DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Personal Protective
Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236

September 24, 2003

LETTER TO ALL INTERESTED PARTIES

SUBJECT: National Institute for Occupational Safety and Health Announcement of Two Public Meetings to be held on October 16, 2003. The meetings are being held to Initiate Conceptual Discussions for Powered Air Purifying Respirator Standards Development Efforts Used for Respiratory Protection Against Chemical, Biological, Radiological, and Nuclear (CBRN) Agents, Docket Number NIOSH-010, and Quality Assurance Standards Module for Respiratory Protective Equipment, Docket Number NIOSH-001

The National Institute for Occupational Safety and Health (NIOSH), National Personal Protective Technology Laboratory (NPPTL) is planning to conduct two public stakeholder meetings on October 16, 2003. The CBRN Public Meeting will be held from 9:00 a.m. until 3:00 p.m. and the Quality Assurance Standards Module Meeting will be held from 3:00 p.m. until 5:00 p.m. at the Radisson Hotel at Waterfront Place, 2 Waterfront Place, Morgantown, West Virginia.

CBRN Topics

The purpose of the CBRN Public Meeting is to initiate conceptual discussions of standards and testing processes for powered air purifying respirator standards suitable for respiratory protection against CBRN Agents. NIOSH, along with the U.S. Army Soldier and Biological Chemical Command (SBCCOM) and the National Institute for Standards and Technology (NIST), will present information to attendees concerning the concept development for the powered air purifying respirator CBRN standard. Participants will be given an opportunity to ask questions on these topics and to present individual comments for consideration.

Interested participants may obtain a copy of the powered air purifying respirator CBRN concept paper, as well as earlier versions of other concept papers used during the standard development effort, from the NPPTL web site, address: **www.cdc.gov/niosh/npptl**. The September 15, 2003, concept paper will be used as the basis for discussion at the public meeting, as well as forming the basis for the new powered air purifying respirator CBRN statement of standard.

The continuing threat of acts of terrorism has created an urgent awareness of domestic security and preparedness issues. Municipal, state, and federal responder groups, particularly those in locations considered potential targets, have been developing and modifying response and consequence management plans. Since the World Trade Center and anthrax incidents, most emergency response agencies have operated with a heightened appreciation of the potential scope and sustained resources requirements for coping with such events. The federal Interagency Board for Equipment Standardization and Interoperability (IAB) has worked to identify personal protective equipment that is already available on the market for responders' use. The IAB has identified the development of standards or guidelines for respiratory protection equipment as a top priority. NIOSH, NIST, the National Fire Protection Association, and the Occupational Safety and Health Administration entered into a Memorandum of Understanding defining each agency or organization's role in developing, establishing, and enforcing standards or guidelines for responders' respiratory protective devices. NIST initiated Interagency Agreements with NIOSH and SBCCOM to aid in the development of appropriate protection standards or guidelines. NIOSH has the lead in developing standards or guidelines to test, evaluate, and approve respirators.

NIOSH, SBCCOM, and NIST hosted public meetings on April 17 and 18, 2001; June 18 and 19, 2002; October 16 and 17, 2002; April 29, 2003; and June 25, 2003, presenting their progress in assessing respiratory protection needs of responders to CBRN incidents. The methods or models for developing hazard and exposure estimates, and the status in evaluating test methods and performance standards that may be applicable as future CBRN respirator standards or guidelines were discussed at these meetings.

Quality Assurance Topics

The purpose of the Quality Assurance Standards Module is to continue conceptual discussions for quality assurance standards for respiratory protective equipment. The concepts for the update of 42 CFR Part 84 to address quality assurance provisions, establish fees, improve labels and update certain administrative provisions were presented in a public meeting held on June 25, 2003.

Participants will be given an opportunity to ask questions on these topics and to present individual comments for consideration. Interested participants may obtain a copy of the quality assurance concept paper from the NPPTL web site, address: www.cdc.gov/niosh/npptl. The July 21, 2003, concept paper and the information presented at the June 25, 2003, public meeting will be used as the basis for discussion at the October 16, 2003, public meeting. Responses to the comments received since the June 25, 2003, meeting will also be discussed.

NIOSH has the lead in developing standards or guidelines to test, evaluate, and approve respirators for use in occupational settings. International trade has led to changes in accepted quality assurance practice in manufacturing environments throughout the world. In attempting to keep respirator standards abreast of current manufacturing practice, NIOSH has met with the public and respirator manufacturers to receive input on the development of new respirator quality assurance standards. NIOSH hosted the most recent of these public meetings on June 25, 2003, where concepts developed up to that date were presented.

