National Personal Protective Technology Laboratory

Technology Evaluation Branch Manufacturers' Meeting

NPPTL
Pittsburgh, PA

December 12, 2005

Replacement Tracking Program

Doris Snyder

Overview

- **Purpose**
  - To help make manufacturers and the Technology Evaluation Branch more efficient
  - Reduce application processing time
  - Reduce backlog
- **Data**

Applications

Most replacements are:

- **Matrices**
- **Drawings**
- **User's instructions**
- **Amended applications**

Projects Opened and Closed by Month

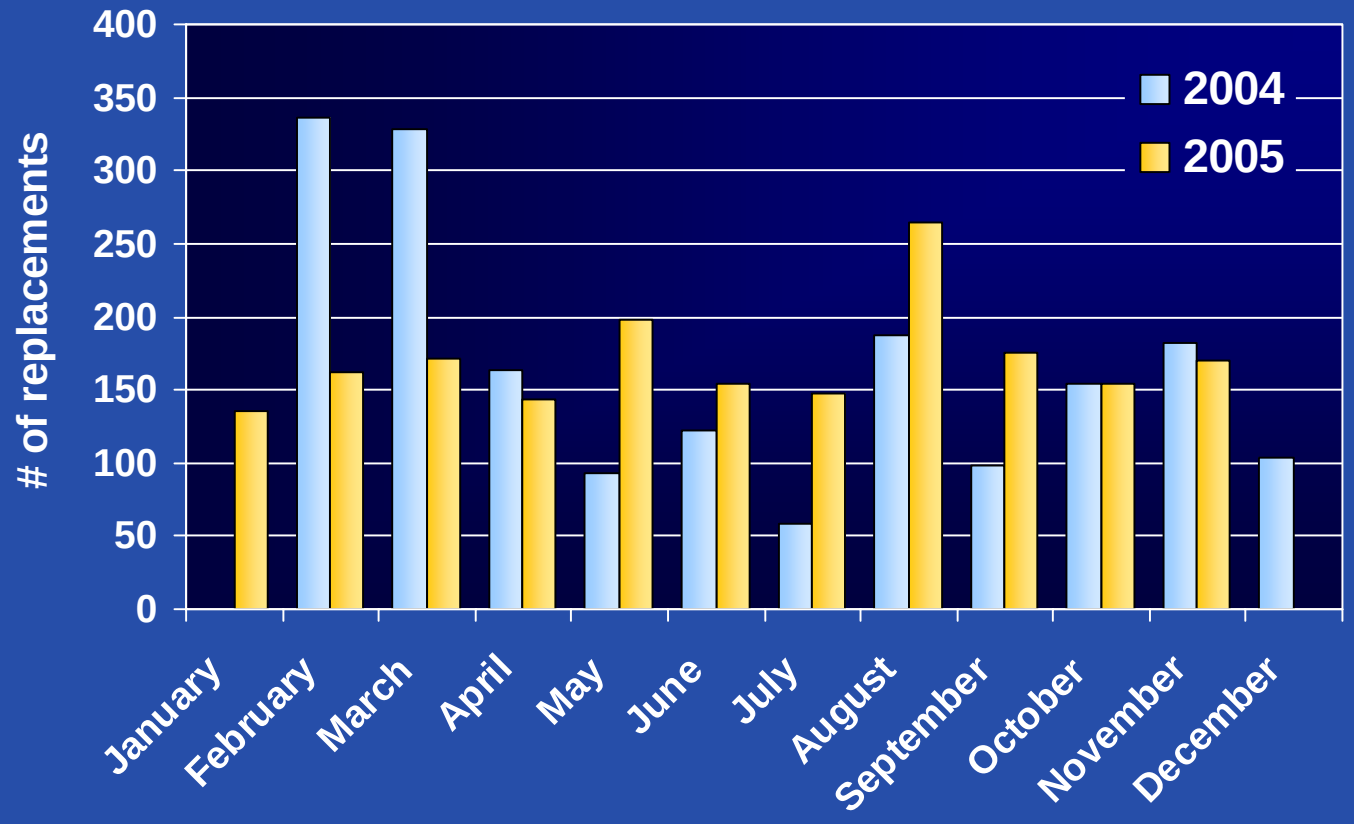
	2000		2001		2002		2003		2004		2005	
Month	Opened	Closed	Opened	Closed	Opened	Closed	Opened	Closed	Opened	Closed	Opened	Closed
January	40	47	44	31	27	39	27	21	35	20	35	12
February	31	54	10	24	51	41	35	9	53	35	27	24
March	38	61	58	12	75	24	45	14	59	75	33	40
April	49	32	35	23	44	24	37	63	48	32	20	40
May	50	35	34	26	23	24	48	64	33	34	23	51
June	38	30	33	13	36	21	59	30	39	47	40	26
July	42	16	41	48	26	31	39	47	46	37	47	24
August	45	21	51	30	36	30	39	39	48	32	30	36
Septembe	20	27	39	17	33	34	46	27	43	44	28	33
October	72	41	37	29	34	18	48	25	25	26	31	24
November	34	35	32	31	63	22	50	19	33	34	26	33
December	12	19	24	32	42	18	66	44	21	27		
Totals	471	418	438	316	490	326	539	402	483	443	340	343

