National Personal Protective Technology Laboratory

CBRN PAPR Standard Development Overview and Step 1 Concept

Sheraton Station Square

Pittsburgh, PA

Jonathan Szalajda

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Why we are here: Continuing Threat of Terrorism

Major attacks Since 1999:

1999-- Russian Apartment Bombings

2000-- USS Cole

2001 – 9/11, Moscow Metro, Anthrax

2002 – Beltway sniper; Moscow Theater

2003 – Riyadh Compound

2004 – Madrid

2005 – London

2006 -- ?

Source:http://en.wikipedia.org/wiki/Terrorist_attack#2000

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Purpose of the Meeting

To continue discussions of:

(1) Concepts for standards and testing processes for PAPR and Closed Circuit SCBA suitable for respiratory protection against CBRN agents

(2)Conceptual discussions for establishing Industrial PAPR requirements

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CBRN Respirator Standards Impact

- NIOSH CBRN Respirator Standards have been recognized and adopted by:
  - The DOD/DHS InterAgency Board
  - DHS, as the first CBRN standards used for issuing grants to responder organizations
  - NFPA in their protective ensemble standards
- British Standards Institute (BSI) is patterning new standards and tests based on NIOSH CBRN standards

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CBRN Respirator Standards

Standards Completed

- SCBA – January 2002
- SCBA upgrades – March 2003
- Gas masks –March 2003
- Escape sets – October 2003

Standards in Development

- PAPRs
- Closed-circuit SCBA
- Combination SCBA/PAPR or SCBA/APR
- SAR

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CBRN Self Contained Breathing Apparatus (SCBA)

Open Circuit CBRN SCBA

Three Tiers of Requirements:

- 42 CFR, Part 84 (NIOSH)
- NFPA 1981, Current Edition
- Special CBRN Requirements:
  - CW Agents (GB & HD)
  - Respirator Fit

Standard Announced December 2001 and Implemented January 2002

CBRN-SCBA Retrofit Announced March 2003

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CBRN Air Purifying Respirator (APR)

Full Facepiece CBRN APR

Three Tiers of Requirements:

- 42 CFR, Part 84 applicable sections
- Enhanced Requirements (Other Standards)
- Special CBRN Requirements:
  - CW Agents (GB & HD)
  - Respirator Fit

Standard Announced and Implemented March 2003

CBRN APR Retrofit in Development

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CBRN Escape Respirator

CBRN escape respirator

- CBRN air-purifying escape
- CBRN self-contained escape

Three Tiers of Requirements

- 42 CFR, Part 84, applicable sections
- Requirements derived from others standards
- Special CBRN Requirements:
  - CW Agents (GB & HD)
  - Respirator Fit

Standards Announced September 2003

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CBRN Respirator Certification

CBRN SCBA: multiple approvals issued to 6 manufacturers

CBRN SCBA Upgrade: multiple approvals (retrofit) issued to 3 manufacturers

CBRN APR:

- Multiple approvals issued to 5 manufacturers
- Additional approvals pending

CBRN Escape:

- 2 approvals issued to 2 manufacturers

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CBRN Respirator Standards Program

- **Continue CBRN Respirator Certification**
- **Complete CBRN PAPR standard**
- **Continue Standards Development Efforts for Remaining Classes of Respirators (CC SCBA, SAR, Combination Units SCBA/PAPR, SCBA/APR)**
  - Public Process
- **Provide clarifications to Existing CBRN Standards (SCBA, APR, APER, SCER) based upon lessons learned over the past four years**
  - Document Clarifications, Not Revisions to Requirements
  - Post Clarifications to Web Site by 2Q FY 2006
  - 30 day Public Review and Comment Period
  - Post Updates by 3Q FY 2006

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CBRN PAPR Standard Development Docket and Meeting Comments

Public meetings

- **October 2003**
- **May 2004**
- **December 2004**
- **July 2005**
- **December 13, 2005**

Docket

- **22 Formal submissions**

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CBRN PAPR Respirator Concept Docket and Meeting Comments

- Comments provided through various sources
  - Formal Docket submissions
  - Public Meeting Feedback
  - Informal Stakeholder Meetings
- Comments are accepted in total or in part as part of standards development process
- Comments are rejected for technical / programmatic reasons
- Some Comments remain under consideration, pending completion of benchmark testing

