Chemical, Biological, Radiological, and Nuclear (CBRN) Powered, Air-Purifying Respirator (PAPR) Concept

Draft November 4, 2005

These concepts are being discussed as a means to approve CBRN PAPR and subsequently upgrade existing 42 CFR Part 84 approved PAPRs to CBRN standards.

Since the introductions of the CBRN PAPR concept, manufacturers and users have expressed the desire and need to have CBRN PAPRs available and to upgrade existing 42 CFR Part 84 approved PAPRs to CBRN standards as soon as possible.

The CBRN PAPR and CBRN PAPR retrofit capability should increase the number of emergency responders afforded protection by NIOSH-approved CBRN respirators.

The CBRN PAPR approval process is essentially conducted in two stages. The first stage requires 42 CFR Part 84 approval. Following 42 CFR Part 84 approval, the manufacturer may apply for CBRN PAPR approval. Following both 42 CFR Part 84 approval and CBRN PAPR approval, manufacturers may continue to a third stage and seek approval for CBRN PAPR retrofit kits. The 42 CFR Part 84 approval process remains unchanged. The CBRN PAPR special test requirements are described in paragraphs 1.0 through 4.3.10 below. The CBRN PAPR retrofit requirements are described in the section 5.0.

The CBRN PAPR must meet the following minimum requirements:

(a) Approval under NIOSH 42 CFR Part 84

(b) Special tests under NIOSH 42 CFR Part 84.63(c)

(1) Durability conditioning
(2) Chemical agent permeation and penetration resistance against Distilled Sulfur Mustard (HD) and Sarin (GB)
(3) Laboratory Respirator Protection Level (LRPL)
(4) Canister test challenge and test breakthrough concentrations

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

1.1 Respirator containers; minimum requirements – CBRN tight-fitting PAPR

1.1.1 Required packaging configuration: (minimum packaging configuration): The CBRN tight-fitting PAPR and the required components shall be subjected to the environmental and transportation portions of the durability conditioning in the manufacturer specified minimum packaging configuration. The canisters shall also be subjected to an additional rough handling drop test in its designated minimum packaging configuration.

1.1.2 The minimum packaging configuration is the protective packaging configuration that the *end user shall store or maintain the CBRN tight-fitting PAPR and the required components inside after it has been issued for immediate use. The user instructions (UI) shall identify the minimum packaging configuration and shall direct the end user how to store or maintain the CBRN tight-fitting PAPR and the required components inside the manufacturer specified minimum packaging configuration while in the possession of the end user. The same minimum packaging configuration identified in the UI shall encase the CBRN tight-fitting PAPR and the components when NIOSH performs the durability conditioning. The level of the minimum packaging configuration, if any, is left to the discretion of the manufacturer. Examples of common minimum packaging configurations are mask carriers, clamshell containers, draw string plastic bags, hermetically-sealed canister bags or nothing at all.

If over cases, packaging, or shipping containers are provided by the applicant over and above the minimum packaging configuration, these additional packaging levels may not be a substitute for the minimum packaging configuration and will not be used by NIOSH in the durability conditioning of the application.

* End user: The definition of the end user is the person who will derive protection from the respirator by wearing it. It is assumed that the end user will store the respirator in a location where it will be available for immediate access and use during an emergency.

1.2 Durability conditioning shall be performed in accordance with Table 1

Table 1 — Durability 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° C (95° F) to 71° C (160° F)	3 Weeks
Cold Constant	Mil-Std-801F, Method 502.4;	Basic Cold (C1), -32° C -25.6° F); Constant	72 Hours
Humidity	Mil-Std-810E, 507.3; Method 507.3; Table 507.3-II	Natural Cycle, Cycle 1, Diurnal Cycle, 31° C (88°F) RH 88% to 41° C (105° F) RH 59%	5 Days, Quick Look
Vibration	Mil-Std-810F, 514.5	U.S. 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.

1.3 Extra batteries (not subjected to the durability conditioning) are required for certification testing

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

2.1 The PAPR, while the blower is running and including all components and accessories except for the battery (or batteries), 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 airflow rate of 40 L/min, 36 respirations per minute, 1.1 liters tidal volume. Test requirements for distilled sulfur mustard (HD) are shown in Table 2. Test requirements for Sarin (GB) agent are shown in Table 3. Chemical agent permeation and penetration resistance testing shall be performed on four PAPR (two for HD and two for GB) following the durability conditioning.

Table 2 —Vapor-liquid sequential challenge 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 test time) ($mg\text{-}min/m^3$)	Number Of Systems Tested	Minimum Test Time (hours)
HD-Vapor	50 mg/m^{3*}	30[*]	40	0.30[‡]	3.0[§]	3	8[††]
HD-Liquid	0.43 to 0.86 ml[*,†,**]	120[*]	40	0.30[‡]	3.0[‡]	3	2

[*] Vapor challenge concentration will start immediately after the test chamber has been sealed. Minimum test time for liquid exposure starts after the first liquid drop is applied

[†] Liquid Volume dependent on accessories used with the respirator. Minimum volume is 0.43 ml based on the respirator only. Liquid challenge required on CBRN tight-fitting PAPRs only

[‡] 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 two (2) minutes

[§] The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test

[**] Liquid agent is applied to respirator at hour six (6) of the vapor test cycle.

[††] The test period begins upon initial generation of vapor concentration and ends at eight (8) hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test.

