National Personal Protective Technology Laboratory

Respirator Manufacturer's Meeting
Crowne Plaza Pittsburgh South
Pittsburgh, Pa

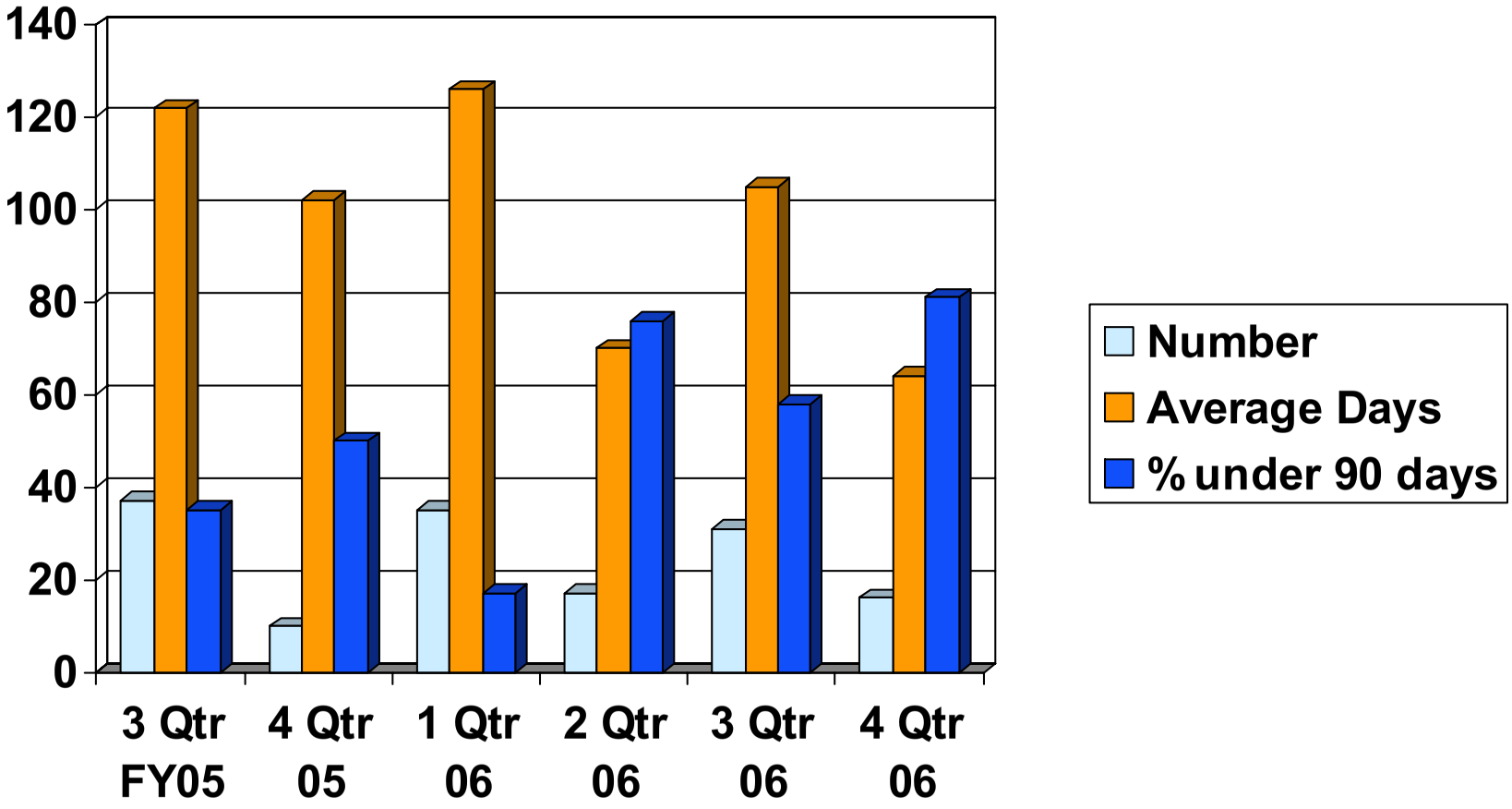
October 11, 2006

National Personal Protective Technology Laboratory

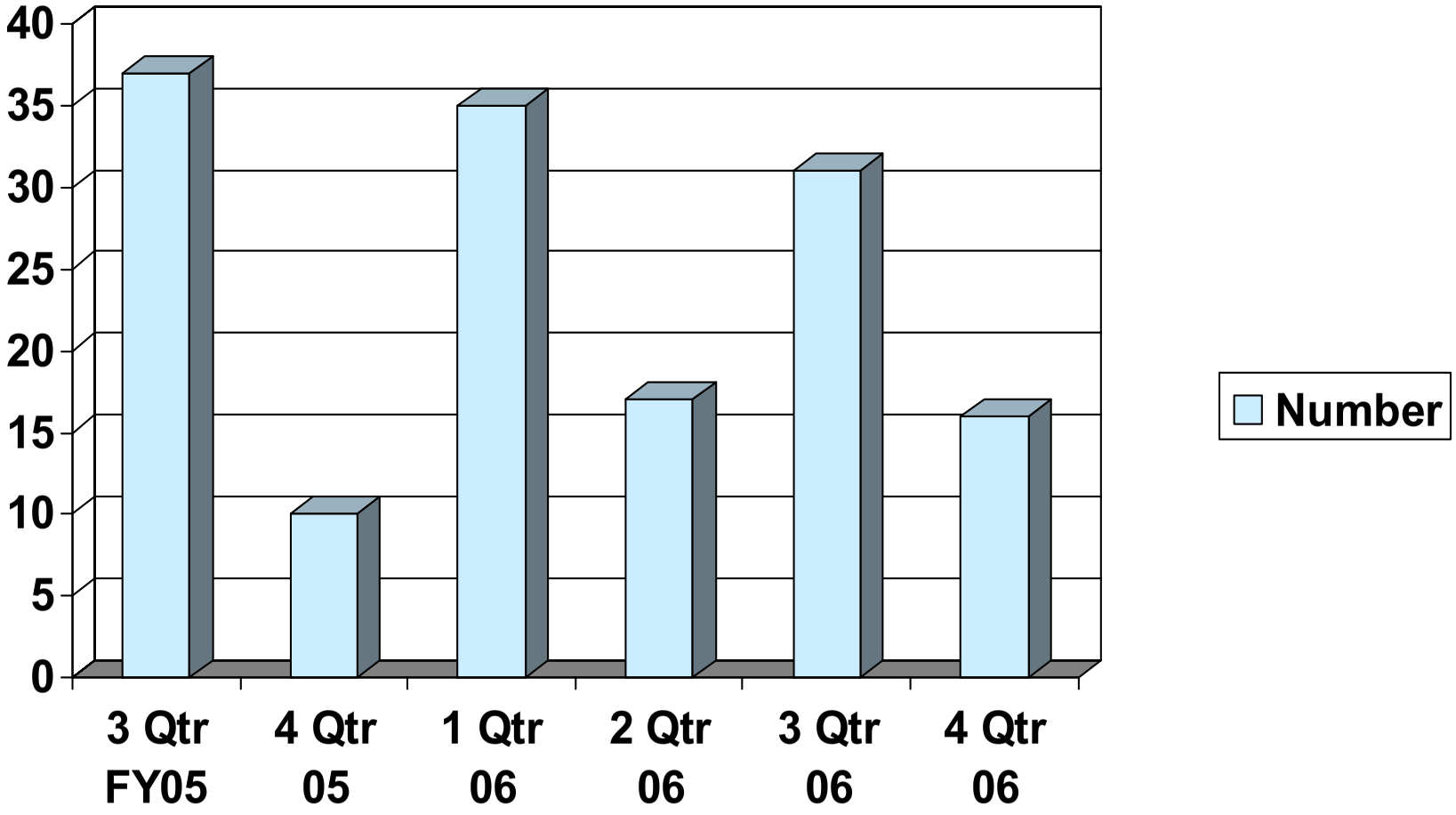
Heinz Ahlers – Approval Processing Statistics Update

