Total Inward Leakage
(for Respirators other than Filtering Facepieces and Half-masks)

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Background

A program concept for Total Inward Leakage (TIL) performance requirements and test methods was established by NIOSH in 2004 and can be found at the following link: http://www.cdc.gov/niosh/npptl/standardsdev/til. The first project performed under this program was benchmark testing of filtering facepiece and elastomeric half-mask particulate respirators in 2005 and 2006. During this testing, 57 filtering facepiece and 43 elastomeric half-mask respirators were evaluated. TIL values were tabulated and test data analysis was subsequently completed in July, 2007.

The current project in the TIL program is the characterization of other classes of respirators that are associated with standards presently in the rulemaking process or under development. This includes Closed-Circuit Self-Contained Breathing Apparatus (CC-SCBA), Powered Air-Purifying Respirators (PAPR), Supplied-air Respirators (SAR), and Air-Fed Ensembles (AFE). The approach for this project will be to determine benchmark testing variables, perform benchmark testing, and set the pass/fail requirements based on the results. Lessons learned during half-mask benchmark testing will provide valuable information with regard to test protocol development, test subject panel size selection, and test agent applicability for the benchmark testing of other classes of respirators.

Options for consideration for the TIL Program – Other Classes of Respirators are presented below. NIOSH encourages readers to comment on any and all topics of this document. Comments should be sent to NIOSH at www.cdc.gov/niosh/docket referencing Docket No. 168.

Sources of inward leakage

Inward leakage can occur through a number of different means. In the case of particulate respirators, such as Filtering Facepiece Respirators, a small percentage of particles pass through the filter media and enter the breathing zone. When chemical cartridge and canister respirators are used, gas or vapor contaminants can pass through the filter media if an inappropriate filter is used or if the filter media is expended. Inward leakage should not occur through chemical cartridges or canisters if the proper respirator canister or cartridge system is selected and worn in accordance with the manufacturer's instructions.

For type C and CE, demand-type, supplied-air respirators, the pressure inside the facepiece normally decreases below ambient during inhalation and inward leakage can occur at this time through the respirator-human interface. Another form of inward leakage for supplied-air respirators happens by permeation of gases or vapors through air supply hoses into the air stream even when the hoses are under positive pressure.

Finally, inward leakage can occur through any connections that do not seal properly, including improperly interfacing respirator components or missing or malfunctioning components.

All of the inward leakage sources, via the means described above, make up Total Inward Leakage. As such, the TIL Test is intended to quantify inward leakage from all sources combined.

Options for Consideration

There are a number of options to consider in establishing the methods for performing benchmarking evaluations. Each option will be thoroughly investigated and the appropriate benchmark testing parameters will be chosen to prepare an unbiased, practical and repeatable protocol which can measure inward leakage. Each variable is discussed below.

1. Selecting test subjects

Manufacturers have addressed wearer and test subject variability by developing more flexible or universal-fitting respiratory inlet coverings that provide a good fit for a large wearer population. This has led to many manufacturers offering respiratory inlet coverings in different sizes and shapes (models), some with two or more retention straps and some have specific sizing components such as face seal inserts. Still, providing a good seal or barrier for the wide array of potential wearers remains one of the most difficult areas in preventing inward leakage.

NIOSH is considering several options in the selection of the appropriate test panels to address this. This is discussed below for each respiratory inlet covering type. For the purposes of TIL testing, the respiratory inlet covering types are proposed to be grouped as: a) Tight-fitting facepiece respiratory inlet coverings b) Loose-fitting respiratory inlet coverings including hoods and helmets, and c) Tight-fitting neck dam respiratory inlet covering.

Following the research performed for the tight-fitting half-mask TIL Project, utilization of the same draft NIOSH Bivariate Panel for tight-fitting facepiece respiratory inlet coverings will cover over 97% of expected respirator wearers. The draft NIOSH Bivariate Panel, based on face length and face width, was developed in accordance with the procedures outlined in the International Organization for Standardization (ISO) 15535:2003 - General Requirements for Establishing Anthropometric Databases. Testing of tight-fitting facepiece respiratory coverings would require that measurements be taken of TIL test subjects to determine both their face length and face width.

The use of head size could be considered for test subject categorizing of some types of respiratory inlet coverings such as hoods, helmets, or possibly other respiratory inlet coverings that may contact but do not seal completely to the face, neck, or upper body. Similarly, neck circumference could be considered for test subject categorizing of

respiratory inlet coverings utilizing a neck dam where the primary purpose of the neck dam is to create a seal or barrier between the ambient air and the breathing air inside the respirator. The NIOSH Anthropometric Database developed to establish the draft NIOSH Bivariate Panel included head and neck circumference measurements of the participating subjects taken in accordance with ISO 15535:2003. This information could be used to develop test fit panels for both head size and neck size for these applications. Head and neck circumference measurements of TIL test subjects would have to be taken to determine their panel placement for the testing of head or neck dam respiratory inlet coverings.

The test panel size for all respiratory inlet coverings will be determined through statistical analysis of benchmark testing data. The initial objective of benchmark testing will be to determine the number of tests that are sufficient to yield statistically reliable data. The number of donnings per test will also be investigated to determine the total number required to yield a repeatable fit.

2. Test configurations

Most respirators are comprised of a great number of accessories that can be assembled in a variety of configurations. The actual number of configurations that will need to be tested will be determined on a case-by-case basis at the discretion of NIOSH. However, all respirators will have to pass TIL testing with any and all accessory combinations during future certification tests.

