

3M Occupational Health and
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
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Philip Eitzman, Ph.D.¹

Comments on Test procedure

- Use of a single respirator per subject means that if the noseclip is misformed by the subject on the first donning and does not fit, it will probably not fit on subsequent donnings
 - New product should be used for each donning
- There is no requirement to train test subjects on the use of the respirator prior to fit testing
 - This appears to assume the respirator will be used in the absence of a respirator program – fit test subjects should be trained as they would be under OSHA 1910.134
- Regardless of whether qualitative or quantitative fit testing is to be used, panel sizes of 15 to 35 subjects will lead to significant panel-to-panel variability and will produce erroneous results

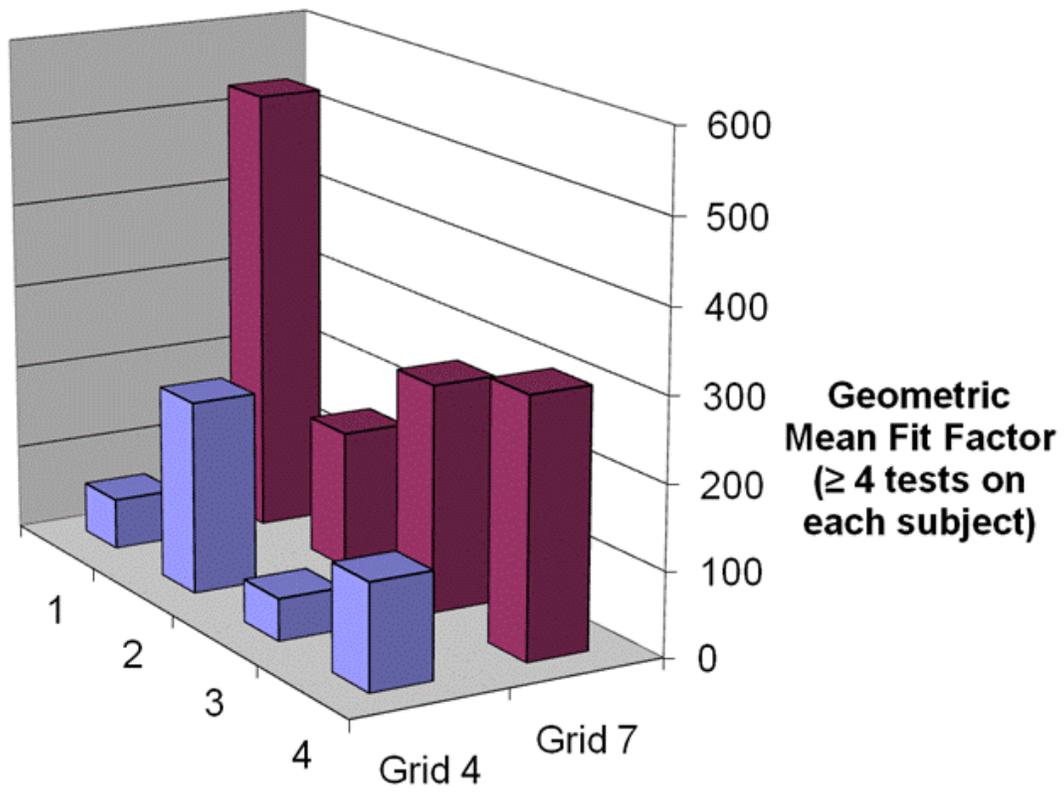
Use of NIOSH Grid

- Development of new NIOSH fit panel grid was important advance from LANL fit panel grid
- Fit panel grids are appropriate for assembling a population sample for evaluation the fit of a respirator
- In general, however, fit panel grids are not appropriate to develop correlations between face size and predicted respirator fit

Fit Factors of 4 Subjects in LANL Grid Cell 4
Elastomeric half-face respirator

Subject #	Respirator Size		
	Small	Medium	Large
1	1940	8700	68
2	11500	1240	
3	1050	5	
4		1320	82700

Geometric Mean Fit Factor Four Subjects Each in LANL Grid Cells 4 and 7 3M 1860



Subjects from NIOSH Grid Cell 4



Subjects from NIOSH Grid Cell 4



Test Variability

- NIOSH has still not adequately addressed this topic
- It is critical that certification test results properly assess respirator fit and not other factors such as test variability:
 - No test enclosure
 - Reproducibility and Repeatability testing needs to be performed to demonstrate test robustness

NIOSH Questions

(from Federal Register Vol.74, No. 209, pgs 56145 & 56149)

- What percentage of the intended user population should be able to achieve adequate TIL performance for the respirator to be approved by NIOSH?
- As the percentage of the intended user population capable of achieving adequate TIL performance from a respirator declines, at what point, if any, should NIOSH set the limit to be nearly certain (e.g., 99 percent or higher probability) that the respirator would not be approved?
- How many test subjects should be included in the testing, considering the fact that testing accuracy increases with the number of test subjects, but that the cost of testing also increases with the number of test subjects?
- Do manufacturers believe they can meet the proposed TIL performance standards and testing requirements and provide adequate product supply to meet anticipated market demand within the proposed 3-year deadline?
- Would any parties affected by this proposed rule incur an exceptional and unsupportable financial or other burden as a consequence of the proposed 3-year limit on the sale and distribution by approval holders of respirators certified under the current requirements (which omit TIL standards and testing)?
- Would a different implementation schedule be better justified in terms of balancing the public health, practical, and economic benefits of removing from the market NIOSH-approved respirators with inadequate TIL performance against the public health, practical, and economic benefits of ensuring that an adequate supply of NIOSH-approved respirators remains constantly available?
- Are other factors that have not been identified by NIOSH important to deciding an appropriate implementation schedule?

Summary

- An extension to the comment period is needed for 3M and others to provide the requested comments on the proposed rule change
- Fit testing of respirator users is a critical component of effective respiratory protection programs
- The impact of the proposed rule change will be economically significant
- The use of the term “Total Inward Leakage” does not correctly describe the fit test that NIOSH is proposing
- The proposed test protocol will lead to significant panel-to-panel variability and will produce erroneous results