

Welcome to the NIOSH NPPTL Meeting for All Respirator Manufacturers

August 27, 2014

AGENDA

Time	Topic
8:30am – 9:00 am	Registration
9:00am – 9:15 am	Welcome/Meeting Protocols/Future Meetings
9:15am – 9:30 am	NPPTL Organization Update
9:30am – 10:30am	Respirator Approval Processing Times
10:30am – 10:45am	Break
10:45am – 12:00pm	Collection of Certification Fees through Pay.Gov
12:00pm – 1:00pm	Lunch
1:00pm – 1:15pm	Overview of Standard Application Procedure
1:15pm – 2:00pm	OMSHR Research Activities
2:00pm - 3:00pm	Staff available for one-on one meetings

Today's Activity Reminders

- Rest rooms off the lobby
- Escorts required for other movement
- Cash Payment for pre-ordered lunches
- Restrictions on departing site
 - Surrender Visitor ID
 - Repeat visitor processing for re-entry
- TEB personnel available for discussions

Save the Date

October 22, 2014 Next Manufacturer's Meeting

- Main Subject: Updates to the Standard Application Procedure
- Other Topics of Interest

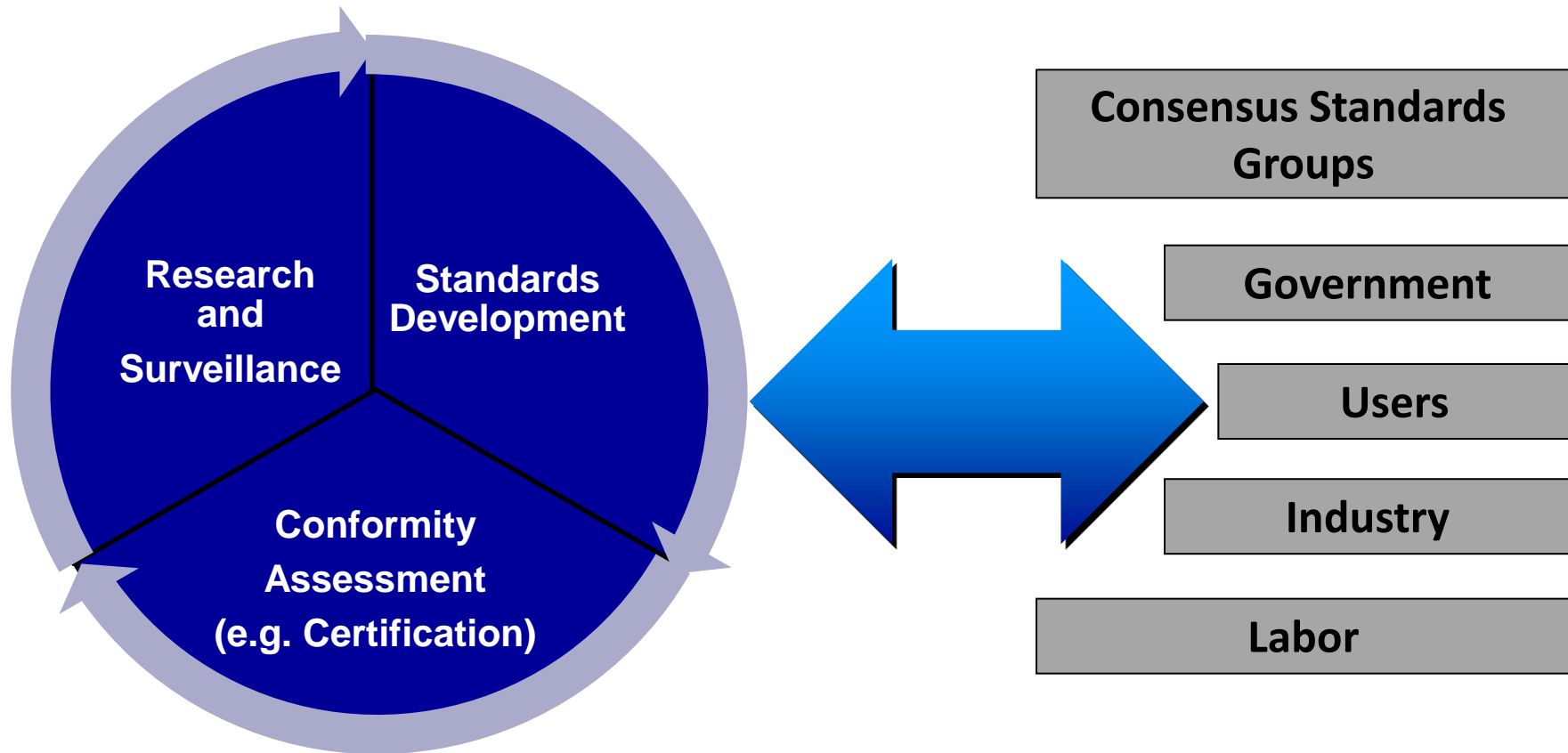
NPPTL Organization Update

Dr. Maryann D'Alessandro

Director

NIOSH - NPPTL

NIOSH continually involves stakeholders in our activities to provide input into relevance, sustainability, and impact.



Stakeholders: Provide inputs, utilize outputs, and together produce positive outcomes affecting worker safety and health

NIOSH/NPPTL is leading a national effort to ensure adequate supplies of various types of RPD for its 12 million healthcare workers during normal operations, as well as emergency situations including pandemics.

