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Sent: Wednesday, November 13, 2002 12:43 PM
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Cc: Waters, Tina M SBCCOM
Subject: Concept for CBRN Full Facepiece Air-Purifying Respirator Standard , dated 16 September 2002

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Comments to Draft NIOSH Concept for CBRN Full Facepiece Air-Purifying Respirator Standard, dated 16 September 2002

Reviewers:
Mr. Stephan Graham,
Ms. Irene Richardson,
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Ms. Tina Waters,

1. Page 1 of 20, paragraph (1) Goal, table listing short and long duration for TICs:

Finding: What is this table trying to convey? Filter performance should be based on actual service life when challenged by the test agents and TICs, with a goal to reach one service life endpoint, such as six hours. See further comments below concerning paragraph 4.4.2.

Recommendation: Delete this table.

2. Page 3 of 20, paragraph (3) Respirator Use: subparagraph A. Warm Use:

Essential change.

Discussion: The current description proposed for full facepiece air purifying respirator (APR) use is in environments containing contaminants between the NIOSH REL but less than IDLH; long term use for decon, traffic control, rehabilitation, rescue and recovery; where the agent is known and quantified.

Finding 1: The Army position is that rescue and recovery is not performed in the warm area but delineates operations that occur in the "hot" zone. The hot zone is not the area where APRs should be used if high levels of contaminants [e.g., greater than the IDLH or maximum use concentration (MUC) of the respirator and canister] could be generated during high intensity activities such as rescue and recovery.

Finding 2: What is the definition or intended use of the term "rehabilitation"?

Finding 3: The use of APRs in an area classified as a warm zone but having potential to become a hot zone due to unknown change in the operating scenario (e.g., uncovering of pockets of high concentration of contaminants) requires continual or routine near real-time monitoring. The current description implies that once the contaminant is initially known and quantified, monitoring may not be continued. The use of APRs requires ongoing monitoring to ensure contaminant levels remain below the MUC limits of the device as the operation changes or progresses.

Recommendation: Delete rescue and recovery. Rewrite description as follows: For Warm Zone Use: For concentrations greater than the NIOSH REL and up to the Maximum Use Concentration (MUC) for the full facepiece respirator and canister, but not to exceed the IDLH; sustained warm zone support operations including long term use for decon, traffic control, and rehabilitation where contaminants are known, quantified and continually or routinely monitored.

3. Page 3 of 20, paragraph (3) Respirator Use: subparagraph B. Crisis Provision.

Essential change.

Discussion: The current description proposed for full facepiece APR includes a short duration contingency, for contaminant concentrations above IDLH concentrations and possible high physiological (flow) demand ; the "contingency" accounts for unforeseen factors such as a secondary device or pockets of entrapped hazard.

Finding 1: The Army position is that risk of secondary devices is a hazard that will always be present. There is no guarantee that secondary devices will not be hidden at a possible terrorist site or that secondary events cannot happen at an accident site. If a secondary device or event were to occur at an emergency response site, the secondary area should then be classified as a separate "hot zone" or be included into or with subsequent expansion of the initial hot zone. Personnel using APRs when a secondary device or event presents itself should immediately retreat to an identified warm zone and only personnel properly equipped to enter a hot zone should continue hot zone operations.

Finding 2: Personnel using APRs who encounter "pockets of entrapped hazard" (which would be above IDLH or MUC of the respirator) should immediately retreat from the source. For example, if the concentration of contaminant emanating from the source is above the IDLH or MUC of the APR, than the area must be classified as a hot zone. Personnel wearing an APR at this point should consider the device as an escape respirator and immediately leave the area. Personnel wearing proper hot zone protective equipment should then be brought in to continue operations until the hazard is reduced to an acceptable level where an APR can again be worn.

Finding 3: Based on our experience and analysis in warm zone environments, pockets of higher concentrations of contamination may exist; however these levels generally will not meet or exceed the IDLH.