October 11, 2006

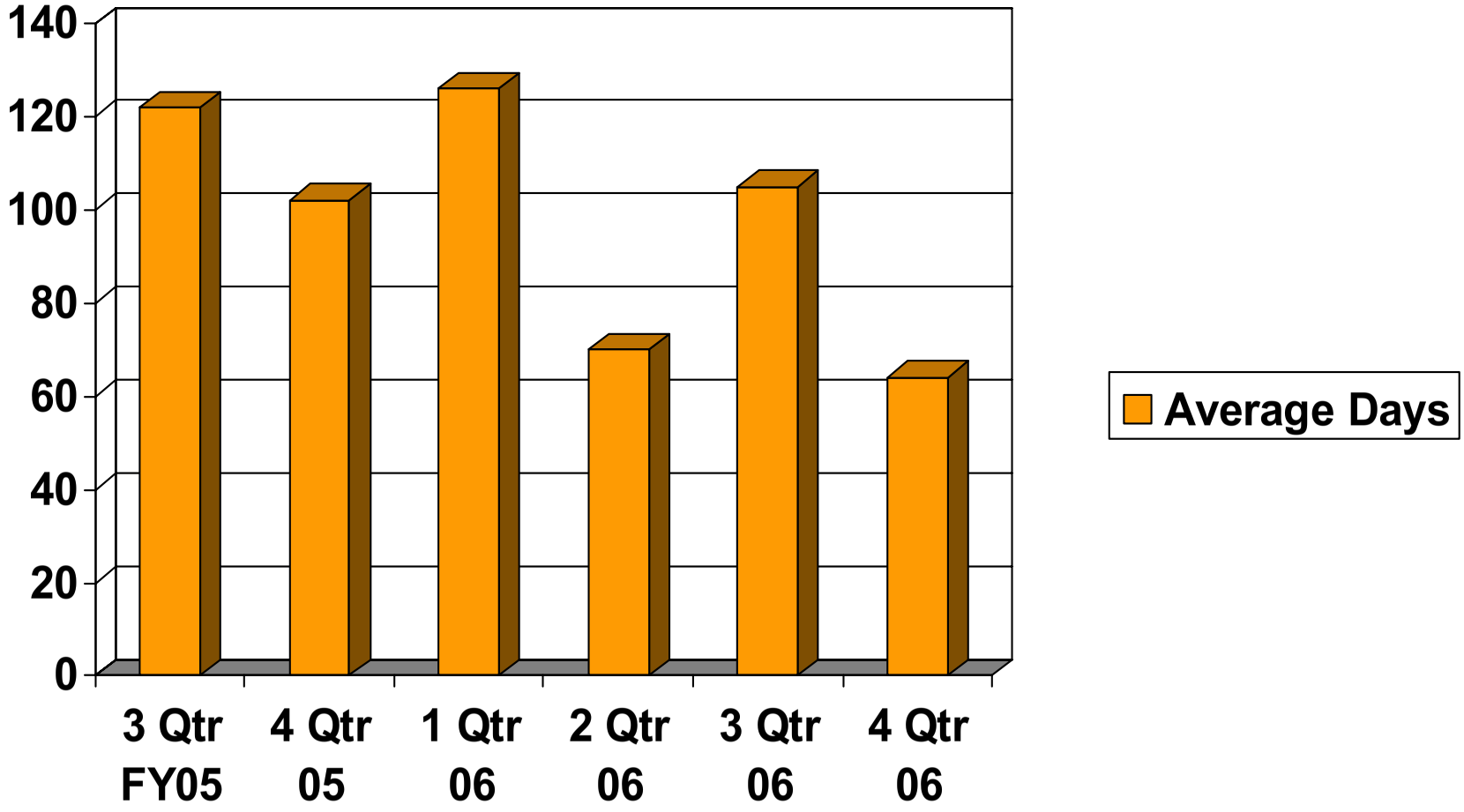
Air Supplying Applications w/o CBRN



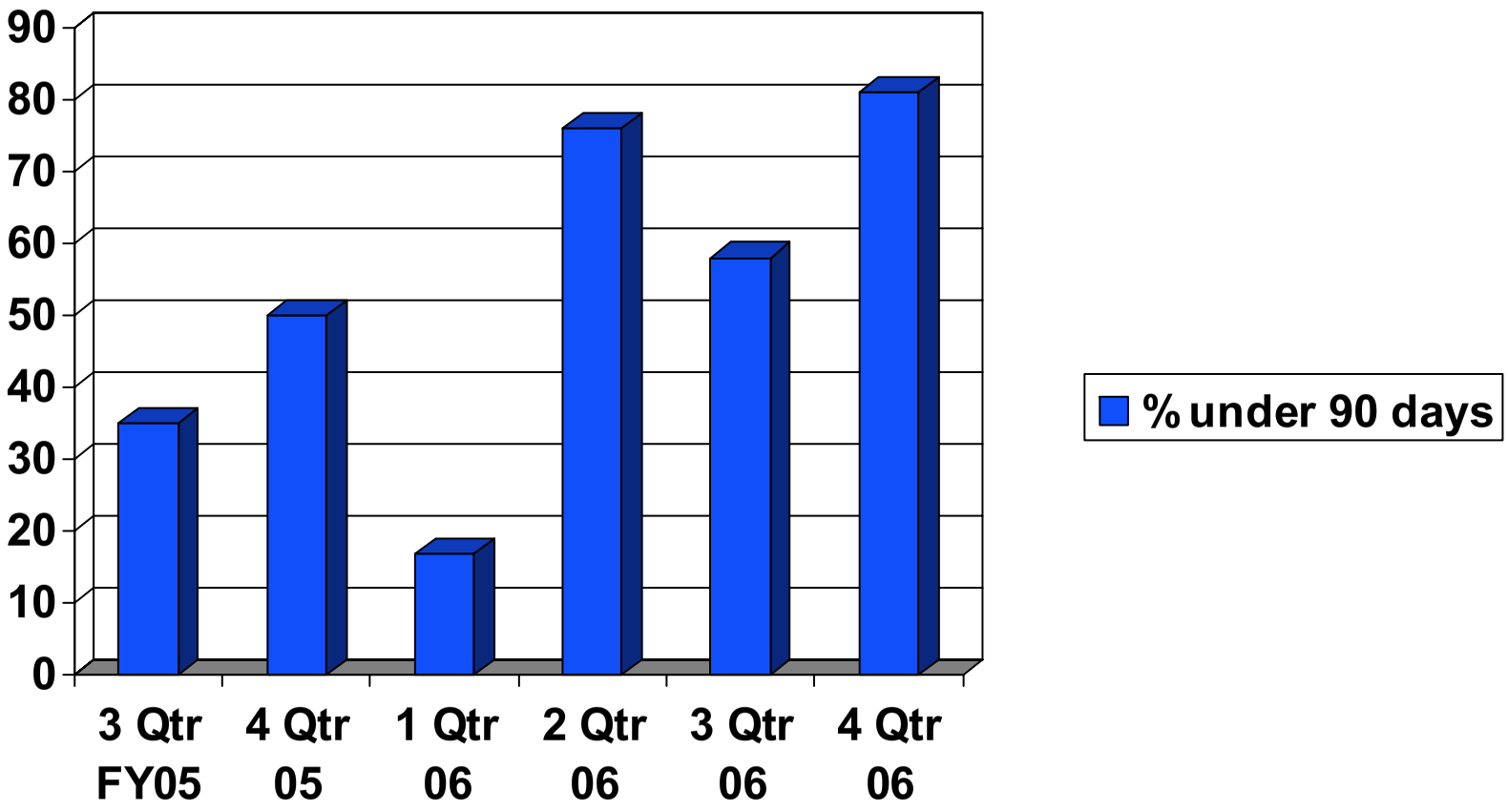
Air Supplying Applications w/o CBRN



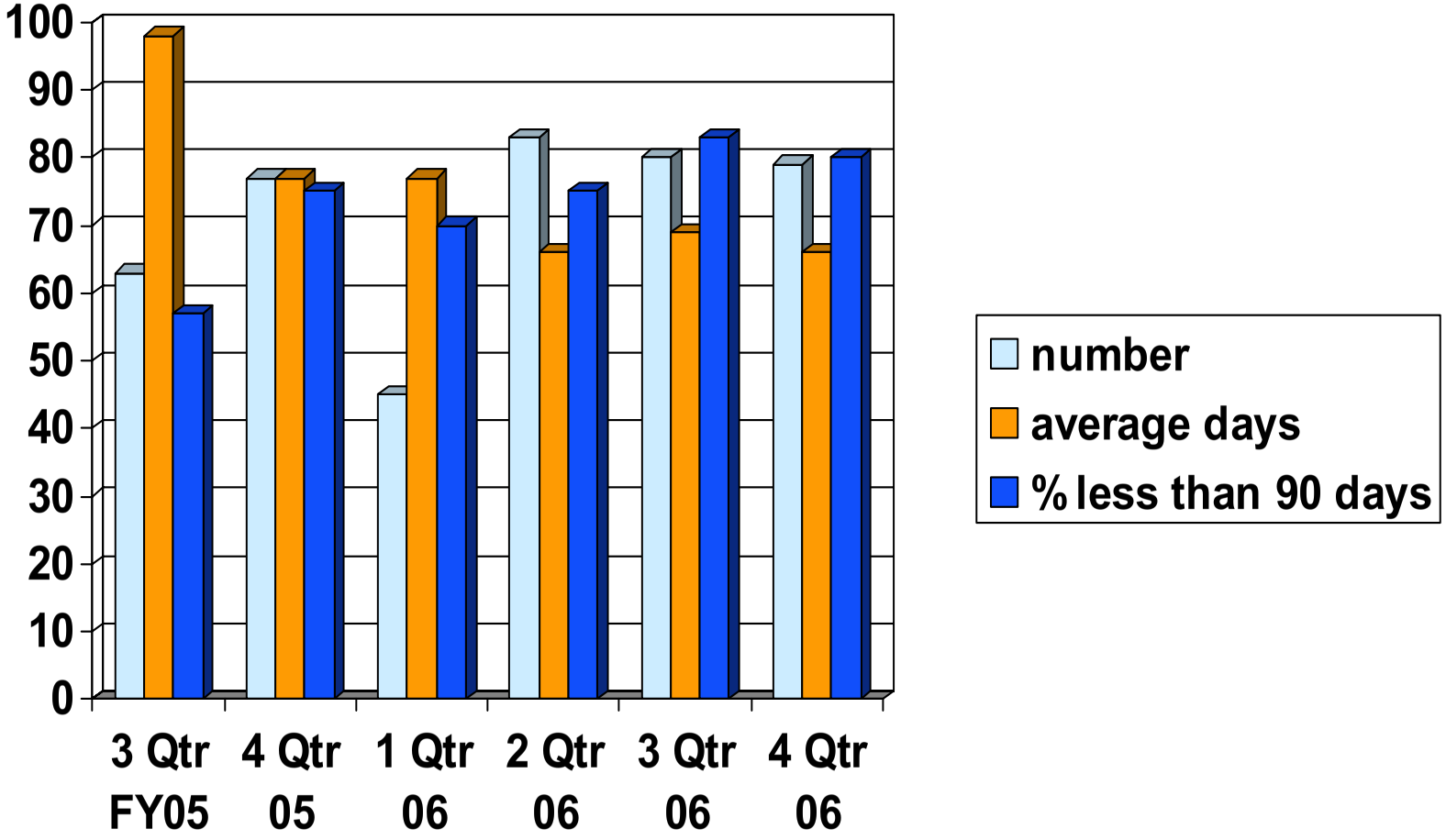
Air Supplying Applications



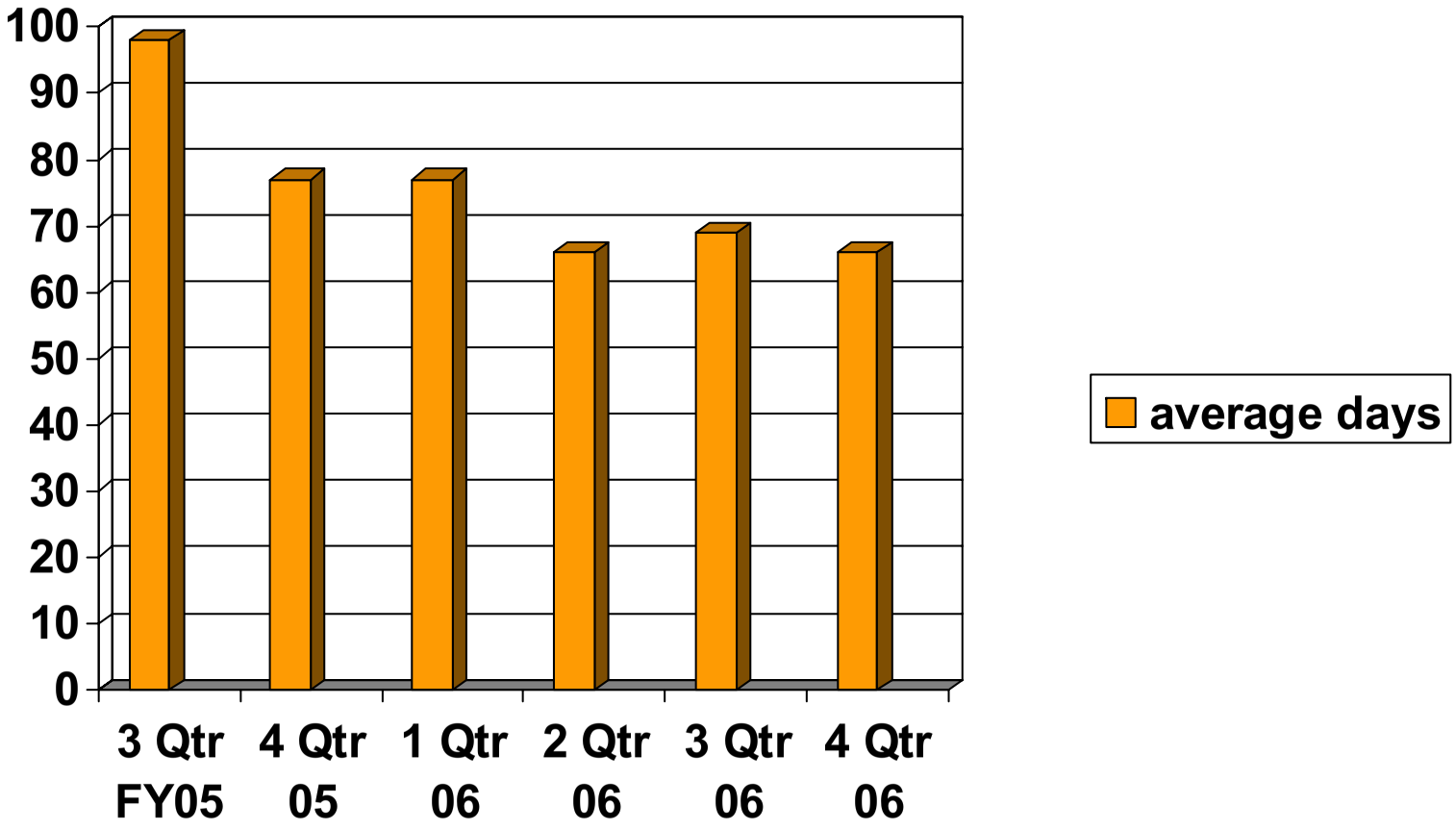
Air Supplying Applications



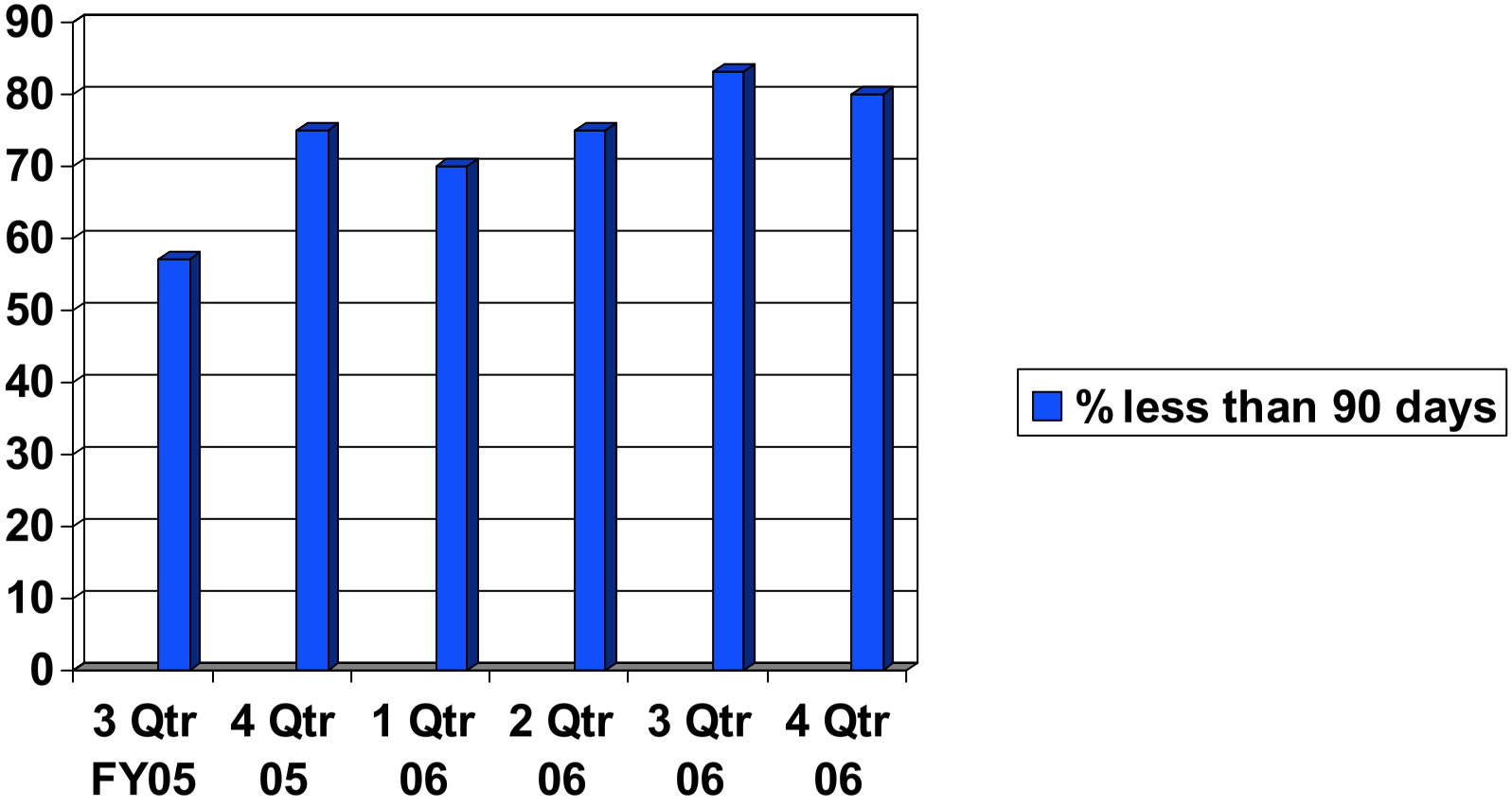
Air Purifying Applications



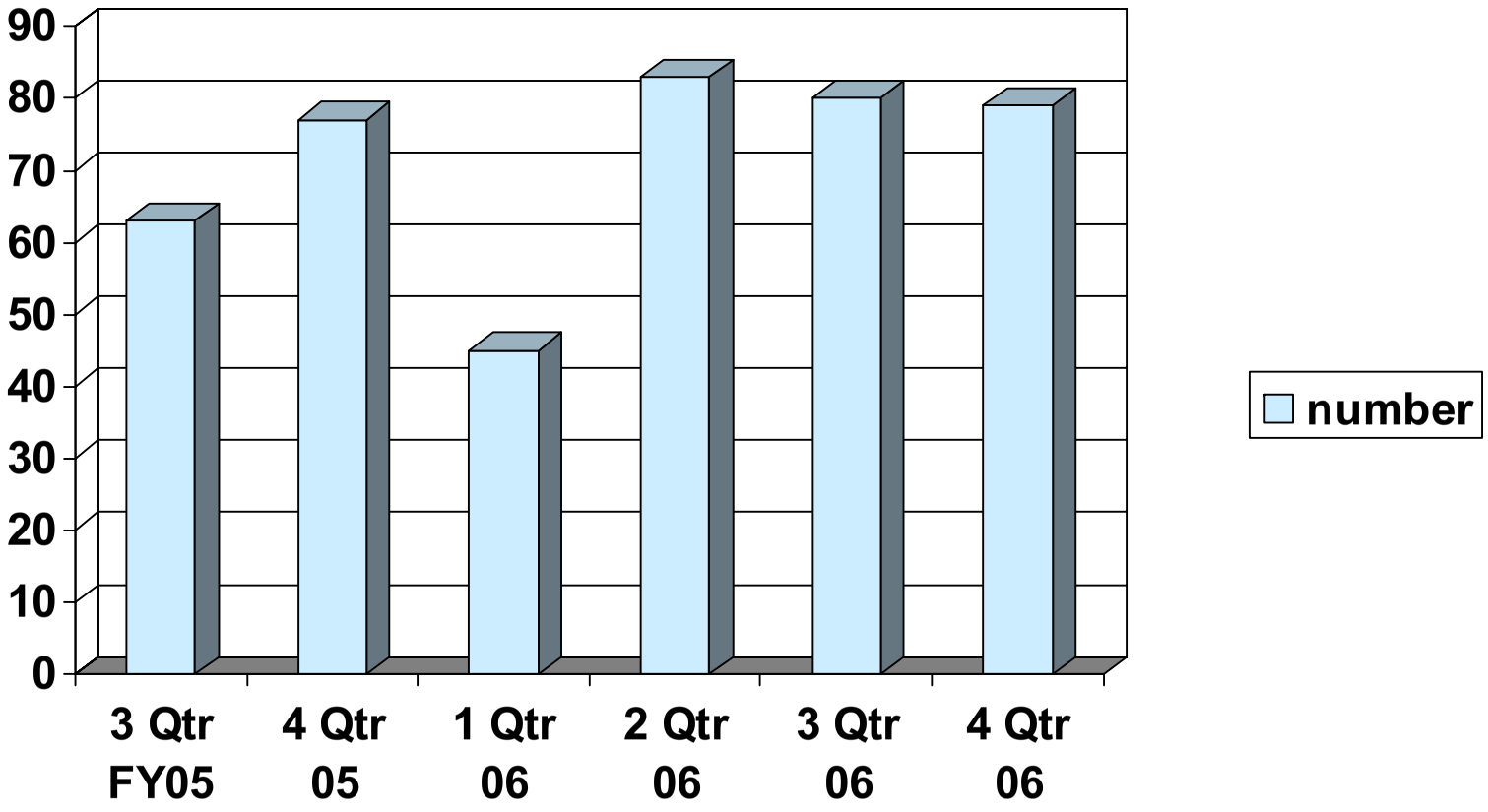
Air Purifying Applications



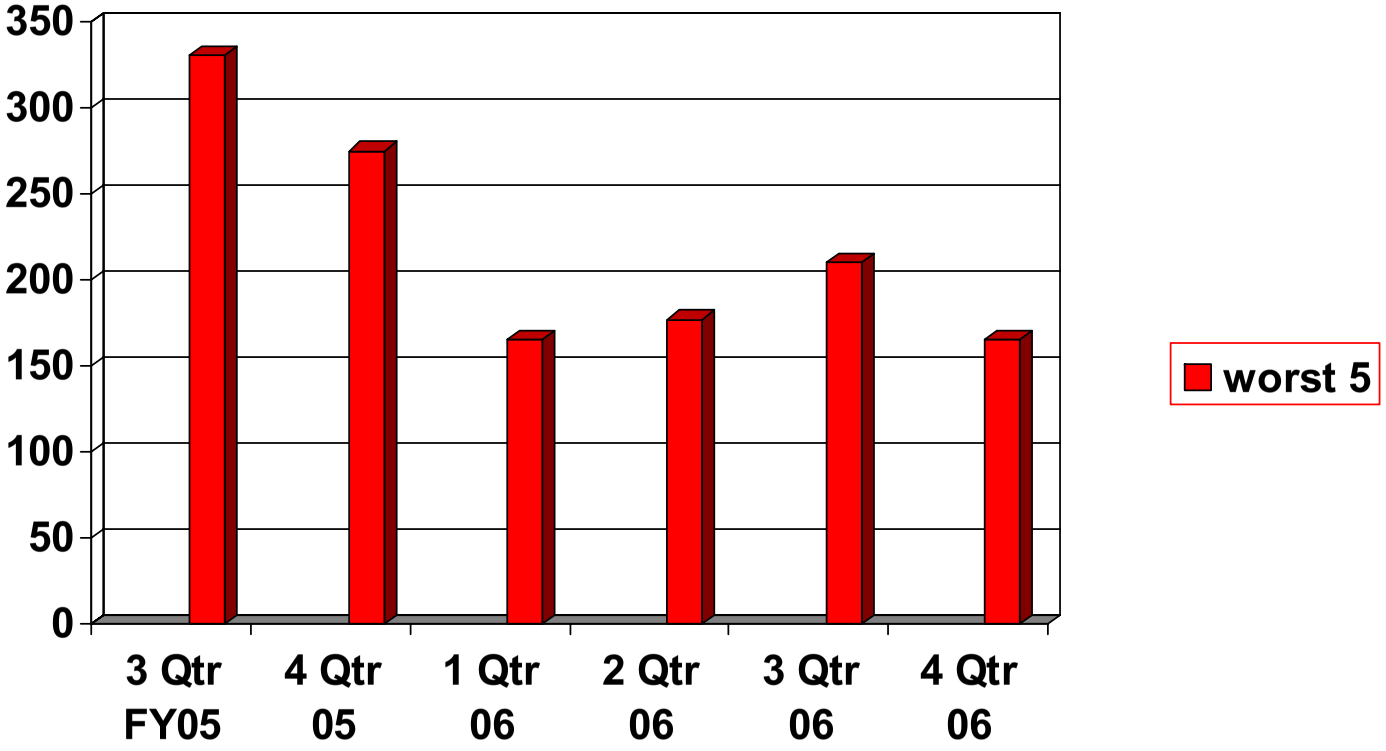
Air Purifying Applications



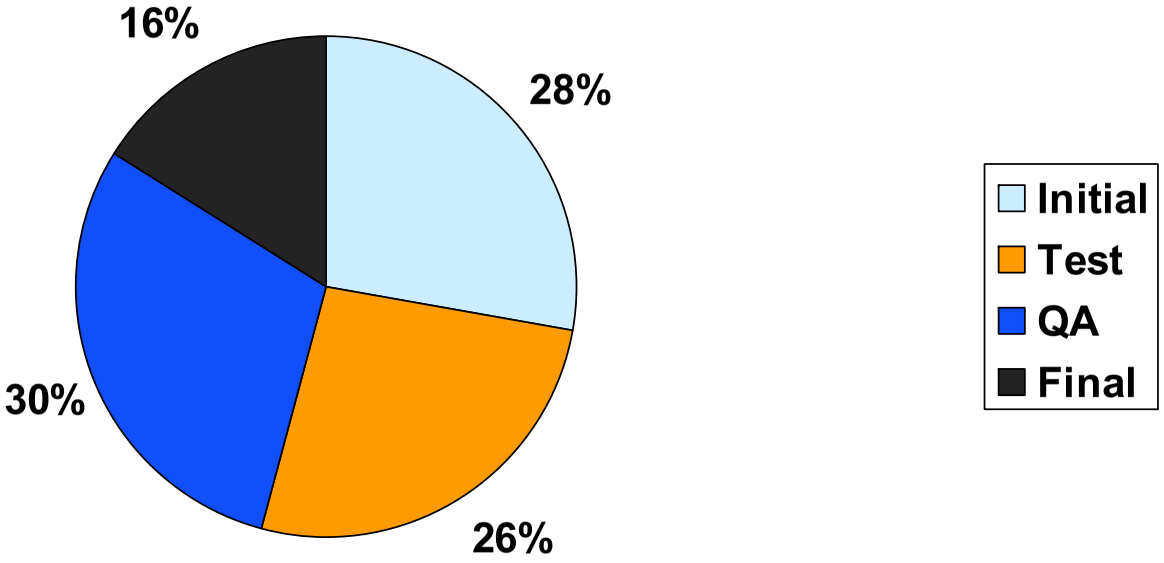
Air Purifying Applications



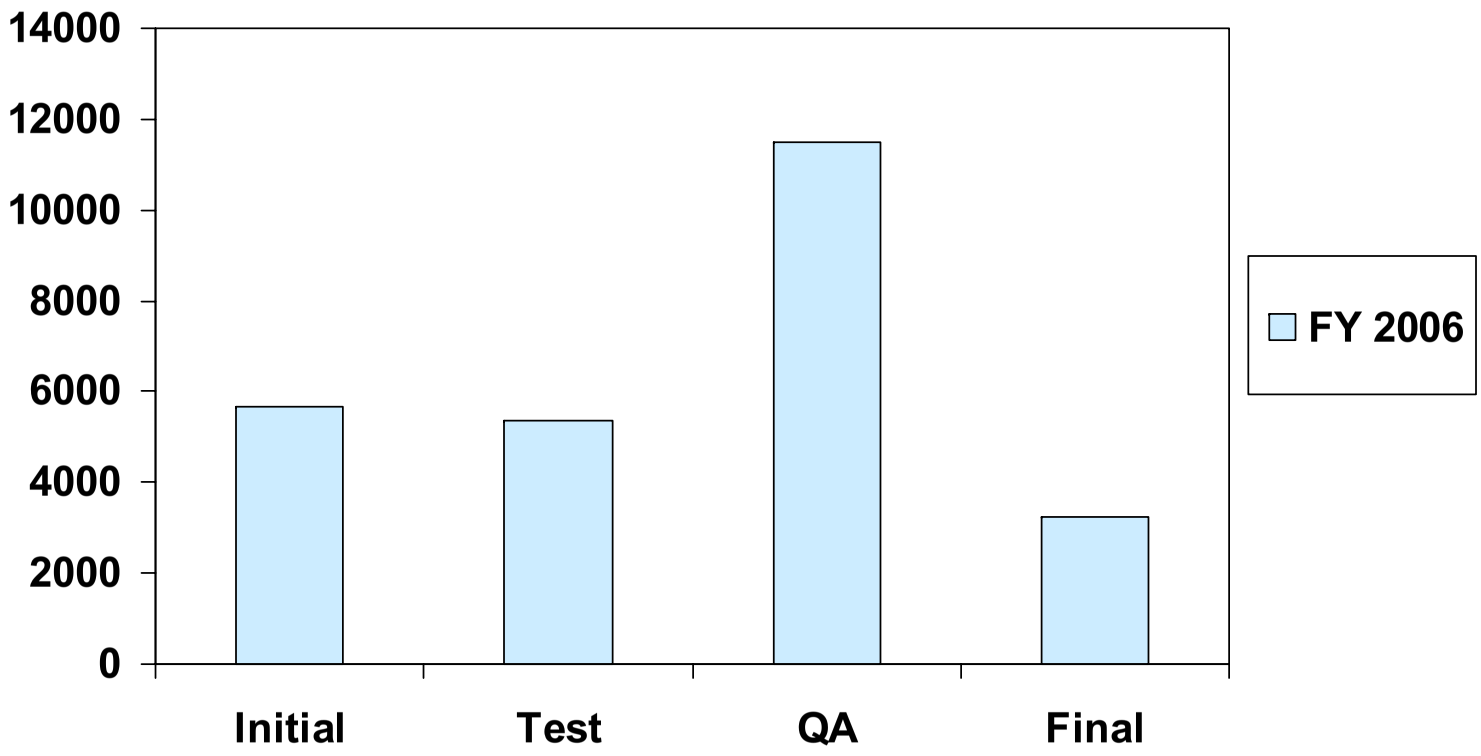
Air Purifying Applications
Worst 5 Application Times



Time Distribution
FY 2006



Time Distribution
FY 2006



Questions?

Technology Evaluation Branch

Heinz Ahlers

Important Initiatives

October 11, 2006

Overview

- DEIMS Update
- NFPA CBRN Update
- “No Test” applications
- Facepiece Fit Testing - Canisters
- Approval Fee Update
- CBRN PAPR

DIEMS Update

- **Major focus over the next three years**
- **Improve the Matrix requirements and allow manufacturer access to Matrix information**
- **Improve the SAF**
- **Internal search improvements**

CBRN PAPR

- **There will be two presentations on the CBRN PAPR Standard, please hold questions until the end.**

"No Test" Applications

- The "No Test" application has been used in the past to speed processing
- 42 CFR 84.35 (e) gives NIOSH the authority to determine if testing is required.
- NIOSH will tend to require testing.
- Applications for extensions of approval to update drawing revisions that do not involve changes in process or materials will likely have a no test decision

Facepiece Fit Testing
Canisters

- **Facepiece Fit testing issues will be discussed under other related topics.**
- **NIOSH intends to allow surrogate test canisters as stated in the May 19, 2006 Letter to All Respirator Manufacturers**

Approval Fee Update

- **NIOSH testing and approval fees are seriously out of date.**
- **NIOSH is gathering data on actual testing cost and will generate a new fee schedule proposal.**

Questions?

National Personal Protective Technology Laboratory

Terry Thornton -- CBRN PAPR Step 1 Technical Requirements Review

October 11, 2006

CBRN PAPR Technical Review

NIOSH implementation concept repackaged the standard requirements into a two step approach for the CBRN PAPR:

Step 1

- **Implement CBRN PAPR via regulatory authorities.**
- **Limited elements of new technology (4 additional tests) combined with existing 42 CFR Part 84 requirements.**

Step 2

- **Implement a PAPR 42 CFR Part 84 module via rulemaking.**
- **CBRN requirements would be a type of PAPR under the new 42 CFR Part 84 module**
- **Technology advancements addressed through the rulemaking process**

CBRN PAPR Step1

Performance criteria under 42 CFR Part 84

Special tests under 42 CFR Part 84.63(c)

- **Durability conditioning (tight-fitting)**
- **Chemical agent permeation and penetration resistance against Distilled Sulfur Mustard (HD) and Sarin (GB)**
- **Laboratory Respirator Protection Level (LRPL)**
- **Canister test challenge and test breakthrough concentrations**

Minimum Requirements of 42 CFR Part 84

Test #	Title