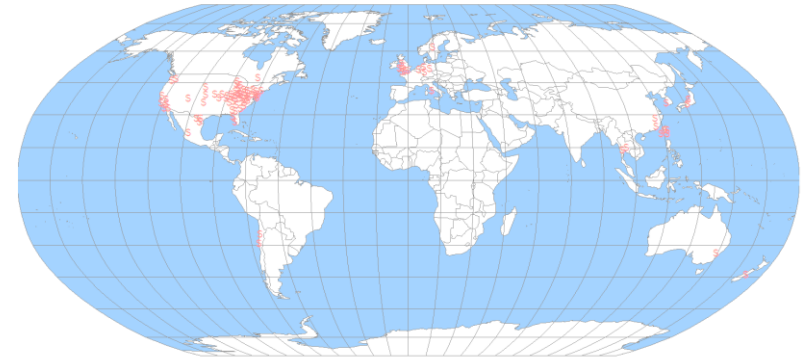


Photos Courtesy of (Left to Right): Kimberly Clark and Moldex,

NIOSH Respirator Approval CY2013 Statistics

- 93 approval holders
- 130 manufacturing sites
 - 20 countries

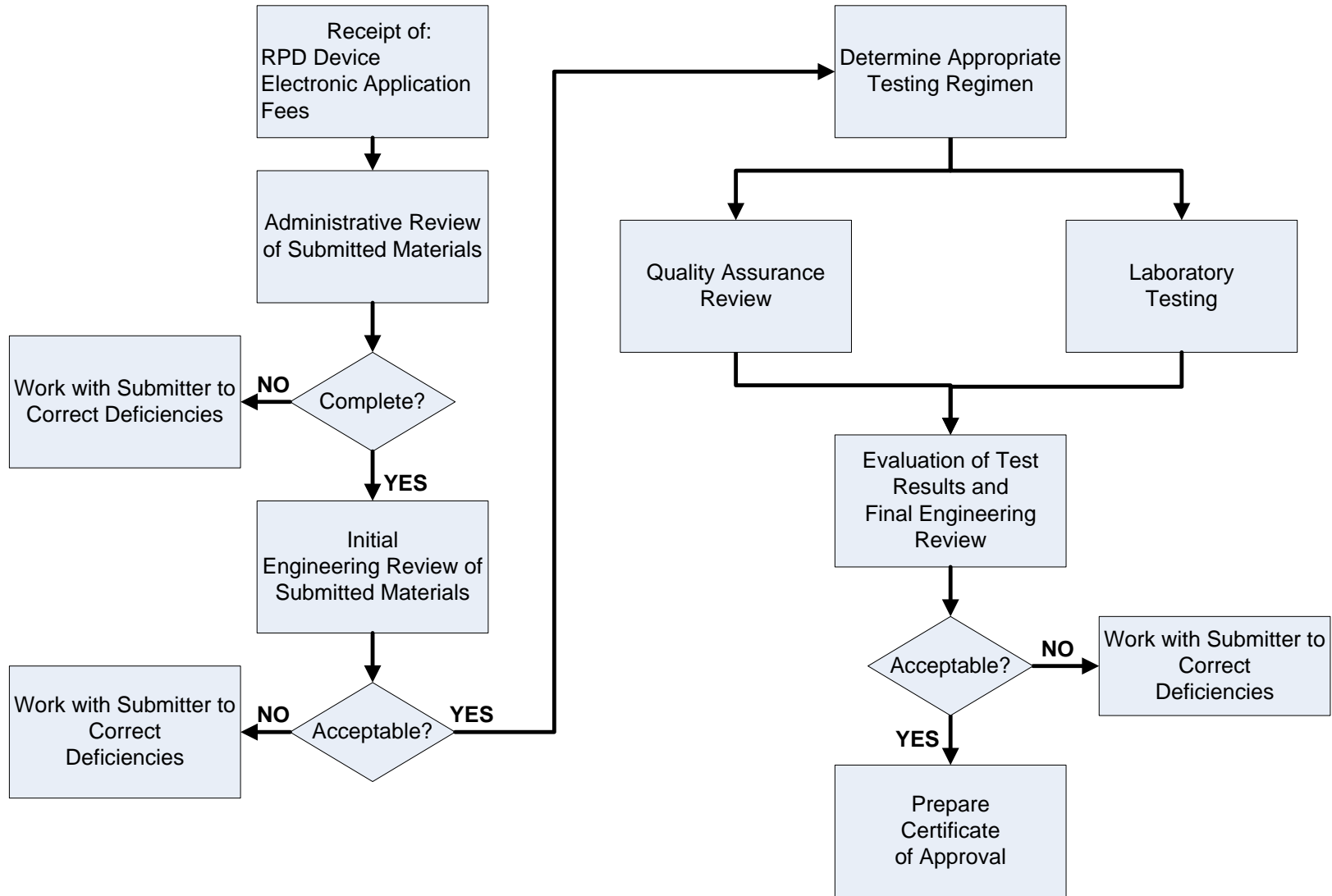
Australia	Brazil	Canada	Chile
China	Columbia	Denmark	England
Finland	Germany	India	Italy
Japan	Korea	Mexico	New Zealand
Taiwan	Thailand	Sweden	U.S.



≈ 354 application decisions
≈ 222 applications approved
≈ 663 new approvals

63% average annual approval rate

Respirator Certification Process is Service Focused



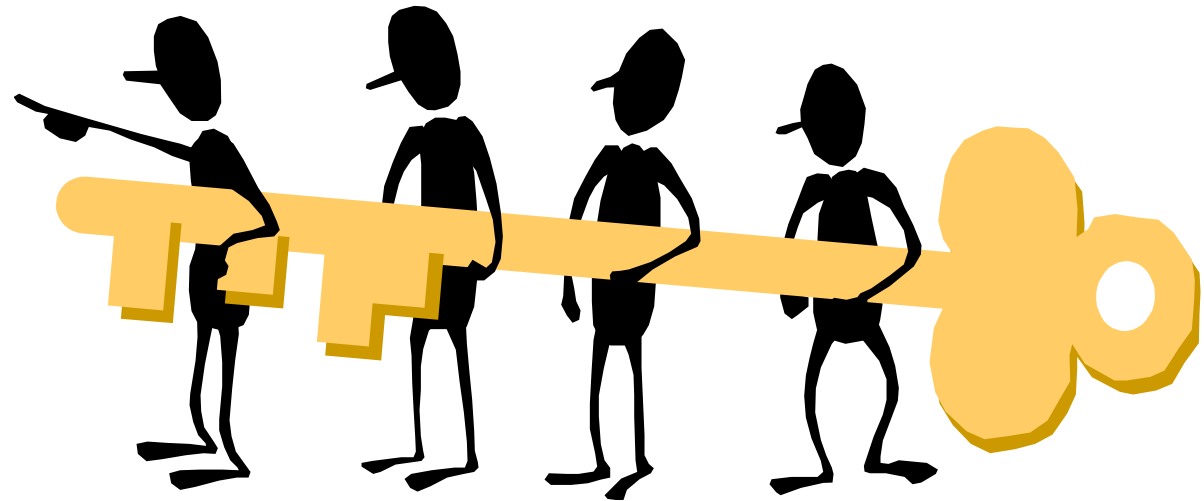
What story is told by the Respirator Certification Statistics?

