

National Personal Protective  
Technology Laboratory

Respirator Manufacturer's Meeting  
Afternoon Session

Les Boord  
Bill Hoffman  
Heinz Ahlers  
Jeff Peterson  
Ron Powelko  
John Perrotte

April 27, 2006

# IAA Testing

- **Overview of IAA testing required in 42 CFR 84**

- The IAA fit test performed by NIOSH assesses the ability of the respirator to fit and continue to maintain a fit during use on persons with various facial shapes and sizes.
- NIOSH currently uses the LANL panel sizes for selection of test subjects
- NIOSH presently has a full panel for both half mask and full facepiece respirator and is continuing to build depth into the panel to ensure that subjects of all sizes will be available

# IAA Testing

- **Fit test procedures and policy**

- Fit test duration is 8 minutes (2 minutes moving head side to side and up and down / 2 minutes with arm movements / 2 minutes running in place / 2 minutes using tire pump)
- Respirators with a full facepiece, hood or helmet are run at a concentration of 500 PPM IAA
- Half mask respirators are run at a concentration of 100 PPM IAA
- Test subjects are now required to don the mask and obtain a user seal check three times after donning it the third time, they will be required to wear the mask 5 minutes prior to entering the chamber to become acclimated to the device
- Test subjects are presently given a physical and screened for their capability to detect 1 PPM of IAA on a yearly basis

- **Effective 5/1/06 Test subjects will be screened each visit for their capability to detect IAA prior to conducting a test**

# IAA Testing

- **Fit test procedures and policy (continued)**

- Respirators submitted by the manufacturer where multiple facepiece sizes are used to insure that the respirator will fit a panel of test subjects of various facial sizes (i.e. -- not intended to fit a full panel consisting of sizes 1 through 10)
  - Small -- panel face sizes 1, 2, 3, 4; panel size 6 (1 or 2 for ea. size to total 6)
  - Medium -- panel face sizes 3, 4, 5, 6, 7, 8; panel size 6 (1 for ea. size to total 6)
  - Large -- panel face sizes 7, 8, 9, 10; panel size 6 (1 or 2 for ea. size to total 6)
  - Small/medium -- panel face sizes 1, 2, 3, 4, 5, 6; panel size 6 (1 for ea. size to total 6)
  - Medium/large -- face sizes 5, 6, 7, 8, 9, 10; panel size 6 (1 for ea. size to total 6)

# IAA Testing

- **Fit test procedures and policy (continued)**

- Whenever less than a full panel (one of each size 1 thru 10) is used to evaluate a single size of any multiple size facepiece, no failures will be allowed
  - Respirators are designed to fit a specific facial size range (such as small) and are expected to fit all subjects of that size range
  - For overlapping panel face sizes (size 3, 4, 7 and 8) a subject need only pass wearing a respirator in one or the other size. Test subjects in the overlapping groups need not pass the test in both sizes; however, all panel face sizes for a specified respirator size must be accounted for during the test as follows:
    - Subject dons respirator and performs a user seal check per the manufacturer's User's Instructions. If the test subject cannot obtain a successful user seal check, he/she will not be sent into the chamber
    - Up to three different test subjects of a specified size will have the opportunity to obtain a successful user seal check before the project is denied

# IAA Testing

- **Fit test procedures and policy (continued)**
  - The test subject must not detect the odor of IAA after exercises have started
  - Respirators submitted by the manufacturer where a single facepiece is intended to fit everyone (i.e.- intended to fit a full panel of sizes 1 through 10)
    - A full panel of sizes 1 through 10 is used to evaluate a one size fits all respirator. All panel face sizes must be accounted for during the test as stated in items 1 and 2 above
    - One failure where the test subject detects the odor of IAA during the exercises will be permitted; however, an additional test using a different test subject of the same size must be performed with passing results. If two or more failures occur, the project will be denied.

# IAA Testing

- NPPTL has purchased several respirators from the open market and run IAA fit tests as well as Portacount fit tests in order to validate the effectiveness of the IAA test
- Important findings
  - Respirators with overall fit factors on the Portacount for the type of respirator evaluated did not always pass IAA test ...i.e. one or two exercises had a fit factor less than that required
    - Respirators that exhibited this usually failed the same exercise in IAA
  - Respirators that had extremely good fits on the Portacount did not pass IAA Testing
    - This has been attributed to the fact that some individuals are more sensitive and can detect IAA at much lower limits

