Testimony on 42 CFR Part 84
Total Inward Leakage Requirements
July 29, 2010

Notice of Proposed Rulemaking
RIN 0920-AA33
published October 30, 2009 in Federal Register
This presentation is a summary of findings based on studies conducted following the last public meeting for the proposed TIL rule. Detailed written comments will be submitted to the docket.
NIOSH Fit Test Proposal

- Requirement to fit persons with various facial shapes and sizes stays the same
  - STP proposal for determining compliance is the issue
- “User instructions for half-mask respirators shall specify information necessary to identify the intended population of users:
  - The applicant shall specify in the user instructions the face sizes or sizes that the respirator is intended to fit…”
Conclusions Stated by NIOSH from their Benchmark Data

- "Approximately 30 percent of this class of respirators have facepiece seals that did not perform adequately to achieve a fit factor of 100”

- "According to NIOSH benchmark testing and other research, ... with significant production capacity are likely to pass the proposed TIL testing and performance standards without modifications."

- "NIOSH benchmark testing indicates ... that the new TIL requirements can be met by current products without additional development or manufacturing costs."

- Not sure how this conclusion was reached because:
NIOSH Benchmark Results

TIL Test Results: 101 Respirator Models

Percentage of Models that Achieve Penetration less than $P_c$ for 19 of 25 Subjects

Penetration Criteria, $P_c$

PF=1000  PF=100  PF=10  PF=1
NIOSH Benchmark Results

TIL Test Results: Filtering-Facepiece Models

Penetration Criteria, $P_c$

Penetration less than $P_c$ for $x$ or 25 Subjects

Percentage of Models that
Benchmark Data Appears Inconsistent with Conclusions

- These data do not support NIOSH’s conclusions nor its intentions
- This discrepancy indicated a need for evaluation
  - 3M reviewed the NIOSH benchmark testing of its respirators
  - 3M conducted a study following the proposed fit test on several products
  - ISEA conducted a similar study
    - Evaluated respirators to the proposed fit test
    - Reviewed respirator manufacturers’ NIOSH data
Federal Register References

- NIOSH mentioned articles by Coffey *et al.* and Lawrence *et al.* that indicate there are well fitting and poor fitting filtering facepiece respirators on the market
  - Using these studies 3M tested well fitting respirators (6) and a poor fitting respirator identified in these articles
  - The proposed fit test is incapable of differentiating between them (eliminates everything)
  - Based on user feedback, there are well fitting respirators on the market
- Together with the NIOSH benchmark data, this demonstrates there will be no filtering facepiece respirators and very few elastomeric respirators approved

- Therefore, this rule should not proceed in its present form
Additional Experience

- AJIC 36(4):298-300 2008
  - QLFT on 1271 health care workers
  - All males fitted, all but 6 females fitted with FFP
  - First FFP choice fitted 95.1% of males, 85.4% females
  - NIOSH study indicated good fitting characteristics
  - WPF results indicate good performance in workplace
  - This respirator model did not pass the benchmark test.
  - When we tested according to the proposal, the model did not pass

- The proposal does not reflect real world experience
Issues with Current Proposal: Individual Fit Testing

- Regardless of how products are designed and tested, it will not ensure respirators fit “out of the box”
  - No fit testing means they have no program
  - No training – donning, user seal checks
  - No supervision – facial hair and other issues that interfere with fit

- UK study on elastomeric respirators tested for TIL (EN140)
  - No fit testing performed
  - 69% of 211 subjects had respirators that did not fit

- To provide effective protection, individual fit testing will still need to be performed within the context of a complete respirator program
Issues with Current Proposal: Panel-to-Panel Variability

- The panel make-up would become more important than the respirator fit characteristics.
- Therefore the test method needs to overcome this issue:
  - Dramatically increase panel size (minimum of 105 subjects)
  - Reduce variability in the panel cells
    - "Standardized" faces, test heads for each cell
  - Change the pass/fail criteria of the test
    - Passing fit factor, pass rate
- NIOSH audits would be another challenge
  - No change to product, no change from QA plan, but fails test
Issues with Current Proposal: Implementation