3. Test agents

Several different inward leakage test agents have been tried and, depending on the variables, have proven effective. These include but are not limited to salt (sodium chloride), corn oil, dioctyl phthalate, ambient particulates, isoamyl acetate vapor, and sulfur hexafluoride. Much work has already been done for half-mask particulate air-purifying respirators and the best test agent was determined to be salt. The reason for the use of salt for half-masks is that this test agent is relatively simple, safe, and reasonably accurate for determining their performance. At the present time, NIOSH is considering corn oil for some other particulate respirators. The reason is that corn oil is easily attainable, does not put the test subject at risk, does not have inherent dangers with storage or handling, is well known, instrumentation is available, and test methods are established. While the purpose of the TIL test is to assess the inward leakage of the respirator and not degradation or material permeation, questions have yet to be answered such as "is corn oil appropriate for testing a gas mask?" or "is the instrumentation which is available accurate and reliable enough for determining TIL for an SCBA?". Other test agents being considered include but are not limited to isoamyl acetate vapor (measured quantitatively) and sulfur hexafluoride. The respirators should not have to be modified to conduct the test in a manner that would affect the results. This would include, but not be limited to, actions such as putting a carbon filter in place of a particulate filter or vice versa, or hanging unsupported tubes or instruments on the facepiece.

4. Test protocols

As a basis, several existing protocols are being considered although modifications would likely be needed. These include the OSHA fit test protocol, the Laboratory Respirator Protection Level (LRPL) corn oil test protocol which is presently being used for NIOSH CBRN testing, industrial fit test isoamyl acetate vapor protocol (measured quantitatively), or a sulfur hexafluoride protocol.

Other protocol issues include: a) Test performance, b) Test exercises and c) Pass/fail criteria. Each of these is discussed below.

a) Test performance

Not every respirator is intended to be used in the same type of environment or can be expected to provide the same level of protection. As such, not every respirator may need to provide the same level of resistance to inward leakage. It is possible that the establishment of TIL performance requirements through benchmark testing could warrant a change in some of OSHA's Assigned Protection Factor (APF). It is also recognized that a given full facepiece respirator, for example, may need to perform at one level when configured as an SCBA but perform at a different level when retested as a P-100. As such, test performance requirements will be determined for the respirator configuration in which they are submitted for approval.

b) Test exercises

Eight test exercises are being proposed and are very similar to those used for the NIOSH half-mask TIL work. Each exercise should be performed for a period of 15 seconds except for grimacing which is only performed for 2 seconds. The test subject would don the respirator and wear it for a short period prior to starting the test. The subject may adjust the respirator as necessary during this period. The subject may not adjust the respirator once the exercises have started. The subject would perform the following exercises.

(1) Normal breathing. In a normal standing position and without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme for 2 seconds and the subject shall inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down at a rate of approximately 2 seconds per up-down cycle. The subject shall inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject shall read from the prepared Rainbow Passage text.

(6) Reach for the floor and ceiling while pausing for two normal inhalations in the standing with arms-up position and in the bent over with arms-down position

(7) Grimace. The test subject shall grimace by smiling or frowning. Note: This exercise is to determine if the respirator is capable of resealing if the seal is broken or if airflow will be disrupted following this activity. During the grimace period, TIL measurements are not proposed to be taken.

(8) Normal breathing. (Same as exercise 1)

These exercises were selected because they represent typical movements that would reasonably be expected to be performed by workers. They are not overly strenuous but do present movement situations where leakage could likely develop. They closely follow the OSHA exercises with some additional criteria added to ensure that the exercises are performed more consistently. Other exercises may be identified to add to this list or one or more of these exercises may be eliminated depending on benchmark test results. Respirator class-specific exercises may also be identified through benchmark testing.

c) Pass/fail criteria

The TIL pass/fail criteria will be viewed as a statistical test. Concepts for an optimal test will be defined through statistical analysis of benchmark test data and will include the following: (1) the number of test subjects required to provide statistically meaningful results; (2) the maximum acceptable TIL level; and (3) the minimum number of test subjects required to have measured TIL levels below the maximum acceptable level in order to provide a passing result for that particular respirator. During TIL benchmark testing of filtering facepiece and elastomeric half-mask particulate respirators, these parameters were identified and will be considered as starting points for the other classes of respirators. While it is anticipated that the pass/fail TIL values will approximate 100%/Fit Factors where Fit Factors are a minimum 10 fold multiple of current OSHA APF, the criteria will be based on benchmark performance test results, not on current APF.

LRPL Focus

NIOSH respirator standards presently in the rulemaking process or under development (CC-SCBA, PAPR, SAR, and AFE) have specified the LRPL test as a means to ensure that respirators are designed to fit persons of various facial and neck shapes and sizes. As the TIL project and development of the TIL module progresses, LRPL requirements will ultimately be replaced by the inward leakage requirements in this TIL program. Work is currently underway in the review of relevant standards for some of these other classes of

respirators to identify applicable inward leakage or peak aerosol penetration requirements for their materials of construction. The final TIL performance requirement for each particular class of respirator will be incorporated into the developing Technical Concept Standard or as a final rule in Title 42 Code of Federal Regulations Part 84 (42 CFR 84) if the respirator class has entered the rulemaking process.

Questions for Consideration

1. Should the TIL pass/fail be based on the type of respiratory inlet covering, the intended use of the respirator, or other?

2. Are there any other test agents that can be used which will work for some or all types of respirators that are safe, environmentally friendly and can be accurately measured at the desired concentration?

3. Is there test equipment available that can reliably measure the concentration of the test agent(s) of choice that are not overly expensive to own, operate, or maintain?

4. Should NIOSH consider accepting TIL test results from independent laboratories?

5. Should the standard set of exercises employed by the fit testing process be used for all TIL testing, or should it be different for various types? Why?

6. Do the options for available respirators dictate what exercises can be done?

7. What will be the strategy for the placement of sample ports for other classes of respirators? Where will the sample point terminate with respect to the test subject for each class of respirator?