

Concept for CBRN Full Facepiece Air Purifying Respirator Standard**(1) Goal:**

Develop a NIOSH, NPPTL, tight fitting, full facepiece, air purifying respirator standard that addresses CBRN materials identified as inhalation hazards and/or possible terrorist hazards using a minimum number of filters for emergency responders.

Target: Four (4) filters

	Short Duration	Long Duration
TIMs	15 minutes*	60 minutes*
TIMs plus CO	15 minutes*	60 minutes*

* Indicated times are for illustration only. Actual times will be established from hazard modeling and developmental test results.

(2) Hazards:

NIOSH has been evaluating various lists of chemicals that could be deployed as a result of a terrorist incident. In an effort to reduce the number of certification tests necessary as part of a Chemical Biological Radiological Nuclear (CBRN) Air-Purifying Respirator (APR) standard, efforts have been underway to categorize potential respiratory hazards into families with a representative test chemical identified for each family. The following information is a synopsis of this effort to date.

The current carbon technology used in canisters and cartridges were reviewed from existing certification standards. The current standards for gas masks in Europe and the U.S.(NIOSH) were reviewed. The military purchasing specification for ASZM-T carbon for C2A1 military canisters was also reviewed. The most common parameters identified from the review of the military specification and the certification standards were the middle range certification challenges. Some of the test chemicals were considered to be redundant, since other test chemicals would guarantee the carbon effectiveness against the chemicals in question (Chlorine, Hydrogen Chloride, Hydrogen Fluoride, Phosphine, CS & CN Tear Gases). Carbon tetrachloride and Cyclohexane are the representative chemicals for organic vapors. Meeting the organic vapor test for a cartridge will provide protection for all organic vapors having vapor pressures less than those of carbon tetrachloride and cyclohexane. From the CWA /TIC list, approximately 61 organic chemicals are covered by this logic, including GB and HD. The acid gases (32 chemicals) are covered by cyanogen chloride, hydrogen cyanide, hydrogen sulfide, and sulfur dioxide. Ammonia represents the base gases, and covers another 4 chemicals on the list. Ethylene oxide, formaldehyde, phosgene, phosphine and nitrogen dioxide are considered special case chemicals. Phosphine is a hydride and must be removed catalytically (copper⁺² and silver impregnates on carbon). Therefore, 105 of the 151 chemicals can be addressed through testing these 11 chemicals. Nine of the test chemicals are listed in ITF 25.

(DRAFT FOR DISCUSSION)

Chemicals	Organization Using as Test Agent
Ammonia	NIOSH & EN
Arsine	Military
Cyclohexane	Organic Vapor- EN
Carbon Tetrachloride	Organic Vapor- NIOSH
Cyanogen Chloride	Military
Ethylene Oxide	NIOSH
Formaldehyde	NIOSH
Hydrogen Cyanide	NIOSH, EN & Military
Hydrogen Sulfide	NIOSH & EN
Nitrogen Dioxide	NIOSH & EN
Phosgene	Military
Sulfur Dioxide	NIOSH & EN
Phosphine	NIOSH

Hazard mapping: Conduct modeling based on the ‘Most Credible Event’ (MCE) scenarios developed for the open-circuit SCBA CBRN standard to determine warm zone operational scenarios. Add or delete scenarios depending on the Toxic Industrial Material (TIM) being evaluated.

(3) Respirator Use:

A. Warm Use: Less than IDLH concentrations, to REL; sustained warm zone support operations; long term use for decon, traffic control, rehabilitation, rescue and recovery; agent known & quantified.

B. Crisis Provision: Short duration, above IDLH concentrations and high physiological (flow) demand possible; use as entry & egress device to the point of a recognized hazard & additional protection needed.