General Information

Interested parties should make hotel reservations directly with the Radisson Hotel at Waterfront Place (304/296-1700 / 1-800-333-3333) before the cut-off date of October 2, 2003. The following special group rates have been negotiated for meeting guests: $66 per night for federal guests and $79.00 per night for non-federal guests. You must reference the NIOSH National Personal Protective Technology Laboratory (NPPTL) Public Meeting to receive these special rates. There is no need to specify which meeting you will be attending.

Please confirm your attendance to either or both meetings by completing the enclosed registration form, marking the public meeting that you wish to attend, and faxing (304/285-4459) the form to the Event Management Office, or completing an electronic registration form from the NIOSH Homepage (**www.cdc.gov/niosh**) by selecting Conferences and then the event.

An opportunity to make presentations regarding the conceptual discussions of standards and testing processes for powered air purifying respirator standards suitable for respiratory protection against CBRN Agents and the conceptual quality assurance standards module will be given. Requests to make such presentations at the public meetings should be made by e-mail (**npptlevents@cdc.gov**) to the NIOSH Event Management Office. All requests to present should include the name, address, telephone number, relevant business affiliations of the presenter, a brief summary of the presentation, and the approximate time requested for the presentation. Oral presentations should be limited to 15 minutes.

After reviewing the requests for presentations, NIOSH Event Management will notify each presenter of the approximate time that their presentation is scheduled to begin. If a participant is not present when their presentation is scheduled to begin, the remaining participants will be heard in order. At the conclusion of the meetings, an attempt will be made to allow presentations by any scheduled participants who missed their assigned times. Attendees who wish to speak but did not submit a request for the opportunity to make a presentation may be given this opportunity at the conclusion of the meeting, at the discretion of the presiding officer.

Submitting Comments on CBRN or Quality Assurance

Comments on the topics presented in this notice and at the meetings should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, Telephone 513–533–8303, Fax 513/533–8285. Comments may also be submitted by e-mail to **niocindocket@cdc.gov**. E-mail attachments should be formatted as WordPerfect 6/7/8/9 or Microsoft Word. Comments should be submitted to NIOSH no later than November 16, 2003, and should reference Docket Number NIOSH-010 in the subject heading for the CBRN Public Meeting and Docket Number NIOSH-001 in the subject heading for the Quality Assurance Standards Module.

For further information, please contact the Event Management Office, 3610 Collins Ferry Road, P.O. Box 880, Morgantown, West Virginia 26507-0880 Telephone 304-285-4750, Fax 304-285-4459, E-mail **npptlevents@cdc.gov**.

Sincerely yours,

Roland Berry Ann
Branch Chief
Respirator Branch
National Personal Protective Technology Laboratory

Enclosure

NIOSH/NPPTL/RESPIRATOR BRANCH/SZALAJDA/EG&G/BELL/08/29/2003
Spelling Verified by: EG&G

bcc:
RB Reading File
Notebook for "Letter to All Manufacturers"

Concur:

Acting Branch Chief, RB _____ _____
Acting Section Chief, CE&T, RB _____ _____
Acting Section Chief, P&SD, RB _____ _____

DRAFT FOR DISCUSSION
CBRN PAPR CONCEPT PAPER

September 15, 2003

1.0 Purpose:

Develop a NIOSH, NPPTL, powered air-purifying respirator standard that addresses Chemical Biological Radiological Nuclear (CBRN) materials identified as inhalation and/or possible terrorist hazards for emergency responders.

2.0 Description:

Powered air-purifying respirators use a powered mechanism to draw ambient air through an air purifying filter element(s) to remove contaminants from the ambient air. They are to be designed for use in atmospheres where the concentrations of contaminants during use are not immediately dangerous to life and health and contain adequate oxygen to support life; in addition, they may be used to escape from an IDLH condition provided there is adequate oxygen to support life.

2.1 Definitions.

(a) Powered Air Purifying Respirator (PAPR) - an air-purifying respirator that uses a powered mechanism (blower) to pass ambient air through an air-purifying element to a respiratory inlet covering.

(b) Tight fitting PAPR - a PAPR which contains a respiratory inlet covering that seals tightly to the face.

(c) Neck Dam PAPR- a PAPR which contains a hood or helmet and which covers and seals tightly around the neck area.

(d). Respiratory inlet covering- A facepiece, hood, helmet or some combination of these which serves as the covering to the nose and mouth area and ensures that only purified air reach these areas.

