NIOSH National Personal Protective Technology Laboratory

Respirator Manufacturers Meeting

Les Boord

January 24, 2008

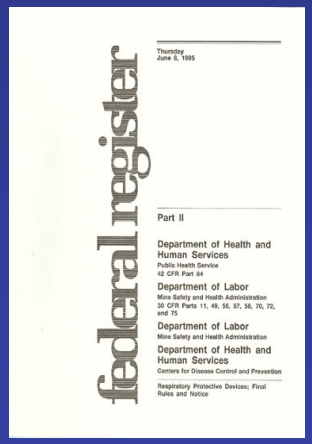
CDC Workplace Safety and Health

NIOSH

NPPTL Research to Practice through Partnerships

Presentation

- **Welcome**
- **NPPTL Refresher**



NIOSH PPT / NPPTL
Vision & Mission

The VISION is to be the leading provider of quality, relevant, and timely PPT research, training, and evaluation.

The MISSION of the PPT program is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies (PPT).




PPT in this context is defined as the technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment worn by individuals to reduce the effects of their exposure to a hazard.

NPPTL Organization

- Program Support
- Admin Support
- **Office of the Director**
  - Scientific Excellence Focus
  - Technology Evaluation Branch
  - Policy & Standards Development Branch
  - Technology Research Branch

FY 2008 Project Planning Guide
PPT Cross Sector Goals

- Strategic Goal 1
  - Reduce Exposure to Inhalation Hazards
- Strategic Goal 2
  - Reduce Exposure to Dermal Hazards
- Strategic Goal 3
  - Reduce Exposure to Injury Hazards
- Intermediate Objectives
  - Goal 1 → 8 Objectives
  - Goal 2 → 3 Objectives
  - Goal 3 → 1 Objective
- Tactics
  - Comprehensive research
  - PPT standards development
  - Respirator certification and PPT evaluation activities
  - r2p → communications & outreach

Quality Performance Initiatives

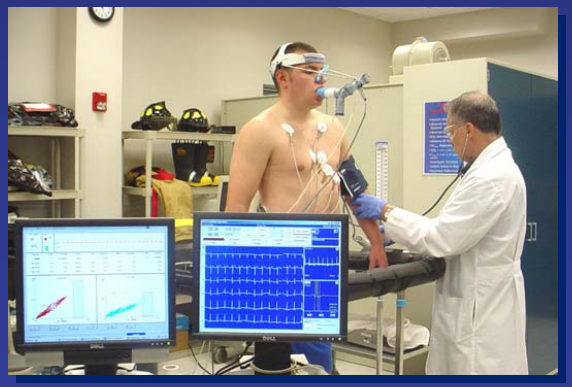
Associate Director for Science: Maryann D'Alessandro

- Evaluations
  - *National Academies involvement in NPPTL*
  - *Scientific information product review*
  - *Benchmarking*
- Customer Relationships and Satisfaction
  - *Customer Satisfaction Surveys (CSS)*
  - *Direct Customer involvement*
- Customer and Market Knowledge
  - *Standards Development Committee Involvement*
  - *Public Meetings and feedback*
  - *Customer Satisfaction Groups (Focus Groups)*

Academia - SDOs - Government Laboratories – Unions – Labor - Manufacturers

Personal Protective Technology Standards

- **Focus on national and international standards**
  - Identifying technology gaps

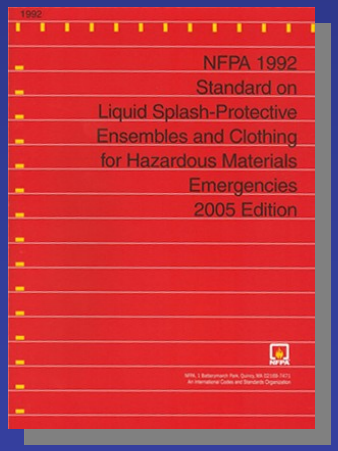


- **Peer-reviewed, quality science**
  - Conducting research

- **Research 2 practice (r2p)**
  - Applying research to standards

NPPTL Participation with Standards Setting Organizations

- 42 Code of Federal Regulations (42 CFR)
- National Fire Protection Association (NFPA)
- American Society for Testing and Materials International (ASTM)
- American National Standards Institute (ANSI)
- International Organization for Standardization (ISO)
- International Safety Equipment Association (ISEA)



NPPTL Staffing

OD	16
Technology Research Branch	13 + 2 Vacancies
Policy & Standards Development Branch	10 + 3 Vacancies
Technology Evaluation Branch	28 + 4 Vacancies

Technology Evaluation Branch

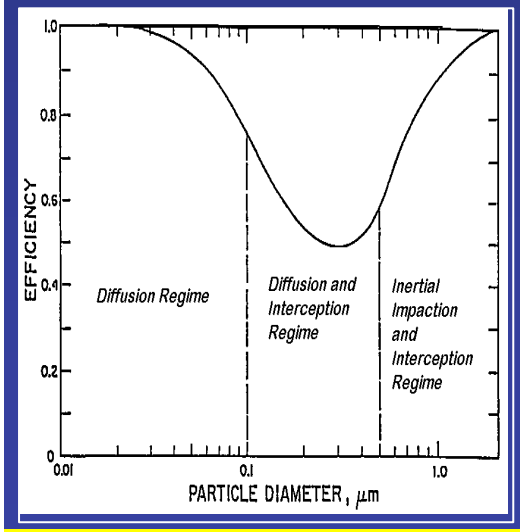
FY 08 Projected Funding: $3,889,035

- **Implement new technology for respirator certification :**
  - QA Module
  - Mine Escape Respirator Standard
  - Total Inward Leakage (TIL)
  - PAPR
- **Ongoing collaboration with FDA for respirator and surgical N95 respirator**
- **Process requests for approval within 90 days of application receipt**
- **Standard Test Procedures (STDs)**
  - Develop STPs for innovative and/or novel technologies
  - Update STPs as available
- **Conduct 2 manufacturer meetings / year**
- **Perform customer satisfaction survey every 12 to 24 months**

NIOSH PPT Program
Relevance and Impact

Mine Escape Issues
- Mine Emergency Respirator Investigations
- New Technology Workshops
- Escape Respirator Research
- Escape Respirator Standards Development
- MSHA Collaboration

CBRN Issues
- Respirator Standards Development
- CBRN PPT Research
- Respirator Certification
- NFPA/IAFF Collaboration
- TSWG IAA
- OSHA Collaboration



Nanotechnology Issues
- Filtration Research
- Protective Clothing Research
- Respirator Research
- Respirator Certification
- Workplace Guidance

Pandemic Issues
- N95 Respirator Research
- Standards (Total Inward Leakage)
- Certification
- FDA Collaboration
- National Academies Activities
- Pandemic Planning

NIOSH Personal Protective Technology Programs

Les Boord

NIOSH / NPPTL

E-mail: zfx2@cdc.gov

Phone: 412-386-6111

Thank you!!!