1	Initial DOP -- HE protection (if applicable)
3	Exhalation resistance, blower off (tight-fitting)
4	Exhalation valve leakage (if applicable)
5/5A	IAA fit test
7	Inhalation resistance with blower off (tight-fitting)
12	PAPR Air Flow*
25	Silica Dust
30	Sound Level (if applicable)
60	ESLI visibility (if applicable)
61	ESLI damage resistance (if applicable)

*115 Lpm for tight-fitting, 170 Lpm for loose-fitting

CBRN PAPR Technical Review

Durability conditioning - CBRN tight-fitting PAPR only (Reference STP CBRN-0311)

Purpose of Tests:

To perform environmental storage, transportation shock and drop tests on the CBRN tight-fitting PAPR to qualify durability and to detect any initial life cycle failures.

Goal:

To ensure CBRN tight-fitting PAPR provides adequate respiratory protection after being subjected to normal environmental storage, transportation and rough handling conditions by the user.

CBRN PAPR Technical Review

Test	Test Method	Test Conditions	Duration	Notes
Hot Diurnal	Mil-Std-810F 501.4	(35^{0}C/ 95^{0}F) to (71^{0}C/ 160^{0}F), 24 Hour cycle	3 Weeks Diurnal Cycle	PAPR, Battery and Canisters
Cold Constant	Mil-Std-810F 502.4	Basic Cold, -32^{0}C (-24^{0}F), Constant	3 Days	
Humidity	Mil-Std-810E 507.3	Realistic, Natural Cycle Humidity Profiles in the U.S. (range 88^{0}F @ 88%RH– 05^{0}F @ 59%RH, 24 hr period)	5 Days "quick look" Mil-Std-810E Table 507.3-II	Batteries in MPC as indicated by Users Instructions.
Transportation Vibration	Mil-Std-810F 514.5	U. S. Roadway Vibration, Unrestrained	12 hours/axis, 3 Axes Total duration = 36 hours = 12,000 miles	Gas Service Life, Filtration (P100) and Filtration After OV Gas Life
Drop Test: In Minimum Packaging Configuration	Canisters Only	1 drop per filter (on one of the 3 axis)	Height of 3 feet	Canisters Only

Live Agent Test (LAT): HD and GB Agent

Reference STPs CBRN - 0550 and 0551

- **Resists the permeation and penetration of distilled sulfur mustard (HD) and Sarin (GB) chemical agents**
- **Breathing machine operating at an airflow rate of 40 L/min, 36 respirations per minute, 1.1 liters tidal volume.**
- **Blower is running and including all components and accessories except for the battery (or batteries)**

CBRN PAPR Technical Review

Live Agent Test (LAT): HD and GB Agent

- **Blower is running and including all components and accessories except for the battery (or batteries)**
- **Eight (8) hour test time, the laboratory shall integrate a power supply delivering the correct voltage and current so that the PAPR operates at the rated flow for the entire test duration.**
- **The manufacturer will be required to supply the correct rated battery voltage for their PAPR system. The manufacturer may be required to supply a means to connect their PAPR system to the power supply, i.e. power leads.**

Live Agent Test (LAT): HD and GB Agent

Tight-fitting PAPR

- QLAT performed on two PAPR (one for HD, one for GB)
- Durability Conditioning
- RLAT performed on four PAPR (two for HD and two for GB).

Loose-fitting PAPR

- LAT performed on six PAPR (three for HD and three for GB).

LRPL Requirements

Reference STPs CBRN - 0550 and 0551

- **All PAPRs (tight-fitting and loose-fitting)**
  - 10,000 for ≥ 95% with blower on
- **Tight-fitting PAPR**