Fiscal Year	Number of Decisions		Types of Requests	Number of Approvals Issued
	Total	Affirmative/Negative	New/Extension	Total
FY14	349	277/72	154/195	513
FY13	325	261/64	103/222	544
FY12	395	321/74	132/263	933
FY11	521	389/132	176/345	505
FY10	466	340/126	159/307	152
FY09	451	356/95	143/308	748

What are the keys to success for NIOSH and manufacturers to most effectively work together?

As focus of certification program is shifted to align with the fees module, how do we work together with the manufacturers to most effectively serve their needs and NIOSH emphasis on

- efficiency (including timeliness)
- integrity (including fairness)
- quality



Respirator Approval Processing Times

**Jon Szalajda, Jeff Peterson, Bob Stein,
Tom Pouchot, Pat Wiltanger**

**Technology Evaluation Branch
Functional Activity: Conformity Verification**

Respirator Approval Program Priorities

- **Conformity Assessment**
- **Pandemic Preparedness**
- **Quantity/Quality of Applications**
- **Laboratory Realignment**

Conformity Assessment Priority Activities

Conformity Assessment priority activities to enhance the respirator certification program

- Increased Post Market Investigations (CPIPs)
- Increased Oversight Activities (ECBC)
- Increased testing to support new standards (NFPA 1981, CCER)

Opportunities for Improvement:

- Reassigning and training staff to address turn-around times
- Procedural/Oversight Changes (e.g. time tracking app)
- Potential use of other resources for testing

Conformity Assessment Priorities

Priority Activities

- Process Team working toward ISO 17025 credentials
- Testing efficiencies are expected through updated STPs
- Additional personnel resources have been established in Initial and Final Review

Opportunities for Improvement:

- Organizational re-alignment to eliminate bottlenecks and create opportunities to distribute expertise in high priority areas.
- Procedures and sub-procedures established to support work flows
- Modification of the Standard Application Procedure to facilitate more efficient processing

Pandemic Planning is a NIOSH Priority Supporting National Preparedness

Challenge: There is an increased national emphasis on pandemic preparedness impacting

- Federal, state and local respirator stockpile management concerns
- FDA/HHS interactions, including FDA workshop
- Shelf-life extension questions

Opportunities for Improvement:

- CDC issued RFI to manufacturers to better understand Respiratory Protective Device supply and distribution issues
- Rescission Process addressed product conformance issues
- Coordination/Discussions with approval holders

NIOSH Observations of Applications Processed

Challenge: Linked projects create complexity in calculating processing times

- Accommodate the applicant's desire to minimize paperwork and expense
- Provides more efficiency for processing interdependent applications
- Counts as more than one project for calculating processing time

Opportunities for Improvement:

- Don't accept linked applications (not desired)
- Change bookkeeping (count as one, not multiple projects)
- Create a work group between NIOSH and applicants to establish a joint solution

NIOSH Observations of Applications Processed

Challenge: Deficiencies in received applications have led to increased in respirator approval times.

- 20% of materials submitted in all applications have to be replaced

Opportunities for Improvement:

- Continue the current operational model to start new projects while waiting for applicant responses and don't stop the clock
- Deny applications when issues are identified instead of working to resolve issues
- Stop the clock while waiting for applicant response
- Create a work group between NIOSH and applicants to establish a joint solution
- Develop an Application Quality Checklist to remind applicants of common errors experienced

Additional Opportunities for Improvement: NIOSH can develop an *Application Quality Checklist* to remind applicants of common errors. **For example:**

- Is a unique AAR used?
- Ensure all major sections of the application are included
- Verify Hardware is labeled properly and matches the application
- Match the Assembly matrix with the application
- Provide a complete listing of files in the SAF
- Ensure the Assembly matrix, exploded view drawing, approval labels, or major sub-assembly drawing are correct
- Verify that the user instructions contain required elements
- Proof the Electronic SAF for errors
- Verify items on the assembly matrix correspond exactly to the Reason for Application
- Verify Drawing revision levels are correct

NIOSH Observations of Applications Processed

Challenge: Complexity of modern applications requires early coordination to discuss how applicants want to address current and future approvals; minimize misunderstandings and rework

Opportunities for Improvement:

- Apply lessons learned from other consolidations based on the situation
- Create a work group between NIOSH and applicants to establish a joint solution

Summary of Opportunities for Improvement

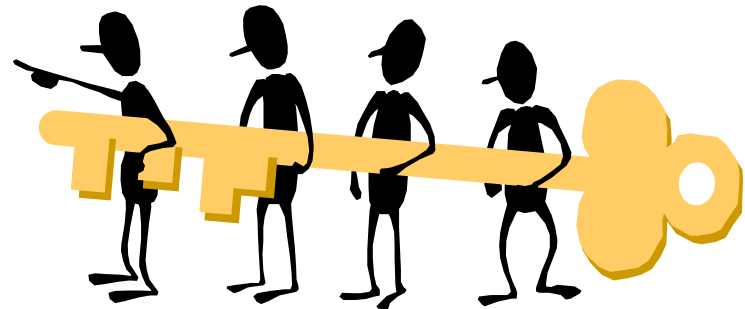
- NIOSH is establishing approaches to monitor and shift resources to support priority NPPTL issues while minimizing impact on routine flow
- Applicants should meet with NIOSH prior to submittal of complex applications or submit new technologies
- Applicants could identify alternate contacts to facilitate interactions
- Communicate times when applications are prioritized based on National Need e.g., FFR, CCER, CBRN SCBA
- Assess interest in establishing working group

Is there sufficient interest in manufacturing community to establish a working group?

- Working group to address key issues designed to improve the respirator certification services provided by NIOSH could be established.
- Identify potential topics to discuss
 - Rejection criteria in SAP
 - Linked applications
 - Identifying alternate applicant contacts to reduce waiting times
 - Prioritizing applications based on National Need
 - e.g., FFR, CCER, CBRN SCBA
 - Exploring opportunities for using alternative test labs

Questions to arrive at keys to success between NIOSH and manufacturers

- How many applications are rejected and where in the process are they rejected?
- How does NIOSH most effectively monitor application processing time including hold times and linked applications?
- What are the tradeoffs between holding a partially completed application open versus denial and beginning anew with a revised submitted application?



Open Discussion And Questions?

