Proposed Total Inward Leakage Testing in NIOSH Certification Technical Concept

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NIOSH/NPPTL PUBLIC MEETING

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Total Inward Leakage Program

- **Technical Concepts**
  - Proposed Requirements
  - Test subjects
  - Test protocol
  - Applicability/Schedule

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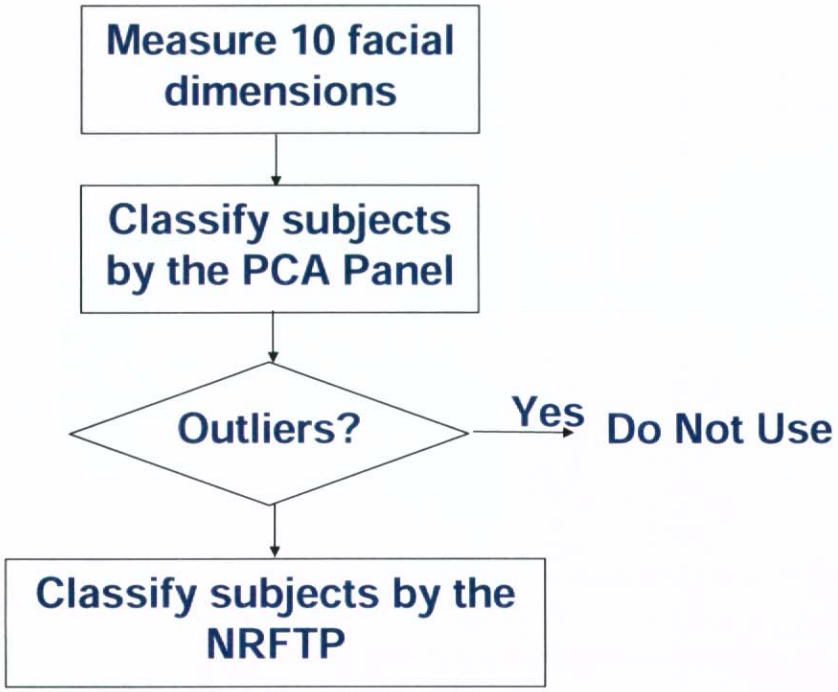
Total Inward Leakage Program

- **Proposed Requirements**
  - Uses the NRFTP
  - Based on Manufacturers' User Instructions for sizing
  - TIL ≤ 5%
  - 26 out of 35 Test Subjects
  - Applicable to all Subpart K Half-mask respirators

Process for Subject Selection



Total Inward Leakage Program

NRFTP

Total = 97.7% of US Respiratory Wearers

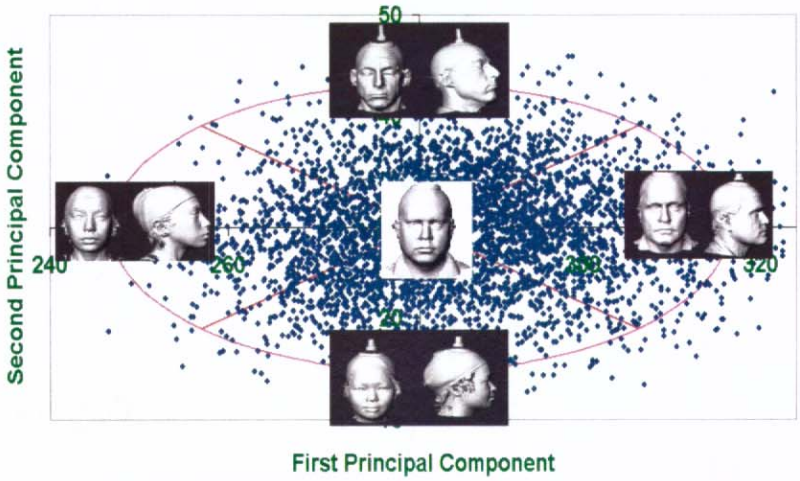
Total Inward Leakage Program

PCA Facial Shape Trends

Long/Narrow Nose

Long Face

Shape



Small Face

Short/Wide Nose

Small — Overall Size — Large

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Total Inward Leakage Program