# IAA Testing

- NPPTL is looking at the relevance of continuing to require overlap sizes
- Test subjects are removed from the panel if they are found to be overly sensitive to IAA
- NPPTL is looking at alternative pre-screening procedures
- Most manufacturers utilize quantitative fit testing for pre-submittal test data and several use the OSHA fit test for this purpose
  - When submitting quantitative data for pre-submission data, NPPTL is considering requiring that the manufacturer use the same exercises as required for the IAA certification test and interpret the data based on the fit factor for each exercise rather than the overall fit factor

# IAA Fit Testing

- **During performance of the Portacount fit tests, it was noted that most manufacturers specify the use of a particulate only filter when conducting the OSHA quantitative fit test in the field**
  - Weight of the cartridges plays an important role in whether or not the respirator fits and NIOSH is now requiring a statement in the User Instruction manual that indicates that the fit test should be performed with the combination that is to be worn or that specific respirator with the heaviest cartridges or filters along with all accessories and personal protective equipment that may interfere with the fit of the respirator
    - Effective on submittals sent in after 6/1/06 the UI must specify a statement similar to the statement above and an additional caution is required on the respirator labels which reads as follows...

Caution FF: Respirators are to be fit tested prior to use with heaviest cartridges, canisters, filters, and/or accessories intended to be used. Respirators should also be fit tested while wearing personal protective equipment intended to be used. See User's Instructions for Fit Test Requirements

# IAA Testing

## Questions?



Workplace  
Safety and Health



**NPPTL** *Research to Practice  
through Partnerships*

NPPTL 06/04/28 RES

# Test Equipment Malfunctions

- **Infrequent occurrences caused by factors beyond our control**
  - Power outages
  - Refrigerant leaks
  - Sensor failures
- **Approach for handling testing affected by equipment malfunctions at NPPTL**
  - Testing or conditioning will stop at the point at which the problem is identified
  - All tests or conditioning affected will have to be repeated and the manufacturer must supply the additional samples that are required.
  - Manufacturers will not be charged for testing or conditioning that must be repeated due to equipment malfunctions when performed at NIOSH
  - Essential for accurate records
  - RDECOM has backup systems that can be utilized for conditioning if NPPTL equipment will be down for an extended period of time

# Test Equipment Malfunctions

## Questions?



Workplace  
Safety and Health



**NPPTL** *Research to Practice  
through Partnerships*

NPPTL 06/04/28 RES

# Respirator Audit Logic Concept

Ron Powelko, M.S.  
Quality Assurance Specialist

John Perrotte  
Manager Enterprise Level  
Information Systems

April 27, 2006

# Respirator Product Audits

- Each year the Technology Evaluation Branch conducts product audits of NIOSH-certified respirators which include private labels
- Selected NIOSH certification tests are performed on these samples and a product verification conducted to determine if the approved respirator continues to meet the applicable requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR Part 84)
- These Respirator Product Audits are conducted under the authority of 84.65(e) and 84.42(c). NIOSH has traditionally exercised this right in obtaining product audit samples for post-certification evaluation and surveillance of NIOSH-approved respiratory equipment

# Respirator Audit Logic Concept

A Respirator Audit Logic Concept is being proposed by the National Personal Protective Technology Laboratory (NPPTL) Technology Evaluation Branch (TEB) in selecting NIOSH-approved respirators for product audit utilizing the Respirator Audit Logic systematic approach. Respirator product audits are obtained on consignment from the manufacturer, open market, or obtained during a manufacturing site audit. These samples are performance-tested and verified for conformance to the NIOSH approval. The Respirator Audit Logic for Respirator Product Audits is designed to give the highest priority to those respirator approvals which, based on the past performance and other characteristics, are most likely to pose a public health risk to workers.

# Respirator Audit Logic Concept

- **Benefits to Manufacturers**

- More systematic approach
- Unbiased selection
- Less products audits for low risk, high quality manufacturers
- Validation of quality plan

- **Benefits to the Consumer**

- Minimize consumer risk
- Assurance of expected performance
- Maintains integrity of approval

- **Benefits to NIOSH**

- More systematic approach
- More accurate and consistent database
- Improving the surveillance of NIOSH approved respiratory equipment
- Validation of quality plan

# Respirator Audit Factor (RAF)

- Products to be audited are determined by computing a Respirator Audit Factor (RAF) and selecting products from a prioritized list
- The RAF is determined by evaluating the 11 categories described, combined with ranking factors using a mathematical formula
- Categories – These represent various parameters determined by the Technology Evaluation Branch to be the most essential in providing a RAF. The results of the data compiled for each category is used in the selection of the respirator product audits
- Weighting Factors – These are numerical values assigned to each category. The higher values indicate the weighing factors determined by the Technology Evaluation Branch to be most significant

# Respirator Audit Factor - continued

- The Respirator Audit Factors are computed using the formula:

$$RAF = \sum_{n=1}^{n=11} F^n C^n$$

- Where C1 through C11 are the numerical values for each category
- F1 through F11 are the weighting factors (importance) assigned to each category

# Respirator Audit Factor (RAF)

- **Categories** – These represent various parameters determined by the Technology Evaluation Branch to be the most essential in providing a RAF. The results of the data compiled for each category is used in the selection of the respirator product audits.