NIOSH PPT

Vision & Mission

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Respirator Certification Program Decision Review Request (DRR)

Purpose

- Establish process
- Review of
  - Program Decisions
  - Program Policy

Respirator Certification Program Decision Review Request

Two Level Process

- Level 1: Review by Technology Evaluation Branch
- Level 2: Review by NPPTL Office of the Director

Respirator Certification Program Decision Review Request

Decision Review Process

- DRR Letter from:
  - Approval applicant, or
  - Stakeholder requesting policy clarification
- Letter sent via mail or email

Respirator Certification Program Decision Review Request

Level 1 Decision Review Request Letter

- Postmarked or emailed within 30 days of written decision or program policy
- Addressed to Technology Evaluation Branch Chief
- Present evidence / rationale for contending program decision or program policy

Respirator Certification Program Decision Review Request

Level 1 Decision Review Request Process

- Technology Evaluation Branch Chief responsible for decision
- May use Technical Review Panel
- Technical Review Panel → Advise to Branch Chief
  - Technology Research or Policy & Standards Branch Chief
  - Deputy Director
  - 1 Additional NIOSH Staff named by Deputy Director

Respirator Certification Program Decision Review Request

Level 2 Decision Review Request Letter

- Postmarked or emailed within 15 days of written decision or program policy
- Addressed to Director NPPTL
- Present evidence / rationale for contending Level 1 Notification

Respirator Certification Program Decision Review Request

Level 2 Decision Review Request Process

- NPPTL Director responsible for decision
- Director may use Advisory Panel
- Advisory Panel
  - 3 NIOSH staff named by NPPTL Director

Respirator Certification Program Decision Review Request

Decision Review Request Policy to be posted on NPPTL Website by January 31, 2008

NIOSH-NPPTL Respirator Manufacturers Meeting
January 24, 2008

NPPTL Approval Times

Fiscal Year 2007

(Oct 1, 2006 to Sept 30, 2007)

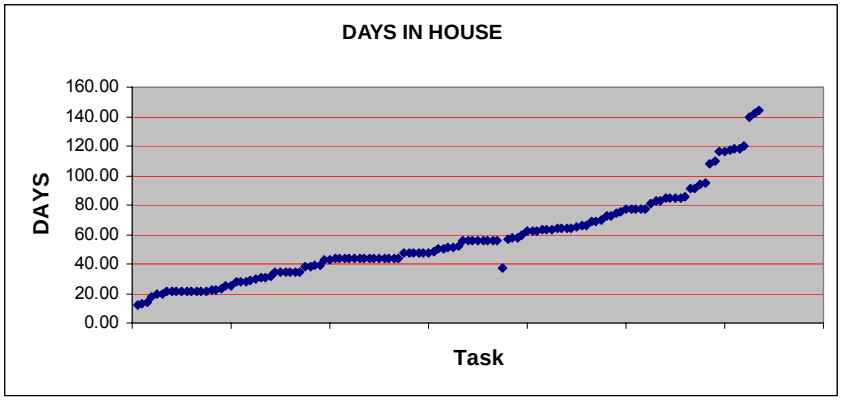
All times in total calendar days

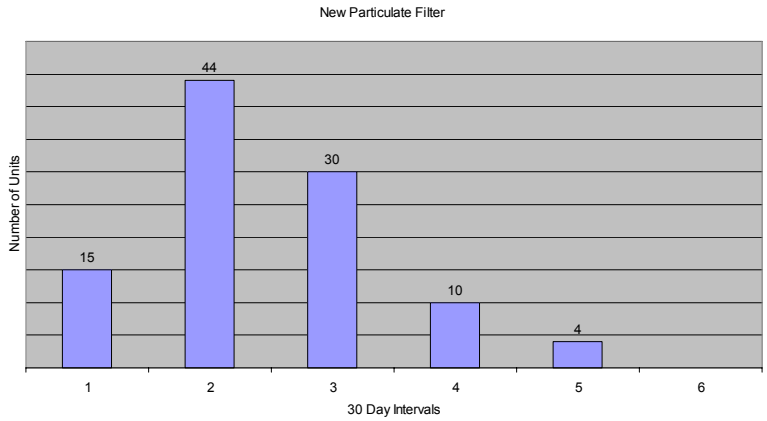
Heinz Ahlers

APR Particulate*
New Approvals

- Average 56 days
- 10% over 90 days
- 90th percentile 90 days
- 125 requests
- 69 granted

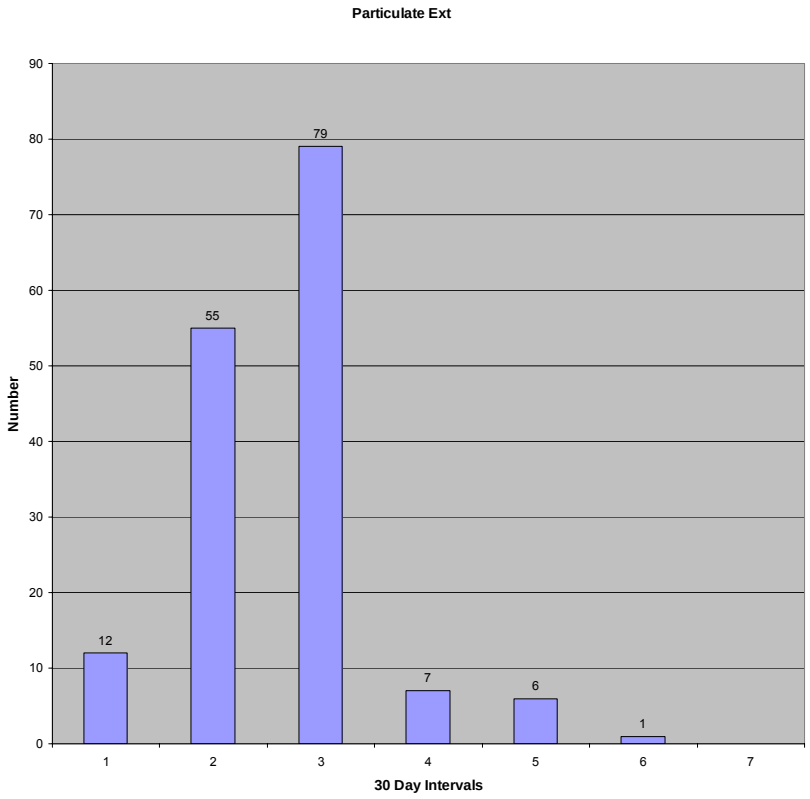
* Includes FF and half mask





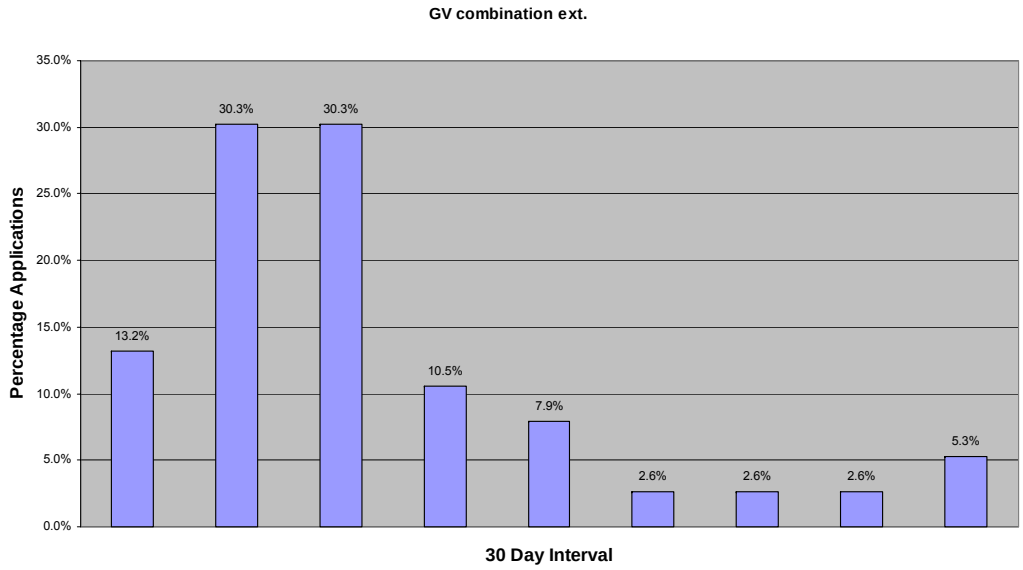
APR Particulate Extensions Time in House