Filter	Configuration	Long Duration Less Than IDLH	Crisis Panic Demand	Short Duration Less Than IDLH
Filter #1, TIM's less CO	Full Facepiece Back or Chest Mounted	60 Minutes*	20 Minutes*	
Filter #2, TIM's plus CO	Full Facepiece Back or Chest Mounted	60 Minutes*	20 Minutes*	
Filter #3, TIM's less CO	Full Facepiece Mask Mounted		5 Minutes*	15 Minutes*
Filter #4, TIM's plus CO	Full Facepiece Mask Mounted		5 Minutes*	15 Minutes*

* Indicated times are for illustration only. Actual times will be established from hazard modeling and developmental test results.

(4) Filter Test Requirements:

	Warm Zone	Crisis⁽¹⁾
	Non IDLH ⁽²⁾	Greater than IDLH ⁽²⁾
64 lpm flow	X	
high flow 100 lpm		X
Rough handling	X	X

(1) Crisis is a high use concentration at a high flow rate, 100 liters, per minute.

(2) Same test concentrations, different flow rates

(5) Special Test Requirements:**(5)(a) Chemical Agent Permeation and Penetration Resistance Against Distilled 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 1.

Table 1: Simultaneous Liquid and Vapor 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	300 mg/m ³	TBD ^{(1)**}	40	0.60 ⁽³⁾	TBD ⁽⁴⁾	3	TBD ^{(2)**}
HD-Liquid	0.50 ml	TBD					

** Duration of challenge and minimum service life will be determined from hazard modeling and developmental test results.

⁽¹⁾ Vapor challenge concentration will start immediately after the liquid drops have been applied and the test chamber has been sealed.

⁽²⁾ The test period begins upon start of initial vapor generation.

⁽³⁾ Three consecutive sequential test data points at or exceeding 0.6 mg/m³ 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 peak data points must not be exceeded for the duration of the test.

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Test requirements for Sarin (GB) agent are shown in Table 2.

Table 2: Vapor Challenge of APR with Sarin (GB)

Challenge Agent	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	2,000 mg/m ³	TBD ^{(1)**}	40	0.087 ⁽³⁾	TBD ⁽⁴⁾	3	TBD ^{(2)**}

** Duration of challenge and minimum service life will be determined from hazard modeling and developmental test results.

⁽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.

⁽³⁾ Three consecutive sequential test data points at or exceeding 0.087 mg/m³ 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 peak data points must not be exceeded for the duration of the test.

(5)(b) Laboratory Respiratory Protection Level (LRPL) Test Requirement:

The measured laboratory respiratory protection level (LRPL) for each full facepiece, air purifying respirator shall be 2000, when the APR facepiece is tested in a negative pressure mode in an atmosphere containing 20-40 mg/m³ corn oil aerosol of a mass median aerodynamic diameter of 0.4 to 0.6 micrometers.

(6) Design Requirements:**(6)(a) Interchangeable consumable filter cartridges and canisters****(6)(b) Rough handling (transportability, temperature range, survivability)**

Test	Test Method	Test Condition	Duration	Sample Size ²	Pass / Fail Criteria ¹
Hot Diurnal	Mil-Std-810F, 501.4	71 °C max, cyclical	3 Weeks	TBD	Gas Life, System Permeation / Penetration
Cold Constant	Mil-Std-810F, 502.4	Basic Cold, -32 °C	3 Days	TBD	Gas Life, System Permeation / Penetration
Humidity	Mil-Std-810E, 507.3	Table 507.3-II, Natural Cycle, Cycle 1	5 Days, Quick Look	TBD	Gas Life, System Permeation / Penetration
Vibration	Mil-Std-810F, 514.5	US Highway Vibration, Unrestrained Figure 514.5C-1	12 Hours / Axis, 36 Hours Total (12,000 miles)	TBD	Gas Life, System Permeation / Penetration
Drop	3 foot drop onto concrete	Filter Only, 3 Axis	N/A	TBD	Gas Life, System Permeation / Penetration

(1) Pass / Fail Criteria is determined after APR has been subjected to Hot, Cold, Humidity and Vibration environmental exposure sequence order. Pass / Fail Criteria for Drop test is determined after 3 drops, 1 drop per axis, is completed.