  - 2,000 for ≥ 95% with blower off
  - Modified, sample size of 8

Test Conditions

- Three tests at 25% RH, 25ºC at capacity requested
- Three tests at 80% RH, 25ºC at capacity requested
- Canisters tested at 115 Lpm per system
- Cartridges tested at 170 Lpm per system
- Individually tested at flow divided by least number of elements on the system

CBRN PAPR Technical Review

Tight-fitting Approval

	Test Concentration (ppm)	Breakthrough Concentration (ppm)
Ammonia	2,500	12.5
Cyanogen chloride	300	2
Cyclohexane	2,600	10
Formaldehyde	500	1
Hydrogen cyanide	940	4.7*
Hydrogen sulfide	1,000	5.0
Nitrogen Dioxide	200	1 ppm NO_2 or 25 ppm NO†
Phosgene	250	1.25
Phosphine	300	0.3
Sulfur dioxide	1,500	5

CBRN PAPR Technical Review

Loose-fitting Approval

	Test Concentration (ppm)	Breakthrough Concentration (ppm)
Ammonia	1,250	12.5
Cyanogen chloride	150	2
Cyclohexane	1,300	10
Formaldehyde	250	1
Hydrogen cyanide	470	4.7*
Hydrogen sulfide	500	5.0
Nitrogen Dioxide	100	1 ppm NO_2 or 25 ppm NO†
Phosgene	125	1.25
Phosphine	150	0.3
Sulfur dioxide	750	5

Test Times

Filter Capacity	Test Time (min)	Filter Capacity (ppm-min)
Capacity # 1	15	Test Concentration X 15
Capacity # 2	30	Test Concentration X 30
Capacity # 3	45	Test Concentration X 45
Capacity # 4	60	Test Concentration X 60
Capacity # 5	90	Test Concentration X 90
Capacity # 6	120	Test Concentration X 120

Particulate / Aerosol Testing

- Must meet 99.97% efficiency
- Canisters tested at 115 Lpm per system
- Cartridges tested at 170 Lpm per system
- Individually tested at flow divided by least number of elements on the system
- 20 canisters/cartridges against DOP
- 6 canisters / cartridges after cyclohexane

National Personal Protective Technology Laboratory

Jeffrey Peterson -- CBRN PAPR Step 1 Submission Overview

October 11, 2006

CBRN PAPR Step 1 Submission Overview

- **Requirements for CBRN PAPR Step 1 Approval**
  - **Must meet PAPR performance criteria from 42 CFR Part 84, as applicable**
  - **Must meet additional performance requirement criteria under NIOSH 42 CFR Part 84.63(c)**

CBRN PAPR Step 1 Submission Overview Continued

- **All submittals related to CBRN PAPR approval will be given priority in the processing queues**
- **Anticipated cost for a CBRN PAPR is approximately $115,500.00**
- **Minimum time frame for completion of CBRN PAPR tests is approximately 10-12 weeks**

CBRN PAPR Step 1 Submission Overview Continued

- **Options for Submitting Approvals**
  - **Option 1**
    - **Submit configuration that is intended to be the CBRN PAPR configuration for 42 CFR 84 approval**
      - **Can submit unit for HE protection only or other protections. If this configuration is to be marketed, the canister cannot carry a dual label and will need a unique part number**
      - **Upon announcement of CBRN PAPR program, submit a new request to have additional testing under 42 CFR 84.63(c) initiated in order to obtain CBRN PAPR approval**
  - **Option 2**
    - **Wait for the CBRN PAPR program to be announced and submit CBRN PAPR configuration**
      - **42 CFR 84 testing will be done first to demonstrate compliance to 42 CFR 84**
      - **Upon successful completion of 42 CFR 84 testing, additional testing under 42 CFR 84.63(c) will be initiated**