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CBRN PAPR

Program Issues

- Technical -- High Flow Aerosol Test Technology
  - Two high flow testers from two manufacturers
  - Complete equipment verification during 2006
- Competing Stakeholder Needs
  - Department of Homeland Security and responder community want CBRN capable PAPR soon
  - Manufacturers want common platform in Part 84 industrial requirements and CBRN requirements
- Draft OSHA Receiver PAPR guidance

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CBRN PAPR Implementation

Considerations for the implementation process:

- Project focus is to provide the user community with required protection through equipment availability as quickly as possible
- Project needs to verify standard test procedures prior to implementation of the standard
- Implementation options are through policy provisions or through rulemaking processes

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CBRN PAPR Implementation

- Previous CBRN Respirator Standards have been implemented using a voluntary approval program pursuant to 42 CFR Parts 84.60(b) and 84.63(c).
- These sections provide NIOSH with the authority to issue approvals for respirators not specifically addressed in Part 84 and to develop additional requirements that the agency determines are "necessary to establish the quality, effectiveness and safety of any respirator used as protection against hazardous atmospheres."
- Using Policy Provisions result in a projected implementation goal of the CBRN PAPR standard release by the end of 2Q FY2006

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CBRN PAPR

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

Step 1

- Implement CBRN PAPR via regulatory authorities 2Q FY 2006
- 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 processes that begins in late 2006 with implementation during 2008
- 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 Step 1 Requirements

Approval under NIOSH 42 CFR Part 84

Special tests under NIOSH 42 CFR Part 84.63(c)

- Durability conditioning
- 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

CBRN PAPR Step 1 Requirements: Approval under NIOSH 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/6	IAA fit test
7	Inhalation resistance with blower off (tight-fitting)
12	PAPR Air Flow*
25	Silica Dust+
30	Sound Level (if applicable)
33-48 or 62	Gas and Vapor (as applicable)
60	ESLI visibility (if applicable)
61	ESLI damage resistance (if applicable)

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

+CBRN Canister evaluated for HE particulate and Silica Dust

CBRN PAPR Step 1 Requirements: Special tests under NIOSH 42 CFR Part 84.63(c)

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 that may occur from typical use.

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.

Durability Test Matrix

Test	Test Method	Test Conditions	Duration	Notes
Hot Diurnal	Mil-Std-810F 501.4	(35°C/ 95°F) to (71°C/ 160°F), 24 Hour cycle	3 Weeks Diurnal Cycle	PAPR, Battery and Canisters
Cold Constant	Mil-Std-810F 502.4	Basic Cold, -32°C (-24°F), Constant	3 Days	
Humidity	Mil-Std-810E 507.3	Realistic, Natural Cycle Humidity Profiles in the U.S. (range 88°F @ 88%RH– 05°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	

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CBRN PAPR Step 1 Requirements: Special tests under NIOSH 42 CFR Part 84.63(c)

Chemical Agent Permeation and Penetration Resistance against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement - (Reference STPs CBRN - 0550 and 0551)

- Blower is running and including all components and accessories except for the battery (or batteries),
- 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.
- Testing performed on four PAPR (two for HD and two for GB) following the durability conditioning.
- QLAT performed on two PAPR (one for HD, one for GB)

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CBRN PAPR Step 1 Requirements: Special tests under NIOSH 42 CFR Part 84.63(c)

Laboratory Respiratory Protection Level (LRPL) Test Requirement – (all Respirators, Reference STP CBRN 0552)

- The measured LRPL for each powered, air-purifying respirator shall be 10,000 for ≥ 95% trials with the blower operating (blower on mode).
- The measured LRPL for each tight-fitting powered, air-purifying respirator shall be 2,000 for ≥ 95% trials with the blower not operating (Blower Off mode)
- All sampling will be performed in the breathing zone of the respirator. The respirator is tested in an atmosphere containing 20–40 mg/m3 corn oil aerosol of a mass median aerodynamic diameter of 0.4–0.6 µm.
- Discussions with OSHA regarding LRPL testing of 10,000 (provides a safety factor of 10 for a potential 1000 PAPR APF)

CBRN PAPR Step 1 Requirements: Special tests under NIOSH 42 CFR Part 84.63(c)

Canister Test Challenge and Test Breakthrough Concentrations– Reference STPs CBRN – 0501, 0502, 0503, 0504, 0505, 0506, 0507, 0508, 0509, 0510)

- Canister capacity tests will be performed at room temperature, 25 °C ± 2.5 degree C; and at 25% ± 2.5% relative humidity and 80% ± 2.5% relative humidity
- Three canisters will be tested at each specified humidity
- Canister test time is fifteen minutes
- Canister capacity testing for the tight-fitting systems will be tested at a flow rate of 115 Lpm divided by the least number of canisters used on the system for which approval is sought
- Canister capacity testing for the loose-fitting systems will be tested at a flow rate of 170 Lpm divided by the least number of canisters used on the system for which approval is sought
- Canister capacity testing shall be performed following the durability conditioning.