BREAK

Collection of Certification Fees through Pay.Gov

Jon Szalajda / Jeff Peterson

Technology Evaluation Branch

Functional Activity: Conformity Verification

Pay.Gov is Available for Use

- **CDC has implemented the use of an electronic government collections system called Pay.Gov**
- **Pay.Gov offers the federal government an Internet method to collect debts owed to them via Automated Clearing House (ACH) and Credit Card processing**
- **This service is free of charge to federal agencies**

Use of Pay.Gov

- Customers can make one-time payments or recurring payments
- Pay.Gov offers customers the option to create customer profiles that can expedite recurring transactions
- All processing is done via the Internet

Draft NIOSH Fee Payment User Instructions

Pay.GOV Registration Process

- Prior to making any payment of respirator certification fees Manufacturers need to establish an account with Pay.GOV

Pay.gov homepage <https://pay.gov/paygov/homepage>

- On the center of the page click on the link “**Click here to register**” to start the process or use the link provided below

Registration:

<https://pay.gov/paygov/accounts/selfEnrollmentRob.html>

Draft NIOSH Fee Payment User Instructions

Review of Draft Word Document

Draft NIOSH Fee Payment User Instructions

- NIOSH is interested in working with manufacturers to conduct pilot applications of Pay.Gov
- If you are interested in piloting the application, please contact Jeff Peterson, jap3@cdc.gov, 412-386-4014

Questions?

LUNCH

Updates to the Standard Application Procedure (SAP)

Bob Stein

Technology Evaluation Branch

Functional Activity; Conformity Verification

Standard Application Procedure

- **The application process is little changed since 1995.**
 - Many applications still incorporated paper documents
 - Much has changed with regard to IT (information technology)
 - Always room to improve

Standard Application Procedure

• Ye Old Way

- All applications are created equally, really?
- One application, one approval?
- It seldom works this way
- Results in missing information that must be synthesized
- Change **process** to match **practice**, or...
- ... change **practice** to match **process**

Standard Application Procedure

• *The New Way!*

- One application, x number of approvals
- Complete description of each requested approval
- The matrix (matrices) as your guide
 - More accurate assessment of work load
 - e.g, identifying unlisted gases and vapor testing
 - Improved review
 - Improved out-processing
 - More direct path into the CEL

Standard Application Procedure

- **More details –**
 - Regarding documents
 - Document numbers???
 - File naming convention
 - Lax enforcement
 - Processing slow-downs
 - Change **process** to match **practice**, or...
 - ... change **practice** to match **process**?

Questions?

OMSHR

Office of Mine Safety and Health Research



**R&D COMPONENTS for
SCSRs in response to the
MINER Act**

OMSHR

OFFICE OF MINE SAFETY
& HEALTH RESEARCH

Extracts from MINER ACT related to Breathing Air Supplies.....

SEC. 2.

“(E) (iii) POST-ACCIDENT BREATHABLE AIR.--.....

“(III)introducing new self-rescuer technology, such as units with interchangeable air or oxygen cylinders not requiring doffing to replenish airflow and units with supplies of greater than 60 minutes,

“(E) (i) POST-ACCIDENT COMMUNICATIONS.--.....communication with the surface for persons underground,

SEC. 6.

“(3) FUNCTIONS.--....., the Office of Mine Safety and Health shall be responsible for research, development, and testing of new technologies and equipment designed to enhance mine safety and health.

“(2) PURPOSE.--.....development of new mine safety technology to expedite the commercial availability and implementation

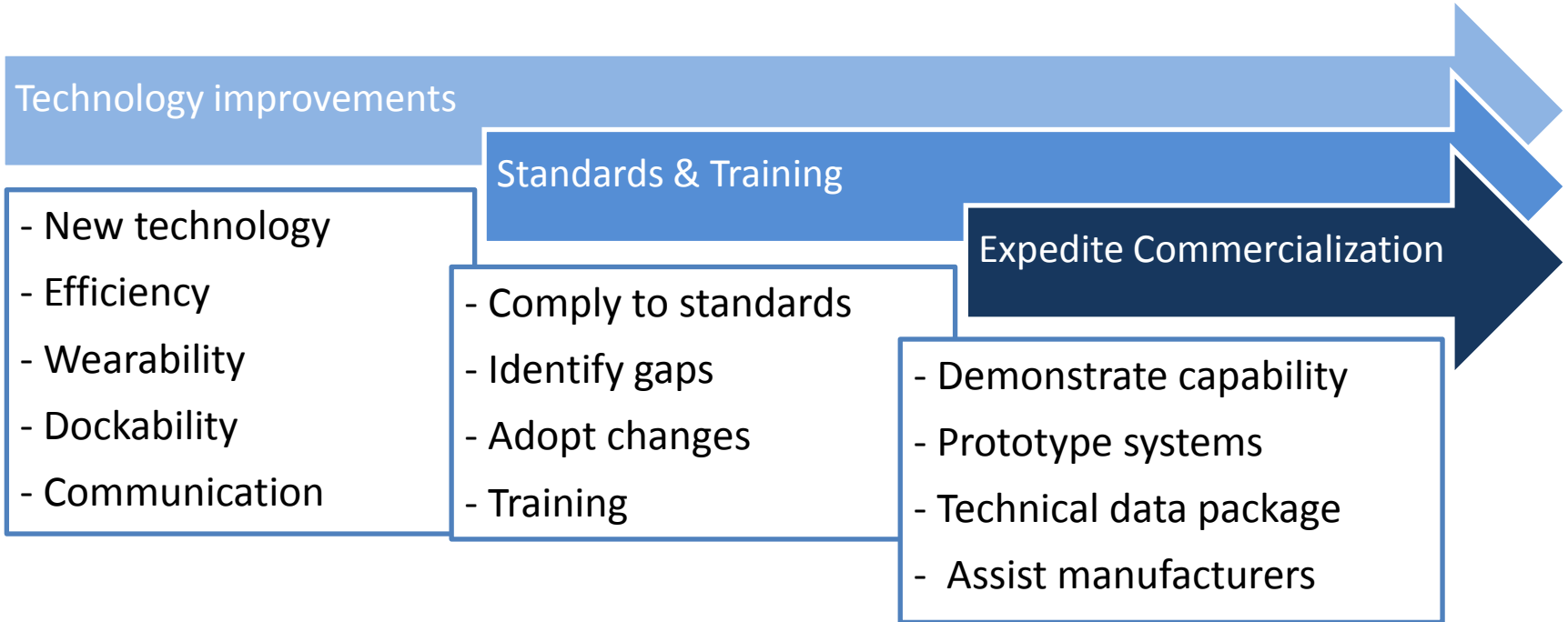
Breathing Air Supplies (BAS) R&D Objectives