Recommendation: Delete Crisis Provision. Personnel should not be put at risk of over exposure due to a false sense of security in the mask. Crisis provision or contingency should be realistically addressed in the proposed escape respirator standard.

4. Page 3 of 20, paragraph (3) Respirator Use: subparagraph B. Crisis Provision, Table.

Essential Change.

Finding: What is the intended use and purpose for this table? What do terms such as "Crisis" and "Panic Demand", mean? There is no explanation on which to base comment regarding NIOSH intent.

Recommendation: Delete the Table.

5. Page 3 of 20, paragraph (3) Respirator Use: subparagraphs C and D.

Essential change.

Finding 1: Description states that the CBRN APR filter is a single use filter. After one use the filter is to be discarded. What constitutes a single use? Is single use considered one shift and, if so, what constitutes shift length (in time) (e.g., an eight-hour shift or 12 hour shift)? Is single use one period of continuous facepiece wear time or can the device be worn, doffed and again donned, more than once, twice, etc during that shift? Is the intent of single use based on particulate filter loading or reaction with aerosols, or depletion of reactive chemical sites in the canister bed?

Recommendation 1: Define single use. Include criteria such as repeated donning and doffing, and shift length in hours. Identify if environmental criteria (if any) can impact use time decision logic.

Finding 2: The overall contamination concern in the warm zone will be that of vapor, not liquid. However, the inclusion of limitations defining filter use and disposal of the respirator if the device is contaminated with warfare agent are items that should be included in paragraph 6.0 CBRN APR Cautions and Limitations for Use.

Recommendation 2: Delete "liquid" and change to "Respirators contaminated with chemical warfare agents are to be disposed of after use". Given the importance of the cautions and limitations and that they specifically define the scope of the respirator's use, recommend moving paragraph 6.0 CBRN APR Cautions and Limitations for Use into paragraph (3) Respirator Use. Include paragraph (3) subparagraphs C and D into the Cautions and Limitations for Use information.

Finding 3: The table in section (3) D indicates that the APR can be worn in concentrations greater than IDLH. Personnel wearing an APR at this point should consider the device as an escape respirator and immediately leave the area. Personnel wearing proper hot zone protective equipment should then be brought in to continue operations until the hazard is reduced to an acceptable level where an APR can again be worn.

Recommendation 3: Delete the "crisis" column of this table. Crisis provision or contingency should be realistically addressed in the proposed escape respirator standard.

6. Paragraphs 4.0 to 6.0.

Editorial change

Finding: Inconsistent system used for identifying main sections/paragraphs and subsequent subparagraphs. The system of numbering used for main sections (1) Goal, (2) Hazards, and (3) Respirator Use, contain parentheses while the main sections 4.0 Concept for Requirements, 5.0 Quality Assurance Requirements and 6.0 CBRN APR Cautions and Limitations for Use, do not. In addition, subparagraphs under main sections (1), (2) and (3) are alphabetical while subparagraphs under main sections 4.0, 5.0, and 6.0 are numerical.

Recommendation: Identify main sections/paragraphs and subparagraphs using one alphabetical, numerical or alphanumeric system.

7. Paragraph 4.2.2, 42 CFR, Part 84 Subpart I.

Essential:

Finding: Why does NIOSH propose to test and certify CBRN APRs against all the requirements in the current 42 Part 84 Subpart I except for the industrial challenge concentrations contained in 84.124 through 84.126? Does this preclude manufacturers from having a respirator certified and tested both as an industrial mask and a CBRN APR? Users may wish to have an APR they can use and carry which allows both industrial use and warm zone CBRN APR capability. The Army does not believe that an APR respirator should be used differently between an industrial work situation verses a CBRN situation given all other factors remain the same (such as respirator construction, filter media specifications, MUC, contaminant and contaminant challenge concentration). This includes the use of commercial respirators approved for CBNR agents by first responders, commercial respirators approved for military chemical warfare agents in military industrial or research, development, testing and evaluation operations; or military masks used by civilians, contractors and non-Federal local and municipal government organizations for potential exposure to industrial chemicals as well as military chemical warfare agents.