2.2 Respirator Use:

A. Warm Zone Use: Concentrations above acceptable exposure limits, but less than IDLH concentrations, to REL. Examples of use scenarios: sustained support operations; long term use for decontamination, traffic control, rehabilitation, rescue and recovery; agent known, quantified, and controlled.

B. Crisis Provision Mode: Egress and escape from above IDLH concentrations, high physiological (flow) demand possible; Contingency for unforeseen factors such as secondary device or pockets of entrapped hazard.

C. The CBRN PAPR filters are single use filters and should be discarded after use. A minimum of two filters are required for use with the CBRN PAPR.

D. CBRN respirators contaminated with liquid chemical warfare agents are to be disposed of after use.

2.3 Hazards:

NIOSH has been evaluating various lists of chemicals that could be deployed as a result of a terrorist incident. In earlier research during the development of the Chemical Biological Radiological Nuclear (CBRN) Air-Purifying Respirator (APR) standard, NIOSH categorized potential respiratory hazards into families. Representative test agents identified for each family shall be the only agent tested for service life in that particular family, thus representing all the agents identified in the family. This effort was conducted in order to reduce the number of certification tests. A total of ten chemical representative agents, plus one particulate test representative, were identified. Testing against these eleven test representatives provides protection for 139 potential respiratory hazards

3.0 Requirements Based on Existing National and International Standards:

3.1.1 Mechanical Connector and Filter Design:

The interface between the canister and the powered mechanism (blower) shall use a standard Rd 40 X 1/7 thread in accordance with Figure 1 (NIOSH CBRN Full Facepiece APR Mechanical Connector and Gasket). The canister shall be readily replaceable without the use of special tools. The interface connector(s) on the blower shall be the internal thread and gasket sealing gland. The canister shall use the external thread.

3.1.1 Gasket, Mechanical Connector:

The dimensions for the interface connector gasket shall be: outside diameter 37.5 mm minimum, inside diameter 28.5 mm maximum, minimum thickness 1.55 mm as illustrated in Figure 1. The gasket material shall be ethylene propylene diene monomer, EPDM, or equivalent meeting the physical and chemical properties of Table 1 (Rubber Gasket Physical and Chemical Properties) when tested in accordance with Table 2 (Gasket Tests, Specimens and Test Methods). The manufacturer is required to provide data indicating compliance with the requirements of Table 1 and 2. Agent permeation data is not required for EPDM gasket material meeting all other properties of Table 1. For gasket material other than EPDM material samples must be tested to the agent permeation requirements.

Table 1: Rubber Gasket Physical and Chemical Properties

Property	Units	Unaged Minimum	Unaged Maximum	Aged Minimum	Aged Maximum
Tensile Strength	Mpa (psi)	8.3 (1200)	---	6.9 (1000)	---
Ultimate elongation	Percent (%)	350	---	300	---

Tensile set at 300% elongation	Percent (%)	---	25	---	25
Tensile stress at 200% elongation	Mpa (psi)	3.4 (500)	---	3.4 (500)	---
Tear resistance Either Die B or Die C [1]	kN/m (lbf/in)	21.9 (125)	---	21.9 (125)	---
Durometer hardness (Shore "A")	---	55	75	---	---
Compression set 22 hrs. at 68°C	Percent (%)	---	25	---	---
Impact resilience	Percent (%)	35	---	---	---
Agent permeation HD, Mustard & GB, Sarin [2]	Minutes Minutes	360 360	---	---	---
Low temperature brittleness at minus 51°C	---	Pass	---	---	---

[1] Test specimens shall be cut from Die B or Die C. Test specimens shall not be a mixture of Die specimens. See Table 2: Tear Resistance Method ASTM 624 D.

[2] The applicant shall submit agent permeation data on materials that are not classified as EPDM. Rubber material formulations that are 51% or greater in EPDM classifies the material as EPDM.

Table 2: Gasket Tests, Specimens and Test Methods

Property	Specimen			Total	Method
	Unaged	Heat Aged [1]	Oxygen aged [2]		
Tensile strength Ultimate elongation Tensile stress at 200% elongation	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	9	ASTM D 412
Tensile set at 300% elongation	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	9	ASTM D 412
Tear resistance, Either Die B or Die C	Cut one specimen from each of three slabs/buttons.	Cut one specimen from each of three slabs.	Cut one specimen from each of three slabs.	9	ASTM D 624
Low temperature Brittleness at –51°C	Cut one specimen from each of five slabs.	None	None	5	ASTM D 746
Durometer hardness (Shore "A")	Cut one specimen from each of three slabs.	None	None	3	ASTM D 2240

Compression set [3]	Three test buttons.	None	None	3	ASTM D 395
Impact resilience [3]	Three test buttons.	None	None	3	ASTM D 2632
Agent permeation [4] [5] Sarin (GB) and Sulfur Mustard (HD)	Cut two specimens from each of six test slabs. Six specimens per agent.	None	None	12	MIL-STD-282 Method 208 Method 209

[1] Heat Aging. The specimens selected for heat aging shall be aged in an air oven at a temperature of 158^0F +/-7^0F (70^0C -/+ 2^0C) for a continuous period of 24 hours as prescribed in ASTM D 573.

