambers lay, geometry, ventilation system, etc. included in the Standard Test Procedure.

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Section 5 Procedure:

8. Our experience has shown that the ambient concentration of particles / cc are higher by at least a factor of 8 in the chambers that we have had used and we would recommend that the 500 particles per cc be increased for this test. The ambient concentration of particles becomes more critical with fit factors higher than 100 and we would suggest that for future consideration that it would also be necessary to describe the minimum measured particle per cc during a time frame otherwise the accuracy would be very low. For example, at 800 particles per cc with a required fit factor of 1000, you would measure in a 10 cc volume only eight particles at a flow rate of 10 ml/min and one particle more or less would provide an uncertainty of more than 10%. Therefore it becomes critical to specify the measurement with time and a minimum flow for a higher fit factor.

Appendix B:

9. For the PCA Analysis panel we would suggest that the method being evaluated by the ISO TC 94 SC 15 committee be considered. In this approach, the center of the 50 percentile elliptical distribution is considered to count as only one cell and is not split into 4 cells and this equates to five cells and five head sizes. Following the same approach for verification as put fort in Comment #4 above, 2 test subjects should be selected per cell which would provide a total of 20 test subjects. This can be judged as adequate due to the fact that 10 parameters of the human face are taken into account for the verification instead of the face length and face width which is the only considered for the respiratory interface (face piece) purposes. A device will be considered as Passing when the average of all 20 subjects is equal to or lower than 5%.

General Comments

10. Draeger Safety believes that the development of this new Quantitative Fit Test Method is a major improvement over the use of the Qualitative Fit Test (Isoamyl Acetate) that is currently being used for respirator certification and that NIOSH should continue its efforts to expand this program for other types of respirators.

11. International approvals for TIL are based on SF_6 or NaCl particle testing as measured by an Aerosolphotometer in accordance with EN-13274-1. How do these test results correlate with the test method being proposed? Also, have any correlation tests to these methods or any other methods been conducted?

12. We suggest that NIOSH evaluate and qualify independent third party labs that could be used to perform the TIL testing in addition to your facility. At the same

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time, we would suggest that once these labs have been qualified that NIOSH permit their data to be used for certification instead of NIOSH repeating the TIL testing.

Draeger Safety thanks NIOSH for the opportunity to provide comments. Please consider our comments concerning the ongoing changes to the standard.

If there should be any questions concerning this matter, please do not hesitate to contact me at 412-788-5685 or via e-mail at Robert.Sell@Draeger.com.

Respectfully,

Robert Sell

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