- C1 = Criticality of Product Approvals (CBRN/IDLH, Other Approvals)
- C2 = Site Audit History
- C3 = Product Audit History
- C4 = Field Problem/Complaint History
- C5 = Number of Approvals per Manufacturer
- C6 = Percentage of Approvals Audited
- C7 = Application Denial/Withdrawal History
- C8 = Percentage of New Product Approvals (Number of New or Extension of Approvals as a percentage of total approvals held.)
- C9 = Test Result Correlation Factor
- C10 = Stop Sales/Recall/Retrofit within last year
- C11 = ISO Registered Facility

- **Weighting Factors** – These are numerical values assigned to each category. The higher values indicate the weighting factors determined by the Technology Evaluation Branch to be most significant.

# Respirator Audit Factor (RAF)

**C1 = Criticality of Product Approvals (CBRN/IDLH, Other Approvals) – Represents respirator classes such as Air Supplied and Air Purifying respirators**

**C2 = Site Audit History – Represents the results from the most recent onsite audit report**

**C3 = Product Audit History – Represents the results from of the most recent product audit report for each approval**

**C4 = Field Problem/Complaint History – Represents the results the most recent verified field problem report for each approval, if applicable**

# Respirator Audit Factor (RAF)

**C4 = Field Problem/Complaint History** – Represents the results the most recent verified field problem report for each approval, if applicable

**C5 = Number of Approvals** – Represents the number of Manufacturer's NIOSH Approvals

**C6 = Percentage of Approvals Audited** – Represents the percentage of Manufacturer's NIOSH approvals that have been audited in the last 10 years

# Respirator Audit Factor (RAF)

**C8 = Percentage of New Product Approvals – Represents in house the quantity of new or extension of approvals which were granted based on a percentage of total approvals held**

**C9 = Test Result Correlation Factor = Represents the manufacturers test data as compared to the NIOSH test report findings for both new and extension of approval applications**

# Respirator Audit Factor (RAF)

**C10 = Stop Sales/Recall/Retrofit within the last year = Represents all products approvals from the manufacturer that have been issued a recent stop sale, recall, or retrofit letters issued for the product. This includes any self reporting by the manufacturers to NIOSH**

**C11 = ISO Registered Facility = Represents the status of approval holder manufacturer sites**





# Other Factors

- **In addition to Respirator Audit Logic (RAL), NIOSH product audits will be conducted for the following reasons:**
  - New manufacturer receives initial NIOSH approval
  - \* Approval Holder Manufacturing Sites relocated
  - \* Respirator product line acquired by another company
  - \* Site audit not conducted within a five-year time frame
  - No product audits on an individual Manufacturer's NIOSH approvals within the last five years
- \* The Technology Evaluation Branch will select a representative sample from each classification of respirator.

# Additional Audits

- **Additional audits may be conducted pursuant to specific requests by HHS, CDC, or NIOSH**
- **These products audits will not use the Respirator Audit Logic criteria**

# Respirator Audit Factor (RAF)

## *Letter to the Manufacturers*

- **Respirator Protection (OV, P100, AG, CBRN SCBA . . .)**
- **Mfg Name**
- **TC Number**
- **Product Status (Active, inactive, obsolete)**
- **Approval Holder Mfg Sites**
- **ISO Registered Facility**

# Respirator Audit Logic - Application Review

- **Respirator Audit Factors**

- Information on C1, C2, C3, C4, C6, C7, C8, C10 is currently being required within the DEIMS database
- The Respirator Audit Logic calculations for (C1 to C11) will be created and incorporated within the DEIMS database
- Modification to the Standard Application Form will be required to capture necessary or additional information from the manufacturers to support the Respirator Audit Logic

# Respirator Audit Factor (RAF)

## Phase 1:

- Post the information for the RAL Concept to the NIOSH/NPPTL website prior to the April 27, 2006 meeting
- Introduce the RAL Concept at the manufacturers' meeting on April 27, 2006
- Receive comments and feedback on the concept by June 2006
- Send a letter to all NIOSH Approval holders to determine production status of approved respirators by July 2006 to be returned by October 2006

# Respirator Audit Factor (RAF)

## Phase 2:

- Develop the DEIMS database
- Input the information received from the manufacturers
- Incorporate the information for the RAL into the DEIMS database
- Modify the SAF to incorporate the necessary information related to the RAL

# Respirator Audit Factor (RAF)

## Phase 3:

- Validation testing of the RAL to ensure calculation and reporting is correct
- Beta test to selected manufacturers
- Status report to manufacturers
- Implementation of the RAL (Summer 2007)

Please review the Respirator Audit Logic (RAL) document at the following NPPTL Webpage under spotlights and email any comments regarding the document to the NPPTL email address below.