[2] Oxygen Aging. Specimens shall be aged in an oxygen environment in accordance with ASTM D 572 for 72 hours.

[3] Same test buttons shall be used for impact resilience and compression set in that order.

[4] If gasket material is not EPDM, applicant shall submit permeation test data for gasket material along with six test slabs for Agent Permeation Test.

[5] Test specimens shall be fabricated in accordance with ASTM D 3182 from material of the same formulation that will be used during regular production of the respirator. The test specimens shall have a cure equivalent to that of the regular production gaskets. The thickness of the test specimens shall be the minimum gasket thickness specified by the applicants design specification. Any finish or treatment, applied to the finished gasket, shall be applied to the test specimens.

3.1.3 Dimensions and Weight, Canister:

The maximum weight of a canister shall be 500 grams. The maximum size of a canister shall be such that the canister shall pass through a 5-inch diameter opening with the threaded connector perpendicular to the 5-inch diameter opening.

3.1.4 CBRN PAPR Powered Mechanism (Blower):

The Powered Mechanism (Blower) must be able to receive the maximum weight and diameter of a canister specified in section 3.1.3

3.2 Breathing Resistance:

3.2.1 Inhalation and Exhalation Resistance:

Resistance to air flow shall be measured in the Respiratory inlet covering of a CBRN powered air purifying respirator mounted on a test fixture with air flowing at a continuous rate of 85 liters per minute both before and after each gas service life bench test. The maximum allowable air resistance to air flow is as follows:

Inhalation:	
Initial	70 mm H_2O
Final [1]	85 mm H_2O
Exhalation:	20 mm H_2O

(1) Measured at end of service life.

3.2.2 Breathing Resistance, Canister:

In addition to the resistance to airflow determined by paragraph 3.2, Breathing Resistance, the canister resistance to inhalation airflow shall be measured at a continuous rate of 85 liters per minute both before and after each gas service life bench test. The maximum allowable air resistance to air flow is as follows:

Inhalation:	
Initial	50 mm H_2O
Final [1]	65 mm H_2O

3.2.3 Canister Element Uniformity:

CBRN PAPR canisters must have a uniformity of resistance within the population of the manufacturers' product. The allowable resistance variance among a specific canister type is $\pm$ 2.5 mm of water based upon the resistance average determined by certification testing. Resistance will be determined at 85 l/min for the canister unit only.

3.3 Field of View:

The CBRN PAPR Respiratory inlet covering shall obtain a Visual Field Score (VFS) of 90 or greater. The VFS shall be obtained by using a medium size respirator or equivalent that is sized to fit the Head Form described in Figure 14 of EN 136, Respiratory protective devices – Full face masks – Requirements, testing, marking; January 1998 or equivalent.

The VFS is determined by using a VFS grid (Dots on visual field) as defined in the American Medical Association *Guides to the Evaluation of Permanent Impairment*, 5th Edition (2000) that is overlaid on the diagram of the visual field plot obtained using the spherical shell of EN 136 apertometer or equivalent. The VFS score is the average of three fittings of the same respirator on the specified head form.

3.4 Respiratory Inlet Covering: Lens Material Haze, Luminous Transmittance and Abrasion Resistance:

3.4.1 Haze: The haze value of the primary lens material shall be 3% or less when tested in accordance with ASTM D 1003-00.

3.4.2 Luminous Transmittance: The luminous transmittance value of the primary

lens material shall be 88% or greater when tested in accordance with ASTM D 1003-00.

3.4.3 Abrasion Resistance: The haze and luminous transmittance of the primary lens material shall be determined in accordance with ASTM D 1003-00 before and after subjecting the lens material to the abrasion test. The abrasion test shall be conducted in accordance with ASTM D 1044-99 using a CS10F calibrase wheel at a minimum of 70 revolutions under a 500-gram weight. After subjecting the lens material to the abrasion test, remove the residue from the test specimens in accordance with ASTM D 1044-99 or by using a cleaning method recommended by the applicant. After the residue is removed from the test specimens, the test specimens shall not exhibit an increase of haze greater than 4% and a decrease of luminous transmittance greater than 4%.