- Average 63.4
- 15% over 90 days
- 90th percentile 106 days
- 114 requests
- 83 granted



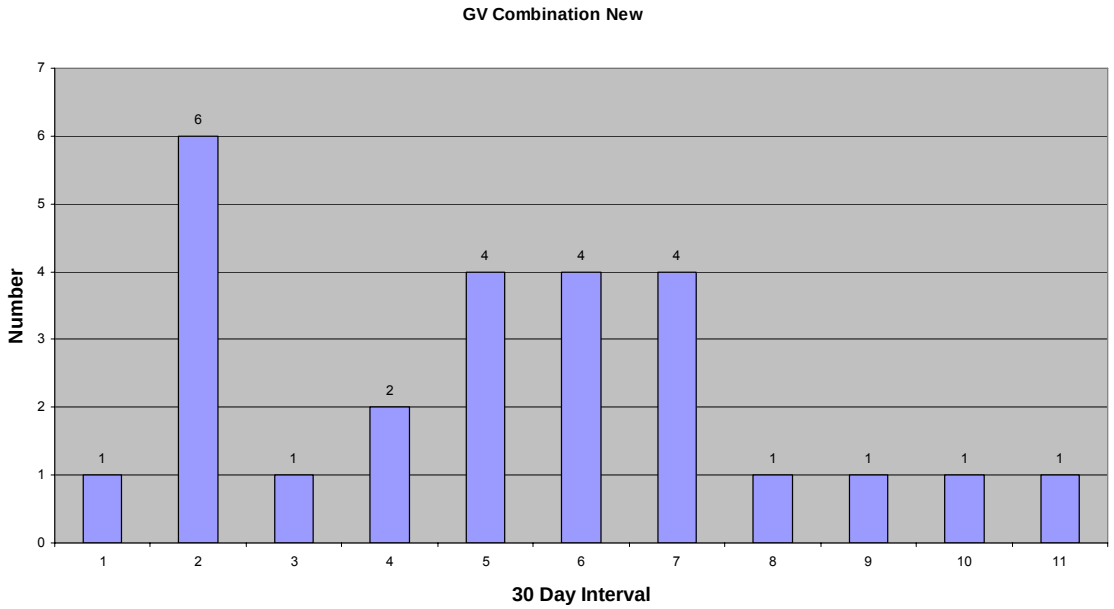
OV and Combination NEW

- Average 96 days
- 45% over 90 days
- 90th percentile 150 days
- 22 requests
- 14 granted



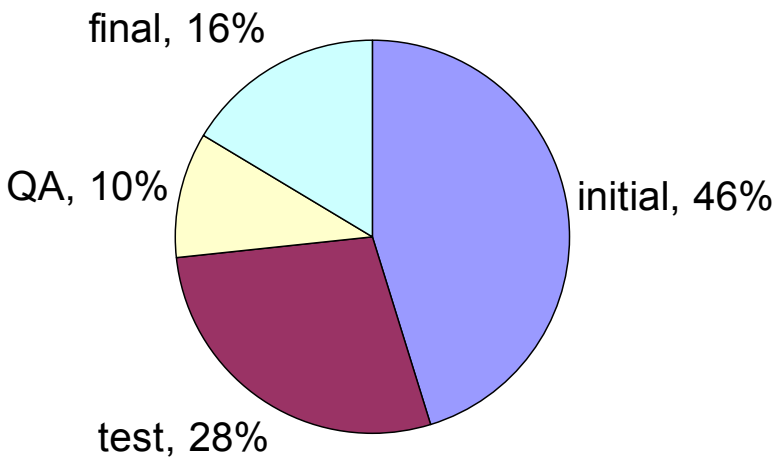
OV and Combination Extensions

- Average 74.3 days
- 22% over 90 days
- 90th percentile 134 days
- 81 requests
- 64 granted

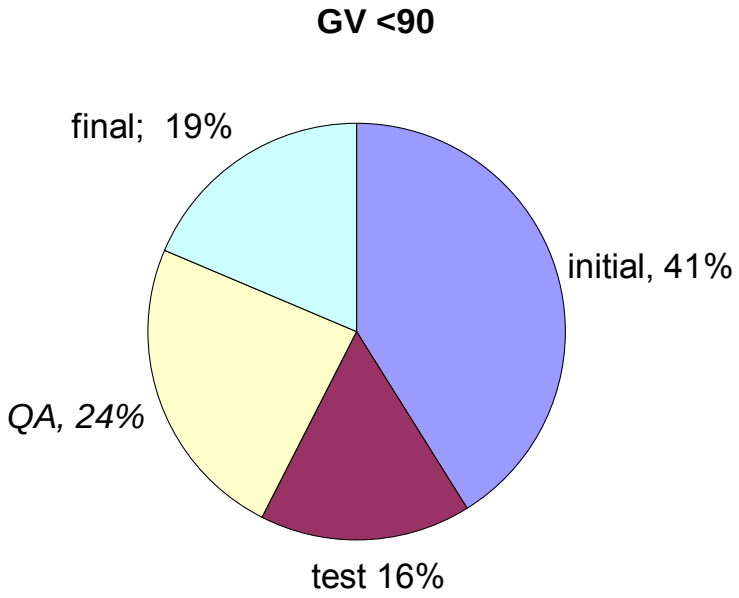


OV Time Distribution

GV 90+



GV <90



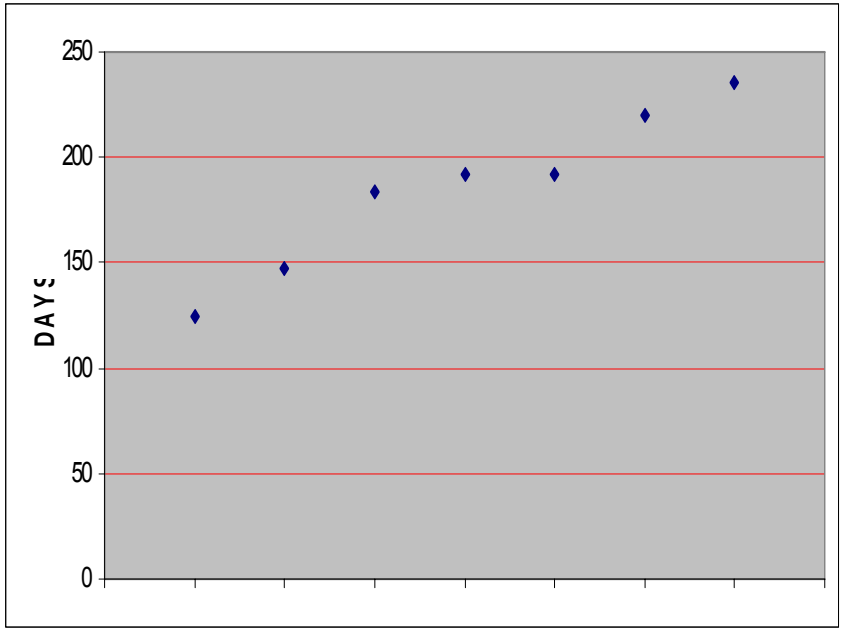
GV Time Distribution

- OVER 90 (31 apps)
- *Average – 219 days*
- *Initial Avg – 100 days*
- *Test Avg – 61 days*
- *QA Avg - 23 days*
- *Final Avg – 36 days*