CBRN PAPR Step 1 Submission Overview Continued

– Option 1 Process

- **Obtain 42 CFR 84 approval of the PAPR system intended to be CBRN PAPR approved**
- **After receiving 42 CFR 84 approval, submit a request for a new approval and reference the approval number and NIOSH Task Number under which 42 CFR 84 testing was completed**
  - **Add CBRN as the last four characters of the applicant assigned reference number (AAR)**
  - **Put both the 42 CFR 84 and CBRN PAPR on the same assembly Matrix**
  - **Submit label drafts, pre-test data and quality documents as required for any new submittal**
  - **Submit the sufficient number of hardware samples required for CBRN evaluation as specified by the Hardware Requirements Guide which will be an interactive web page that manufacturers will have access to**
  - **Manufacturer will be invoiced and must pay fees prior to receiving approval/denial letter**

CBRN PAPR Step 1 Submission Overview Continued

- **Option 2 Process**
  - **Submit a request for a new CBRN PAPR approval**
    - **Add CBRN as the last four characters of the applicant assigned reference number (AAR)**
    - **Identify only the CBRN PAPR configuration on the assembly Matrix**
    - **Submit label drafts, pre-test data and quality documents as required for any new submittal**
    - **Submit the sufficient number of hardware samples required for CBRN evaluation as specified by the Hardware Requirements Guide as well as enough hardware to complete the 42 CFR 84 compliance evaluation as per the Respirator Selection Guide contained in the Standard Application Procedures**
    - **All 42 CFR 84 testing will be completed before any additional testing required under 42 CFR 84.63(c) will be performed**
    - **Manufacturer will be invoiced and must pay fees prior to receiving approval/denial letter**

CBRN PAPR Step 1 Submission Overview Continued

- **CBRN PAPR's will be marked with a CBRN rating and the canister/label shall be olive (Munshell notation 7.5 Y 5/6)**
  - **Loose fitting Protections will be listed as CBRN PAPR CAP 1**
  - **Tight fitting protections will be listed as CBRN PAPR CAP 1**
- **Standard Cautions and Limitations for CBRN PAPR's**
  - **Loose fitting CBRN PAPR's will need to have Cautions and Limitations A, B, C, F, H, I, J, L, M, N, O, R, S, Y, GG, QQ, UU, and VV listed as per hand-out**
  - **Tight fitting CBRN PAPR's will need to have Cautions and Limitations A, F, H, I, J, L, M, N, O, R, S, Y, Z, BB, CC, GG, UU and VV listed as per hand-out**

CBRN PAPR Step 1 Submission Overview Continued

- **Once PAPR system(s) have been evaluated as per 42 CFR 84 requirements and achieved 42 CFR 84 approval, manufacturers may apply for retrofit kits to upgrade existing 42 CFR 84 approved PAPR's to CBRN PAPR's as per the requirements that will be listed in the final version of the Statement of Standard**

Questions?

National Personal Protective Technology Laboratory

John Perrotte

Ann Levitsky

UPDATE OF THE STANDARD APPLICATION FORM REVISIONS

October 11, 2006

STANDARD APPLICATION FORM

Standard Application Form (SAF) Minor Revisions

The SAF and the DEIMS (internal system used to track application information) will be slightly modified in October 2006 to incorporate new information for NFPA and SEI as listed below. This information will be added to the SAF to help processing and coordination of the application between the two agencies.

- Checkbox for CBRN/NFPA Joint Application
- Checkbox for SEI Retrofit

SAF Update

- Review of the SAF for redevelopment is currently in progress
- Upgrade the technology to ASP.NET and SQL Server
- Create an application that is platform independent
- Make SAF more user friendly
- Redevelopment of the SAF will begin 2007

STANDARD APPLICATION PROCEDURE

Revision 1 of the “Standard Application Procedure for the Certification of Respirators under 42 CFR Part 84” was released in July 2005.

A definite improvement over the original issue, but still hard to find information.

A web-based interactive procedure is being developed and should be available by March 2007.

Applying for Respirator Certification

Welcome to the NPPTL web site that replaces the *Standard Application Procedure for the Certification of Respirators Under 42 CFR 84*, Revision 1, July 2005. Here we've captured the relevant information you'll need to successfully submit an application for respirator certification. Compliance with all instructions is essential for quick and efficient processing of an application. Failure to follow these instructions completely may result in the rejection and return of your application. It is imperative that each applicant invest the time necessary to become familiar with these instructions.

The Process | Types of Approvals | General Information | Application How-To | Documents | Checklists

Test Selection Guide | Definitions | Acronyms | CBRN Guidance | Contact NPPTL

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General Information

New Approval and Extension of Approval applications must contain the following items. If any of the items are not submitted, the applicant must state the reason why, i.e., "has not changed since TN-xxxxx."

NIOSH Standard Application Form
Pre-test data
Simplified drawings
Assembly matrix
Draft approval label(s)
Quality Assurance manual
Process Quality Control Plan
Fees
Service Life Plan (for SCSRs only)
User's Instructions
Test samples / hardware

Assembly Matrix | Service Life Plans | User's Instructions | PQP | QA Manual | Test Samples and Ha

Pre-Test Data | Drawing Info | File Naming | Cautions/Limitations | Protections | Approval Schedules

NIOSH Documents | Denial Criteria | Fees

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Types of Approvals

There are three basic types of applications for which NIOSH issues formal certificates of approval when the submitted items meet all of the applicable requirements of 42 CFR Part 84:

New Approvals | Extension of Approva | QA

Products may be submitted for certification while still in the prototype stage. However, NIOSH will not issue a formal certificate of approval for prototype hardware. In addition to the three approval types listed above, you may sometimes have to re-submit an application for approval or submit an Amended Application:

RESUBMITTAL APPLICATIONS

If your application is for hardware or documentation that has been previously submitted to NIOSH and denied, select request type 'Resubmittal of New' or 'Resubmittal of Extension' as appropriate. The *Reason for Application* must include the changes made to address the product or documentation deficiencies, an explanation why the product or documentation now meets NIOSH requirements, and the task number (TN) of the previously denied application. Failure to provide this information will result in your application being returned, unprocessed.

AMENDED APPLICATIONS

An amended application is submitted only at NIOSH's request, and is used on open applications that have an inaccuracy somewhere in the application. Manufacturers should submit only the portion of the application requested by NIOSH. The application will retain the same Applicant-Assigned Reference Number and NIOSH-assigned Task Number. NIOSH will advise the applicant as to any additional documents required to be submitted for an amended application.

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Prototypes

Respirators may be submitted for certification while still in the prototype stage. However, NIOSH will not issue a formal certificate of approval for prototype hardware. NIOSH issues certificates of approval only for individual, completely assembled respirators that are indicative of regular production units and which meet the applicable construction, performance, and respiratory protection requirements set forth in 42 CFR Part 84.

A prototype unit is defined as a respirator that (a) involves a new design produced using temporary molds, non-production tooling, or regular production tooling in a new fashion, and (b) has demonstrated by the manufacturer's pre-testing to meet 42 CFR 84 minimum design and performance requirements.

Submit a prototype respirator using a NEW application form. You must state "prototype testing only - product is not submitted for certification" in the 'Reason for Application' section. Pre-test data must be submitted. NIOSH will examine, inspect, and test the prototype respirator in accordance with 42 CFR Part 84. If it is found that the respirator meets the minimum requirements set forth in 42 CFR Part 84, NIOSH will inform the applicant in writing of the results of the examinations, inspections, and tests.

NIOSH may request samples made on regular production tooling and production quality control (Ref. 84.30 (c)).

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New Approvals

A manufacturer must provide all the requested information on the NEW application form when a respirator is a **new design, or where a different type or different level of protection** is sought for an existing product. NIOSH assigns a new TC number for each new respirator system design that is approved.

An application may be submitted for only **one** basic new respirator design per application. If an application contains more than one design, the application will be denied. If a manufacturer submits a new product with two new facepieces, for example, a half-mask and full-facepiece that use the same new filter, NIOSH would require two separate applications resulting in two new approvals because each facepiece represents a separate design and level of protection.

New Approval applications must contain the following items. If any of the items are not submitted, the manufacturer must state the reason why, i.e., "has not changed since TN-XXXXX."

NIOSH Standard Application Form Pre-Test Data Simplified drawings Assembly Matrix Fees

Draft Approval Label(s) Quality Assurance Manual (if not already on file at NIOSH) User's Instructions

Process Quality Control Plan (if not already on file for that respirator family) Service Life Plan (for SCSRs only)

Test samples / hardware

Guidance specific to a single respirator type can be found at...

Supplied Air PAPR SCBA Filtering Facepiece

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SCBA

Information specific to Self-Contained Breathing Apparatus (SCBA)

Self-Contained Breathing Apparatus are normally classified under approval schedule 13F: Self-Contained Breathing Apparatus (SCBA) for entry or escape, demand or pressure-demand, open-circuit or closed-circuit, Self-Contained Self-Rescuers (SCSR), and combination escape only Self-Contained Breathing Apparatus/Supplied-Air Respirator (ESCBA/SAR).

The approval labels must be included in the User's Instructions for all Air-Supplied Respirators, including combination air-purifying/supplied-air respirators and combination gas mask/supplied-air respirators. The approval label may be an insert in the User's Instructions.

Major sub-assemblies which must be listed on the approval labels and assembly matrix (if they are part of the respirator assembly) include, but are not limited to:

Facepiece (including hood, helmet, etc.) Breathing tube Regulator assembly Pneumatic assembly

Harness and backpack assembly Cylinder and valve assembly Accessories (optional on approval label, required on assembly matrix)

Service life plan (SCSR only) and User's Instructions (required on assembly matrix)

Links to document examples specific to SCBAs:

Assembly matrix, Continuous-flow SAR SCBA drawing checklist SCSR drawing checklist

Draft approval label for combination SCBA/SAR Draft approval label for SCBA Draft approval label for SAR with egress cartridges

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Documents

Click on one of the links below for samples of respirator certification documents required with applications. Here you can find sample Approval Labels and examples of Assembly Matrices for most respirator types. You will also find the "Private Label Notification" form that should be used for certain private labels. Examples of PQP flowcharts and Exploded View Drawings are also found here.

Approval Labels | Assembly Matrices | Private Label form | PQP Flowcharts | Exploded View Dwg

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Approval Labels

Approval labels used in final User's Instructions, on packaging, or on devices must be legible. Labeling requirements will vary based on the type and intended use of the respirator. To see sample label formats for different respirator types, click on a button at the bottom of this page. The list of protections must be in the same order and identical in every way to the matrix. Submit draft versions of the appropriate labels. If you're not able to submit draft labels, you must obtain pre-authorization from NIOSH for each application.

Labels must be submitted for all New Approvals and for Extensions of Approval where the components change. Labels must be done in Excel and follow the format of the examples below. All major sub-assemblies in the approved respirator configuration must be on the approval label. Accessories may be listed on the approval label, but are not required. Due to the large size of the files when the NIOSH and DHHS logos are imbedded, NIOSH will accept draft labels with the location of the logos noted. The manufacturer is responsible for inserting the logos during label production. Approval Labels may not contain future submittals or show unapproved assemblies.

If the respirator contains electrical components and the manufacturer wishes to list the product **on the NIOSH approval label** as intrinsically safe, first obtain intrinsic safety approval from the Mine Safety and Health Administration (MSHA) under Title 30, CFR, Part 18 and submit verification of such approval in the application.

Click on a link below to view a sample approval label:

Filtering Facepiece | Abbreviated FFP | Half-mask | Filter | Chemical Cartridge | SAR w/egress

SAR | SCBA | Combo SCBA/SAR | SCBA Harness | Chemical Scrubber | Abbreviated Cartridge

Gas mask canister

CBRN Guidance

Welcome to the beginning page for your trip through the world of NIOSH CBRN respirator approval applications. From this page you should be able to navigate your way to the applicable instructions on submitting an application to NIOSH for CBRN approval.

Applications for CBRN approval are processed similarly to the 42 CFR 84 approvals. This section documents the CBRN process, with links to the 42 CFR 84 process where appropriate.

Compliance with all instructions is essential for quick and efficient processing of an application. Failure to follow these instructions completely may result in the rejection and return of your application. It is imperative that each applicant invest the time necessary to become familiar with these instructions.