- If no FFPs approved, everyone would need to move to the remaining elastomeric respirators
- According to NCEL, 413 FFPs approved
  - The time needed to redesign, test and certify with fit test results for 413 existing models will be ???
    - Assuming fit tests only
    - $413 \times 35 \times 1-3 = 14,455 - 43,365$ fit tests
    - $0.25$ hours/fit test $= \sim 3614 - 10,841$ hrs ($1355 \times 8$ hr days, max)
Issues with Current Proposal: Financial Impacts

- Due to the huge variability in panel results, significant chance of failure with any given respirator model
- As respirators are designed to pass the proposed panels, the standard becomes design focused instead of performance
  - Re-design and improvements would be discouraged, so fewer models from one manufacturer
  - Less diversity between manufacturers, “hard to fit” person falls out (e.g. small faces)
Issues with Current Proposal: User Instructions

- The two dimension facial measurements from the panel do not predict fit
- Providing this guidance would not assure fit, but people would most likely think that it would
- The proposed rule requires respirator manufacturers to specify the face size or sizes the respirator is intended to fit in the user instructions.
  - For respirator selection, employers would need to:
    - acquire calipers,
    - receive training on their use,
    - measure facial dimensions of each wearer, and
    - acquire respirators for those face sizes.
    - fit test each wearer in those respirators.
  - Fit testing becomes cumbersome and time consuming
3M Technical Assessment

- 3M supports a fit performance requirement in certification evaluation.
- NIOSH's proposed change to 42 CFR 84 with a "TIL" test for half-facepiece respirators has significant gaps and inconsistencies.
- Based on 3M's experience and research, the proposed rule will not accomplish NIOSH's stated objectives:
  - Remove poor-fitting respirators from the market while approving well-fitting respirators.
  - Improve respiratory protection of workers not in complete respiratory protection programs.
3M Recommended Modifications to NIOSH TIL Rule

- Replace the term “TIL” with “face fit factor” or “fit factor”

- Remove any language that implies that the fit of a respirator on an individual can be effectively predicted based on face length and width – the selection of respirators in the workplace must include fit testing

- Remove the “one pass per cell” requirement
  - Little or no predictive capability, especially for NIOSH grid cells with two subjects

- Change required subject pass rate to between 50% and 60% at a fit factor of 50 to 100
  - This will separate poor-fitting respirators from well-fitting respirators
Well-fitting and poor-fitting respirators

- Stated objective of modified rule is to remove poor-fitting half-facepiece respirators from the market
- A NIOSH study (Lawrence et al., JOEH, 2006) presented fit test results of surgical masks, filtering facepieces and half-face elastomeric facepieces
- In comments supplied to the docket 3M and ISEA have evaluated well-fitting respirators identified in Lawrence et al (high probability of passing workplace fit test)
- 3M has evaluated a poor-fitting respirator identified in Lawrence et al (low probability of passing workplace fit test)
What is a well-fitting respirator?

- For an individual respirator user a well-fitting respirator is simply a respirator that fits them, i.e. they pass a fit test.

- For an employer, a well-fitting respirator is a respirator that will fit some workers as determined with fit testing.

- In some cases a well-fitting respirator may not fit any workers at worksite, but this should be unlikely.
Some real-world experience with well-fitting respirators

<table>
<thead>
<tr>
<th>Company</th>
<th>Industry or application</th>
<th>Estimated # of workers in user pool</th>
<th>Estimated Fit Test Pass Rate for User Pool</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Chemical, plastic, fiber manufacturing</td>
<td>2000</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>80-85%</td>
</tr>
<tr>
<td>2</td>
<td>Pharmaceutical</td>
<td>400</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Pharmaceutical</td>
<td>200</td>
<td>90%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>90-95%</td>
</tr>
<tr>
<td>4</td>
<td>Pharmaceutical</td>
<td>150</td>
<td>95%</td>
</tr>
<tr>
<td>5</td>
<td>Ingot manufacturing</td>
<td>115</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Flavor/food additive manufacturing</td>
<td>35</td>
<td></td>
</tr>
</tbody>
</table>
What is a poor-fitting respirator?

For an employer, a poorly-fitting respirator is a respirator that fits significantly fewer workers than expected.

Poor-fitting respirators do exist.

Lawrence et al. identified a number of filtering facepiece respirators which had a "no pass" result for 25-member test panels.
How can well-fitting and poor-fitting respirators be identified?