To help develop the next generation Breathing Air Supplies that provide:

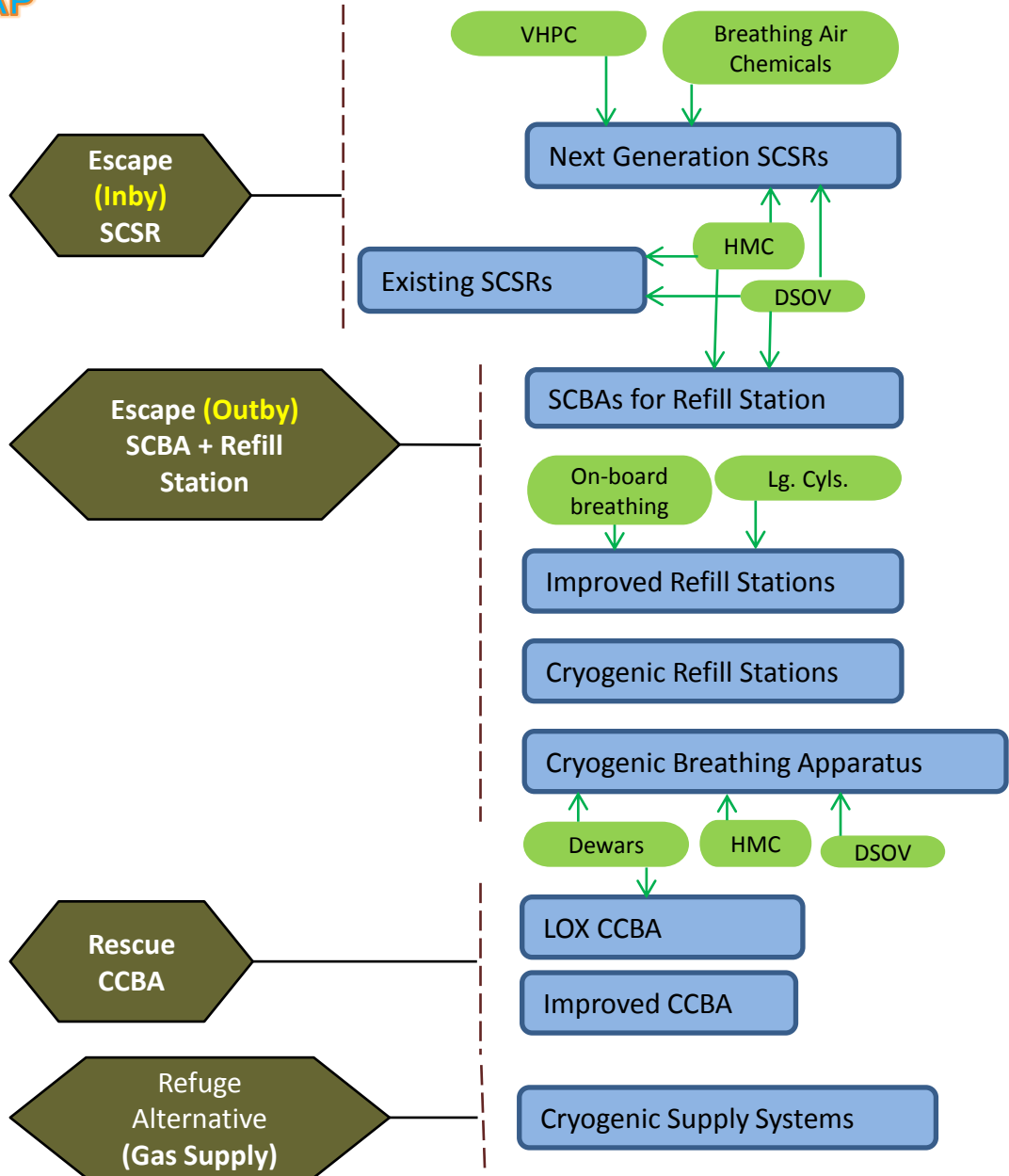
- Seamless changeover between breathing devices
- Communication among escaping miners
- Design characteristics for optimizing efficiency
- Replenishable breathing air supplies to sustain escape

Breathing Air Supplies (BAS) **STRATEGIC APPROACH**

IMPROVE BAS and HELP to Expedite Commercialization



BAS R&D MAP

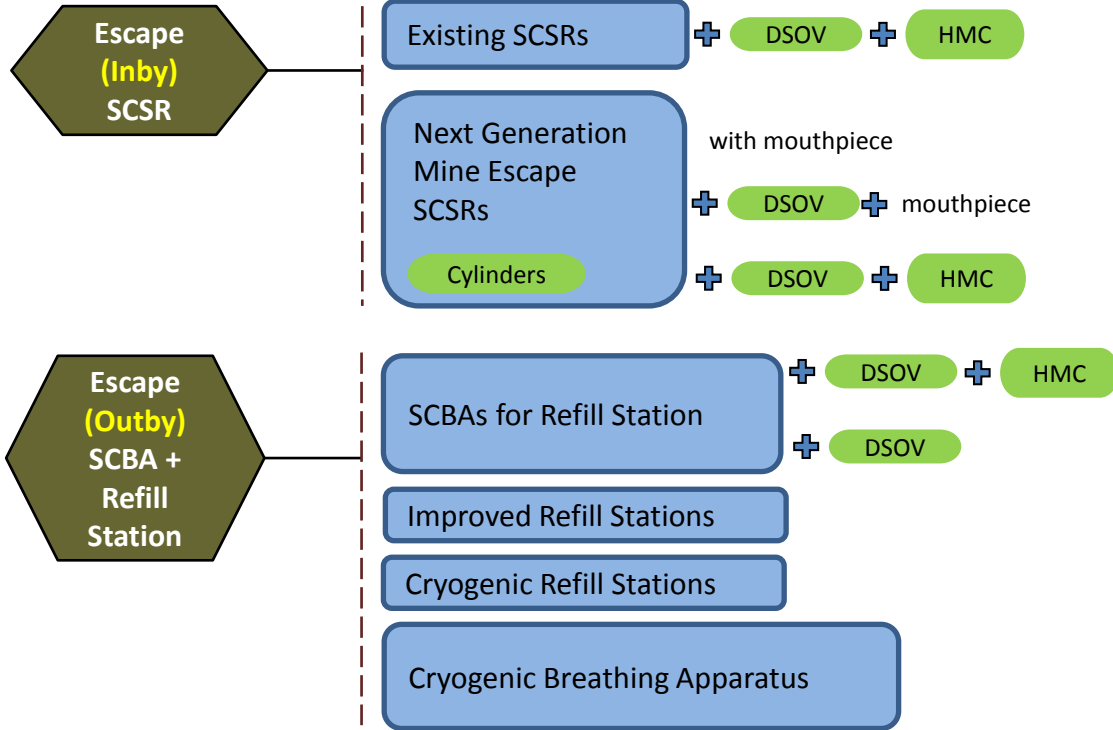


Breathing Air Supplies - R&D Projects

Inter-Agency Agreements and Contracts

- Interagency Agreements:
 - with the Navy (NEDU & NSWCC) on escape and rescue breathing apparatus improvement
 - with NASA on cryogenic breathing apparatus and supply systems
- Contracts with industry on critical component development