- Under 90 (74 apps)
- *Average – 57 days*
- *Initial Avg – 23 days*
- *Test Avg - 9 days*
- *QA Avg - 13 days*
- *Final Avg – 11 days*

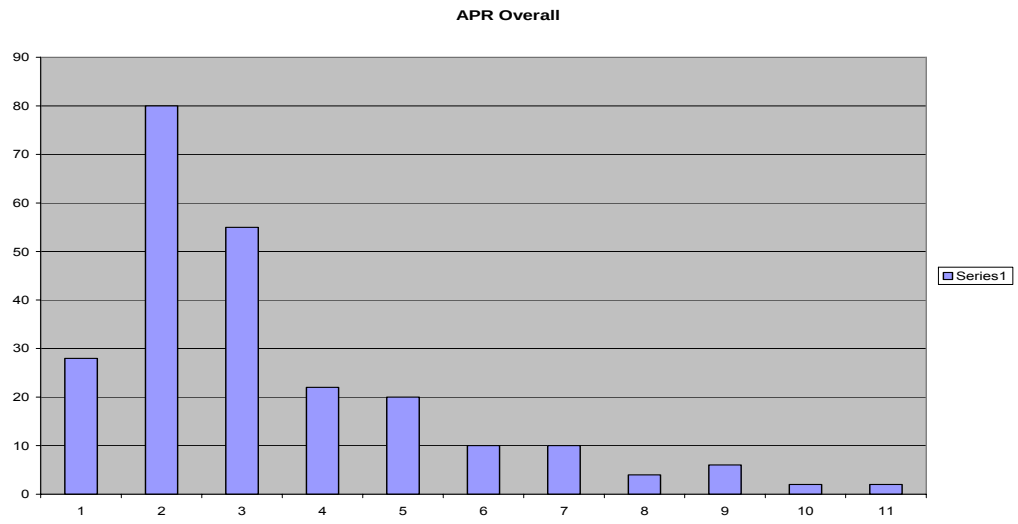
CBRN APR

- Average 185 days
- 100% over 90 days
- 90th percentile 220 days
- 7 requests
- 5 granted
- 3 APR, 4 PAPR

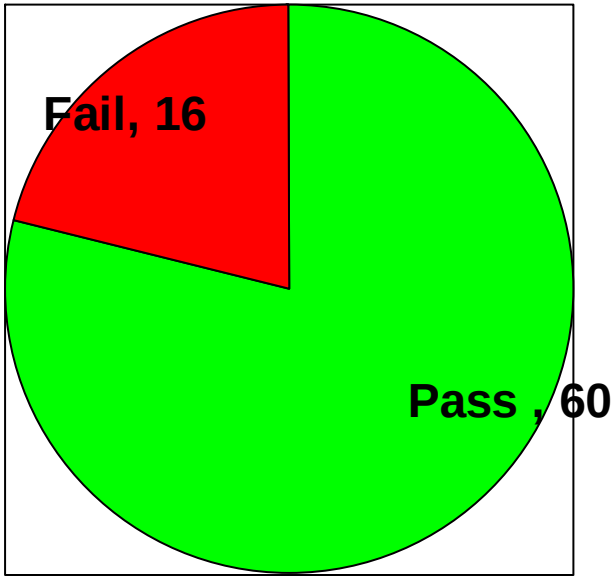


All APR
Time in House

- Average 70 days
- 20% over 90 days
- 90th percentile 134 days
- 355 requests
- 233 granted

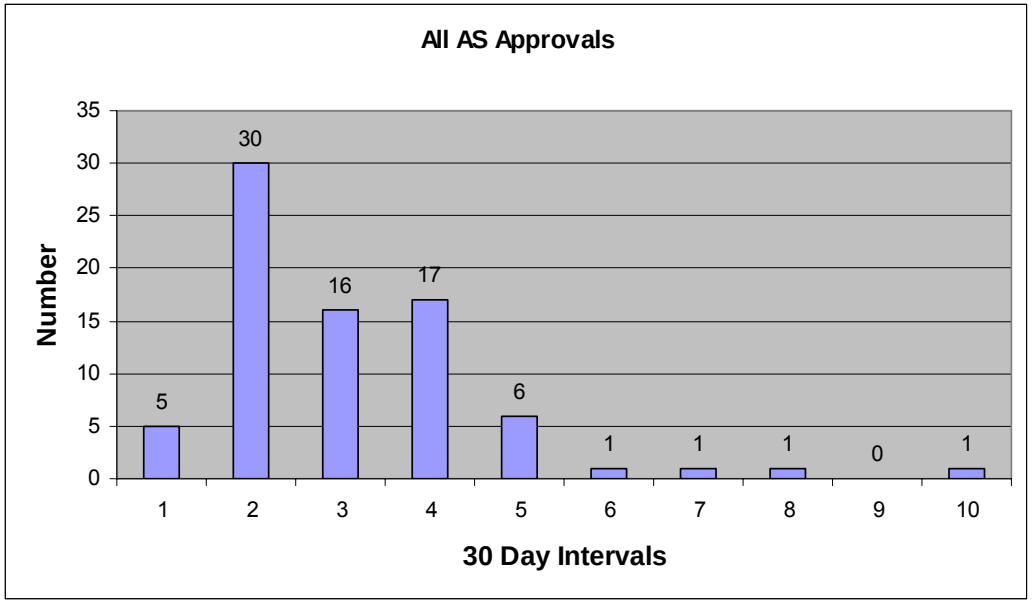


Default to Test
APR



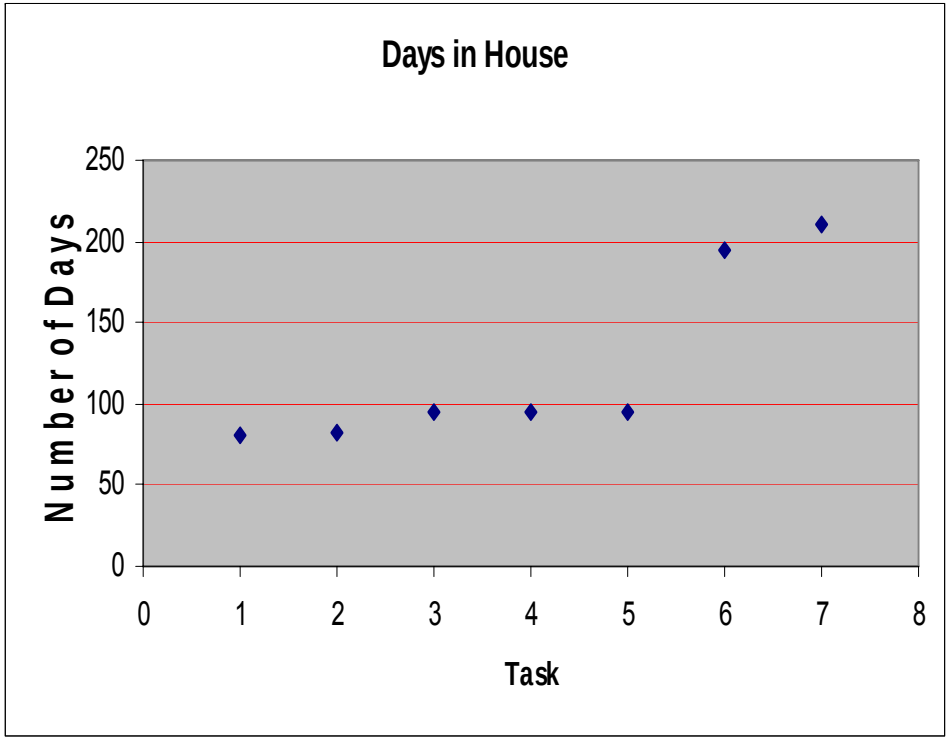
ALL Atmosphere Supplying Time in House

- Average 77
- 21% over 90 days
- 90th percentile 119 days
- 75 requests
- 65 granted



