Program Concept for Total Inward Leakage (TIL) Performance Requirements and Test Methods

1.0 Goals

The NPPTL Total Inward Leakage (TIL) program will establish TIL performance requirements and laboratory test capability for testing of personal protective equipment (PPE), including all classes of respirators and protective garments.

The NPPTL TIL program will be organized into multiple projects. The initial TIL project will address half-mask respirator requirements and testing. Other classes of respirators will be incorporated into the program following completion of the half-mask project. The half-mask respirator TIL project will span a period of approximately 12 months, concluding with introduction of respirator testing in April 2005.

Although respirator TIL testing is intended to quantify the ability of respirators to fit individuals, it is not intended to replace individual fit testing as mandated by OSHA or to predict the workplace protection offered by respirators during actual use. However, the requirements will have a respiratory margin of safety over expected respirator selection criteria. While total inward leakage testing performed under laboratory conditions does not necessarily reflect expected actual field level PPE performance, it does represent a criterion for performance that influences PPE design.

2.0 Background

Recent trends in the field PPE testing have focused on the need to effectively evaluate PPE systems performance for TIL under laboratory conditions.

In the preamble to 42 CFR Part 84, NIOSH stated, “The purpose of face fit testing in the certification program has been to assure that respirators have generally good face fitting characteristics. However, at this time NIOSH does not have studies that define the effectiveness of either isoamyl acetate or ANSI/OSHA accepted fit tests... NIOSH is presently conducting research for this purpose. In the interim, lacking validation and correlation of testing protocols, worker's health concerns are best served through the application of fit-testing and fit-checking procedures on individual workers in a quality respirator program. Therefore, ...fit tests are not included in this final rule. NIOSH will address issues associated with face fit efficacy in a separate module upon completion of the necessary research.”

It has been almost nine years since this Rule was promulgated and NIOSH believes that research and technical advances have made the inclusion of fit testing requirements as part of respirator certification practical as well as necessary.

3.0 Research and Technical Advances

Advances in the number of effective, validated TIL test procedures have made TIL practical as a requirement for respirator certification.
It is anticipated the TIL performance requirement will be based on state-of-the-art respirator performance and will account for differences between laboratory test conditions and workplace conditions. The performance requirements will be respirator class specific, and while they may be used by OSHA to establish APFs, the requirements will not be the same as present or proposed APF values.

The TIL test will use a panel of subjects from a NIOSH updated Los Alamos panel, in sizes specified by the respirator manufacturer. The revised panel will cover more of the diversity that is found in today's US workforce.

The exercises will be those used by OSHA in current fit tests but may be augmented by others now used by NIOSH in other tests conducted in accordance with 42 CFR Part 84. These exercises may include multiple donnings.

Emphasis will be put on manufacturer's user instructions for proper selection criteria and the ability to conduct user seal checks. Both of these instructional matters will be reviewed and used as a basis in the TIL testing process.

4.0 TIL Test Program—Half-Mask Respirator Project

Major aspects of the TIL test program—half-mask respirator project include:

- Development of respirator TIL requirements and test protocol,
- Establishment of a TIL test facility,
- Benchmark and consistency testing,
- Peer review, and
- Public meetings.

The project is organized into three phases over a 12-month period. The phases, although independent, may run concurrently. The three project phases and objectives of each phase are:

**Phase 1: Investigative/Concept Draft**
- Gather and review existing TIL respirator information,
- Review existing TIL test equipment capabilities and technical specifications,
- Identify a peer review team composed of manufacturers, users, academia and government,
- Develop initial TIL concept addressing performance requirements and test protocol,
- Establish technical specification for TIL test facility.

**Phase 2: Test Facility/Benchmark Testing**
- Establish NPPTL TIL test facility,
- Perform benchmark testing to establish state of the art respirator performance,
- Continue development of TIL concept requirement and protocol,
- Identify draft implementation plan.

**Phase 3: Consistency Testing/Implementation Plan**
- Conduct validation testing for TIL facility,
- Finalize implementation plan,
TIL Program Concept
Revised April 20, 2004

- Finalize TIL concept requirement and protocol.

5.0 Half-Mask Project Objectives and Milestones

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<tr>
<th>Phase</th>
<th>Dates</th>
<th>Objectives</th>
<th>Milestones</th>
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<tbody>
<tr>
<td>Investigative/</td>
<td>Mar. '04</td>
<td>• Gather information</td>
<td>• TIL concept</td>
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<td>Concept draft</td>
<td>Through</td>
<td>• Review test equipment</td>
<td>• Facility specification</td>
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<td></td>
<td>Aug '04</td>
<td>• Identify peer review team</td>
<td>• Peer review</td>
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<td>• Develop TIL concept</td>
<td>• Public meeting</td>
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<td>• Establish facility specification</td>
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<tr>
<td>Phase 2:</td>
<td>May '04</td>
<td>• Establish Test Facility</td>
<td>• Draft implementation plan</td>
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<tr>
<td>Test Facility/</td>
<td>Through</td>
<td>• Benchmark tests</td>
<td>• Peer reviews</td>
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<tr>
<td>Benchmark testing</td>
<td>Feb '05</td>
<td>• Continued concept development</td>
<td>• Public meetings</td>
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<td>• Draft implementation plan</td>
<td>• Complete test facility</td>
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<td>Phase 3:</td>
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<td>• Validation testing</td>
<td>• Peer review</td>
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<td>Validation testing/</td>
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<td>• Implementation plan</td>
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<tr>
<td>Implementation plan</td>
<td>April '05</td>
<td>• Final TIL concept</td>
<td>• Final TIL concept</td>
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