CBRN Escape Hoods | CBRN APR | CBRN SCBAs

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CBRN APR

Instructions for New Air-Purifying Respirator CBRN Approval

GENERAL

a. The applicant may request approval in one of two ways: 1) as a complete application with all the required hardware and all pre-submission test data except for GB and HD testing, or 2) in an abbreviated format (qualifier application) that consists of three test samples along with an application. It is not necessary to provide any pre-submission test data with a qualifier application. For both types of applications, all of the remaining required documentation (e.g., matrices, draft labels, drawings, etc.) must be provided in a timely manner.

b. The qualifier application is offered as a way to mitigate the full cost of testing for hardware that may fail critical tests. The applicant will be notified after the first-stage Live-Agent Testing (LAT) is completed. Upon successful completion of first-stage LAT, the applicant will have up to 8 weeks to submit an amended application that must include all pre-submission test data, the list of test equipment, and the remainder of the test hardware.

c. An invoice for payment of all fees will be submitted to the applicant at the conclusion of the tests.

Up | CBRN APR MATRIX | CBRN APR SAF | APPROVAL LABELS | USER'S INSTRUCTION | QA REQUIREMENTS | TEST SAMPLES / FEE

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CBRN APR SAF

STANDARD APPLICATION FORM

Start with a New Approval application form. Follow the form completion guidance except as modified below:

a. Add the suffix "CBRN" to your Applicant Assigned Reference Number.

b. Include in the "Reason for Application," the phrase "This request is for a new CBRN APR configuration." State the capacity of the respirator and include the respirator description and all related part numbers for components and accessories as identified on the assembly matrix.

c. Select the type of respirator as "Gas and Vapor." Skip the selections for specific contaminants and select "Other Gasses and Vapors." Then type in CBRN Cap X where X is the cartridge capacity. Capacity is defined as follows: Cap 1 = minimum 15 minutes test time, Cap 2 = minimum 30 minutes test time, etc.

d. The components and accessories to be tested at RDECOM must be clearly identified as the "worst case" configuration. The logic and rationale for determining the worst case configuration, i.e. engineering or fault analyses, must be clearly stated. Applicants must be aware that if multiple accessories are submitted for approval, additional QLAT and RLAT tests may be required to verify the integrity of all components against Live Agents.

e. Complete the remainder of the application form in the usual manner

Up | CBRN APR MATRIX | CBRN APR SAF | APPROVAL LABELS | USER'S INSTRUCTION | QA REQUIREMENTS | TEST SAMPLES / FEE

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STANDARD APPLICATION PROCEDURE

- Are there any volunteers to kick the tires on the pre-release procedure once it's on the internet?
- It's YOUR procedure and any comments and suggestions for improvement will gladly be accepted.
- Please see Ann sometime today, or send email to AOL&@CDC.GOV and she'll send you the URL once the procedure is ready for review.

Questions?

National Personal Protective Technology Laboratory

John Perrotte

DEIMS and CEL Update

October 11, 2006

Certified Equipment List and DEIMS Update

Certified Equipment List – Updates and Redevelopment

- CEL updated October 3, 2006--monthly updates planned
- Why CEL Website had not been updated
  - Processes failed to complete, which required manual intervention
  - Software updates applied and/or technology changes required
  - Software application and methods currently defined for data storage
- CEL Redevelopment
  - Objective: Provide a real time product that meets the needs of stakeholders, manufacturers, and NPPTL
  - Redefine the current business process used for updates
  - Develop and modernize the application storage/update procedures
  - Eliminate MS Access databases and transfer to SQL Server tables

Certified Equipment List and DEIMS Update

- DEIMS Update (What we are doing to improve DEIMS, the internal system used to track application information?)
  - Enhance and improve each business process
  - Upgrade the technology to ASP.NET and SQL Server
  - Create a browser-based application that is platform independent
  - Provide the same functionality to stakeholders and manufacturers

- Currently the DEIMS redevelopment will begin with the following project phases
  - Standard Application Form (SAF)
  - Assembly Matrix and Manufacturer Database
  - Respirator Audit Logic (RAL)
  - Certified Equipment List (CEL)
  - AS Lab data

Questions?

National Personal Protective Technology Laboratory

Gary Walbert

Upgrade of CO_2 Dead Space Test System

October 11, 2006

Upgrade of CO_2 Dead Space Test System

- **Objectives for Upgrading the CO_2 Dead Space Test System**
  - **Improve accuracy in setting test conditions and performing data analysis**
  - **Reduce variability from test to test – make more repeatable and less subjective**
  - **Allow manufacturers to duplicate the test system using commercially available components for direct correlation with NIOSH testing and certification data results**

Upgrade of CO_2 Dead Space Test System

- **What has happened since December, 2005?**
  - **Received Sheffield Head headform and half-torso**
  - **Received breathing machine**
  - **Received all remaining test components including instruments, tubing, fittings, valves and calibration gases**

Upgrade of CO_2 Dead Space Test System

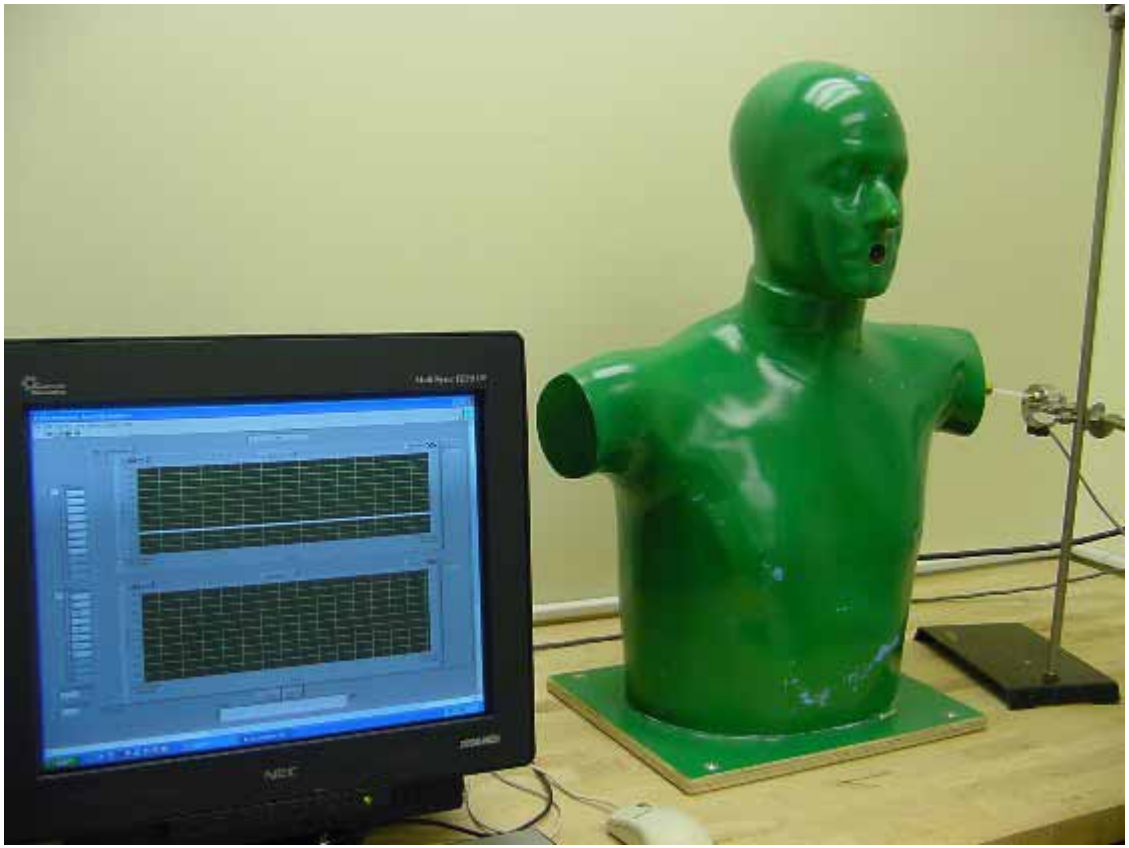
- **What has happened since December, 2005?**
  - **Completed installation of all equipment and instruments and assembly of the instrument cabinet**
  - **Installed personal computer, data acquisition system (DAS) input/output (I/O) device, and LabVIEW software application for data monitoring/recording**
  - **Connected instruments to DAS I/O device**

Upgrade of CO_2 Dead Space Test System

- **What has happened since December, 2005?**
  - **Tuned and calibrated instruments**
  - **Performed shakedown testing**

Upgrade of CO_2 Dead Space Test System

- **Sheffield Headform/Half-Torso on Lab Bench**



Upgrade of CO_2 Dead Space Test System

- **Breathing Machine**

Upgrade of CO_2 Dead Space Test System

- **Gas Sample System – CO_2 / O_2 Sensors**

Upgrade of CO_2 Dead Space Test System

- **Instrument Cabinet**

Upgrade of CO_2 Dead Space Test System

- **What has happened since December, 2005?**
  - **Relocated existing CO_2 Dead Space Test System from B37 to the new test system lab in B21**
  - **Made alternate connections of the existing test system's CO_2 gas analyzer and pressure transducer outputs to the new test system's DAS - Not using strip chart recorder to record data**

Upgrade of CO_2 Dead Space Test System

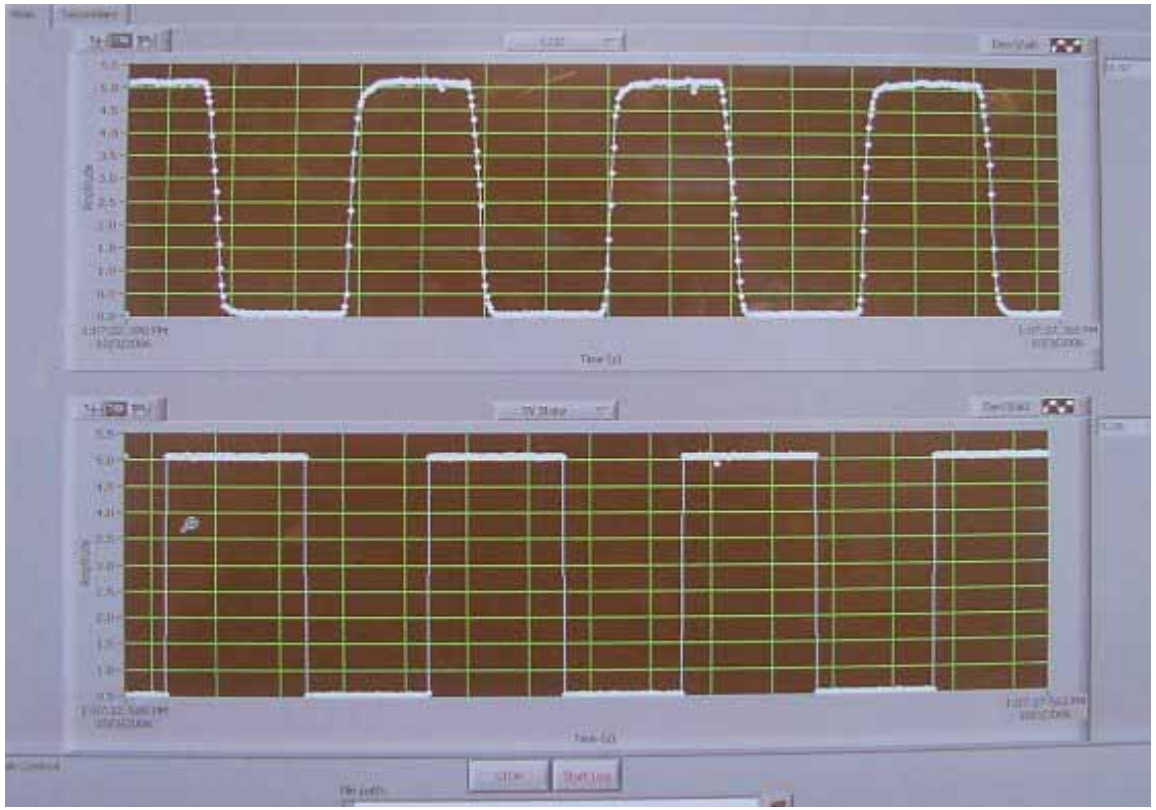
- **Existing Test System in New Lab**

Upgrade of CO_2 Dead Space Test System

- **Data Analysis System**
  - **Data monitoring/recording system powered by custom-made LabVIEW software application**
  - **Data recorded/monitored are Date/Time, CO_2, O_2, Facepiece Resistance, and Breathing Gas ON/OFF Solenoid Valves' status**
  - **Data recording interval is 25 milliseconds or 4 times more frequent than the existing test system's data recording frequency when using a strip chart recorder**