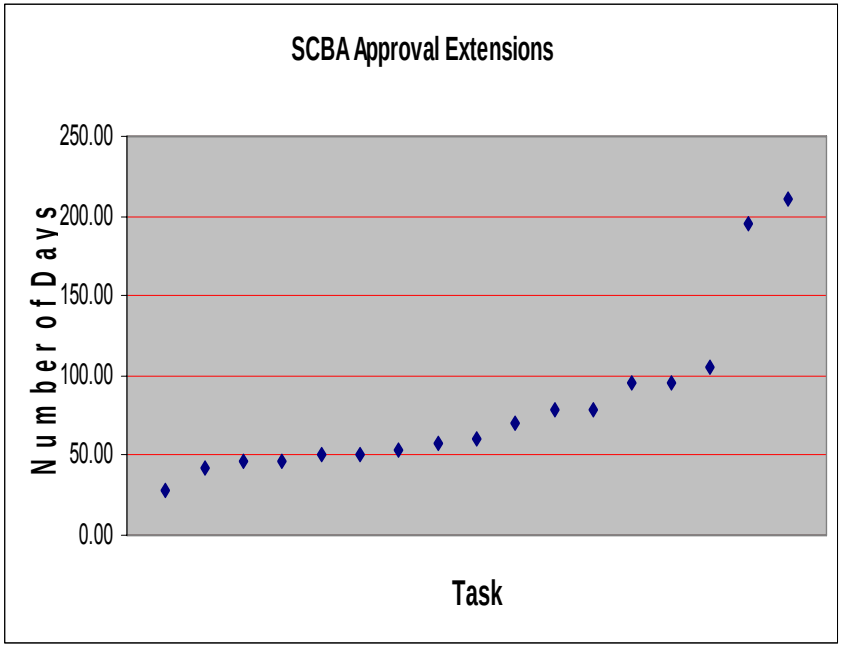
SCBA Approvals New

- Average 94 days
- 43% over 90 days
- 90th percentile 103 days
- 7 requests
- 4 granted



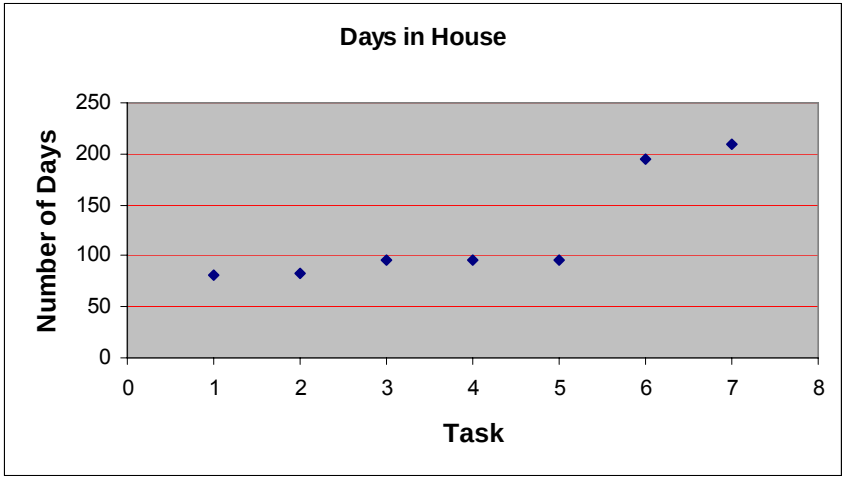
SCBA Approvals Extensions

- Average 80 days
- 30% over 90 days
- 90th percentile 106 days
- 17 requests
- 16 granted



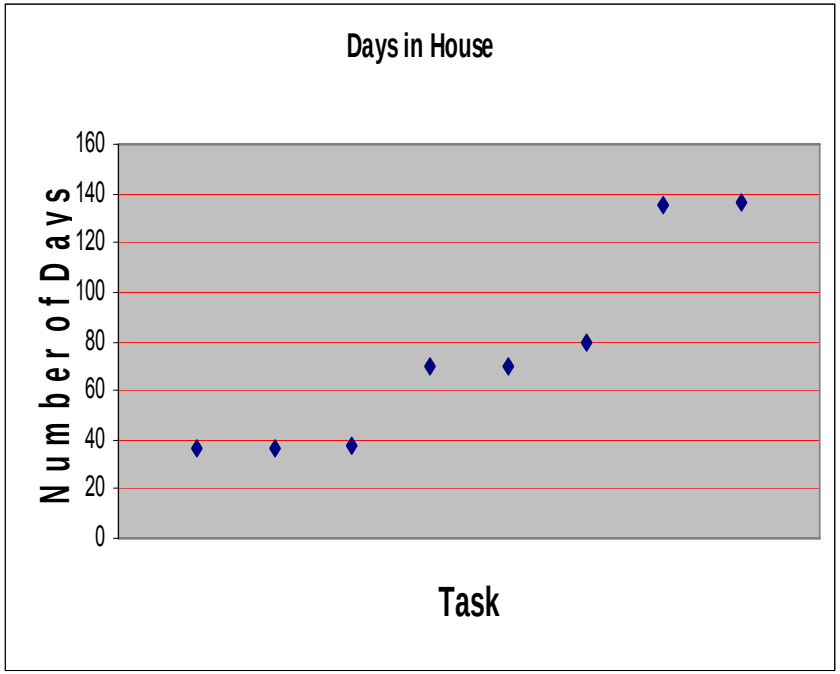
CBRN SCBA
Avg = 122; 90% = 195

- Average 122 days
- 75% over 90 days
- 90th percentile 190 days
- 8 requests
- 8 granted



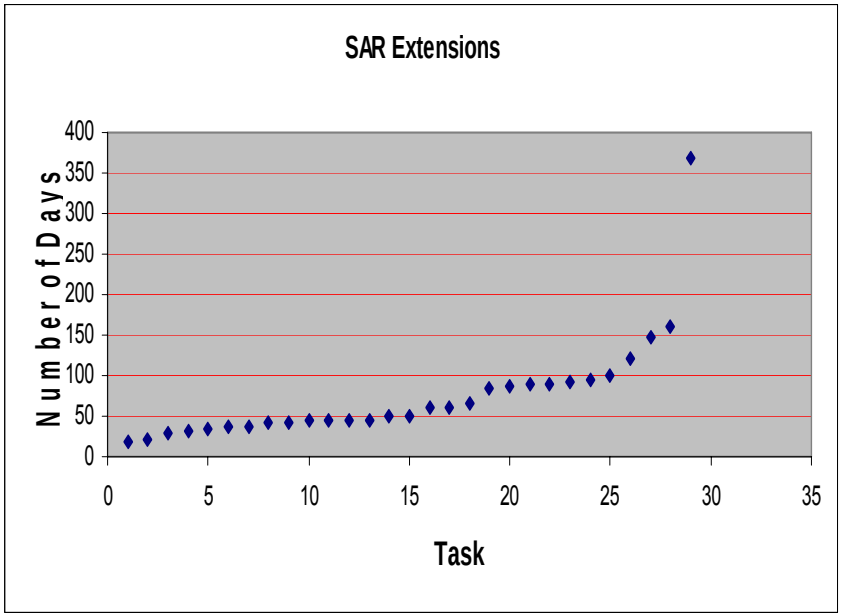
Combination SAR New

- Average 72 days
- 25% over 90 days
- 90th percentile 190 days
- 8 requests
- 8 granted