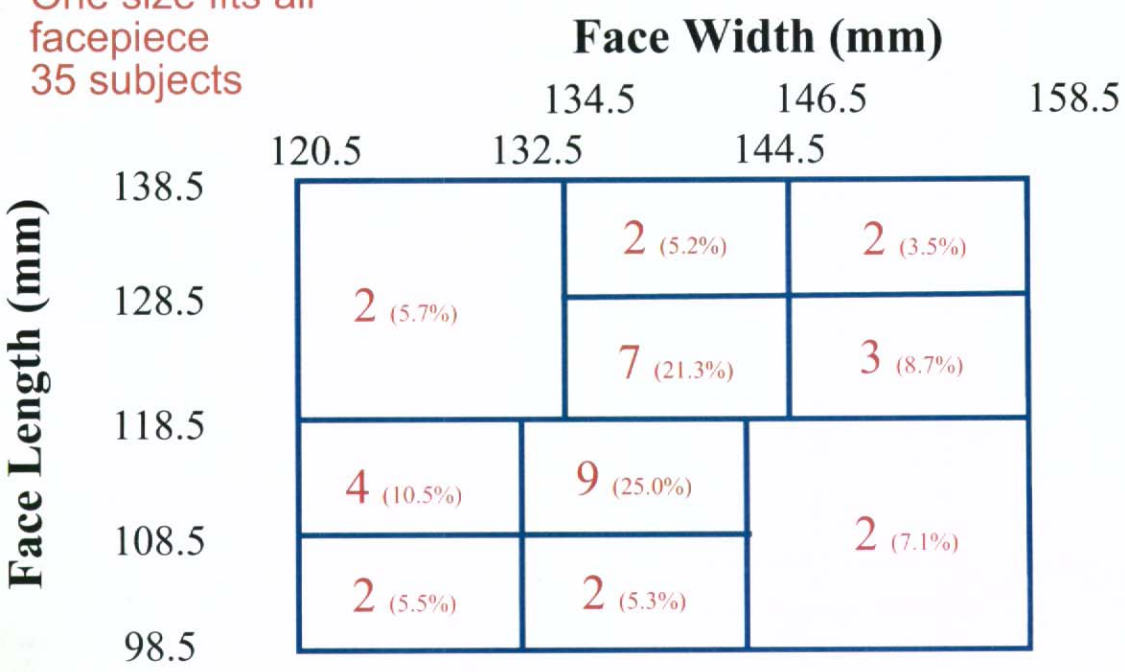
Subject Selection

- Based on the NIOSH test panel
  - Will screen out subjects not fitting into the PCA panel
- Select 35 subjects for each facepiece
  - Unlike what is done today
- User instructions must dictate which subjects correspond to a given facepiece
- Correlation of respirator size to facial dimensions is not required to follow the NRFTP