3.4.4 The test specimens shall be the flat four (4) inch (102mm) square version as prescribed in ASTM D 1044-99 and shall have the same nominal thickness and within the tolerance range as the primary lens of the CBRN APR. The test specimens shall be subjected to the same coating process and any other processes, as the primary lens would be under normal production conditions. A total of 6 specimens shall be furnished to NIOSH for certification testing, three pre-abrasion specimens and three specimens after being tested for abrasion in accordance with ASTM D-1044-99.

3.5 Carbon Dioxide:

The maximum allowable average inhaled carbon dioxide concentration shall be less than or equal to 1 percent, measured at the mouth, while the respirator is mounted on a dummy head operated by a breathing machine with the blower running. The breathing rate will be 14.5 respirations per minute with a minute volume of 10.5 liters. Tests will be conducted at ambient temperature of 25 ± 5^{0}C. A concentration of 5 percent carbon dioxide in air will be exhaled into the respiratory inlet covering. The minimum allowable oxygen concentration shall be 19.5 percent. NIOSH Test Procedure RCT-APR-STP-0064 is used for Carbon Dioxide Testing.

3.6 Hydration:

For CBRN PAPR respirators equipped with a hydration facility, the CBRN PAPR respirator shall meet all requirements of the CBRN PAPR standard with the hydration facility in place. Dry drinking tube valves, valve seats, or seals will be subjected to a suction of 75mm water column height while in a normal operating position. Leakage between the valve and the valve seat shall not exceed 30 milliliters per minute. NIOSH Test Procedure RCT-APR-STP-0014 is used for hydration facility leakage

3.7 Powered air-purifying respirators; required components.

Powered air-purifying particulate respirators shall, where its design requires, contain the following component parts:

(1) Respiratory inlet covering
(2) Cartridge, canister and/or filter unit;
(3) Harness assembly;
(4) Powered Mechanism (Blower);
(5) Breathing tube;
(6) Battery and/or power cord;
(7) Flow indicator;
(8) Battery charge indicator

3.7.1 Breathing tubes; minimum requirements:

Flexible breathing tubes used in conjunction with respirators shall be designed and constructed to prevent:
(a) Restriction of free head movement;
(b) Disturbance of the fit of the respiratory inlet covering;
(c) Interference with the wearer's activities; and
(d) Shutoff of airflow due to kinking, or from chin or arm pressure.

3.7.2 Harnesses; installation and construction; minimum requirements:

(a) Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

(b) Harnesses shall be designed and constructed to permit easy removal and replacement of respirator parts, and where applicable, provide for holding a respiratory inlet covering in the ready position when not in use.

3.7.3 Respirator Containers; minimum requirements.

(a) CBRN PAPRS shall be equipped with a container bearing markings which show the applicant's name and the type and commercial designation of the CBRN PAPR on all appropriate approval labels.

(b) Containers for CBRN PAPRS shall be designed and constructed to permit easy removal of the mask.

(c) Containers shall prominently list the battery duration of the unit and provide adequate information on the function and operation of low flow, battery charge, and/or low pressure indicators.

3.7.4 Labels

(a) The Battery service life must be prominently displayed on the respirator battery pack or other suitable location as a supplement to the approval label. For example - " NIOSH approved one hour battery".

(b) Additional cautions and limitations appropriate to CBRN PAPRs must be added as deemed necessary by NIOSH, such as "Observe battery service life", and "Observe low flow or pressure alarm indicators."

3.7.5 General Construction Requirements

3.7.5.1 Battery Requirements:

(a) The user's instructions will include battery service life recommendations

(b) Each CBRN PAPR equipped with a battery must contain an indicator to show that the battery is fully charged.

(c) A low battery indicator, if provided, must indicate when the battery can no longer provide the unit with adequate power to properly power the unit.

3.7.5.2 Low Flow Indicators:

Each CBRN PAPR shall have an indicator which alarms the user, via a readily visible light or other means, when the airflow in the breathing zone drops to a flow within 10% of the identified flow rate of the CBRN PAPR.

3.7.5.3 Operational Controls:

(a) CBRN PAPR units must have readily accessible switches and controls designed to prevent accidental shutoff.

(b) Tight fitting and neck dam CBRN PAPR units must be designed to prevent unpurified air from entering the system.