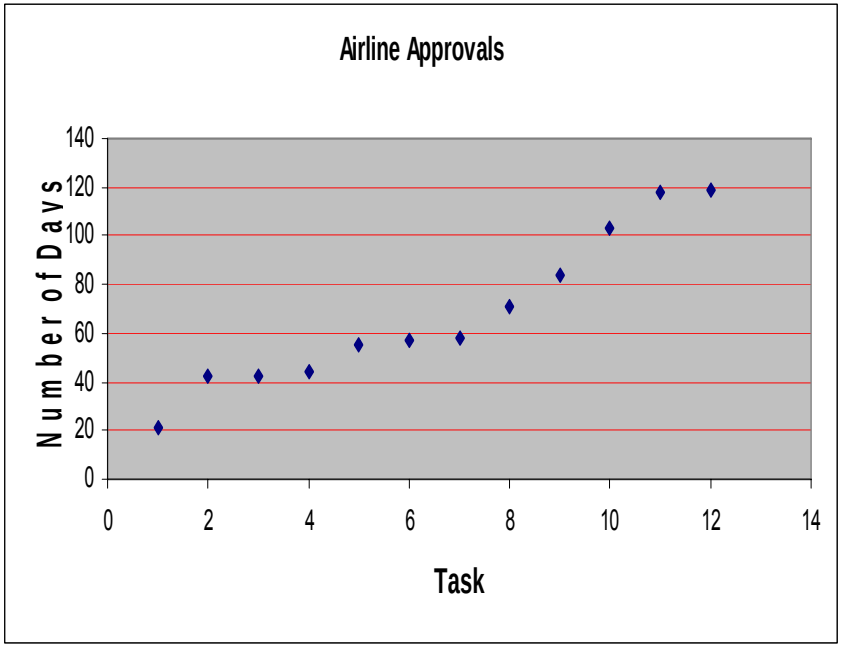
Combination SAR Extension

- Average 75 days
- 25% over 90 days
- 90th percentile 120 days
- 29 requests
- 25 granted



Airline Approvals

- Average 68 days
- 28% over 90 days
- 90th percentile 103 days
- 11 requests (1 new)
- 11 granted



Overall Performance

- 430 applications processed
  - 355 APR @ 70 day average
  - 75 ASR @ 77 day average
- Roughly 80% of applications processed in less than 90 days.
- We are improving times in more complex test areas
  - Focus on PAPRs and multi gas canisters in FY 08

Matrix Modifications

Heinz Ahlers and Jeff Peterson

Matrix as a Tool

- The Matrix identifies the parts and protections of approved respirators
- The Matrix serves to identify common parts across different approvals
  - Modifications of revision levels are a frequent issue
- Current technology allows NPPTL more flexibility in tracking design configurations

Some Matrix Issues

- Keeping revision levels current
  - Some drawings may be used only for NPPTL
  - Some design configurations may be dormant
- Bundling of approvals
  - Interdependence on companion approvals for hardware and testing
  - Failures on unrelated features can have domino effect

Improvements

- NPPTL is seeking input from manufacturers on improving the matrix system and the matrix update process

NIOSH-NPPTL Respirator Manufacturers Meeting

January 24, 2008

FDA & EPA Role in NIOSH Approval of Antimicrobial Filters

Heinz Ahlers

Jeff Peterson

FDA & EPA Role in NIOSH Approval of Antimicrobial Filters

- NIOSH does not approve respirators for specific use categories
  - Approval holders must not imply that NIOSH endorses approved respirators for specific use
  - Exception for N95 surgical masks which are evaluated by FDA and NIOSH

FDA & EPA Role in NIOSH Approval of Antimicrobial Filters

- Claims for protection against specific disease-producing airborne pathogens are medical claims and place a device under the regulatory jurisdiction of FDA

- FDA will not permit claims for protection for specific pathogens unless performance testing is submitted and new labeling is cleared for either N95 respirators or for surgical masks

FDA & EPA Role in NIOSH Approval of Antimicrobial Filters

- CDC/FDA MOU is in place and permits confidential communication between NIOSH and FDA

  - NIOSH is communicating with FDA on a regular basis when medical claims are part of a submission that NIOSH receives
    - Claims that a respirator provides protection for specific pathogens
    - Antimicrobial/Antiviral Claims
    - Respirators for Public Health Emergencies

FDA & EPA Role in NIOSH Approval of Antimicrobial Filters

- Approval holder must have either FDA pre-market clearance or FDA approval to submit an approval request to NIOSH (Usually 510K)

- NIOSH will not issue an approval until FDA approves the request

FDA & EPA Role in NIOSH Approval of Antimicrobial Filters

- For filters treated with antimicrobials
  - Active ingredients must be specified as part of the request
  - FDA will evaluate the efficacy of the antiviral treatment on the mask against the claims that are being made as well as the safety data that is provided
  - EPA must evaluate the antiviral treatment and approve it as being safe for use in the breathing zone
    - Not "FIFRA-exempt“
    - EPA waiver based on the "article" exemption is not adequate

FDA & EPA Role in NIOSH Approval of Antimicrobial Filters

Questions/Comments

SCBA Cylinders and Approvals

Vance Kochenderfer and

Tom Pouchot

SCBA Cylinders and Approvals

- Replacement Cylinders and Cylinder and Valve Approval Questions
  - Only those assemblies authorized by the SCBA approval holder/manufacturer and NIOSH are Approved
  - A Department of Transportation (DOT) approval on a cylinder Does Not imply NIOSH approval

SCBA Cylinders and Approvals

- NIOSH's current position on replacement cylinders
  - Only the cylinder/valve assemblies listed on the approval label are NIOSH-approved part of the SCBA respirator
  - These cylinders have gone through the approval holder's QA system

SCBA Cylinders and Approvals

- Approval Holders QA System May Include:
  - Additional inspections
  - Additional testing
  - Final inspection of the whole respirator

SCBA Cylinders and Approvals

- Fire service has requested an easier-to-use reference of approved equipment especially cylinder and valve assemblies.

SCBA Cylinders and Approvals

- To answer Fire Service Request
- Put together information on current SCBA units and list on our web site
  - Also make information available upon request.

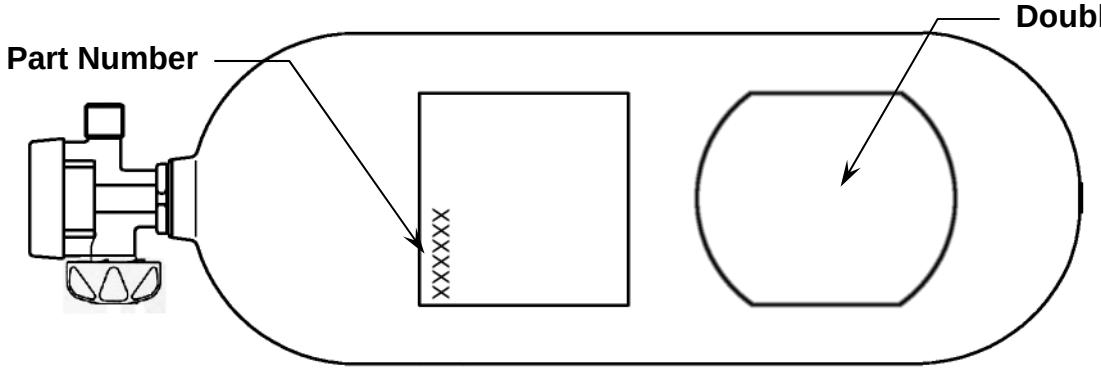
SCBA Cylinders and Approvals

- What information will NIOSH list?
  - SCBA Model name
  - Approval Number
  - Cylinder and Valve model/part numbers
  - Cylinder description

DOUBLE WING MANUFACTURING Models:

Model	NIOSH Approval Numbers	Cylinder/Valve Assembly Part Numbers	Notes
Easy-Carry	TC-13F-950, TC-13F-951, TC-13F-952, TC-13F-953	Z15221 Z15261 Z15262 Z15263 Z15264	Cylinders ship with decal bearing a black Double Wing logo.
Easy-Carry Plus 2007	TC-13F-950, TC-13F-950CBRN, TC-13F-951, TC-13F-951CBRN, TC-13F-952, TC-13F-952CBRN, TC-13F-953, TC-13F-953CBRN	Z15221 Z15261 Z15262 Z15263 Z15264	Cylinders ship with decal bearing a black Double Wing logo.
PyroLight	TC-13F-974, TC-13F-975, TC-13F-976, TC-13F-977	Z15285 Z15286 Z15287 Z15288	Cylinders ship with decal bearing a red Double Wing logo.

