

3M Occupational Health &  
Environmental Safety Division  
St. Paul, MN

Testimony on 42 CFR Part 84  
Total Inward Leakage Requirements  
for Respirators  
December 3, 2009

Notice of Proposed Rulemaking  
RIN 0920-AA33

published October 30, 2009 in *Federal Register*

# 3 Occupational Health & Environmental Safety Division – Representatives

- Craig Colton
  - Division Scientist
- Phil Eitzman
  - Product Development Specialist

These presentations are a summary of primary areas of concern. Detailed written comments will be submitted

# 3M's Respirator Fit Experience

- 3M has always been an advocate and innovative leader in advancing the importance of fit
  - 3M has developed both qualitative fit test (QLFT) and quantitative fit testing (QNFT) methods
  - 3M has used QNFT for evaluating fit of half facepiece respirators, including filtering facepiece respirators, for > 25 years – long before NIOSH began working on this Concept
  - Workplace Protection Factor studies support the success of these efforts
- 3M supports efforts to improve respirator fit

# Significant Regulatory Action

- NIOSH states this proposed rule is “Not considered economically significant” (74 *Fed. Reg.* 56147)
  - Benchmark testing appears to be used to support its conclusion that proposal is not economically significant
  - We believe NIOSH erred by using the benchmark testing to substantiate its conclusions on the economic impact of the current proposal

# Benchmark testing

- NIOSH states this benchmark testing “indicates that the new TIL requirements can be met by current products without additional development or manufacturing costs.”
- 101 respirator models tested
- 25 person panel
- Pass/Fail fit factor of 20, Avg of 3 tests
- Used the same respirator and straightened out nose clip (where nose clip was present)
- Difference between 100 and 95 level filters was not addressed

# Differences with Current NIOSH Proposal

- 35 person panel
- Pass/Fail fit factor of 100
  - Must pass one out of three trials
- Use same respirator for all trials without straightening nose clip
- For respirator designed to fit wide range of people over the entire panel, must have a pass in every face panel cell

# NIOSH Benchmark Test Data Conclusions

- ~30% of half mask, air-purifying particulate respirators had facepiece seals that did not achieve a fit factor of 100
- Our review of the NIOSH benchmark testing of 3M respirators does not support NIOSH's reliance on benchmark data to predict that the proposed "TIL" requirements can be met without development or manufacturing costs
- 3M submits the proposed rule may potentially:
  - Have an economic impact > \$100 million
    - Job loss
    - Impact economic stability of Communities
    - High cost of product
    - Impact respirator supply

# NIOSH Proposal: User Instructions

- Shall specify:
  - Information necessary to identify the intended population of users
  - Face size or sizes that the respirator is intended to fit
  - Any additional descriptions necessary to indicate the subpopulation



# User Instructions

## Comments on NIOSH Proposal

- The two dimension facial measurements from the panel do not predict fit
  - These dimensions do not consistently correlate to fit (IOM, 2007)
  - 3M supplied data and information to the concept docket that these measurements do not correlate to fit
- Providing this guidance will not assure fit, but people will most likely think it does
- Likely to provide false sense of security

# User Instructions

## Comments on NIOSH Proposal

- Identifying the sizes of faces a respirator fits may establish an implied warranty
- This will likely result in less fit testing because the packaging and User Instructions state the respirator fits their face size
- Because a wearer's facial dimensions can not predict fit, this warranty would be misleading and can not be made
- This requirement could cause manufacturers to eliminate all facepieces from the market

# User Instructions

## Comments on NIOSH Proposal

- Another major issue is how the wearer will know what facial size they are
- Logistical issues
  - Training to make the measurements
  - Frequency of measurements
    - Cost of determining face size negates savings  
NIOSH mentions for not guessing at sizes
    - If fit testing not performed, why would facial measurements be taken

# User Instructions

## Comments on NIOSH Proposal

- This proposed approach encourages non-compliance with OSHA regulations which may jeopardize worker safety
  - No incentive for workplaces without fit testing to begin fit testing because “they fit better out of the box” now
  - Stockpiled respirators might be deployed without a respirator program and without fit testing
    - Better solution would be to require evidence of a program and fit testing in order to be eligible for respirators from the stockpile

# Pass/Fail Criteria

## Comments on NIOSH Proposal

- NIOSH states:
  - “...maximum allowable leakage (FF of 100) is now equivalent to fit test criteria required by OSHA for this type of respirator” (74 *Fed Reg* 56144)
  - “The technology is identical to that in common use for measuring respirator fit and is accepted by OSHA” 74 *Fed Reg* 56143)

# Pass/Fail Criteria

## Comments on NIOSH Proposal

- The method NIOSH has proposed is not one of the accepted protocols published in Appendix A of 29 CFR 1910.134
- 29 CFR 1910.134 Appendix A published January 8, 1998 and did not mention N95 Companion
- There were no sales of the N95 Companion until after Appendix A was published
- No study or publication confirming that N95 companion is accurate and reliable as required by OSHA
- Does 100 (Portacount w/Companion) = 100 (by OSHA accepted method)????
- 100 from Portacount w/ Companion is arbitrarily chosen

# TIL

- This nomenclature will cause confusion
- IOM points out that the scientific community (except NIOSH) refers to the assessment of respirator fit as a fit test and not TIL
  - In a fit test the challenge aerosol has been chosen to match the filtering element in order to measure face seal leakage only
    - For N95 level filters, the Portacount™ measures both filter penetration and face seal leakage whereas the Portacount™ with Companion only measures face seal leakage or fit
    - High penetration in the Automatic Filter Tester (AFT) with same particle size does not correspond to high penetration in fit test with Companion
    - Example: Portacount N95 - 2 percent penetration
      - Portacount w/Companion N95 – 0.7 percent penetration

# Summary

- Support improving respirator fit
- Benchmark testing is NIOSH support for its conclusions and position
  - Concern on how the data were interpreted and extrapolated
- Concern on specifying face sizes in UIs
  - Logistically
  - Usefulness
- Pass/Fail criteria arbitrarily chosen and does not relate to OSHA fit testing as implied
- Based on STP, this is a fit test, not TIL