Annual Replacements

	2004	2005
January		135
February	336	162
March	328	172
April	164	143
May	93	198
June	122	154
July	58	148
August	187	264
September	98	175
October	154	154
November	182	170
December	103	

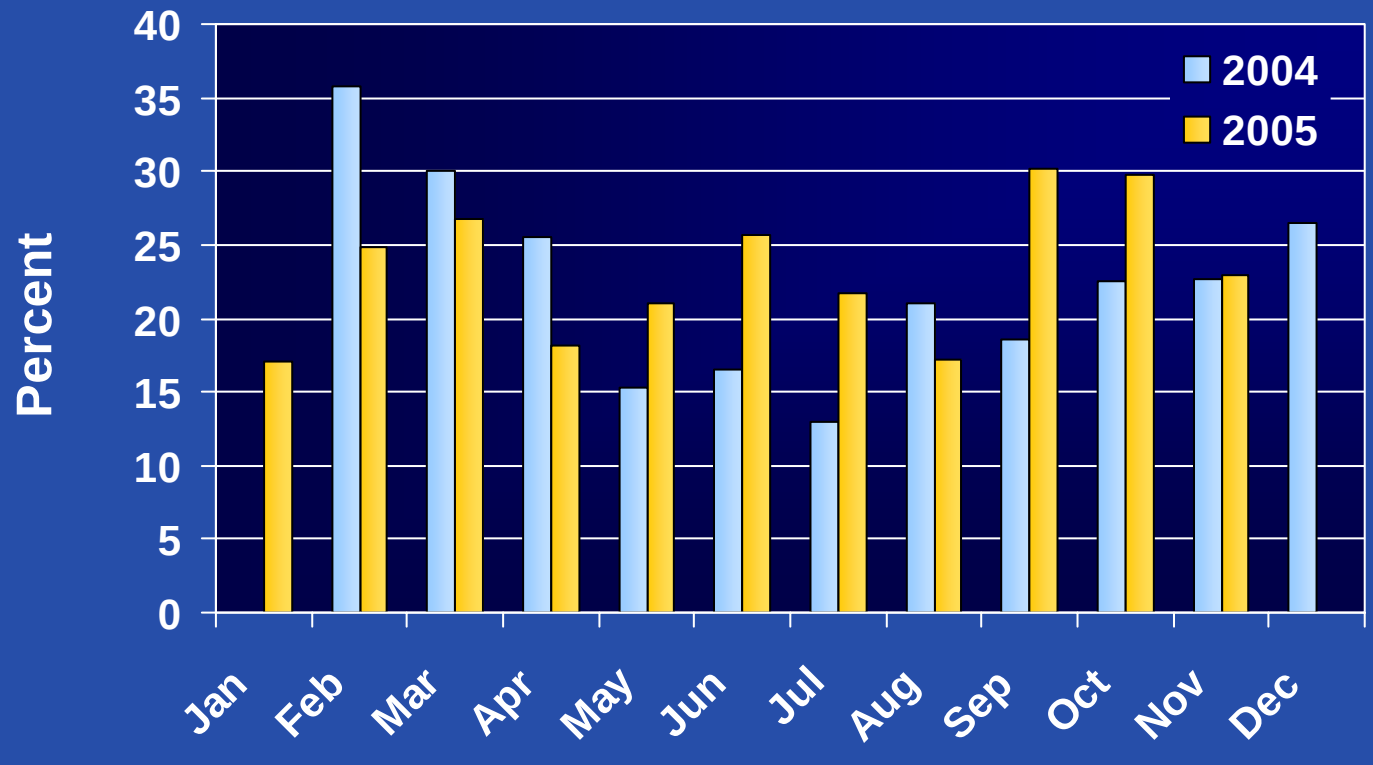
TOTAL	1825	1875

Replacements for 2004 and 2005



Percent Replacements

Monthly Rates



Replacements Compared to Total Documents

Applications

Replacements Compared to Total Documents

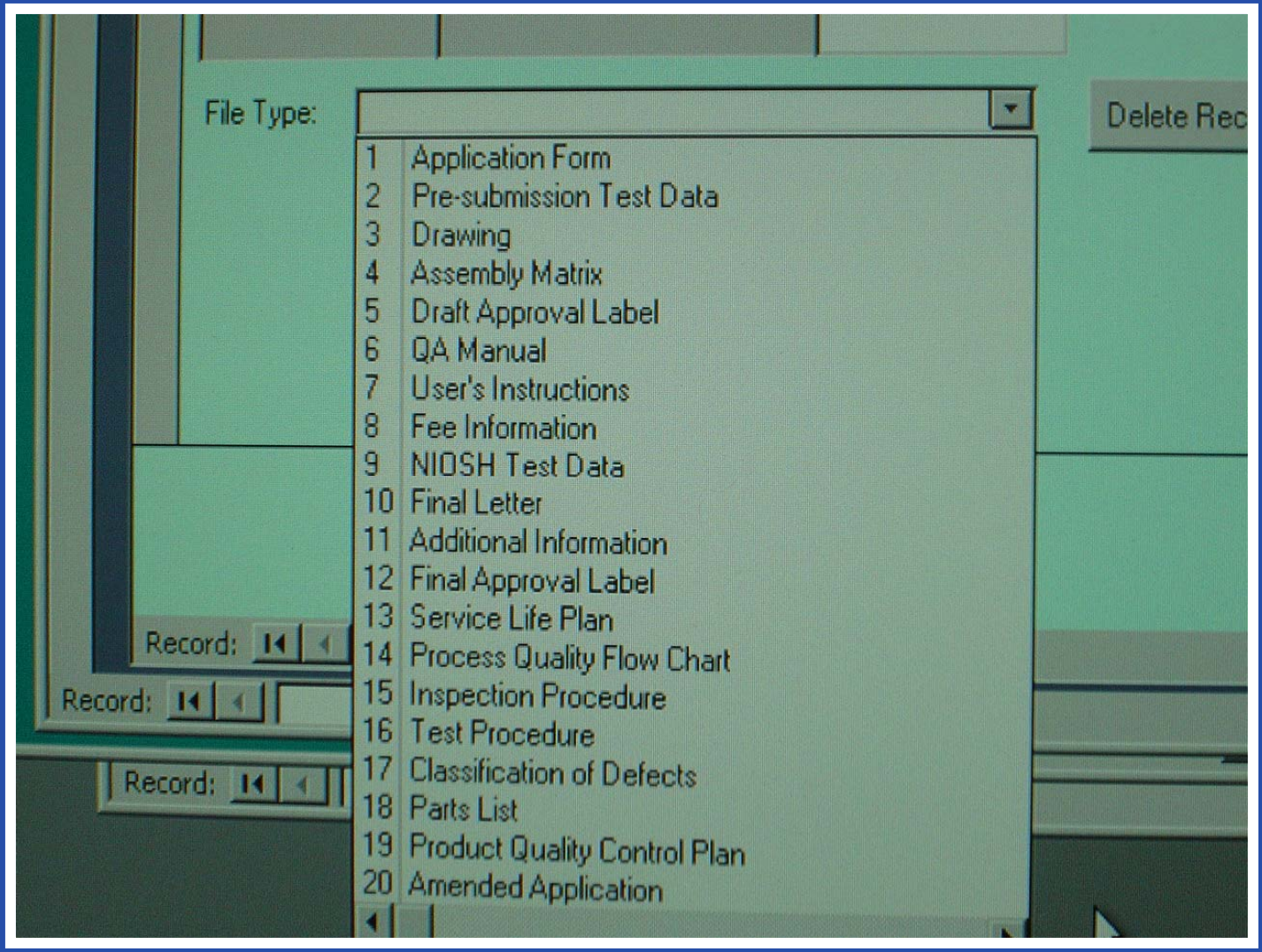
From 04/06/05 To 4/6/2005

Manufacturer Code	*Task Number*		*Replacements*	*Total Docs*	*Percentage*
		Total	#Error	#Error	#Error
		GRAND TOTAL	#Error	#Error	#Error

Wednesday, April 06, 2005

Page 1 of 1

Replacement File Type



Applications

- **Presently using Version 6**
- **Common errors:**
  - Not using current version
  - Incorrect format for AAR#
  - Incorrect extensions
  - Document list does not match the MDB file
  - Revision levels on the drawings
  - Incorrect check information or check is too old
- **Version 7**

Quality Partnerships Enhance Worker Safety & Health

Questions?

Thank you

User's Instructions

Heinz Ahlers
Ann Levitsky

User's Instructions

- **Must be included on assembly matrix**
- **When must changes be submitted to NIOSH?**
  - Changes to 'form, fit, or function' or use of the respirator may require an extension of approval application
  - Call if there are questions

User's Instructions

- **Link to user's instructions on the web**

N95: This Side Up

Heinz Ahlers

N95: This Side Up

- **N95 respirators are often worn by inexperienced users**
- **N95 respirators are frequently observed being worn upside down**
- **NPPTL recommends the use of an arrow or "This side up" marking**
- **Approvals to make this change are cost-free and will be expedited**

QA Manual Updates