Total Inward Leakage Program

One size fits all facepiece
35 subjects

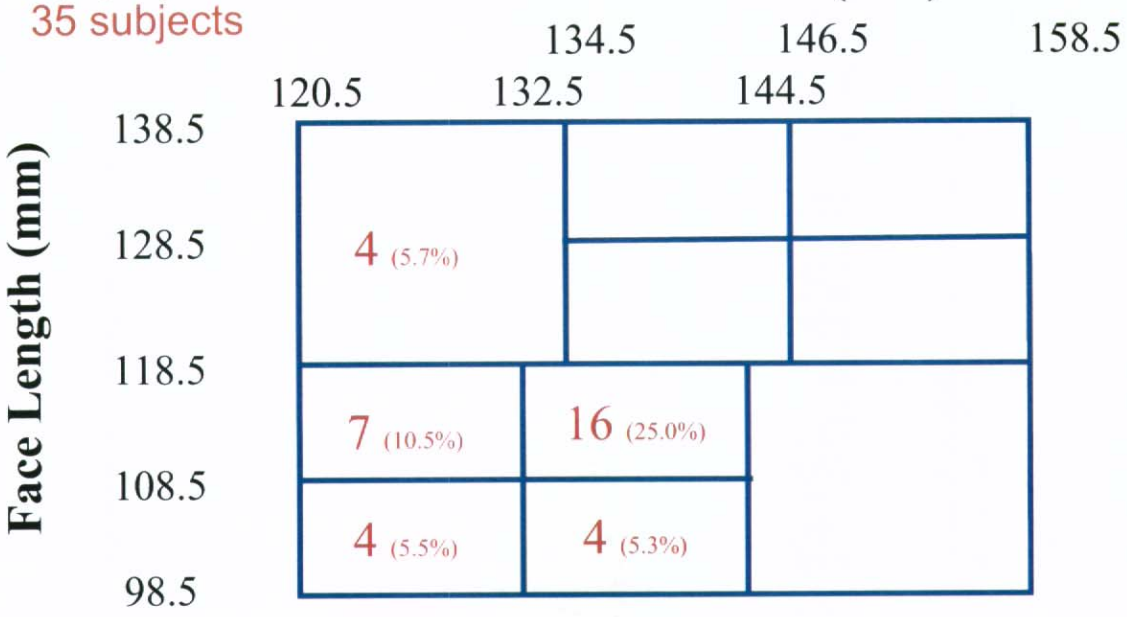
NRFTP



Total Inward Leakage Program

Small that fits
1, 2, 3 ,4 & 6
35 subjects

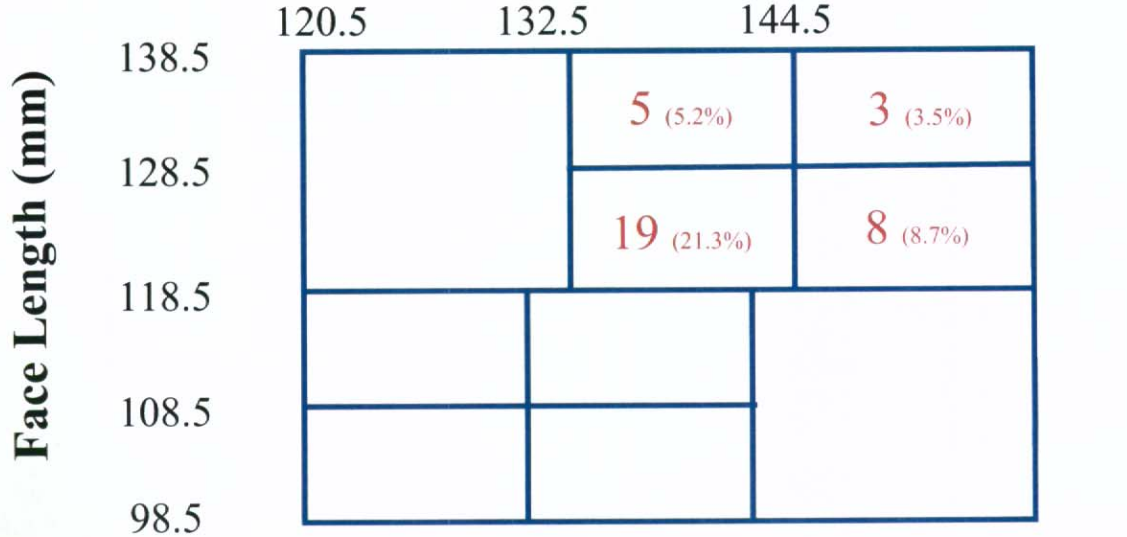
NRFTP



Total Inward Leakage Program

Large that fits
7, 8, 9 & 10
35 subjects

NRFTP



Total Inward Leakage Program

- **Test Protocol**
  - Instrumentation
    - TSI PortaCount® with Companion™ in direct reading mode
  - Challenge agent
    - Generated NaCl ≥500 particles/cc
  - Sample preparation
    - Flush probe located as close as possible between the subject's nose and mouth

Total Inward Leakage Program

- **Test Protocol**
  - Donning
    - Trained using the manufacturer's User Instructions
  - Pretest acclimation
    - Wait 5 minutes before starting
  - Exercises
    - OSHA exercises for 30 seconds/ exercise

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Total Inward Leakage Program

- **Test Protocol**
  - Exercises
    - Normal breathing
    - Deep Breathing
    - Turning head from side to side
    - Moving head up and down
    - Recite the Rainbow Passage out load
    - Reaching for the floor and ceiling
    - Grimace (not included in the TIL calculation)
    - Normal Breathing

Total Inward Leakage Program

- **Test Protocol**
  - Individual test TIL Calculation
    - TIL= Average penetration for the 7 exercises
  - Duplication
    - Each test is repeated three times for each subject/respirator combination
  - TIL Calculation
    - Average TIL for the three tests

Total Inward Leakage Program

- Recap
  - Each subject dons the respirator 3 times and completes a range of exercises
  - Calculate average penetration over all exercises
  - Calculate average over the 3 donnings
  - If penetration ≤ 5%, fit is considered acceptable
  - For each model (facepiece), count the number of subjects with acceptable fit (out of 35)
  - 26 of 35 must have an acceptable fit
  - TIL ≠ APF

Total Inward Leakage Program

- Cost
  - Estimated cost of testing each facepiece is $ 8,500 - $12,000

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Total Inward Leakage Program

- **Proposed Implementation Concept**
  - Effective 30 days after codification
  - Applicable to all new approvals
  - 3 year grandfathering of old approvals
- **Other Possible Scenarios**
  - Process extensions of old approvals for 2 years
  - Comments and Suggestions welcome!

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Thank you

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