CBRN PAPR Step 1 Requirements: Special tests under NIOSH 42 CFR Part 84.63(c)

Tight - Fitting Canister test challenge and test breakthrough concentrations

Test Representative Agent (TRA)	Test Concentration (ppm)	Breakthrough Concentration (ppm)
Ammonia	2500	12.5
Cyanogen chloride	300	2
Cyclohexane	2600	10
Formaldehyde	500	1
Hydrogen cyanide	940	4.7*
Hydrogen sulfide	1000	5.0
Nitrogen Dioxide	200	1 ppm NO_2 or 25 ppm NO†
Phosgene	250	1.25
Phosphine	300	0.3
Sulfur dioxide	1500	5

CBRN PAPR Step 1 Requirements: Special tests under NIOSH 42 CFR Part 84.63(c)

Loose - Fitting Cartridge test challenge and test breakthrough concentrations

Test Representative Agent (TRA)	Test Concentration (ppm)	Breakthrough Concentration (ppm)
Ammonia	1250	12.5
Cyanogen chloride	150	2
Cyclohexane	1300	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

CBRN PAPR Step 1 Requirements: Special tests under NIOSH 42 CFR Part 84.63(c)

Particulate/aerosol testing:

- The canister shall meet the requirements of 99.97% particulate filter efficiency
- Canister particulate testing for the system will be tested at a flow rate of 170 Lpm divided by the least number of canisters used on the loose-fitting system
- Canister particulate testing for the tight-fitting system will be tested at a flow rate of 115 Lpm divided by the least number of canisters used on the system
- Current test technology limits flow rate testing to 95 Lpm. When test equipment has been validated to test at higher flows, single filter elements will be able to be evaluated

CBRN PAPR Cautions and Limitations

Units will have two labels: One for 42 CFR Part 84 and one for CBRN Rating

Units will include appropriate cautions and limitations:

- Industrial 14 G (tight-fitting) or 23 C (loose-fitting) requirements
- Previously identified CBRN cautions and limitations
- CBRN Loose-Fitting PAPR unique cautions and limitations

Cautions and Limitations from 42 CFR Part 84

For respirators approved under 30 CFR Part 11 & 42 CFR Part 84:

- Not evaluated as an ignition source in flammable or explosive atmospheres by MSHA/NIOSH.
- Not for use in atmospheres containing less than 19.5 percent oxygen.
- Not for use in atmospheres immediately dangerous to life or health.
- Tight-fitting facepiece: Do not use if airflow is less than four cubic feet per minute.
- Loose-fitting facepiece: Do not use if airflow is less than six cubic feet per minute.
- In making renewals and repairs, parts identical with those furnished by the manufacturer under the pertinent approval shall be maintained.
- Refer to approval label and instruction and maintenance manuals for additional information on use and maintenance of the respirators.
- Follow the manufacturer's instructions for changing filters, cartridges, and/or canisters.
- This respirator shall be selected, fitted, used and maintained in accordance with Mine Safety and Health Administration and other applicable regulations.

Cautions and Limitations from 42 CFR Part 84

For respirators approved under 30 CFR Part 18:

- Not evaluated as an ignition source in flammable or explosive atmospheres by MSHA/NIOSH, except evaluated under Part 18 for use in methane air atmosphere.

Additional limitations under 42 CFR Part 84:

- Do not use powered air-purifying respirators if airflow is less than four cfm (115 lpm) for tight-fitting facepieces or six cfm (170 lpm) for hoods and/or helmets.
- Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by MSHA/NIOSH

Cautions and Limitations from 42 CFR Part 84

General Limitations - All Gas Masks (14G):

- Not for use in atmospheres immediately dangerous to life or health.
- Not for use in atmospheres containing less than 19.5 percent oxygen.
- Refer to approval label, and instruction and maintenance manuals, for additional information on use and maintenance of these respirators.
- In making renewals and repairs, parts identical with those furnished by the manufacturer under the pertinent approval shall be maintained.
- Approval may include protection against particulates and multiple gases and vapors. The type of additional approval is listed in the approval record under the approval number.
- Follow the manufacturer's instructions for changing canisters.
- Do not wear for protection against gases or vapors with poor warning properties or those which generate high heats of reaction with sorbent materials in the canister.
- Respirators shall be selected, fitted, used and maintained in accordance with Mine Safety and Health Administration and other applicable regulations.