BAS R&D MAP

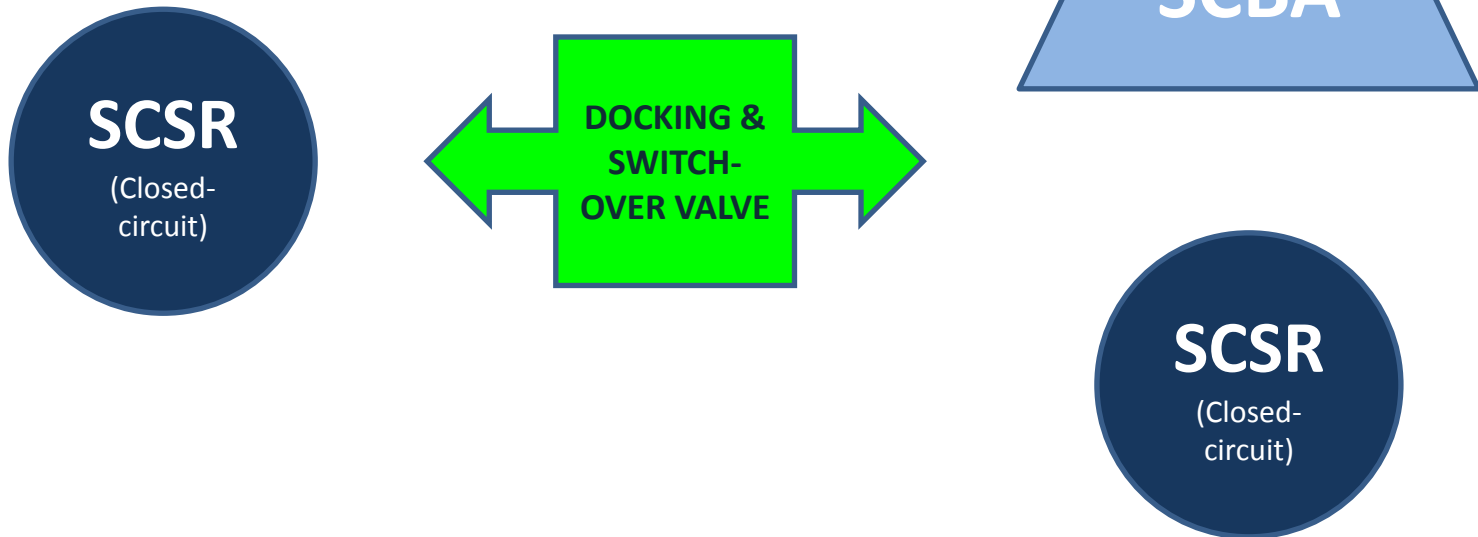


USABILITY STUDIES
conducted continually for
improvement

Seamless Changeover (Dockability)

to have uninterrupted breathing when switching apparatus

- ❑ Dockable Self-Contained Self Rescuers (SCSR) to have continued breathing protection while escaping
- ❑ User can connect and start a 2nd (new) SCSR or change to a SCBA while still breathing from the first unit and then switch over



COMPONENT Overview

Development of Docking/ Switch-over Valves, Hoods, Masks & Comms. and V.High P.Cylinders

Contractor/ Agency: **Carleton Technologies Inc.**
Location: **Orchard Park, NY; Westminster, MD**

PROJECT OBJECTIVE:

Design and produce prototypes of docking valves, hoods/mask/comms and integrate to current SCSRs & SCBA. Develop high pressure oxygen cylinders for SCSRs

PROBLEM STATEMENT:

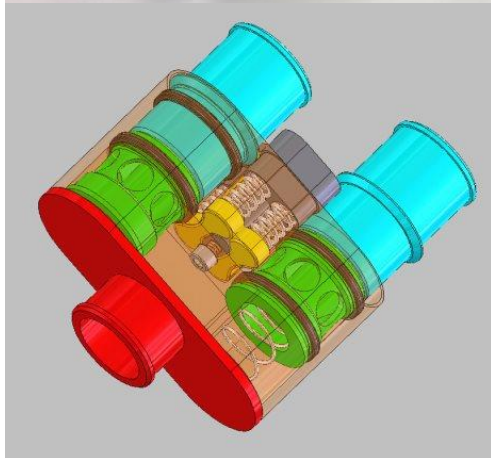
Capability for seamless transfer from one breathing apparatus to another, speech communication & head/face protection with donned SCSR, Smaller cylinders for next gen SCSRs

CURRENT STATUS

- **DSOV prototype delivered**
- **HMC prototype delivered**
- **VHPC designed, DOT test & certification in progress**

Commercialization Potential

- Information and assistance to potential manufacturers for integration of Components into BA



- **Plug type connection using spring triggered latch for SCRS and SCBA insertion and release**
- **Normally closed ports will only open after inserting an SCRS/SCBA connection**
- **Dust plug on lanyard prevent dirt and grime from contaminating an inactive port**
- **Adaptors are specific for different SCRS & SCBAs**

Dimensions: 3.13" x 2.95" x 1.28"
(7.95 cm x 7.49 cm x 3.25 cm)

Weight: 0.28 lbs (0.13 kg)



- **Half mask integrated directly into hood**
- **Large lenses with anti-fog film for improved vision**
- **Anti-suffocation valve with automatic lock-open functionality**
- **Adjustable elastic straps on exterior of hood.**
- **Communication element – speech diaphragm**
- **Elastic neck dam**

Dimensions-Collapsed: 5.5" x 6.5" x 4.5"
(14.0 cm x 16.5 cm x 11.4 cm)

Dimensions-Unfurled: 12" x 8" x 12"
(30.5 cm x 20.3 cm x 30.5 cm)