Recommendation: Test all CBRN APRs for ability to pass existing 42 CFR 84 Subpart I requirements including paragraphs 84.124 through and including 84.126. Allow manufacturers to develop full facepiece APRs that are certified and tested as appropriate for both industrial use and CBRN warm zone work.

8. Paragraphs 4.4.1 and 4.4.2

Essential change

Discussion: Paragraph 4.4.1 states the breakthrough concentrations shown in Table 1 "...shall be used to establish the filter service life." In paragraph 4.4.2 the applicant is required to state the specific rating period for short and long duration filter use. The maximum time interval under long duration use is 120 minutes. The shortest service time is 15 minutes under short duration use. Service life testing is performed to the minimum specified service time.

Finding 1: As was discussed at the Public Meeting, 16 & 17 October 2002, NIOSH's intent for identifying use duration is to allow users to calculate filter use time before contaminant breakthrough occurs at the challenge concentrations shown in Table 1. From knowing the maximum filter time, breakthrough concentration and quantified worksite contaminant concentration the user can calculate how much time the worker can spend in the contaminant at the worksite. This is mathematically a linear function of concentration verses time. For example, a 120 minute duration filter can be used in a work environment at a concentration of 300 parts per million (ppm) cyanogen chloride before the user would experience a breakthrough (and therefore inhale) 2 ppm of the contaminant. If the work environment concentration is 150 ppm cyanogen chloride then the user could work twice as long or 240 minutes.

However, is the concept of halving the exposure and doubling the time always a linear calculation? Does the calculation work for all possible contaminants? Does the calculation work for all short and long duration time periods (e.g., 15, 30, 45, 60, 90, 120 minutes), and filter bed construction and type filter media? How does this calculation work with mixtures? Does the duration of use dictate maximum wear time? For example, a filter identified with a 120 minute duration of use would mean that filters must be changed every 120 minutes? Does duration of use include only time of calculated exposure to contaminant or include total wear time? For example, can a worker wearing a 120 minute duration of use filter, exposed to the MUC of the filter and facepiece, work right up to the duration of use time (120 minutes) in the contaminated area and then leave for decon and doffing; or does the time in the contaminated zone need to be subtracted from the overall time of wear including travel to the clean zone?

Recommendation 1: Discuss the concept of duration of use in more detail. Provide theoretical and experimental data and documentation proving the concept "halving the exposure doubles the time" for contaminants listed in Table 1, and selected mixtures. Information should also include data for all long and short duration time periods, and differentiation between filter bed construction, and type media fill. Define or provide examples of how duration of use calculations can be used for establishing time of wear during actual operations.

Finding 2: The Army does not understand how specifying filter duration based on a variable, manufacturer's specified duration-of-use can allow for interchangeability of filters between manufacturers and facepieces? In addition, some of the filter duration times are so short as to be completely impractical for use at a CBRN event (i.e.: a fifteen minute filter duration is of no real use except for an escape mask). The use of any filter should be standardized based on one minimum time of use as tested against the challenge contaminants. This would eliminate a lot of confusion, allow for users to base wear times on one starting or end point, and provide confidence if users must interchange filters from one manufacturer with another manufacturer's facepiece.

Recommendation 2: The Service Life test should identify one minimum breakthrough time for all filters. The Army recommends the absolute minimum service time be established somewhere above 120 minutes (ideally between 4-6 hours). Eliminate proposed duration times of 15, 30, 45, 60, 90, and 120 minutes. All filters should be tested against the challenge contaminants until the minimum breakthrough is achieved. In addition, run all tests to the time of breakthrough and provide users with the maximum time of duration at which breakthrough occurs. This would develop confidence in the capability of the filter.