Cautions and Limitations from 42 CFR Part 84

General Limitations - All 23 C Chemical Cartridges:

- Not for use in atmospheres containing less than 19.5 percent oxygen.
- Not for use in atmospheres immediately dangerous to life or health.
- Do not exceed maximum use concentrations established by regulatory standards.
- Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G-7.1 Grade D or higher quality.
- Use only the pressure ranges and hose lengths specified in the User's Instructions.
- Do not use powered air-purifying respirators if airflow is less than four cfm (115 lpm) for tight-fitting facepieces or six cfm (170 lpm) for hoods and/or helmets.
- If airflow is cut off, switch to filter and/or cartridge and immediately exit to clean air.
- Do not wear for protection against organic vapors with poor warning properties or those which generate high heats of reaction with sorbent.

Cautions and Limitations from 42 CFR Part 84

General Limitations - All 23 C Chemical Cartridges (cont.)

- Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by MSHA/NIOSH.
- Failure to properly use and maintain this product could result in injury or death.
- The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- Follow the manufacturer's User's Instructions for changing cartridges and/or filters.
- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- Refer to User's Instructions, and/or maintenance manuals, for information on use and maintenance of these respirators.
- Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions for donning

CBRN APR Cautions and Limitations

- Not for use in atmospheres containing less than 19.5 percent oxygen.
- Not for use in atmospheres immediately dangerous to life and health or where hazards have not been fully characterized.
- When used at defined occupational exposure limits, the rated service time cannot be exceeded. Follow established canister change schedules or observes End of Service Life Indicators to ensure that canisters are replaced before breakthrough occurs.
- Failure to properly use and maintain this product could result in injury or death.
- Follow the manufacturer's User's Instructions for changing canisters.
- All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- Use replacement parts in the configuration as specified by the applicable regulations and guidance.
- Refer to User's Instructions and/or maintenance manuals for information on use and maintenance of these respirators.
- Consult manufacturer's User's Instructions for information on the use, storage, and maintenance of these respirators at various temperatures.

CBRN APR Cautions and Limitations (continued)

- This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.
- If during use an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air.
- Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained.
- Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.
- Direct contact with CBRN agents requires proper handling of the respirator after each use and between multiple entries during the same use. Decontamination and disposal procedures must be followed. If contaminated with liquid chemical warfare agents, dispose of the respirator after decontamination.
- The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours.
- These limitations are not all inclusive. The respirator manufacturer may also identify further cautions and limitations for their respirators. In addition, regulatory agencies may also place a limit on the use of respirators in their standards.

CBRN PAPR Unique Cautions and Limitations

- The CBRN loose-fitting PAPR should not be used in emergency response (fire service, law enforcement, emergency medical technician) applications where high physiological demand is expected
- Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained. Appropriate dermal protection for use with CBRN loose-fitting PAPR should include a shroud that provides dermal protection to the head and upper torso
- The CBRN loose-fitting PAPR should not be used for escape purposes

CBRN PAPR Step 1
Anticipated Certification Fees

• 42 CFR Part 84	$ 1,250
• Durability Conditioning (NIOSH)	$21,900
• CWA Testing	$18,960
• LRPL	$18,156
• Gas/Vapor/Particulate (averaged @ $990/gas)	$ 9,900
• NPPTL processing cost	$ 1,000
• RDECOM processing cost	$ 6,000
Total	$77,166

Additional testing, if needed, charged on a per-test basis.

Fees calculations based on RDECOM 2005 fees.

CBRN PAPR Step 1 Advantages

- Supports CBRN respirator standards development three tier approach by using the current 42 CFR Part 84 requirements for the first tier of performance
- Provides for equipment availability in the near term
- Provides a Safety and Health Benefit through addressing Draft OSHA First Receiver Guidance recommendations for PAPR with an APF of 1000

Information Docket
CBRN PAPR

- **Mail:**
  NIOSH Docket Office
  Robert A. Taft Laboratories, M/S C 34
  PAPR – NIOSH 010
  4676 Columbia Parkway
  Cincinnati, OH 45226
- **Email: niocindocket@cdc.gov**
- **Fax: (513) 533-8285**
- **Phone: (513) 533-8303**
- **NPPTL Web Site: http://www.cdc.gov/niosh/npptl**

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