3.8 Noise Levels:

Noise levels generated by the respirator will be measured inside the respiratory inlet covering, at each ear location, at the maximum airflow obtainable, and shall not exceed 80 dba.

3.9 Airflow:

(a) The CBRN PAPR shall contain a sufficient number of mechanical connectors to ensure that the face velocity through the filter does not exceed the face velocity achieved

through the canister 64 Lpm. A minimum of two mechanical connectors is required. The CBRN PAPR shall have a minimum airflow of 115 Lpm.

(b) Airflow will be measured in the oral/nasal region of the respirator

(c) The minimum airflow identified by the applicant must be maintained for the battery duration as specified by the applicant, + 20 minutes without using auxiliary power sources.

4.0 Special CBRN Requirements:

4.1 Canister Test Challenge and Test Breakthrough Concentrations:

The gas/vapor test challenges and breakthrough concentrations shown in Table 1: Canister Challenge, Breakthrough Concentrations, and Canister Efficiency shall be used to establish the canister service life:

Table 1: Canister Test Challenge and Test Breakthrough Concentrations

	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[1]
Hydrogen Sulfide	1000	5.0
Nitrogen Dioxide	200	1 ppm NO_2 or 25 ppm NO[2]
Phosgene	250	1.25
Phosphine	300	0.3
Sulfur Dioxide	1500	5

[1] Sum of HCN and C_2N_2.

[2] Nitrogen Dioxide breakthrough is monitored for both NO_2 and NO. The breakthrough is determined by which quantity, NO_2 or NO, reaches breakthrough first.

4.2 Canister Service Life:

The applicant shall specify a minimum service life as part of the application for certification. Applications shall be identified in 15-minute intervals (15 minutes, 30 minutes, and 45 minutes) for service life less than 60 minutes. For a service life of 60 minutes or greater, applications shall be identified in 30-minute intervals (60 minutes, 90 minutes, 120 minutes). Gas life tests are performed at room temperature, 25±5°C; 25±5 percent relative humidity; and 80 + 5 percent relative humidity. Three canisters will be tested at each specified humidity with a flow rate of 64 liters per minute, continuous flow. Tests will be conducted to the minimum specified service time. The canisters shall meet or exceed the specified service times without exceeding the identified breakthrough

concentrations in Table 3. Gas life testing shall be performed following environmental conditioning and rough handling.

4.3 Particulate/Aerosol Canister:

The canister shall meet the requirements of a P100 particulate filter in accordance with the following criteria. Particulate filter efficiency testing shall be performed following environmental conditioning and rough handling.

1) Twenty filters for the air-purifying respirator shall be tested for filter efficiency against a dioctyl phthalate or equivalent liquid particulate aerosol.

2) Filters including holders and gaskets; when separable shall be tested for filter efficiency level, as mounted on a test fixture in the manner as used on the respirator.

3) When the filters do not have separable holders and gaskets, the exhalation valves shall be blocked so as to ensure that leakage, if present, is not included in the filter efficiency level evaluation.

4) For air-purifying particulate respirators with a single filter, filters shall be tested at a continuous airflow rate of 85 $\pm$ 4 liters per minute. Where filters are to be used in pairs, the test-aerosol airflow rate shall be 42.5 $\pm$ 2 liters per minute through each filter.

5) A neat cold-nebulized dioctyl phthalate (DOP) or equivalent aerosol at 25 $\pm$ 5°C that has been neutralized to the Boltzmann equilibrium state shall be used. Each filter shall be challenged with a concentration not exceeding 200 mg/m^3.

6) The test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 200 $\pm$ 5 mg has contacted the filter. If the filter efficiency is decreasing when the 200 $\pm$ 5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency.

7) The DOP aerosol shall have a particle size distribution with count median diameter of 0.185 $\pm$ 0.020 micrometer and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

8) The efficiency of the filter shall be monitored and recorded throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation.

9) The minimum efficiency for each of the 20 filters shall be determined and recorded and be equal to or greater than the filter efficiency criterion listed for the P100 filter: $\geq$99.97%.

4.4 Service Life Testing, High Flow:

Each canister shall provide a minimum service life of 5 minutes when tested at a flow rate of 100±10 liters per minute, 50±5 percent relative humidity and 25±5^{0}C for each of the gases/vapors identified in Paragraph 4.1, Canister Test Challenge and Test Breakthrough Concentrations.

4.5 Low Temperature/Fogging:

The CBRN PAPR Respiratory Inlet Covering shall demonstrate an average Visual Acuity Score (VAS) of greater or equal to 75 points for all measurements of acuity with the blower operating. The respirator shall be cold soaked for four (4) hours and then worn in an environmental chamber maintained at minus 21 ^{0}C.