Part Number Location



Product Information: doublewing.example.com
Technical Support Group at 1-800-123-4567

SCBA Cylinders and Approvals

- How can the approval holders help?
- By supplying information

SCBA Cylinders and Approvals

- Submit a list of active SCBA approvals
  - SCBA Model identifier
  - List all cylinder and valve combination part numbers
  - Description of the cylinders including markings and identify where the part numbers are placed on the cylinder
  - Drawings or Sketches of cylinders
  - Contact Information and/or where additional information may be found

SCBA Cylinders and Approvals

- Next Step

- List Serve request will be sent out to approval holders requesting the information.
- As the information is gathered, it will be posted on the NPPTL website

SCBA Cylinders and Approvals

- Send the information to either Vance Kochenderfer (vck6@cdc.gov) or Tom Pouchot (clq0@cdc.gov)
  - Questions or comments on the program
  - Comments on the information presentation format

NIOSH-NPPTL Respirator Manufacturers Meeting

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Update on CBRN SCBA/NFPA 2007 Approval Coordination

Jeff Peterson

Steve Sanders

Update on CBRN SCBA/NFPA 2007 Approval Coordination

- The NIOSH CBRN Statement of Standard for CBRN approval of SCBA devices requires NFPA 1981 approval as a component of the CBRN SCBA approval

- Changes to the NFPA 1981 2007 edition required NIOSH CBRN approval as a component of NFPA 1981 approval

- The combined effect of these two standards is that NFPA compliance and NIOSH CBRN SCBA approvals must be issued jointly

Update on CBRN SCBA/NFPA 2007 Approval Coordination

- The application process for submitting approvals for Title 42, *Code of Federal Regulations*, Part 84 (42 CFR Part 84), NIOSH CBRN and NFPA 1981 2007 was modified as follows to allow the following options

  – Option 1

    - 42 CFR Part 84 approval obtained
    - Submit simultaneous applications for NFPA 1981 compliance certification testing and NIOSH CBRN approval testing

Update on CBRN SCBA/NFPA 2007 Approval Coordination

– Option 2

- 42 CFR Part 84 approval obtained
- Initiate NFPA 1981 compliance certification first with NIOSH CBRN testing taking place in sequence after NFPA certification testing is successfully completed

- Under either option, NIOSH CBRN and NFPA 1981 compliance is jointly issued upon completion of both testing requirements

Update on CBRN SCBA/NFPA 2007 Approval Coordination

- Preferred option by manufacturers has been Option 1
- To date NPPTL/SEI has received requests from 6 of the 7 manufacturers that have historically marketed previous editions of NIOSH/NFPA approved SCBA
- Cooperative efforts by NPPTL and SEI resulted in timely recertification of firefighter SCBA

Update on CBRN SCBA/NFPA 2007 Approval Coordination

- Focus is now on approval of upgrade kits which will allow approval holders to upgrade NFPA 2002 edition units to NFPA 2007 edition units
  - Upgrade kits must be submitted using the same options presented earlier
  - NPPTL is following the criteria specified in the March 11, 2003 letter regarding upgrade kits except for testing costs

Update on CBRN SCBA/NFPA 2007 Approval Coordination

- NPPTL Requirements for CBRN Upgrade Kit
  - Upgrade must be performed by an authorized service center
  - At a minimum, upgrade kit must include
    - Instructions
    - All replacement components
    - Appropriate approval labels
    - Registration materials
  - Live agent testing of two field deployed units which have been upgraded

Update on CBRN SCBA/NFPA 2007 Approval Coordination

Questions/Comments

Classification of Defects and Sampling Plans

Heinz Ahlers

Classification of Defects

- 42 CFR 84.41 provides:
  - (c) The sampling procedure shall include a list of the characteristics to be tested by the applicant or his agent
  - (d) The characteristics listed in accordance with paragraph (c) of this section shall be classified according to the potential effect of such defect and grouped into the following classes. . .

Importance of Classification of Defects

- NPPTL looks for the classification of defects in all applications for approval
  - The classification of defects indicates a sound application of engineering principals to a design
- The classification of defects does not have to be a static document
  - Experience can lead to a manufacturer re-evaluating the potential effect of a listed defect

- Re-evaluation of classifications of defects can result in modified sampling plans
  - The modification of the classification of defects can be an acceptable method for adjusting an AQL
  - Modification can be based on data accumulated to show control parameters that eliminate the need to test for a defect at the original AQL

LRPL TESTING
Capabilities and Fees

Terry Thornton

NIOSH/NPPTL Respirator Manufacturers Meeting

Double Tree Hotel Airport
Pittsburgh, Pennsylvania

January 24th, 2008

LRPL History

- **L**aboratory **R**espirator **P**rotection **L**evel
- US Army opens their facility for measuring Protection Factors (PF) in the mid 80's.
- In 2002 NIOSH developed the LRPL test based on the US army PF Testing.
- LRPL test was developed and used in the new CBRN Application.

LRPL Laboratory Pittsburgh

- 16 ft long X 16 ft wide X 11 ft ceiling
- Particle generation by two *MSP Corp. High Output Aerosol Generators,* Model 2045
- Corn Oil Generation of 30 to 40 mg/m^3
- Particle size Mass Median Aerodynamic Diameter (MMAD) of 400 to 600 nm

LRPL Laboratory Pittsburgh

- Particle detection using TSI model 8587A Rear Light Scanning Laser Photometer
- Handle four personnel at a time
- One detector per person does both inside and outside concentration (two detectors per person with CBRN Escape hoods)
- Maximum fit factor is 100,000

LRPL Laboratory Pittsburgh

CBRN LRPL is 12 one minute exercises

1. Normal Breathing
2. Deep Breathing
3. Turn head side to side
4. Move head up and down
5. Reach for the floor and ceiling
6. Recite the “Rainbow Passage”
7. Sight the rifle
8. Reach for the floor and ceiling
9. On hands and knees, look side to side
10. Facial Grimaces
11. Climb the stairs at a regular pace
12. Normal breathing

LRPL Laboratory Pittsburgh

Standard test procedures for CBRN LRPL

- SCBA/APR: CET-APRS-CBRN-STP- 0352
- APER: CET-APRS-CBRN-STP-0452
- PAPR Tight Fitting: CET-PAPR SCBRN-STP-0552
- PAPR Loose Fitting: CET-PAPR-CBRN-STP-0553