[http:// www.cdc.gov/niosh/npptl/default.html](http://www.cdc.gov/niosh/npptl/default.html)

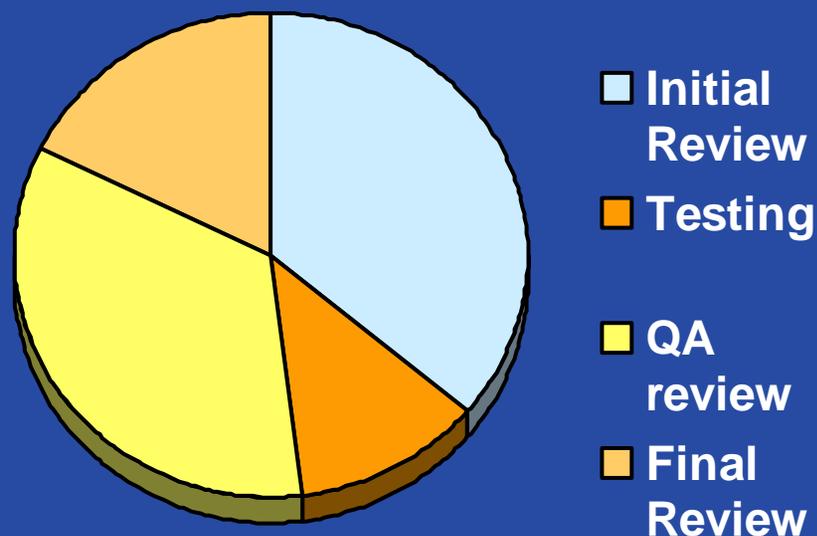


[NPPTL@cdc.gov](mailto:NPPTL@cdc.gov)

Questions/Comments?

# Time Distribution March 2006

- All applications completed in March 2006
- 62.25 average days
- 22.5 initial
- 7.5 testing
- 21 QA
- 11 final



# Time Ranges

- **Initial Review: 3 to 133 days**
  - Median 11 days
  
- **Test: 0 to 100 days**
  - Only 32 of 48 projects required lab testing
  - Median 3 days, Average 11.9 days

# Time Ranges

- **QA Review: 0 to 142 days**
  - Median 9, Average 21
  
- **Final Review**
  - Median 11, Average 11

# Areas Needing Attention

- **Initial Review**
  - Over 25% of the projects required over 30 days in Initial Review
- **QA Review**
  - 20% of the projects required over 30 days
  - 10% of the projects required over 90 days

# Possible Solutions

- **Initial review**

- Review only to assure application is complete on its face
- Applications with excessive errors will be rejected
  - This removes them from queue freeing up following applications
  - Accuracy of SAF is manufacturers responsibility

# Possible Solutions

- **Quality Assurance Review**
  - Lab Testing and QA are already parallel processes
  - QA waits on corrections of matrix, QA manual
- **Notify manufacturer when project has passed testing**
  - Schedule conference to address QA
  - Set time for correction or rejection

# Time Distribution

## Questions?



Workplace  
Safety and Health



**NPPTL** *Research to Practice  
through Partnerships*

NPPTL 06/04/28 RES

# TIL Half-mask Project

- **Benchmark testing is complete - 101 models tested**
- **Data review and analysis has begun**
- **Data shows a wide range of fit factors**
- **Validation of the new NPPTL panel is still underway**
- **Public meeting will be scheduled later this year to present findings and propose certification criteria and implementation plan**

# QA Module

- **Does not included administrative aspects, just QA**
  - More emphasis on consumer as opposed to manufacturer risk
  - Module and preamble regulatory language have been drafted
  - Impact analysis is being completed
  - Needs internal NIOSH, CDC, OMB approvals
  - Proposed rule to be published sometime later this year or early next year

# NFPA CBRN 1981 Standard

- NIOSH working in cooperation with NFPA
- Concurrent approval process
- Details being worked out

TIL, QA, NFPA

Questions?



Workplace  
Safety and Health



**NPPTL** *Research to Practice  
through Partnerships*

NPPTL 06/04/28 RES

# Closing Remarks



Workplace  
Safety and Health



**NPPTL** *Research to Practice  
through Partnerships*

NPPTL 06/04/28 RES