David Book

Legal Requirement for QC Plan

- **42 CFR 84.40 Quality Control Plans**

  "As part of each application for approval or modification of approval submitted pursuant to this part, each applicant shall file with the Institute a proposed quality control plan…"

- **42 CFR 84.35 Changes or modifications of approved respirators**

  "(c) The application shall be accompanied by appropriate drawings and specifications, and by a proposed quality control plan…"

Definition of a QC Plan

NIOSH considers a Quality Control Plan to consist of three parts:

- **A Quality Manual - covers all manufacturing activities**
- **A Product Quality Control Plan (PQP) - covers a single approval or respirator**
- **Classification of Defects - covers a single approval or respirator**

Historic Problem

The number of Quality Manuals discovered to be "out-of-date" remains unacceptably high

- **During FY 2004 > 70% of manuals were out-of-date**
- **During FY 2005 > 25% of manuals were out-of-date**
- **Compliance statistics come from site audit**

Scope of Problem

- **The Quality Manual applies to all approvals during the time that it is the "Manual of Record"**
  - If the Quality Manual is discovered to be out-of-date, all approvals granted since the "Manual of Record" became obsolete are subject to review
  - This is becoming a point of emphasis in trying to integrate the various components of the NIOSH approval and monitoring programs

Future Plans

- **NIOSH is considering what additional investigations will be required when non-compliant quality systems are discovered**
  - Please get your Quality Manuals submitted and approved on a timely basis
  - Once the Quality Manuals are under control, the next point of emphasis will be PQPs

QA Manual Updates

Questions?