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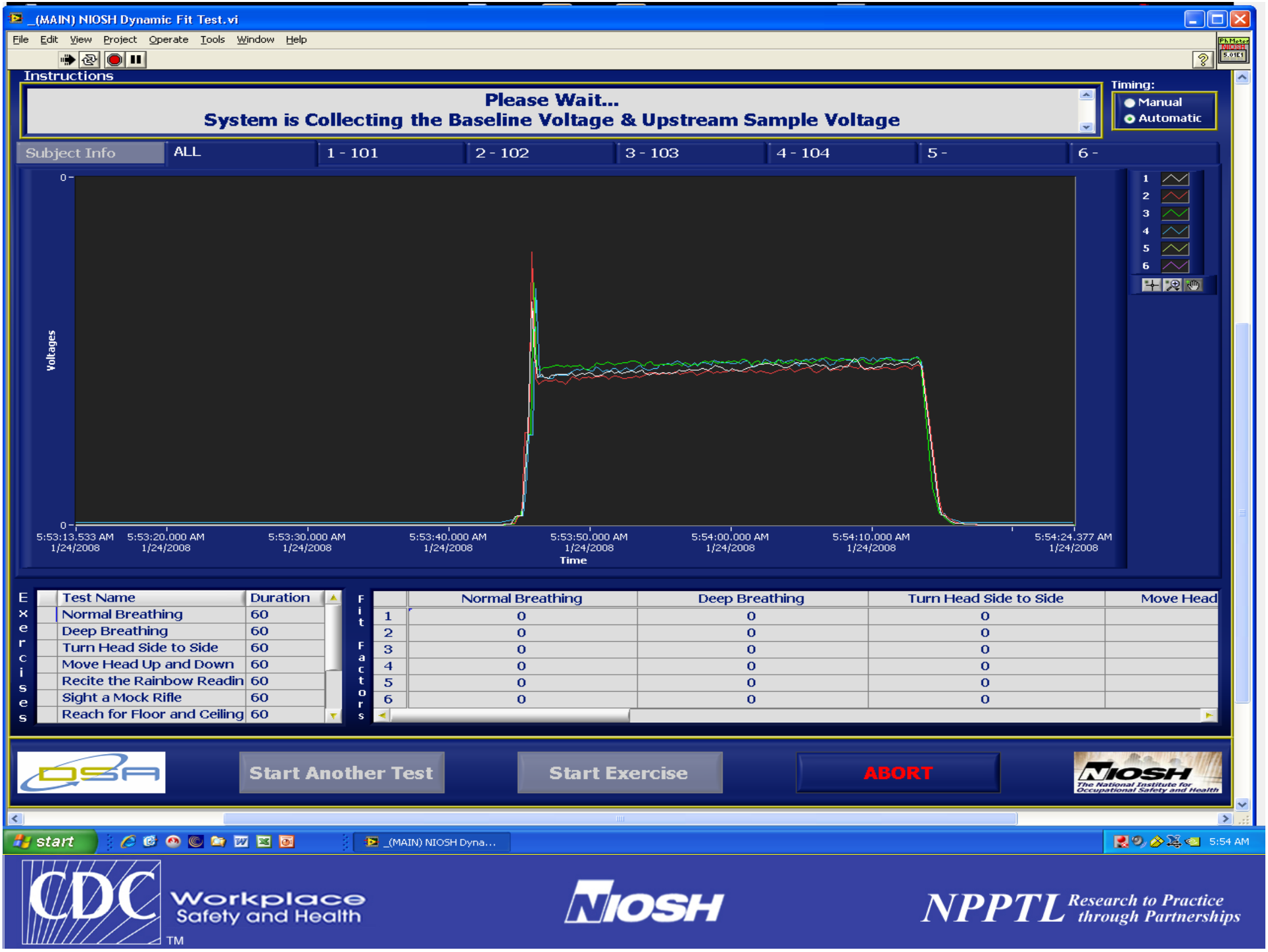
_(MAIN) NIOSH Dynamic Fit Test.vi
File Edit View Project Operate Tools Window Help
Instructions
Please Wait...
System is Collecting the Baseline Voltage & Upstream Sample Voltage
Timing:
Manual
Automatic
Subject Info
ALL
1 - 101
2 - 102
3 - 103
4 - 104
5 -
6 -
Voltages
Time
5:53:13.533 AM 1/24/2008
5:53:20.000 AM 1/24/2008
5:53:30.000 AM 1/24/2008
5:53:40.000 AM 1/24/2008
5:53:50.000 AM 1/24/2008
5:54:00.000 AM 1/24/2008
5:54:10.000 AM 1/24/2008
5:54:24.377 AM 1/24/2008
Exercises
Test Name | Duration
Normal Breathing | 60
Deep Breathing | 60
Turn Head Side to Side | 60
Move Head Up and Down | 60
Recite the Rainbow Readin | 60
Sight a Mock Rifle | 60
Reach for Floor and Ceiling | 60
Fit Factors
Normal Breathing | Deep Breathing | Turn Head Side to Side | Move Head
1 | 0 | 0 | 0
2 | 0 | 0 | 0
3 | 0 | 0 | 0
4 | 0 | 0 | 0
5 | 0 | 0 | 0
6 | 0 | 0 | 0
Start Another Test
Start Exercise
ABORT
NIOSH The National Institute for Occupational Safety and Health
start
_(MAIN) NIOSH Dyna...
5:54 AM

LRPL Pittsburgh Fees

LRPL costs for SCBA/APR/PAPR

- Full LRPL -- $17,535.00
- Partial LRPL -- $14,825.00

LRPL costs for APER/SCER

- Full LRPL -- $18,490.00
- Partial LRPL -- $14,825.00

LRPL Replacement for IAA

- 42 CFR part 84 calls for **Isoamyl A**cetate (IAA) for Industrial PAPRs with HE protection only
- Surrogate cartridges have to be made
- LRPL testing can be substituted

LRPL Replacement for IAA

- Exercises
  - 2 minutes head movements
  - 2 minutes arm movements
  - 2 minutes running in place
  - 2 minutes bicycle pump
- Pass/Fail
  - Each exercise over
  - Loose Fitting Hood 250
  - Tight Fitting Facepiece 500

IAA Replacement Fees

Corn Oil testing for HE only PAPRs for one size fits all is $1350.00

Corn Oil testing for HE only PAPRs for multiple sizes is $2600.00

NIOSH-NPPTL Respirator Manufacturers Meeting

January 24, 2008

Private Label Approval Requirements

Jeff Peterson

Private Labeling

- Allows an approval holder to enter into an agreement with another company to sell respirators with that specific company's name on the product

- The present approach makes it appear to the user that the company whose name appears on the approval labels and User Instructions is the approval holder

- The approval holder is liable for product

Private Label Approval Requirements

- Since May 1, 2007, Private Label Notification Form was discontinued

- All Private Label requests must be submitted as extensions of approval due to labeling issues that NIOSH has discovered in the past year
  - Submission will include assembly matrix, approval labels, user instructions and drawings
  - Drawings should list all relevant Private Labels
  - Submit hardware and fee if base model has not been evaluated in the past year

Private Label Approval Requirements

- Effective March 1, 2008, all Private Label requests must be made by filing an extension of approval with all associated documentation as discussed earlier

- Additional information that will be required
  - Specific contact information for company receiving private label will need to be provided in the reason for application (RFA)
  - Statement acknowledging who the approval holder is and under what approval number the respirator has been private labeled must appear as a Special ‘S’ statement in the user instructions and must appear on the packaging
  - The model ABC filtering facepiece respirator has been manufactured by Approval Holder A for Company B under

Private Label Approval Requirements

- The contact, provided as part of the request, for the company whose name will appear on the label will be contacted by NIOSH to insure that they are aware of what a Private Label is and what they can and cannot do since they are not the approval holder

Private Label Approval Requirements

Questions/Comments