Table 3—Vapor challenge with Sarin (GB)

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 test time) ($mg\text{-}min/m^3$)	Number Of Systems Tested	Minimum Test Time (hours)
GB	210[*]	30[*]	40	0.044[‡]	1.05[§]	3	8[††]

[*]The vapor challenge concentration generation will be initiated immediately after test chamber has been sealed

[†] The test period begins upon initial generation of vapor concentration and ends at 8 hours. Supplemental electrical power to the PAPR is permissible to allow the system to run for the purpose of this test

[‡] 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

[§] The cumulative Ct including all maximum peak excursion data points must not be exceeded for the duration of the test

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

3.1 The measured laboratory respiratory protection level (LRPL) for each powered, air-purifying respirator shall be 10,000 for $\geq$ 95% trials with the blower operating (blower on mode). 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 0.4–0.6 µm.

3.2 The measured laboratory respiratory protection level (LRPL) for each tight-fitting powered, air-purifying respirator shall be 2,000 for $\geq$ 95% trials with the blower not operating (Blower Off mode). A modified LRPL using a sample size of 8 subjects will be used for evaluation. 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 0.4–0.6 µm.

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

4.1 Tight-fitting facepiece

4.1.1 The gas/vapor test challenges and breakthrough concentrations shown in Table 4. Canister capacity tests will be performed at room temperature, 25 ºC ± 2.5 °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 system 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 shall be performed following the durability conditioning.

Table 4 —Canister test challenge and test breakthrough concentrations

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

* Sum of HCN and C_2N_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 Loose-fitting facepiece

4.2.1 The gas/vapor test challenges and breakthrough concentrations shown in Table 5. Canister capacity tests will be performed at room temperature, 25 ºC ± 2.5 °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 system 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.

Table 5 —Canister test challenge and test breakthrough concentrations

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

* Sum of HCN and C_2N_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.

4.3 Particulate/aerosol testing

4.3.1 The canister shall meet the requirements of 99.97% particulate filter efficiency in accordance with the following criteria. Particulate filter efficiency testing shall be performed following the durability conditioning.

4.3.2 Twenty (20) canisters shall be tested for filter efficiency against a dioctyl phthalate or equivalent liquid particulate aerosol

4.3.2.1 Additionally, six canisters from the cyclohexane gas life test of paragraphs 4.1 and 4.2 shall be tested for filter efficiency against dioctyl phthalate or equivalent liquid particulate aerosol.

4.3.3 The canister 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

4.3.4 When the canister does not have separable holders and gaskets, the exhalation valves shall be blocked to ensure that leakage, if present, is not included in the filter efficiency level evaluation

4.3.5 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 for which approval is sought. 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 for which approval is sought

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

4.3.7 The test shall continue until minimum efficiency is achieved or until an aerosol mass of at least 200 mg ± 5 mg challenge point is reached, the test shall be continued until there is no further decrease in efficiency

4.3.8 The DOP aerosol shall have a particle size distribution with count median diameter of 0.185 µm ± 0.020 µm and a standard geometric deviation not exceeding 1.60 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent

4.3.9 The efficiency of the canister shall be monitored throughout the test period by a suitable forward-light-scattering photometer or equivalent instrumentation and recorded

4.3.10 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.

5.0 CBRN PAPR Upgrade Retrofit

Once approvals have been issued for 42 CFR Part 84 approval and subsequent CBRN PAPR approval, manufacturers may apply for approval of CBRN PAPR retrofit kits to upgrade existing 42 CFR Part 84 PAPR to CBRN PAPR standards. In doing so, the following applies:

5.1 PAPR units must be 42 CFR Part 84 and CBRN PAPR approved prior to submitting them for upgrading to CBRN capability

5.2 Retrofit of previously approved 42 CFR Part 84 and CBRN tight-fitting PAPR must be performed by manufacturer-trained and authorized technicians, who ensure the retrofit complies with the approved CBRN PAPR configuration, quality assurance and performance requirements

5.3 The CBRN PAPR retrofit kit must, as a minimum, contain the following:

- CBRN PAPR retrofit kit instructions

- Replacement packaging, components, parts, materials, and operation instructions required to retrofit the PAPR configuration to the approved CBRN configuration level

- Registration materials for recording PAPR information as required by the manufacturer to track specific units that have been updated

- CBRN PAPR retrofit approval label(s) for the respirator retrofit kit

- Respirators which are to be retrofitted must be in “fully operational and protective condition”

5.4 Manufacturers will need to submit a Standard Application Form and associated documents which clearly define the respirators eligibility for retrofit and explain the configuration changes achieved with the retrofit kit

5.5 The manufacturer must provide four PAPRs which have been in service for one to five years. As a minimum, submitted respirators are to be from two different conditions of use: Two from a light condition of use category. Light use is defined as a PAPR primarily in a storage configuration; used intermittently throughout the service life. Two from a heavy condition of use category. Heavy use is defined as PAPR used routinely for respiratory protection as part of an OSHA-compliant respirator program.

5.6 The units should be supplied with the retrofit kit installed

5.7 NIOSH testing performed on the respirators will be evaluated to the special tests for chemical agent permeation and penetration resistance against Distilled Mustard (HD) and Sarin (GB) for each respirator use condition provided plus any other tests described above or as deemed necessary by NIOSH