(2) Sample size to be determined.

(6)(c) Operational Characteristics (donning, field of view/acuity, flow, resistance, storage life, usage life)**(6)(c)(1) Full Facepiece Fogging**

The respirator performance rating for resistance to fogging shall be greater than or equal to 70% when tested in accordance to the fogging test procedure, Appendix A:

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(6)(c)(2) Communications

The respirator performance rating for communications shall be greater than or equal to 70% when tested in accordance with the communications test procedure, Appendix B.

(6)(c)(3) Breathing Resistance

Resistance to air flow shall be measured in the facepiece of a CBRN 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 resistance to air flow is as follows:

	Chin Style	Non Facepiece Mounted
Inhalation:		
Initial	65 mm H ₂ O	70 mm H ₂ O
Final ⁽¹⁾	80 mm H ₂ O	85 mm H ₂ O
Exhalation:	26 mm H ₂ O	26 mm H ₂ O

⁽¹⁾ Measured at end of service life

(6)(c)(4) Optical Requirements for CBRN facepiece lens:

(6)(d) Long term field auditing/maintenance procedures/ inspection

(6)(e) Extracts from 42 CFR, Part 84

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Appendix A – Full Facepiece Fogging

Two individuals with a visual acuity of 20/70 better shall perform each test while wearing the apparatus according to manufacturers directions. Test participants shall be assigned a properly sized and fitted test respirator for each environmental exposure condition. All participants shall be trained in the donning and usage of the respirator per manufacturer's instructions.

Prior to testing, visual acuity shall be recorded for each subject while wearing the respirator using Snellen Eye Test charts or an equivalent method.

Test 1

The APR shall be cold soaked in an environmental chamber at minus 21°C (-6°F) for 4 hours.

At the start of each cold temperature wear trial a test participant shall enter the test chamber (maintained at -21°C) and sit quietly for five minutes. Once the five minute rest period transpires, subjects shall self-don their assigned respirator.

A visual acuity test shall then be administered to quantify the impact of any lens fogging on vision.

The test participant shall then complete a 12-minute work-rest-work regimen comprised of five minutes of exercise, 2 minutes of rest, and an additional five minutes of exercise with the exercise periods consisting of treadmill walking at 4.8 km/hr (3 mph) on a level grade.

Visual acuity tests shall be repeated at the end of each walk period (i.e., after five minutes of walking and at the end of the 12 minute period immediately following the treadmill walk).

Test 2

The APR shall be conditioned in an environmental chamber at 15.5°C (60°F), 75% RH for 4 hours.

At the start of each cool/humid temperature wear trial a test participant shall enter the test chamber (maintained at 15.5 C) and sit quietly for five minutes. Once the five minute rest period transpires, subjects shall self-don their assigned respirator.

A visual acuity test shall then be administered to quantify the impact of any lens fogging on vision.

The test participant shall then complete a 12-minute work-rest-work regimen comprised of five minutes of exercise, 2 minutes of rest, and an additional five minutes of exercise with the exercise periods consisting of treadmill walking at 4.8 km/hr (3 mph) on a level grade.

Visual acuity tests shall be repeated at the end of each walk period.

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Interpretation of Results

Visual acuity scores obtained during each environmental test with the respirator shall be divided by a subject's visual acuity score obtained with the mask prior to testing to calculate a *performance rating* using the following equation:

$$\text{Performance Rating (\%)} = \text{VA}_{\text{CHAMBEREX}} / \text{VA}_{\text{INITIAL}} \times 100 \quad (1)$$

where $\text{VA}_{\text{chamber } x}$ = visual acuity score during chamber test at time x and $\text{VA}_{\text{initial}}$ = visual acuity score obtained with the mask prior to testing.

Visual acuity performance ratings calculated from measurements taken post-donning and at the end of each treadmill walk shall be averaged for each individual subject to obtain an average visual acuity performance rating for each subject based on the environmental condition.