Joint Applications

Heinz Ahlers

Joint Applications

- **Requested by manufacturers**
- **Respirators comprised of components from one or more manufacturers**
- **Components retain original approval holder's name and part number**

Joint Applications

- **A letter or partnership agreement must be sent to NIOSH from each applicant company explaining the upcoming joint venture**
- **The NIOSH Records Room will issue a new manufacturer code exclusive to the joint venture**
- **One application with one primary contact**
- **All company names and addresses are required on the full approval labels and matrix**
- **Individual components of the respirator may be marked with the separate company name and part number**

Joint Applications

- **Each company must first have a quality system manual approved by NIOSH**
- **Quality documents such as inspection procedures, test requirements, and classification of defects for individual components are required**
- **A specific, detailed product quality control plan including a sampling plan is required. This plan must specify periodic audits of the complete respirator by each partner.**

Joint Applications

- **After the respirator has gained NIOSH approval, all partners are jointly and fully responsible for compliance of the complete respirator (jointly and several liability for all components). This includes any field problems or audit failures.**
- **All existing requirements, as applicable, remain in effect**

Joint Applications

Questions?

Private Labels

Doris Walter

What Is It?

- **A Private Label is a respirator that is labeled and sold as belonging to or concerning a company or interest that is not the manufacturer**
- **Only the manufacturer may apply for a Private Label**
- **Private-labeled products carry the same TC number that was issued to the manufacturer**

How to Apply

Is the part number different from the original part number?

Yes – An extension of approval application must be sent to NIOSH with updated assembly matrix, drawings, approval labels, and user's instructions

No – The private label notification form must be used

Assembly Matrix Showing Private Label

Double Wing Manufacturing Company
St. Xavier, Almost Heaven, USA
1-800-123-4567

TN or AAR# of approved or pending matrix - TN-XXXXX; DWM-05-15
Exploded view drawing number - N7502 rev A

KEY:
X - Currently Approved
N - New

THE PERFECTION FAMILY RESPIRATOR APPROVAL MATRIX

				Alternate Filtering Facepiece	
			DESCRIPTION	Double Wing	Taylor Hardware
			DRAWING NO.	N7502	N7502
			REVISION	B	B
MFG. REFERENCE NUMBER	NIOSH APPROVAL NUMBER, TC-	PROTECTION	PART NO.	Perfection 100	1027
DWM-05-16	84A-6100	P100	[redacted]	X	N
NIOSH task number where LAST tested				TN-XXXXX	N

Original Approval Label

Double Wing Manufacturing Company
St. Xavier, Almost Heaven, USA
1-800-123-4567

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection[1]	Respirator	Cautions and Limitations[2]
		Perfection 100	
84A-6100	P100	X	ABCJMNOP

1. Protection

P100- Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols.

2. Cautions and Limitations

A - Not for use in atmospheres containing less than 19.5 percent oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
J - Failure to properly use and maintain this product could result in injury or death.
M- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P - NIOSH does not evaluate respirators for use as surgical masks.

Private Label Approval Label

Taylor Hardware
48 Pine Street
Taylor PA 18517
1-800-555-1321

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection[1]	Respirator	Cautions and Limitations[2]
		1027	
84A-6100	P100	X	ABCJMNOP

1. Protection

P100- Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols.

2. Cautions and Limitations

A - Not for use in atmospheres containing less than 19.5 percent oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
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P - NIOSH does not evaluate respirators for use as surgical masks.

New Requirement!

- **A request for approval of a private label where the part number does not change must include:**
  - Private label notification form

AND

  - Abbreviated approval label

Private Label Notification Form

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Certification, Evaluation and Testing
626 Cochrans Mill Road
Pittsburgh, PA 15236

PRIVATE LABEL NOTIFICATION FORM

This manufacturer and approval holder is providing the following information to NIOSH regarding its intent to "private label" certain of our approved products, or to update status.

New: X **Discontinued:** _____ **Modified:** _____

Approval Holder Information:

Manufacturer/Approval Holder: Double Wing Manufacturing Company

Certification/Approval Number(s): TC-84A-6100

Model or Trade Name(s): Perfection 100

Private Label Vendor Information:

Vendor Name: Taylor Hardware

Address: 48 Pine Street

City: Taylor State: PA

Country: USA Zip/Postal Code: 18517

Phone: 800-555-1321 FAX: 800-555-1322

Date

Signature of Manufacturer's Authorized Representative

Sample Abbreviated Label for a Filtering Facepiece

This side up

TAYLOR HARDWARE
PERFECTION 100
NIOSH P100
LOT xxxxxx

Frequently Asked Questions

Where can I find the form?

