Dragon, Karen E.

From: Janice Comer Bradley [jbradley@safetyequipment.org]
Sent: Wednesday, September 08, 2004 2:53 PM
To: NIOSH Docket Office; Boord, Leslie F.; Metzler, Rich
Cc: Cristine Fargo
Subject: ISEA comments PAPR CBRN

Please see the attached written comments to the NIOSH docket.

INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION ISEA

September 9. 2004

ISEA Comments to the proposed NIOSH Certification Standard for Powered Air-Purifying Respirator (PAPR) Used for Respiratory Protection Against Chemical, Biological, Radiological, and Nuclear (CBRN) Agents

RE: Docket number, NIOSH-010

The International Safety Equipment Association (ISEA) is the leading organization representing manufacturers and suppliers of personal protective equipment and apparel. We offer the following comments in response to the recently posted NIOSH Concepts of Powered Air-Purifying Respirator (PAPR) Standards Development Efforts Used for Respiratory Protection Against Chemical, Biological, Radiological, and Nuclear (CBRN) Agents (dated April 1, 2004):

Background

The scenario described in paragraph 4 of this section specifically mentions only tight-fitting and loose-fitting facepiece designs. ISEA believes that this proposal should include hoods and helmets, which have not been specifically referenced.

3.1 Definitions

The definitions as provided in the April 1, 2004 concept paper exclude PAPR's with loose fitting hoods and helmets from CBRN applications. Loose fitting respiratory inlet coverings have many benefits over tight fitting mechanisms and should be included in the standard. The definition for respiratory inlet covering should be changed to include hoods and helmets with neck dams. NIOSH should include the following definitions for these devices in Section 3.1. Further evidence of this exists in that the current draft does not address any abrasion resistance testing or LRPL testing that would be compatible with the type of materials that would be used in the fabrication of a hood (flexible materials).

> Hood: A respiratory inlet covering that completely covers the head and neck and may cover portions of the shoulder.
>
> Helmet: A hood that also provides protection against impact and/or penetration.
>
> Loose-fitting facepiece: A respiratory inlet covering that is designed to form a partial seal with the face, does not cover the neck and shoulders, and may or may not provide head protection.

The statement "ensures that only purified air reach these areas" should be removed, as this information offers no discussion as to whether the PAPR is turned on or not, implying that the PAPR must do this even when it is turned off thus requiring fit testing by all users.

3.2 Respirator Use

As currently stated, Item C does not require that filtering elements be discarded after use. Once the cartridges have reached the end of service life, or when used for even a very short time against chemical warfare agents, they must be discarded. NIOSH should define the term "use", and require that a change schedule be established by the user, similar to what is required by the APR CBRN statement of standard.

The language regarding liquid chemical warfare agents (Item D) should be consistent with other CBRN standards. Specifically the following CBRN APR language should be incorporated into the CBRN PAPR draft standard "The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours."

3.3 Hazards

NIOSH should not imply that devices certified to this standard provide protection only against the 139 respiratory hazards identified as potential WMD. Based on testing against cyclohexane, these devices will be at least as effective against organic vapors with a vapor pressure less than cyclohexane even if that organic vapor has not been identified as a possible chemical warfare agent. NIOSH should not indicate that respirators under this approval category are not effective against them.

We suggest rewording this statement to "Testing against these 11 TRAs ensures that the respirator provides protection for the 139 identified potential weapons of mass destruction respiratory hazards and other organic vapors."

5.1 Respirator Containers

Section 5.1.1 requires that CBRN PAPRs 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. Manufacturers view this requirement as a significant change in existing NIOSH policy and seek specific rationale for this requirement if retained in the final standard.

5.2 Labels

Manufacturers believe that the language in Section 5.2.1 may be confusing to the user. NIOSH should provide examples of other suitable locations for clarity.

5.3.1 Battery Requirements

PAPR battery performance shall be evaluated according to the duration and specifications stated by the manufacturer.

5.3.2 Low Flow Indicator

This is a function of the motor/battery and particulate loading, not the gas loading of the canisters. As written, this could give users a false sense of security that saturated canisters are still usable by simply relying on an indicator to leave the area.

5.3.3 Operational Controls

While we agree with NIOSH on the importance of readily accessible, better protected switches and controls, it would be difficult to evaluate this requirement for product certification. What is "immediately accessible" to one person will not be to the next person.

We suggest that NIOSH eliminate this requirement, as this is a feature that needs to be determined by the user, ultimately becoming a market driven issue.

5.4 Breathing Performance

The transducer response time in Sections 5.4.2 and 5.4.3 is not indicated. The two machines identified have two different transducers specified between the NFPA and NIOSH. The NIOSH transducer is faster than the NFPA version. This needs to be addressed before a final Statement of Standard is published. It is also important that NIOSH indicate that these requirements apply to CBRN PAPRs and not all PAPRs.

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

Manufacturers note that the abrasion resistance was lifted out of the full facepiece specification and should be modified to include a different provision for hoods based on the materials used for hoods or eliminated altogether.

ISEA believes that manufacturers should not provide the abraded samples (Section 5.6.4). If this is to be third party testing, NIOSH (or its designee) should be abrading the samples supplied by the manufacturer.

5.9 Noise Levels

Manufacturers request that NIOSH explain the rationale used to reduce the noise level from 80 dba to 75 dba, given that the noise value in 42 CFR 84 is 80 dba. This contradicts the NIOSH position indicated in the steps to the development of CBRN standards.