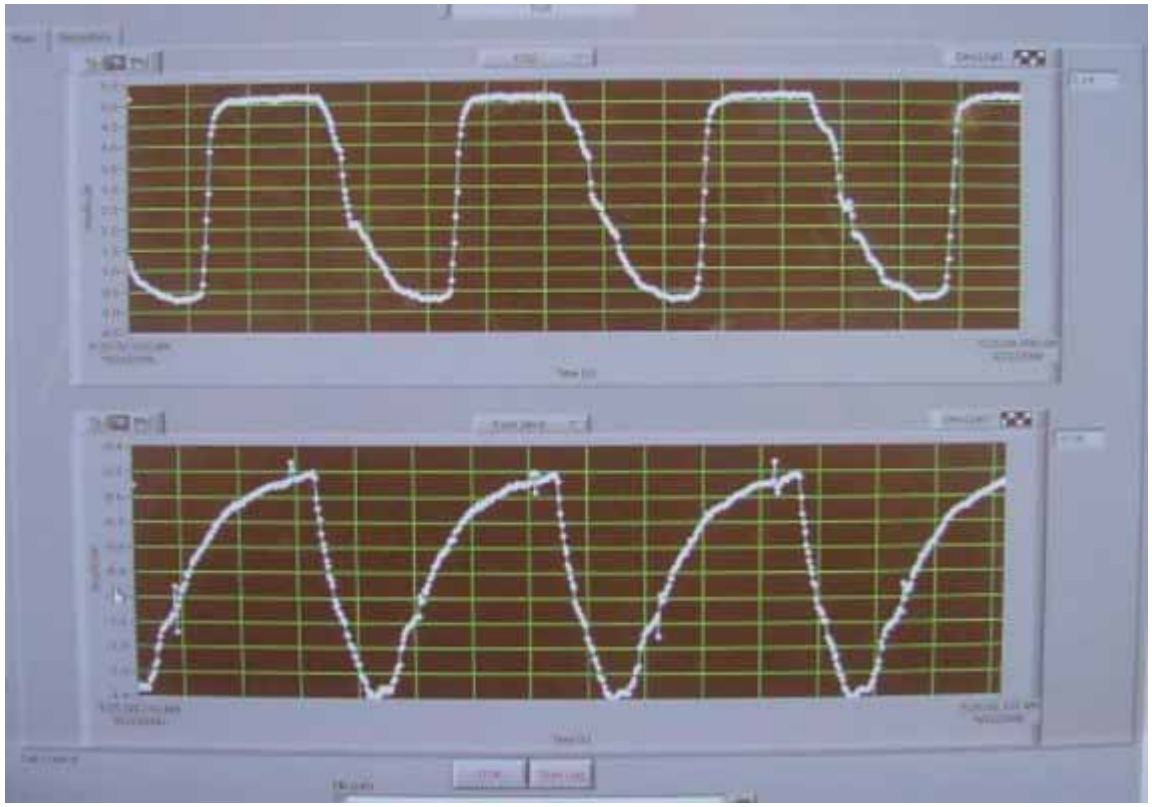
Upgrade of CO_2 Dead Space Test System

- **CO_2 (Top) / Solenoid Valves' State (Bottom) – During Blank Run at New Test System**



Upgrade of CO_2 Dead Space Test System

- **CO_2 (Top) / Facepiece Resistance (Bottom) – During Respirator On Run at New Test System**



Upgrade of CO_2 Dead Space Test System

- **Data Analysis Tools**
  - **More frequent data recording rate facilitates use of abrupt change in facepiece resistance as indicator for the start and end of the inhalation phase of the breathing cycle**
  - **Exhalation and Inhalation ON/OFF solenoid valves' actuation time is also recorded and this can be used to identify the end of the inhalation phase of the breathing cycle**

Upgrade of CO_2 Dead Space Test System

- **New Test System – Start of Inhalation Phase – Respirator On**

Date/Time	Solenoid Valve State	CO_2 Concentration, %	Facepiece Resistance	Delta Pressure
45:41.7	5	5.03	-0.3055	+0.0104
45:41.7	5	5.01	-0.3079	-0.0024
45:41.7	5	5.02	-0.3122	-0.0043
45:41.7	5	5.02	-0.3076	+0.0046
45:41.8	5	4.98	-0.3067	+0.0009
45:41.8	5	4.94	-0.3159	-0.0092
45:41.8	5	4.91	-0.3265	-0.0107
45:41.8	5	4.90	-0.3790	-0.0525
45:41.9	5	4.86	-0.3973	-0.0183
45:41.9	5	4.87	-0.4254	-0.0281
45:41.9	5	4.85	-0.4440	-0.0186
45:41.9	5	4.75	-0.4626	-0.0186
45:42.0	5	4.67	-0.4880	-0.0254
45:42.0	5	4.61	-0.5240	-0.0360
45:42.0	5	4.50	-0.5200	+0.0040

Upgrade of CO_2 Dead Space Test System

- **New Test System – End of Inhalation Phase – Respirator On**

Date/Time	Solenoid Valve State	CO_2 Concentration, %	Facepiece Resistance	Delta Pressure
51:09.3	5	0.44	-1.1676	+0.0024
51:09.3	5	0.42	-1.1563	+0.0113
51:09.4	5	0.42	-1.1502	+0.0061
51:09.4	5	0.44	-1.1407	+0.0095
51:09.4	5	0.43	-1.1383	+0.0024
51:09.4	5	0.44	-1.1340	+0.0043
51:09.5	1	0.41	-1.1234	+0.0107
51:09.5	1	0.42	-1.1047	+0.0186
51:09.5	1	0.41	-0.8356	+0.2692
51:09.5	1	0.41	-1.1099	-0.2744
51:09.6	1	0.41	-1.0324	+0.0775
51:09.6	1	0.42	-1.0672	-0.0348
51:09.6	1	0.41	-1.0483	+0.0189
51:09.6	1	0.42	-1.0187	+0.0296
51:09.7	1	0.42	-0.9848	+0.0339

Upgrade of CO_2 Dead Space Test System

- **Improve Data Quality Through Statistical Analysis**
  - **Reviewing current and previous test data to quantify the variability in test results across differing numbers of cycles for both the blank measurements and the respirator on measurements, with the end objective of determining how many cycles need to be run to reach an acceptable level of precision**
  - **Summary statistics will be used to descriptively characterize differences in test results between the existing and new test systems**

Upgrade of CO_2 Dead Space Test System

- Recent test results show that more blank cycles are better
- Comparison of 3-cycle blanks vs. 12-cycle blanks shown below

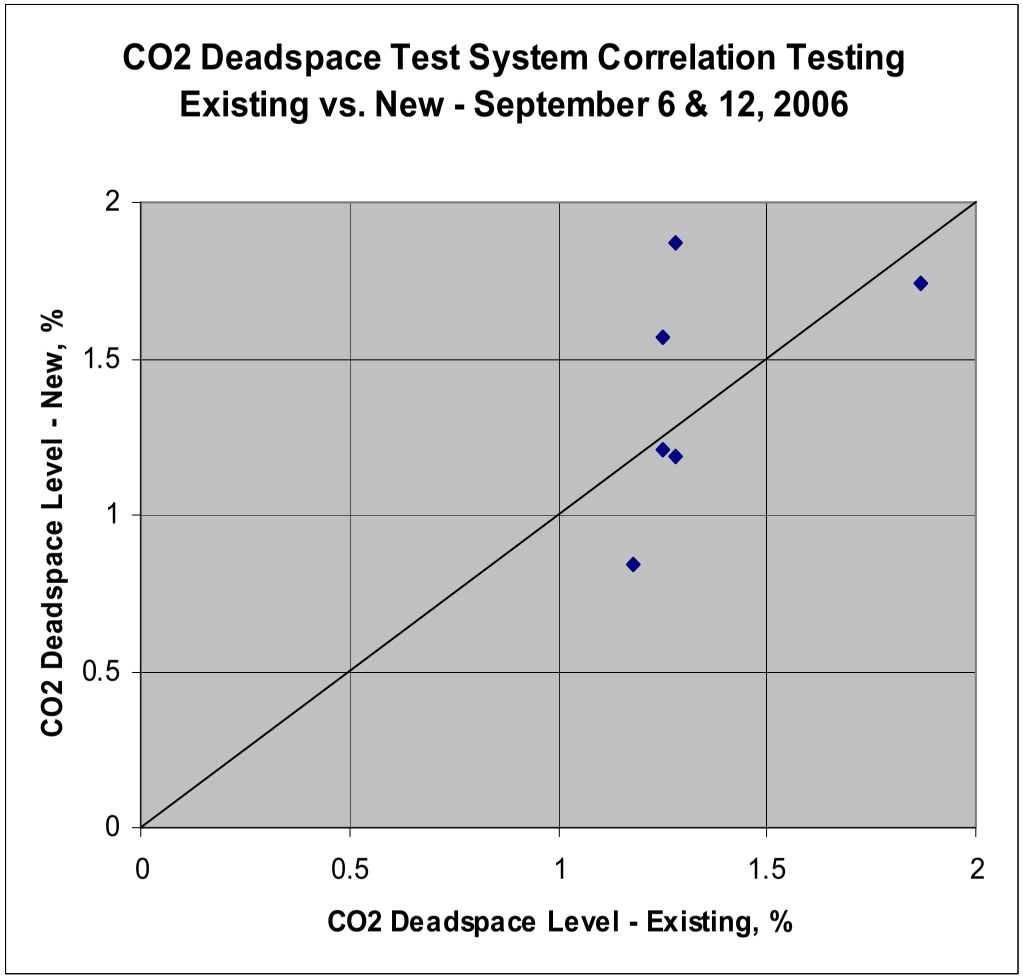
Time	09:30	10:48	11:56	1:36	2:52	3:32	3:37
Blank CO_2 (3 cycles)	0.69	0.64	0.70	0.76	0.82	0.72	0.81
Blank CO_2 (12 cycles)	0.80	0.81	0.82	0.71	0.89	0.84	0.85

Upgrade of CO_2 Dead Space Test System

- **Correlation Tests between Existing and New Test Systems**
  - **Main objective is to equate test results from the new test system with test results previously obtained from the existing test system**
  - **Modifications in equipment and test procedures will be made to the new test system as necessary to achieve this objective**
  - **Recent test results show that CO_2 Deadspace Levels measured by the new test system are generally equal to or higher than those measured by the existing test system**

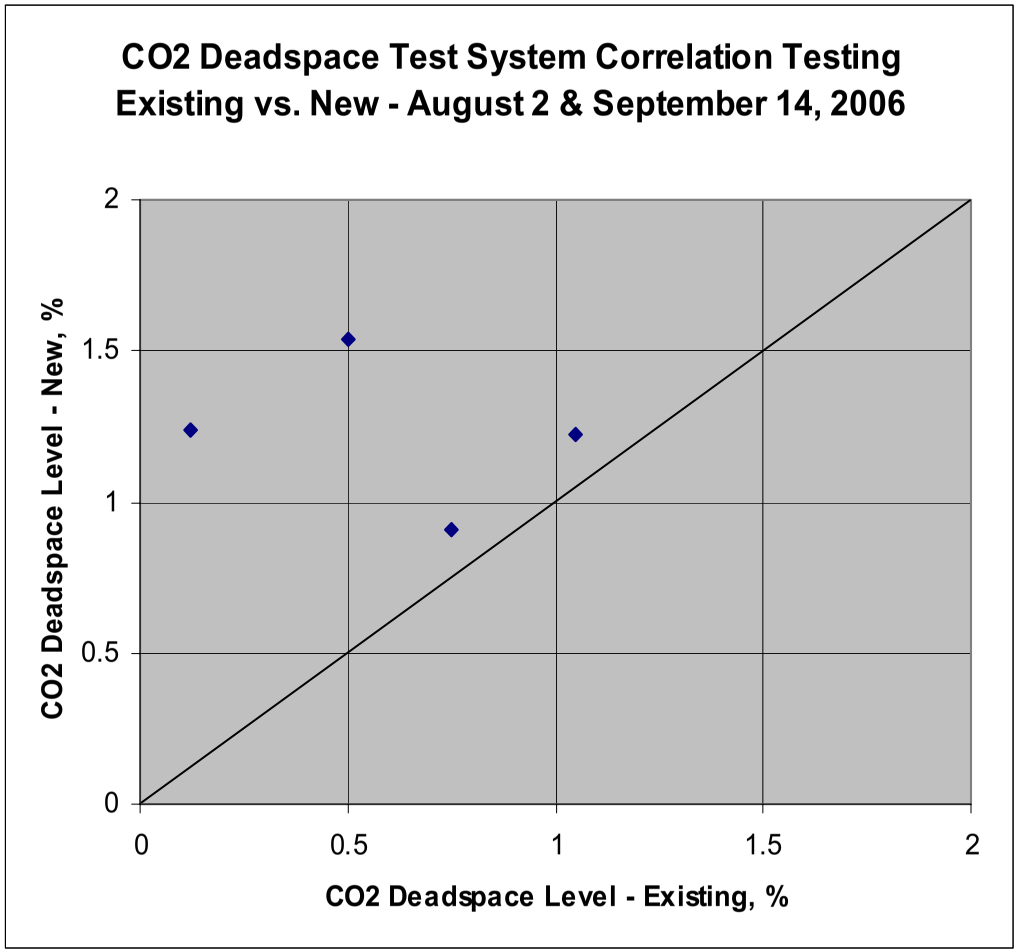
Upgrade of CO_2 Dead Space Test System

- **Recent Correlation Test Data**



Upgrade of CO_2 Dead Space Test System

- **Recent CO_2 Deadspace Test Data**



Upgrade of CO_2 Dead Space Test System

- **Schedule for Completion of Correlation Testing**
  - **Unable to make this determination at the present time**
- **Existing test system will continue to be used for certification testing, but with the use of the new data monitoring/DAS**

Questions?