- NIOSH's proposed TIL rule attempts to identify poor-fitting respirators that should not be approved
  - 35-member panel based on the bivariate NIOSH grid with exclusion of outliers through use of NIOSH PCA panel
  - Quantitative fit test
  - At least 26 subjects in the panel must pass at least one out of three fit tests (fit factor $\geq 100$)
  - At least one subject in each cell of the bivariate grid must pass a fit test
Additional 3M studies

- 3M is continuing to evaluate NIOSH’s proposed TIL rule during the extended comment period.
- The fit performance of a poor-fitting respirator was compared to a well-fitting respirator.
  - One of the six filtering facepieces with a “no pass” result in Lawrence et al. was evaluated with three 35-member panels per NIOSH’s procedure RCT-APR-STP-0068.
  - Poor-fitting respirator was designated model H.
  - The well-fitting respirator was 3M filtering facepiece model A (see previous 3M comments to NIOSH docket 0137).
Analysis of Well-fitting and Poor-fitting Filtering Facepiece Respirators

- Three 35-member panels of fit test subjects were assembled for each product to be tested
- Each 35-member panel complied with requirements in NIOSH Procedure RCT-APR-STP-0068
- Each subject was tested three times with each sample
Fit Test Results of Model A and H

- Model A - 79 out of 105 test subjects (75%) had at least one fit test with a fit factor $\geq 100$
- Model H - 1 out of 105 test subjects (1%) had at least one fit test with a fit factor $\geq 100$
What Criteria Can Be Used To Differentiate Between Models A and H?

- Data sets for each model were used to create 1000 simulated 35-member panels
  - Each simulated 35-member panel was randomly selected (without replacement) from 105 subjects tested for each model
  - Each simulated panel complied with the requirements of NIOSH procedure RCT-APR-STP-0068
  - Over $10^{23}$ simulated panels could be created

- Simulation process shows predicted variation between different 35-member panels

- Each simulated panel was evaluated for a range of approval criteria
Possible approval criteria evaluated

- Minimum fit factor from 10 to 100
- Subject pass rate from 0% (0 out of 35) to 100% (35 out of 35)
  - A subject passes if at least one of three fit tests has a fit factor $\geq$ minimum fit factor
- "One pass per cell" was evaluated as part of the written comments submitted previously
  - This presentation will not include that analysis
Minimum fit factor of 10

Pass Fit Factor \( \geq 10 \)

Number of simulated panels

- Model H - Poor-fitting
- Model A - Well-fitting

Subjects with at least one fit factor \( \geq 10 \)
Minimum fit factor of 20

Pass Fit Factor ≥ 20

Number of simulated panels

Subjects with at least one fit factor ≥ 20
Minimum fit factor of 50

Pass Fit Factor \( \geq 50 \)

| Model H - Poor-fitting | Model A - Well-fitting |

Number of simulated panels

Subjects with at least one fit factor \( \geq 50 \)
Minimum fit factor of 100

Pass Fit Factor ≥ 100

60% of subjects with fit factor ≥ 100
Proposal from 3M comments submitted March, 2010

Number of simulated panels

- Model H - Poor-fitting
- Model A - Well-fitting

Subjects with at least one fit factor ≥ 100
Conclusions from evaluation of possible approval criteria

- Fit factor of 20 or lower does not differentiate between poor- and well-fitting respirators
- Fit factor of 50 provides good differentiation
- Subject pass rate of 50% (18 out of 35) is sufficient to reject poor-fitting respirator
3M Supports a Fit Requirement as Part of Certification

- Unfortunately, the current NIOSH TIL proposal will remove well fitting devices from general industry and healthcare workplaces.

- In order to meet the proposed test method, the forced redesigns of respirators would:
  - Reduce diversity among available designs
  - Reduce or eliminate respirators for "hard to fit" people
  - Eliminate respirators that fit people outside the bivariate grid
3M Recommendation

- Replace %TIL maximum with minimum fit factor of 50 and a 50% pass rate
- Remove "one pass per cell" requirement
- Change the UI requirement:
  - 84.175 (h) User instructions for half-mask respirators shall specify information or procedures necessary to identify the intended population or sub-population of users.