- **The form can be found in the Standard Application Procedures and copied as needed**
- **If an electronic version is needed, please call the Records Room or any of the reviewers to request it**

Frequently Asked Questions, cont.

How should I send the form and the abbreviated label to NIOSH?

- **They can be faxed, mailed, or submitted electronically to the Records Room**

Frequently Asked Questions, cont.

Is there a fee for requesting a Private Label approval?

- **No fee is required**

Private Labels

Questions?

PAPR Silica Dust Test Replacement

Tom Pouchot

Introduction

- **Industrial PAPR Standard**
  - Change in approval requirements
  - Investigate replacement of silica dust test
    - Evaluate current test
    - Propose improved certification test process
    - Propose new test

Current Test Evaluation

- **Positive**
  - Unit under a specific dust load
  - Battery and blower under a load for a set timeframe
- **Negative**
  - Silica dust low REL
  - Hard-to-hold concentrations
  - Repeatability

Improving Current Dust Test

- **Other particulate materials**
  - Dolomite
    - EN test
  - Amorphous silica
    - Higher REL
  - Talc
  - Polymers
  - Salt

New Test Proposals

- **Combination tests**
  - Motor / blower / battery performance
    - Service time with added filter load
  - Unit performance with loaded filter
    - Service time under constant load
  - Loading / performance test
    - Set dust load

Current Status

- **Investigating other dust materials**
  - 10 different dust materials
    - Higher RELs
  - Dolomite
  - Polymer
    - Polystyrene
  - Salt

Current Status

- **Performing salt loading test**
  - Feasibility testing
  - In conjunction with unit performance
  - Matching salt load to silica dust load
    - Side-by-side tests

Salt Loading Test

- **Results to date**
  - Using current TSI machine to load filters
    - Load time is more than 1 hour
  - PAPR unit flow after assembly with salt loaded filter greater than silica dust test final flow

Current Status

- **Investigating other tests procedures**
  - EN dust test with dolomite
  - Combination tests:
    - Developing test protocols
    - Evaluating test process

Industry Input

- **Input on program**
  - Other tests or processes investigated
  - Suggestions
  - Comments

PAPR Silica Dust Test Replacement

Questions?

Fit Test Alternative

Bill Hoffman

Presently

- **Isoamyl acetate (IAA) fit test**
- **Test subjects screened for ability to detect IAA**
- **Exercises performed**
  - 2 minutes nodding and turning head
  - 2 minutes calisthenic arm movements
  - 2 minutes running in place
  - 2 minutes pumping with tire pump into a 28 liter container
- **Pass/fail based on detection of IAA**

Proposed

- **Utilize the Portacount Plus**
- **This will be an additional test when IAA test results are in question**
- **May lead to regulation change**
- **Presently undergoing evaluation on a series of respirators**

Portacount Test Setup

- **Obtain manufacturer's probe kit or pre-probed masks**
- **Set Portacount in "realtime" mode**
- **Perform same exercises as for IAA**
- **Note real time readings**
- **Not an attempt to see if respirator fits an individual**
- **Purpose is to see if respirator can fit and continue to fit general population**

Proposed Pass/Fail Criteria

- **Observe the fit factor**
- **Record any occurrences where the fit factor falls below the pass/fail level of APF X10**
  - 50 for quarter masks
  - 100 for half masks
  - 250 for hoods or helmets
  - 500 for full facepieces

If a Failure Should Occur

No change from present

- **1 failure for 1 size fits all**
- **No failures for multiple sizes**
- **If fit check reveals a fit problem, re-fit or use a different subject**

Fit Test Alternative

Questions?

NPPTL Certified Product Investigation Process (CPIP)

Kim C. Gavel

CPIP Goal

The main goal of CPIP is to provide a consistent, quality service for the Technical Evaluation Branch customers by investigating the nonconformance of NIOSH-certified products.

CPIP / Post-certification Activities

- **Manufacturer site audits**
- **Product audits**
- **Firefighter performance testing**
- **Long-term field evaluation**
- **Investigations**

Manufacturer Site Audits

- **On average, NPPTL performs 40 site audits per year, 20 domestic and 20 international**
- **Identify areas for improvement and verify the resolution of previous site audit findings and any QA / performance issues**
- **Document audit results and submit report to manufacturers**

Product Audits

- **NPPTL conducts an average of 58 product audits per year**
  - 18 air-supplied
  - 40 air-purifying
- **Conduct quality assurance evaluation**
- **Conduct respirator performance testing**
- **Initiate corrective actions to address any failure**
- **Work with manufacturer to resolve failures**
- **Submit report to manufacturer**

Firefighter SCBA Performance Testing

- **Conduct an average of 12 investigations per year**
- **Conduct performance testing on questionable units**
- **Document findings and submit report to requesting agency**