Weight: 0.62 lbs (0.28 kg)





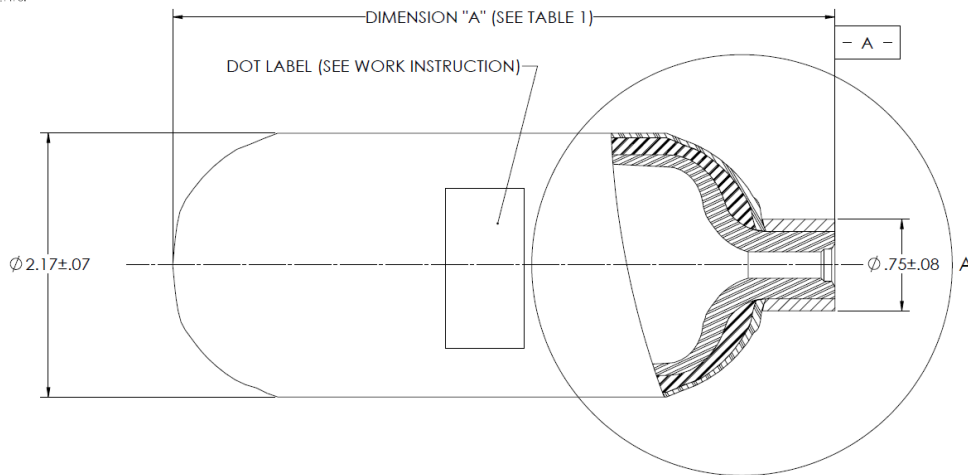
- Two sizes of carbon composite cylinders with aluminum liners to contain oxygen with expanded volumes (at 1 atm) of 140 liters & 70 liters respectively
- Service pressure 10,000psi
- Service life of 15 years

L = 5.45" – Wvol. = 0.14 L (8.3 cuin)

L = 9.25" – Wvol. = 0.28 (17.2 cuin)

Dia = nom. 2.2 inches

△ COATING: ENTIRE CYLINDER TO BE COATED PER CUSTOMER REQUIREMENTS.



COMPONENT Overview

Development of Docking/ Switch-over Valves, Hoods, Masks & Comms

Contractor/ Agency: **Essex Industries Inc.**

Location: **St. Louis, MO**

PROJECT OBJECTIVE:

Design and produce prototypes of docking valves, hoods/mask/comms and integrate to current SCSRs & SCBA.

PROBLEM STATEMENT:

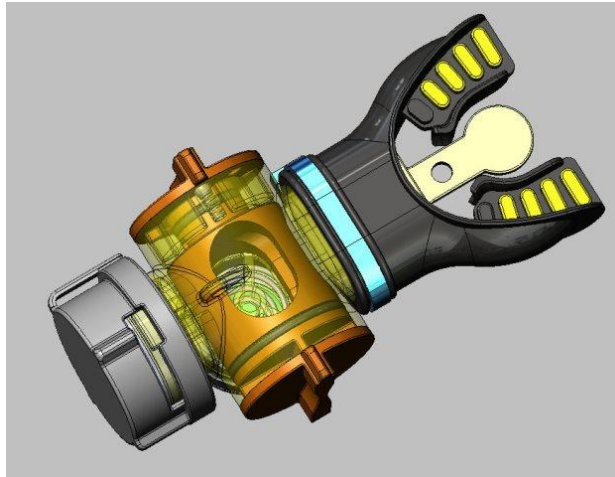
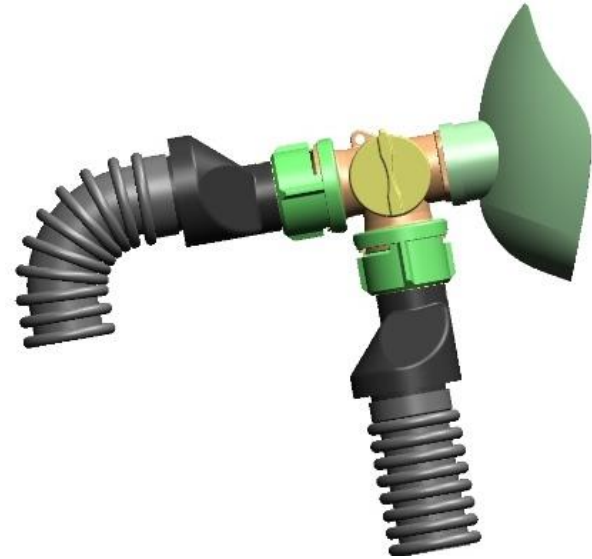
Capability for seamless transfer from one breathing apparatus to another, speech communication & head/face protection with donned SCSR.

CURRENT STATUS

- **DSOV prototype delivered**
- **HMC prototype under construction**

Commercialization Potential

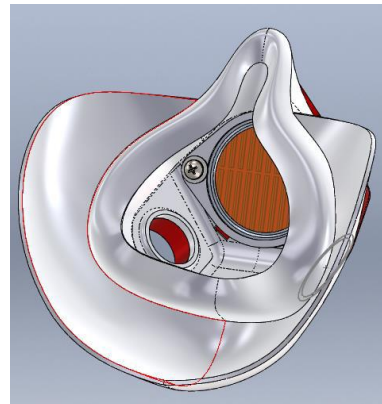
- Information and assistance to potential manufacturers for integration of Components into BA



- Bayonet type connection using adaptors for SCSR and SCBA
- Selector knob for directing airflow
- Front & bottom connections to breathing apparatus
- Normally closed ports will only open after inserting an SCSR/SCBA connection
- Flat mating surface and dust cap to minimize dirt accumulation on an inactive port
- Adaptors are specific for different SCSRs & SCBAs



- **Half mask with chin seal integrated directly into hood**
- **Lenses with anti-fog film for improved vision**
- **Anti-suffocation valve with automatic lock-open functionality**
- **Adjustable elastic straps on outside of hood**
- **Communication element – speech diaphragm**
- **Elastic neck dam**



COMPONENT Overview

Development of Docking/ Switch-over Valves

Contractor/ Agency: **Avon Protection Systems Inc.**

Location: **Cadillac, MI**

PROJECT OBJECTIVE:

Design and produce prototypes of docking valves

PROBLEM STATEMENT:

Capability for seamless transfer from one breathing apparatus to another

IMPACT ON H&S PROBLEM

Prototype docking valves available to integrate to current and next generation escape breathing apparatus