4.6 Communications:

Communication requirements are based upon performance using a Modified Rhyme Test (MRT). The communications requirement is met if the overall performance rating is greater than or equal to seventy (70) percent. The MRT will be performed with a steady background noise of 60 dBA consisting of a broadband "pink" noise with the blower operating. The distance between the listeners and speakers shall be 3 meters.

4.7 Chemical Agent Permeation and Penetration Resistance Against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement:

The air purifying respirator system, including all components and accessories shall resist the permeation and penetration of Distilled Sulfur Mustard (HD) and Sarin (GB) chemical agents when tested on an upper-torso manikin connected to a breathing machine operating at an air flow rate of 40 liters per minute (L/min), 36 respirations per minute, 1.1 liters tidal volume.

Test requirements for Distilled Sulfur Mustard (HD) are shown in Table 2:

Table 2: Vapor-Liquid Sequential Challenge of APR with Distilled Sulfur Mustard (HD)

Agent	Challenge Concentration	Duration of Challenge (min)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough (concentration integrated over minimum service life) (mg-min/m^3)	Number of Systems Tested	Minimum Service Life (hours)
HD-Vapor	50 mg/m$^{3(1)}$	30	40	0.30$^{(3)}$	3.0$^{(4)}$	3	8$^{(6)}$
HD-Liquid	0.43 to 0.86 ml$^{(1)(2)(5)}$	120	40	0.30$^{(3)}$	3.0$^{(4)}$	3	2

(1) Vapor challenge concentration will start immediately after the test chamber has been sealed. Minimum Service Life for liquid exposure starts after the first liquid drop is applied.

(2) Liquid volume dependent on accessories used with the respirator. Minimum volume is 0.43 ml based on the respirator only.
(3) Three consecutive sequential test data points at or exceeding 0.3 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.
(4) The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.
(5) Liquid agent is applied to respirator at hour 6 of the test cycle.
(6) The test period begins upon initial generation of vapor concentration and ends at 8 hours.

Test requirements for Sarin (GB) agent are shown in Table 3:

Table 3: Vapor Challenge of APR with Sarin (GB)

Challenge Concentration	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion mg/m^3	Maximum Breakthrough (concentration integrated over minimum service life) (mg-min/m^3)	Number of Systems Tested	Minimum Service Life (hours)
GB	210(1)	30	40	0.044(3)	1.05(4)	3	8(2)

(1) The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed.
(2) The test period begins upon initial generation of vapor concentration and ends at 8 hours. Vapor challenge of 50 mg/m^3 will be applied for the last 10 minutes of the test.
(3) Three consecutive sequential test data points at or exceeding 0.044 mg/m^3 will collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.
(4) The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test.

4.8 Laboratory Respiratory Protection Level (LRPL) Test Requirement:

The measured laboratory respiratory protection level (LRPL) for each powered air-purifying respirator shall be 10,000 for ≥ 95% of trials with the blower operating. All sampling will be performed in the breathing zone of the respirator. The respirator is tested in an atmosphere containing 20-40 mg/m^3 corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers. The LRPL shall be calculated using eleven exercises: Normal Breathing, Deep Breathing, Turn Head Side to Side, Move Head Up and Down, Recite the Rainbow Reading Passage or equivalent, Sight a Mock Rifle, Reach for the Floor and Ceiling, On Hands and Knees - Look Side to Side, Facial Grimace, Climb Stairs at a Regular Pace, and Normal Breathing.

Test subject and replication numbers are outlined in Table 4.

Table 4.—Anthropometric test criteria

	Small	Medium	Large
Face Length and Face Width	**Cell A** **Use LANL boxes 1, 2, 3, 4 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 10 Trials= 20	**Cell D** **Use LANL boxes 3, 4, 5, 6, 7, 8; panel size 17 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 17 Trials= 34	**Cell G** **Use LANL boxes 7, 8, 9, 10; panel size 11 (2 or 3 subjects each box, 2 trials per subject)** Subjects= 11 Trials= 22
Head Circumference*	**Cell B** **N/A** Subjects= 0 Trials= 0	**Cell E** **N/A** Subjects= 0 Trials= 0	**Cell H** **568-594 mm** Subjects= 10 Trials= 20
Neck Circumference*	**Cell C** **306-378 mm** Subjects= 10 Trials= 20	**Cell F** **355-403 mm** Subjects= 10 Trials= 20	**Cell I** **378-451 mm** Subjects= 10 Trials= 20

*If applicable to design of PAPR.