Long-Term Field Evaluation

- **Conduct performance tests on 200 self-contained self-rescuers (SCSR) each year**
- **Conduct performance tests on 50 filter self-rescuers (FSR) per year**
- **Monitor performance of field deployed units**
- **Document findings and recommendations**

Certified Product Investigation Process

- **NPPTL investigates an average of 45 respirator nonconformance events per year**
- **Investigations determine contributing factors leading to the QA / performance failure**
- **Initiate corrective actions with manufacturer**
- **Document investigation and corrective actions**
- **Report corrective actions to end users**

Current Status

Open Projects – 2005

	Jan 1, 2005	Nov 30, 2005
CPIP investigations	99	42
Product audits	94	13
Firefighter investigations	12	7

NPPTL Certified Product Investigation Process (CPIP)

Questions?

Upgrade of CO_2 Dead Space Test System

Gary Walbert
EG&G Technical Services, Inc.

Upgrade of CO_2 Dead Space Test System

- **Why upgrade the CO_2 Dead Space Test System?**
  - Improve accuracy in setting test conditions and performing data analysis
  - Reduce variability from test to test
  - Allow manufacturers to duplicate the test system using commercially available components for direct correlation

Upgrade of CO_2 Dead Space Test System

- **What has happened since the last Manufacturer's Meeting in July 2005?**
  - Finalized specifications for Sheffield Head headform and half-torso assembly and breathing machine with sedentary cam
  - Completed specification of all remaining test components, including instruments, tubing, fittings, valves, and calibration gases

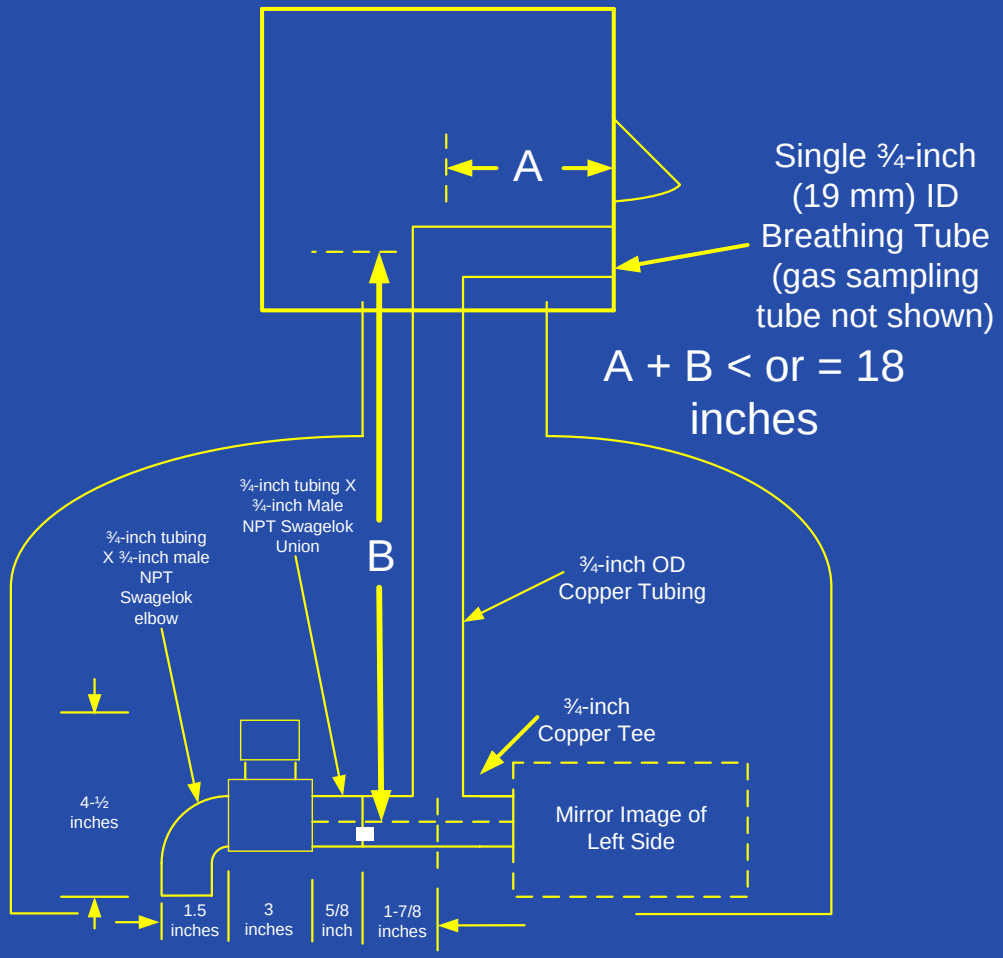
Upgrade of CO_2 Dead Space Test System

- **What has happened since the last Manufacturer's Meeting in July 2005?**
  - Obtained prices for all required components from their vendors/manufacturers and placed purchase orders
  - All components have been delivered with the exception of the breathing machine
  - Inspected Sheffield Head headform and half-torso upon delivery – gas sample tube inner diameter was found to be 0.027-inch instead of 0.05-inch ID requested

