Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering Facepiece Respirator Fit: Part II – One Year Assessment of Fit Changes

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Objectives
• The objectives of this study are to assess changes in respirator fit and facial dimensions as a function of time for a representative sample of subjects wearing filtering facepiece respirators (FFRs) (Figure 1) and to investigate factors (e.g., weight change) that affect change in fit.

Materials and Methods
• Subjects were trained to don and doff FFRs using standardized videos.
• Inward leakage (IL) was measured with the TSI PORTACOUNT® instrument during five – exercise fit tests. Filter penetration was measured to calculate face seal leakage (FSL).
• The study included only subjects who (a) passed one of the first three fit tests and (b) demonstrated, through a series of nine donnings, that they achieved adequate fit. A subject was considered to have achieved adequate fit if 90th percentile FSL was 5% or less.
• On each subsequent visit, subjects repeated the series of nine five-exercise fit tests for their specific style, model and size respirators.
• Three-dimensional (3-D) scans of subjects were captured; height, weight and 13 facial dimensions were measured using traditional measurement techniques (Figures 2-3).

Background
• Over three million American workers are required to wear respirators and receive annual fit tests in accordance with the 1988 Occupational Safety and Health Administration (OSHA) standard 29 CFR 1910.134.
• Four commenters were considered in establishing the OSHA annual fit test requirement:
  – Texas Chemical Council: found that virtually no individuals fail fit tests a year after initial test.
  – Exxon Company: < 1% annual fit test failure rate.
  – Lord Corporation: < 1-3% annual fit test failure rate.
  – Hoffmann-La Roche: 7% switch to different specific style, model and size respirators.
• The National Institute for Occupational Safety and Health completed the first year of its three year study to assess changes in respirator fit and facial dimensions as a function of time to improve the scientific basis for the periodicity of fit testing.
• A representative sample of 229 subjects was initially enrolled in the study with 199 subjects continuing to participate. The results of the first year of testing including baseline, 6 month and 12 month evaluations, are presented.

Study Design
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Results

Conclusions
• These preliminary results demonstrate that ~11% of subjects tested experienced a significant change in fit during the first year, but additional work is needed to understand the cause of those changes.

Future Directions
• Complete second year of data collection with the remaining 199 subjects.
• Conduct an elastomeric pilot study with 10 subjects in conjunction with the overall study.
• Assess 3-D data to determine ability to capture changes in facial characteristics over time.

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