Finding 3: There is no consistent rationale for determining the test concentrations for the TICs listed in Table 1. Two methods identified by NIOSH include: multiplying the REL by 50 (assigned protection factor for a fullface APR) and again by a safety factor of 2... or multiplying the IDLH value by 3. In fact, for all of the challenge TICs (except for formaldehyde), if you just multiply the REL by 50 to calculate a standard theoretical maximum use concentration (MUC) for an APR, that value is well above the IDLH (therefore, the IDLH value would become the MUC for the APR in that situation). Do the challenge levels in Table 1 realistically represent the concentrations that an APR can potentially encounter in a warm zone? As stated earlier in this document, a warm zone analysis conducted by SBCCOM indicates that pockets of entrapped hazard will not meet or exceed IDLH.

Also, by regulation, an APR cannot be worn into concentrations exceeding IDLH.

Recommendation 3: The Army believes that a suitable challenge concentration should be no more than two times the IDLH value for TICs.

Finding 4: Table 1 presents several challenge contaminant breakthrough concentrations that are above American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) ceiling concentrations and NIOSH REL ceiling values (as 15 minute exposures). Specifically:

- Cyanogen chloride breakthrough concentration is 2 ppm while the TLV is 0.3 ppm as a ceiling, and the REL is also 0.3 ppm as a ceiling;
- Formaldehyde breakthrough concentration is 1 ppm while the TLV is 0.3 ppm as a ceiling, and the REL is 0.1 ppm as a 15 minute ceiling;
- Phosgene breakthrough concentration is 1.25 ppm while the REL is 0.2 ppm as a 15 minute ceiling;

By definition, a ceiling value is a concentration that shall not be exceeded during any part of the working exposure. If these concentrations are used to pass applicant filters then the potential exists that CBRN APR users could be over-exposed to the particular contaminant even though the user follows the duration of use limits. Besides the potential for future litigation, the Army position is that no workers should be provided protective equipment that intentional allows for their potential exposure above contaminant exposure guidelines even though the user is following all legal requirements. No organization can guarantee misuse of protective equipment. However, as the testing and certification standard is currently drafted, workers could be using APR respirators appropriately and unknowingly be over-exposed to harmful contaminants.

It is also the Army's position that the first responders using these devices would be using them under an occupational situation. First responders are trained professionals; it is their job to respond, and they are specifically educated to deal with hazmat response, while using appropriate PPE. They will receive the same potential exposure to a toxic chemical, in the line of duty, regardless of whether it was released by accident or intentionally released by a terrorist (i.e.: the human body cannot differentiate between chlorine that came from a derailed tank car or chlorine released from a storage tank after being detonated by a bomb). Support personnel (such as police directing traffic, FEMA teams, etc.) who expect to operate in a warm zone must be prepared to wear a respirator (and other PPE), and have to be trained and fit tested per OSHA regulation. Those who are not trained/fitted have no business being in the warm zone (unless concentrations are below published occupational exposure limits and PPE is not necessary). However, when unpredictable human nature prevails and the well-intended untrained volunteer disregards site security, grabs a mask, and enters the warm zone, they would be protected under the more conservative occupational protection levels.

Furthermore, from the TIC perspective, the Army does not agree with the concept that a CBRN event will be a "one time event"... sadly, toxic industrial chemicals are spilled on a fairly regular basis throughout the country. Also, any fire fighter who simply responds to a burning building or vehicle fire is automatically exposed to many TICs released by the burning of materials contained within the structure/vehicle; this is just another example of an occupational exposure to uncontrolled TICs. Contaminant exposure to APR users could also be more than just a "one time event" if the user is entering and leaving a disaster site to change out the filter based on duration of use criteria. What physiological impact and increased risk to the safety of the user and others does potential overexposure to these contaminants create?

Recommendation 4: NIOSH to work with ECBC and CHPPM to establish consistent breakthrough concentrations that do not exceed current exposure guidelines (e.g., TLVs, short term exposure limits, ceiling values) of the ACGIH or NIOSH RELs. If breakthrough concentrations are codified that are above current exposure guidelines or NIOSH RELs, then develop severe limitation and use warnings to notify perspective users that specific contaminants have breakthrough concentrations that could expose the user to harmful effects. Identify specific contaminants with specific warning signs and symptoms from possible overexposure.