Upgrade of CO_2 Dead Space Test System

- **What has happened since the last Manufacturer's Meeting in July 2005?**
  - Pressure drop through 0.027-inch ID tube at sample gas flow rate of 500 cm^3 per minute is excessive
  - 0.05-inch ID gas sample tube is consistent with 42 CFR, Part 84
  - INSPEC agreed to fabricate new Sheffield Head headform and half-torso

Upgrade of CO_2 Dead Space Test System



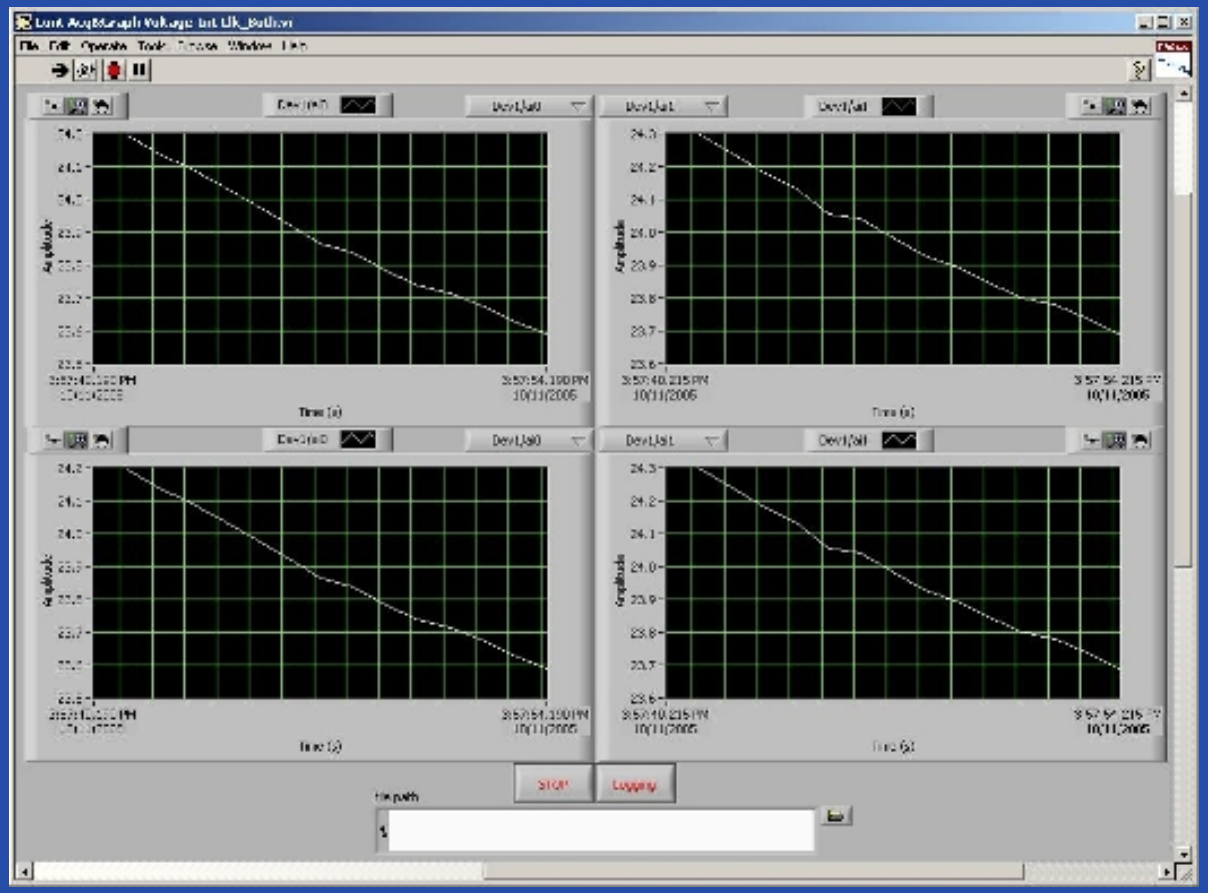
Proposed Sheffield Head w/Half Torso and Single Breathing Tube

Upgrade of CO_2 Dead Space Test System

- **What has happened since the last Manufacturer's Meeting in July 2005?**
  - Specified Data Acquisition System (DAS) run by LabVIEW software
    - Test data recording frequency of 25 milliseconds
    - Pressure trend logging delayed by 0.2 seconds relative to CO_2/O_2
    - Set-up mode with trending of data on up to four user-selectable, single-plot charts
    - Run mode – same as set-up mode, but will include logging instrument inputs and relative time in second(s) to a spreadsheet file