Average *performance rating* for each test participant shall be greater than or equal to 70% for both Test 1 and Test 2 to meet the fogging requirement.

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Appendix B—Communication

- 1) Speech intelligibility testing shall be accomplished through the use of the Modified Rhyme Test (MRT), which evaluates a listener’s ability to comprehend single words and provides an indication of speech transmission of the selected words. The MRT consists of multiple lists of 50 monosyllabic, phonetically balanced words each. A sample word list is provided in Table 1.

Table 1. Sample MRT stimulus word list

1. lick	11. same	21. pad	31. pip	41. name
2. beat	12. peal	22. din	32. seen	42. soil
3. puff	13. kit	23. sit	33. way	43. fin
4. cook	14. sat	24. win	34. west	44. cuff
5. tip	15. sin	25. teak	35. pace	45. heal
6. rave	16. gold	26. dent	36. bat	46. hark
7. hang	17. buff	27. sub	37. mop	47. heat
8. till	18. lay	28. led	38. big	48. then
9. math	19. nun	29. tot	39. tab	49. law
10. sale	20. must	30. dub	40. case	50. bean

- 2) Three test listeners consisting of two males and one female shall comprise the subject test panel. All participants shall be tested for “normal” hearing prior to testing by a qualified individual.
- 3) An additional five individuals (four males and one female) without obvious speech defects or strong regional accents shall serve as MRT speakers.
- 4) All participants shall be trained in the donning and usage of the respirator per manufacturer’s instructions and all shall pass a qualitative facepiece-to-face fit check according to the manufacturer’s instructions.
- 5) Procedure:
 - a. The three test listeners shall be seated opposite a single test speaker for each MRT trial at a distance of 3 meters (10 ft), and they shall be facing one another. Each listener shall be given a multiple choice answer sheet or positioned before a computer and monitor that will be used to input his or her responses.
 - b. Data for the MRT will be collected with a steady background noise of 60 dBA consisting of a broadband “pink” noise. A Brüel and Kjaer Type 1405 Noise Generator or equivalent will be used to produce the background noise. Background noise levels will be monitored at a position near the listening panel using a Type 2 digital sound level meter and recorded at the beginning, middle, and end of each MRT session.

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- c. The test speaker shall present each stimulus word using the carrier phrase “The word is _____.”
- d. Speakers will be instructed and trained to maintain a constant output volume at 75 dBA to 85 dBA for all presented words. A Type 2 digital sound level meter will be positioned in front of the speaker within his or her sight to provide feedback concerning the loudness of their voice during testing. Speaker output levels will be recorded at the beginning, middle, and end of each MRT session for verification.
- e. Listeners will select the word that was perceived to be spoken from a list of six response words presented on the computer monitor by clicking a button on the monitor that corresponds to the perceived word. If given a paper answer form, subjects will circle their selection. A sample answer sheet is provided in Figure 1.
- f. Test listeners shall then provide a thumbs-up hand signal to the speaker to cue him or her to say the next word.
- g. An individual speaker will present a total of 50 stimulus words to complete one MRT trial. A different speaker shall then be used to present the next MRT trial. Test speakers will continue to rotate among the speaker test panel until all trials have been complete. A sample test matrix is provided in Table 2.
- h. Data will be obtained without the respirator and with the respirator worn and operated per the manufacturer’s instructions by both speakers and listeners. All conditions shall be randomly assigned and a different word list shall be used for each test. Again, an example of a test matrix is provided in Table 2.