For each size category (Small, Medium, and Large), each cell corresponding to the anthropometric parameter will be tested. Cells can be either exclusively (if the test subjects only meet the requirements of a specific cell) or concurrently (if the test subjects meet the requirements of more than one cell) tested for each size category.

Example: For the 'Large' category, 11 subjects are needed for the 'Face Length and Width' category (cell G). If 10 of these 11 subjects also meet the measurement range for the 'Large Head Circumference' category (cell H), then the number of subjects required for cell H is simultaneously met. If only 6 of the 11 subjects needed for the 'Large Face Length and Width' category (cell G) meet the measurement range for the 'Large Head Circumference' category (cell H), then an additional 4 subjects will need to be tested in cell H.

4.9 Environmental Conditioning (transportability, temperature range, survivability):

Environmental conditioning shall be performed in accordance with Table 4:

Table 4: Environmental Conditioning

Test	Test Method	Test Condition	Duration
Hot Diurnal	Mil-Std-810F; Method 501.4; Table 501.4-II; Hot-Induced Conditions	Diurnal Cycle, 35^{0}C (95^{0}F) -71^{0}C (160^{0}F);	3 Weeks
Cold Constant	Mil-Std-810F, Method 502.4;	Basic Cold (C1), -32^{0}C (-95^{0}F); Constant	3 Days
Humidity	Mil-Std-810E, 507.3; Method 507.3; Table 507.3-II	Natural Cycle, Cycle 1, Diurnal Cycle, 31^{0}C (88^{0}F) RH 88% -41^{0}C (105^{0}F) RH 59%	5 Days, Quick Look
Vibration	Mil-Std-810F, 514.5	US Highway Vibration, Unrestrained Figure 514.5C-1	12 Hours/Axis, 3 Axis; Total Duration =36 Hours, equivalent to 12,000 miles
Drop	3 foot drop onto bare concrete surface	Canister only; In individual canister packaging container	1 drop/filter on one of the 3 axes.

Note: Extra batteries are required to be subjected to the environmental testing for the human subject testing

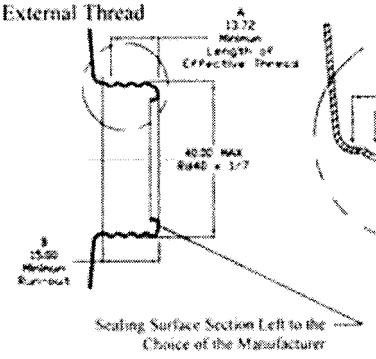
Figure 1

(Revision 1) 17 Mar 2003

NIOSH CBRN Full Facepiece APR Mechanical Connector and Gasket

A

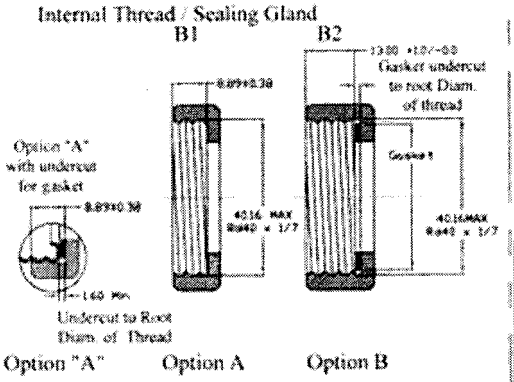
External Thread



Sealing Surface Section Left to the Choice of the Manufacturer

B

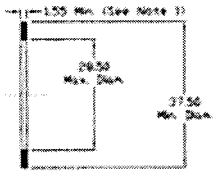
Internal Thread / Sealing Gland



C

Note: All Dimensions in Millimeters

Gasket

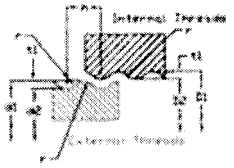


Note:

1. Gasket thickness determined by option B1 or B2 internal thread - sealing gasket
2. Positive retention of gasket in sealing gland required
3. Right hand threads

D

Dimensions of Threads



Dimensions in millimeters

Thread	Thread limits						Pitch P	Number of threads per 25.4	Thread height	Radius
	External			Internal						
	Major diameter d1		Minor diameter d2	Major diameter D1	Minor diameter D2					
	max	min	max	max	min	max	P	Z	H1	r
Rd40 x 1/7	40.00	39.70	38.40	40.16	38.56	38.86	3.629	7	0.8	1.225