CURRENT STATUS

- **DSOV delivered**

Commercialization Potential

- Information and assistance to potential manufacturers for integration of DSOV into BA



- Plug type connection using adaptors for SCSR and SCBA
- In-line connecting ports perpendicular to mouth
- Release latch to eject breathing apparatus
- Adaptors insert directly into breathing hoses of current NIOSH approved SCSRs for mine use
- Normally closed ports will only open after inserting an SCSR/SCBA connection
- Adaptors are specific for different SCSRs & SCBAs



COMPONENT Overview

Development of 5,000psi Cylinders

Contractor/ Agency: **Luxfer Cylinders Inc.**
Location: **Riverside, CA**

PROJECT OBJECTIVE:

Develop and produce high pressure oxygen cylinders for SCSRs

PROBLEM STATEMENT:

Smaller cylinders for next gen SCSRs

CURRENT STATUS

- **VHPC designed, DOT test & certification in progress**

Commercialization Potential

- Information and assistance to potential manufacturers for integration of Components into SCSRs

Luxfer VHP cylinders

- Carbon composite, fully wrapped
- Two sizes: 0.46L & 0.32L WV
- Service pressure: 5,000psi (3,000psi for oxygen)
- DOT approved



Maximum Service Pressure is 5,000psi (345 bar) for containing Air, Argon, Carbon Dioxide, Helium, Hydrogen, Methane, Nitrogen and Nitrox Oxide

Maximum Service Pressure is 3,000psi (345 bar) for containing Oxygen

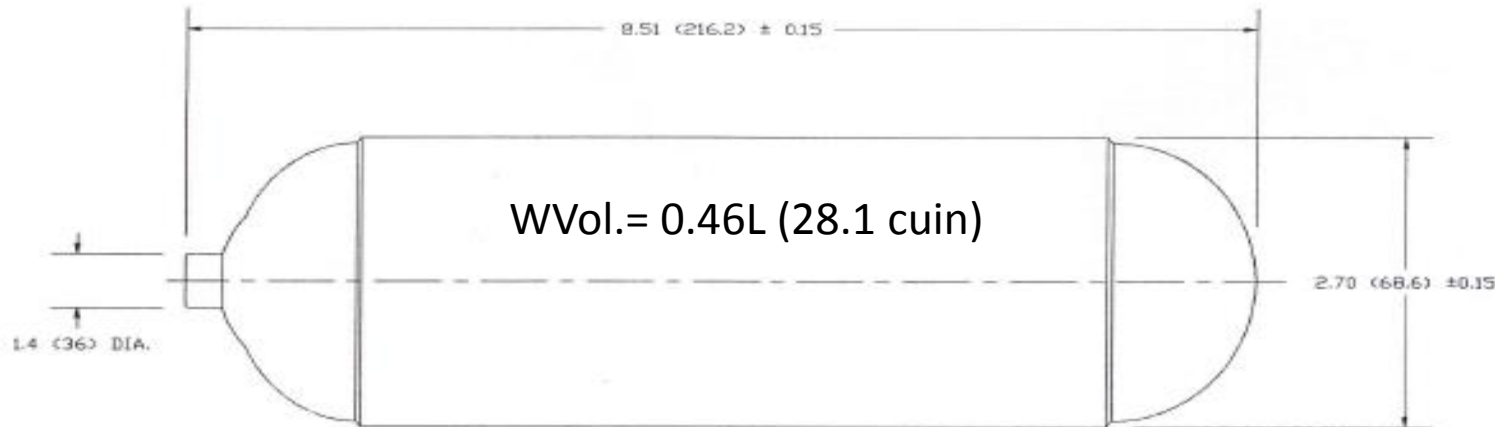
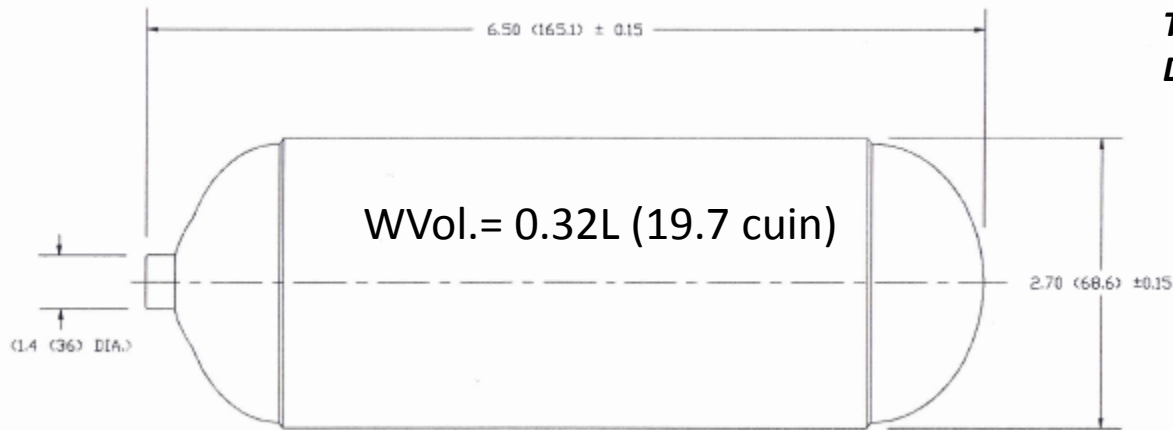
Test Pressure is 8333 psi (696 bar)

Approval: DOT SP-10915

Qualification tests: acc. to DOT CFFC

Thread form: 0.625-18 UNF-2B

Diameter: Nominal 2.7 inches (68.6 mm)



Thank You

Questions and Discussion

Presented by: Rohan Fernando

Contact info: 412 386 6619 - rfernando@cdc.gov

Division of Mining Science & Technology

Office of Mine Safety and Health Research (OMSHR) www.cdc.gov/niosh/mining

National Institute for Occupational Safety and Health (NIOSH)

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the National Institute for Occupational Safety and Health (NIOSH). Mention of any company or product does not constitute endorsement by NIOSH.

Save the Date

October 22, 2014 Next Manufacturer's Meeting

- Main Subject: Updates to the Standard Application Procedure
- Other Topics of Interest

Quality Partnerships Enhance Worker Safety & Health



Visit Us at: <http://www.cdc.gov/niosh/npptl>

Disclaimer:

The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.

Thank you

Photos Courtesy of (Left to Right):
Dräger, Kimberly Clark, and MSA (2)