Table 2. Sample MRT test matrix

Speaker	Speaker Condition	Listeners’ Condition	Word list
1	No mask	No mask	1
2	No mask	No mask	3
3	Masked	Masked	5
4	Masked	Masked	7
5	No mask	No mask	9
2	Masked	Masked	2
4	No mask	No mask	4
1	Masked	Masked	6
5	Masked	Masked	8
3	No mask	No mask	10

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- i. A total of 10 MRT trials shall be performed. The 10 trials will result in a total of 15 MRT scores (five per listener) for the unworn mask condition and 15 scores for the worn condition.
- j. Listener performance on the MRT shall be scored in terms of the percentage of words correctly identified using the equation:

$$\% \text{ correct} = (\text{number correct} - (\text{number incorrect}/5)) * 2 \quad (1)$$

The equation accounts for chance or guessing made possible by the multiple-choice form of the answer sheet (*Human Engineering Guide to Equipment Design*, American Institutes for Research, Washington, DC, 1972).

- k. Individual listeners' scores for the unworn and worn respirator conditions shall be averaged for each condition.
- l. Each individual listener's average score with the respirator shall be divided by their average unmasked MRT score to calculate a *performance rating* (ref equation (2)). (Because the listening subjects serve as their own controls, the performance rating allows the effect of the respirator condition to be isolated from the effect of the individual).

$$\text{Performance rating (\%)} = \left(\frac{\text{MRT \%correct with respirator}}{\text{MRT \%correct without respirator}} \right) \times 100 \quad (2)$$

- m. The communications requirement shall be met if the average *performance rating* is greater than or equal to 70%.

MRT Listener Response Sheet Date: _____ Listener Position: _____ TP#: _____

Scenario: _____ Speaker: TP#: _____ Mask Condition: _____

**** 1-A ****

1	kick	lick	sick	14	sack	sad	sap	27	sup	sub	sud	40	cake	came	cave	
	tick	wick	pick		sag	sat	sass		sum	sun	sung		cane	case	cape	
2	neat	beat	seat	15	sit	sip	sill	28	wed	fed	bed	41	tame	came	fame	
	meat	feat	heat		sick	sin	sing		led	shed	red		same	name	game	
3	pun	puff	pup	16	fold	sold	gold	29	pot	hot	lot	42	toil	boil	foil	
	pub	pus	puck		hold	cold	told		not	tot	got		coil	oil	soil	
4	hook	shook	book	17	but	bug	bus	30	duck	dud	dung	43	fig	fizz	fit	
	took	cook	look		buff	bun	buck		dun	dug	dub		fib	fin	fill	
5	lip	hip	dip	18	late	lake	lay	31	pit	pin	pig	44	cuss	cud	cup	
	sip	rip	tip		lame	lane	lace		pill	pick	pip		cut	cub	cuff	
6	rake	rate	ray	19	run	bun	fun	32	seethe	seek	seen	45	heel	peel	keel	
	raze	race	rave		sun	nun	gun		seed	seep	seem		feel	eel	reel	
7	fang	bang	hang	20	dust	gust	must	33	say	pay	may	46	mark	bark	dark	
	sang	gang	rang		bust	just	rust		gay	way	day		lark	hark	park	
8	will	hill	kill	21	path	pack	pass	34	best	west	nest	47	heath	heave	heap	
	bill	fill	till		pat	pad	pan		vest	test	rest		heat	heal	hear	
9	map	mat	math	22	dip	dim	din	35	page	pane	pace	48	then	den	ten	
	mad	mass	man		dill	did	dig		pave	pale	pay		pen	hen	men	
10	pale	sale	bale	23	fit	hit	bit	36	bash	bat	ban	49	law	saw	paw	
	gale	male	tale		sit	kit	wit		back	bath	bad		jaw	raw	thaw	
11	sane	sake	safe	24	tin	fin	sin	37	hop	cop	shop	50	beat	beak	beach	
	save	same	sale		win	pin	din		mop	pop	top		beam	bean	bead	
12	peak	peach	peas	25	tear	teal	teak	38	dig	wig	big	Score				
	peal	peace	peat		team	tease	teach		fig	pig	rig					
13	kin	kid	kick	26	dent	tent	rent	39	tack	tan	tab					
	king	kit	kill		went	sent	bent		tang	tam	tap					