6.2 Canister Capacity

We recommend that NIOSH delete the reference to ppm-min as this will confuse most people reading this standard and does not provide any useful information to the concept.

Table 3

In this concept paper NIOSH has identified the peak flow rate for two types of CBRN as a basis for determining the flow rate to be used for canister capacity testing. NIOSH should explain the rationale behind the choice of 87% of this value or the constant flow rate of the PAPR, whichever is higher as the test flow rate. Despite the absence of rationale for this value, it is not clear why they are even needed at all. It seems more appropriate to use the constant flow of the blower as the flow rate. NIOSH should not have to specify the minimum flow rate for the test if the flow rate of the blower is sufficient to pass the NIOSH positive pressure test and LRPL test. This becomes a design specification rather than a performance specification, which should be eliminated.

ISEA questions the choice of flow rates selected for the demand responsive PAPR. It would be more appropriate to test the unit at the maximum designed flow rate. Essentially, the user flow rate of these devices is unknown to NIOSH. The only way to ensure that the capacity is sufficient is to use the maximum flow rate of the device.

ISEA also requests the details of the test procedure based on STP- 0012 as noted on Page 9, paragraph under Table 3. Specifically, clarifying the terms "stacking and family capacity" as they are referred to in the TRAs. NIOSH needs to identify the testing families and the TRAs for each.

The current text for adjusting the flow rate based on the number of air purifying elements should be changed to, "The filter canister capacity airflow rate shall be divided by the number of filter elements used on the PAPR."

6.3 Particulate/Aerosol Canister

Section 6.3.3 should be revised to read, "When the canisters do not have separable holders and gaskets, the exhalation valves shall be blocked to ensure that valve leakage, if present, is not included in the filter efficiency level evaluation." PAPR filters and canisters do not generally have valves on them. Any valves present are on the facepiece.

6.4 Crisis (Panic Demand) Provision

The Crisis (Panic Demand) Provision test specified in section 6.4 is not a reasonable test for canister capacity and should be deleted. Even though peak inspirations of 430 lpm are possible under extreme conditions, NIOSH has not provided any data that indicates that this is consistent with a degradation in protection. This work rate would be sustainable for only several minutes, with these peak flow rates occurring for fractions of a second per breath. During normal PAPR operation, these peaks would be superimposed onto the PAPR flow through the canister(s), and would have negligible effect on canister bed loading.

The canister tests at a minimum flow rate of 115 L/min or 300 L/min are the appropriate tests for canister capacity. If NIOSH feels it necessary to have a five minute test at the maximum possible work rate, a breathing machine with a sinusoidal pattern, a Ve of 114 L/min and a peak flow rate of ~360 L/min should be used.

NIOSH provides no explanation as to why the "panic mode" for CBRN PAPRs should be different than the CBRN full face piece APR devices. In the APR statement of standard, the flow rate used is 100 liters per minute, 50±5 percent relative humidity and 25±5° C for each of the gases/vapors tested against. ISEA does not believe that it is necessary to increase performance requirements for another type of air purifying device to more than 4 times the performance of the full face piece CBRN APR.

6.6 Communications

The proposed communication test is the same as that for the CBRN full face piece APR but does not take into account that there will be four CBRN PAPRs running at the same time in the test room. This additional noise should be included in the steady background noise of 60 dBA consisting of a broadband "pink" noise.

6.7 Chemical Agent Permeation and Penetration Resistance against Distilled Sulfur

Mustard (HD) and Sarin (GB) Agent Requirement

This section should specify whether the CBRN PAPR is running during the test. If the PAPR is off, the proposed test airflow rate is appropriate for a moderate breathing rate PAPR, but not for high breathing rate PAPRs. Because the higher flow rate could affect vapor permeation, this PAPR should be tested at a higher airflow rate during the distilled sulfur mustard (HD) and Sarin (GB) chemical agents tests.

6.8 Laboratory Respiratory Protection Level (LRPL) Test Requirement:

Manufacturers believe that an APF of 10,000 for the LRPL test is excessive. A required LRPL of 10,000 could eliminate hoods, without a neck dam. Market data indicates that first receivers (hospital personnel) prefer loose fitting hoods. If these devices are eliminated, than the vital needs of first receivers will not being addressed.

Loose fitting hoods and helmets are most likely to be provided in just one size. This criteria needs to address the panel requirements when the respirator is provide in only one size.

6.9 Durability Conditioning

The final note of Table 7 should more clearly state that the low battery indicator must still work after conditioning.

6.12 Practical Performance

NIOSH needs to define "acceptable practical performance" and how they plan to measure this requirement. The inability to accidentally turn off the respirator is subjective and could be very dependent upon the tests subjects chosen.

The requirement for identifying, "the inability for hoses and electrical wires to tangle, causing the respirator position on the wearer to move to an improper position, such as the respirator face piece or hood being removed from the wearer's head" will be captured during the LRPL test and therefore not necessary. We recommend that NIOSH delete this language.

Before NIOSH finalizes this concept, the other factors that NIOSH plans to evaluate under "practical performance" must be identified and the tests procedures written and reviewed by stakeholders. Many of these items of practical performance are design features that the purchaser evaluates when selecting a device and should not be evaluated for product certification.

6.14 Cautions and Limitations

Cautions and limitations need to be established and reviewed by stakeholders before the Statement of Standard is published instead of being finalized as NIOSH is accepting submissions.

Thank you for your consideration.

Janice C. Bradley, CSP
Technical Director