Upgrade of CO_2 Dead Space Test System

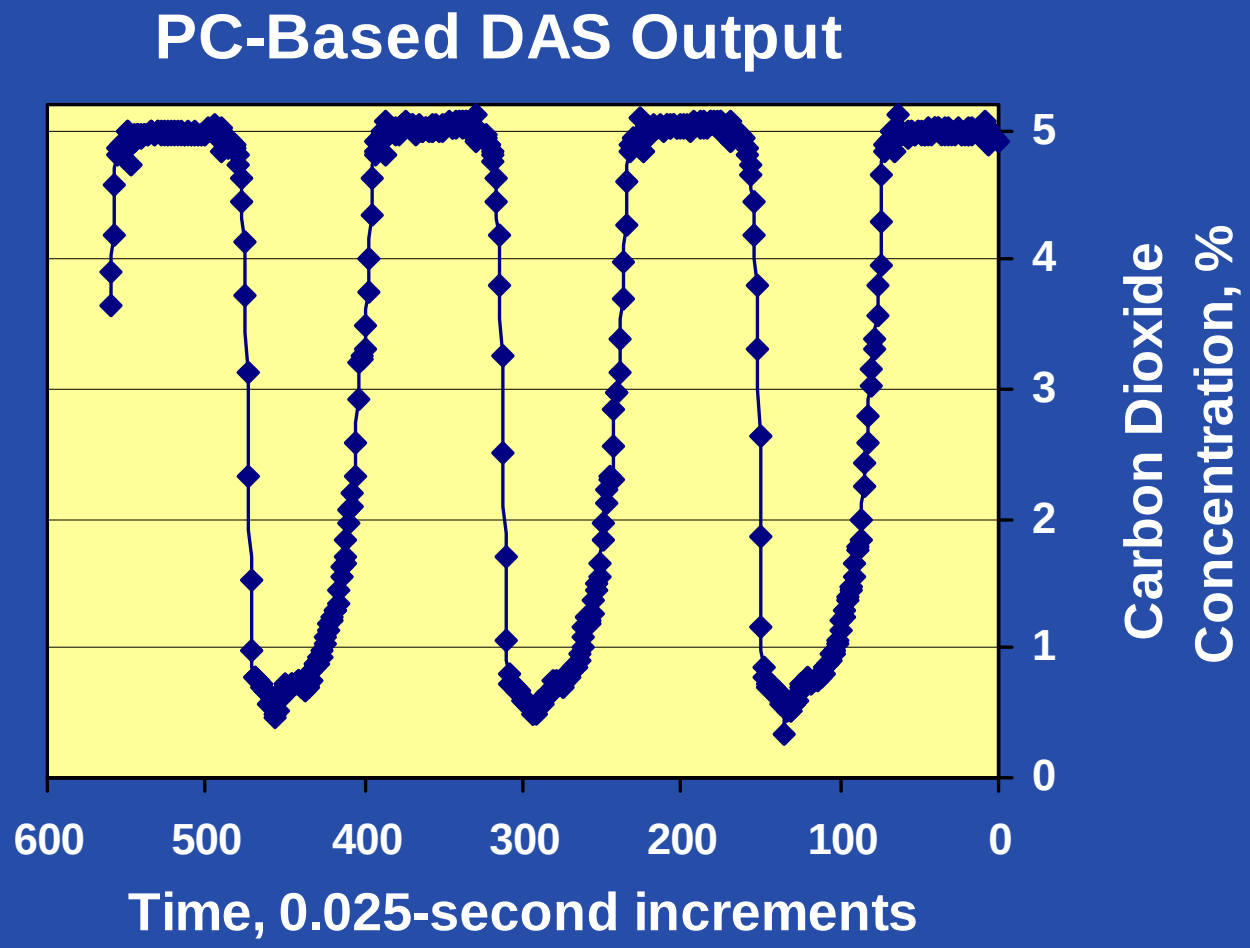
Data Acquisition System Screen Shot



Upgrade of CO_2 Dead Space Test System

- **What has happened since the last Manufacturer's Meeting in July 2005?**
  - Connected CO_2 gas analyzer of existing CO_2 Dead Space Test System to new personal computer (PC)-based DAS and strip chart recorder installed in parallel
  - Performed trial test using PAPR installed on headform with blower turned off
  - Results from two data collection methods compared favorably
  - CO_2 concentrations measured using new DAS were slightly lower than those recorded by strip chart recorder for each inhalation cycle

Upgrade of CO_2 Dead Space Test System



Upgrade of CO_2 Dead Space Test System

Inhalation Cycle No.	PC-Based Data Acquisition System	Strip Chart Recorder
1st Cycle	1.58% CO_2	1.62% CO_2
2nd Cycle	1.48% CO_2	1.61% CO_2
3rd Cycle	1.60% CO_2	1.65% CO_2
Average	1.55% CO_2	1.63% CO_2

Upgrade of CO_2 Dead Space Test System

- **What has happened since the last Manufacturer's Meeting in July 2005?**
  - Identified location to house the new CO_2 Dead Space Test System
  - Remodeled the western portion of Building 21 and built new room that contains an 8-foot X 6-foot area for new test system
  - Photographs of the new area follow

Upgrade of CO_2 Dead Space Test System

Building 21 Exterior

Upgrade of CO_2 Dead Space Test System

Test System Room within Building 21

Upgrade of CO_2 Dead Space Test System

Test System Bench

Upgrade of CO_2 Dead Space Test System

Test System Components

Upgrade of CO_2 Dead Space Test System

Questions?