National Personal Protective Technology Laboratory

Ron Powelko, M.S.
Quality Assurance Specialist

John Perrotte
Manager Enterprise Level Information Systems

Respirator Audit Logic Concept Update

October 11, 2006

Respirator Audit Logic (RAL)

- Update on the RAL (Respirator Audit Logic) that was presented on April 27, 2006 at the Marriott Key Bridge in Arlington, VA. The information pertaining to the RAL is currently posted on the NPPTL internet website.
- Letter to all NIOSH approval holders to determine the production status of approved respirators was sent out in early August.
- Responses received from NIOSH approval holders is currently 32 out of 87.
- Original deadline of October 2006 will be extended until December 2006 to give NIOSH approval holders additional time to complete and respond to the request for the production status of approved respirators.
- Follow up reminder will be sent to all NIOSH approval holders in November 2006. This is simply a reminder to complete the information request for the RAL database.

Respirator Audit Logic (RAL)

Phase 1 :

- Introduce the RAL Concept at the manufacturers' meeting on April 27, 2006 (Complete)
- Send a letter to all NIOSH Approval holders to determine production status of approved respirators by July 2006 to be returned by October 2006 (Complete)
- Receive comments and feedback on the concept or questions regarding the production status of approved respirators by December 2006 (In progress)

Phase 2

- Evaluate and develop detailed specifications for the development of the RAL and integration into the DEIMS (In progress)
- Incorporate the information for the RAL into the DEIMS (January - March 2007)
- Modify the SAF to incorporate the necessary information related to the RAL (April - May 2007)

Respirator Audit Logic (RAL)

Phase 3

- Validate the information in the CEL, DEIMS (Mfg Information) and information received from the NIOSH Approval Holders
- Validation testing of the RAL to ensure calculation and reporting is correct (June 2007)
- Status report to manufacturers (Summer 2007)
- Implementation of the RAL (Summer 2007)

Please review the RAL document at the NPPTL Webpage listed below and email any comments regarding the document to the NPPTL email address below.

http://www.cdc.gov/niosh/npptl/resources/certpgmspt/meetings/042706/pdfs/MMPresent.pdf

NPPTL@cdc.gov

Questions?

Technology Evaluation Branch

Heinz Ahlers

Other Respirator Topics

October 11, 2006

Facepiece Fit Testing
Canisters

- **May 19, 2006 letter**
  - Cartridge, canister and/or filter weight plays an essential role in respirator fit.
  - User‘s Instructions will indicate that the fit test should be performed with the exact configuration that is to be worn by the end user in the workplace
  - Where the configuration that is to be worn by the end user is not appropriate for fit testing, a specific respirator facepiece with cartridges, canisters and/or filters representative in weight and configuration may be used for fit testing.

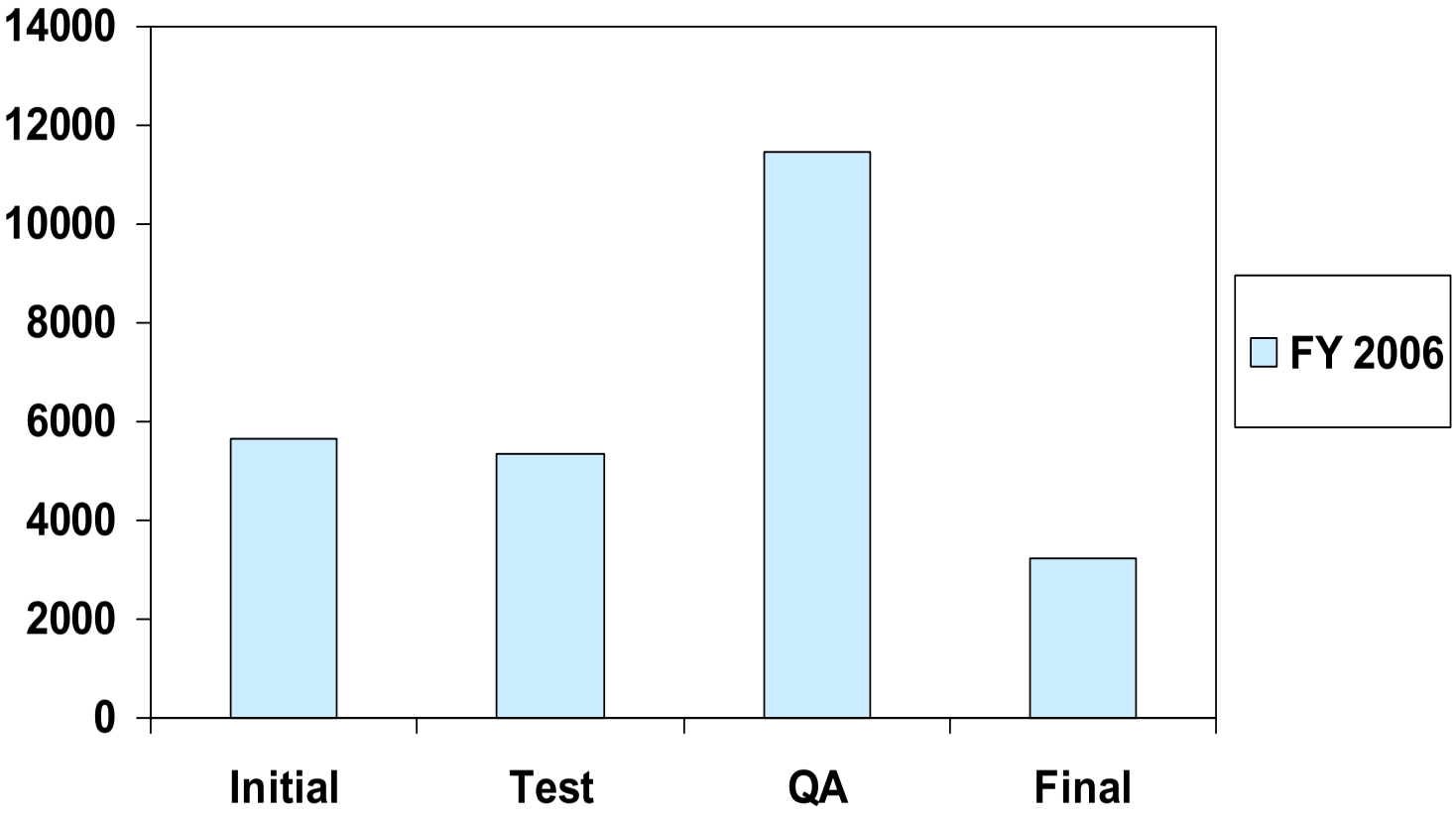
Fit Testing Continued

- **Surrogate canisters are acceptable.**

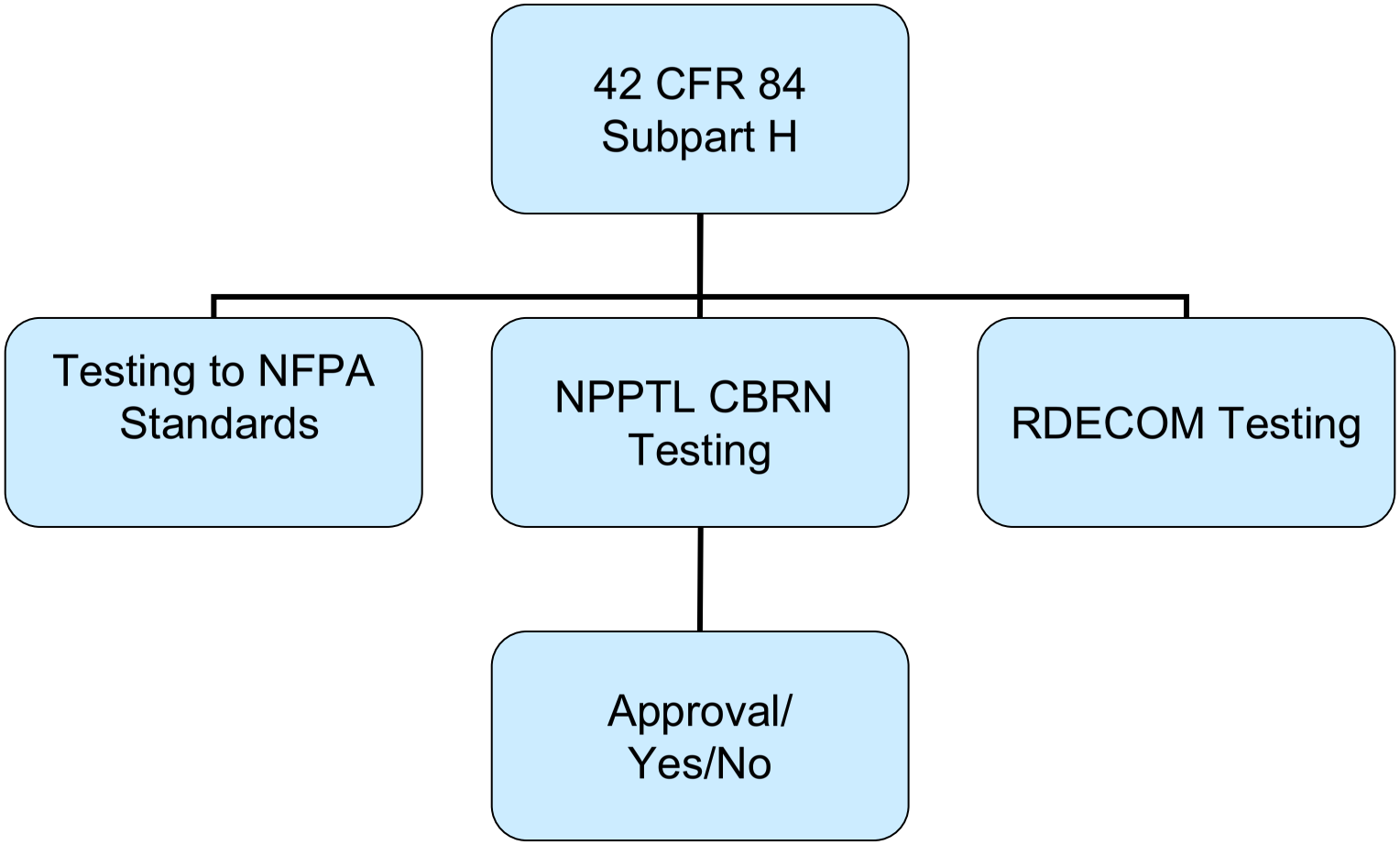
Testing on Extensions of Approvals

- **42 CFR 84.35 (e) gives NIOSH the authority to determine if testing is required.**
- **NIOSH will tend to require testing.**
- **Applications for extensions of approval to update drawing revisions that do not involve changes in process or materials will likely have a no test decision**

Time Distribution
FY 2006



NFPA NIOSH CBRN Approval



Questions?