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Sent: Tuesday, April 01, 2008 10:00 AM
To: NIOSH Docket Office (CDC)
Cc: Cristine Fargo
Subject: ISEA comments to Docket No.008
Attachments: ISEA Comments on Industrial PAPR-Mar312008final.doc

Please see the attached comments to the NIOSH Docket No. 008

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NIOSH Docket Office
NIOSH Mailstop: C-34
PAPR – Docket #008
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via email to nioshdocket@cdc.gov

Re: Powered Air-Purifying Respirator (PAPR) Standard – Concept Paper dated December 21, 2007 - NIOSH Docket No. 008

http://www.cdc.gov/niosh/npptl/standardsdev/other/PAPR/concepts/pdfs/paprcon-010308.pdf

The International Safety Equipment Association (ISEA) is the leading trade association that represents suppliers of safety equipment. ISEA member manufacturers of respiratory protection offer the following comments on the December 21, 2007 proposed concept paper for Powered Air-Purifying Respirators (PAPR) intended to establish performance requirements for PAPR devices under 42 CFR Part 84, Subpart P.

General Comments

ISEA supports the overall concept of basic and enhanced requirements in order to provide distinction between the expected use and application scenarios for PAPRs. However, manufacturers believe that some of the basic requirements are too elaborate for a basic unit and would dramatically increase the cost of this equipment.

With regard to the general construction requirements, ISEA believes that some of the proposed language is too prescriptive for a performance-based product standard and that NIOSH should reevaluate the sections that impose design restrictions. Additionally, the detailed Standard Testing Procedures (STP) must be linked to the test requirements in future concept papers. Providing detailed test procedures allows stakeholders to provide feedback, giving NIOSH adequate time to consider and address the comment without further delaying the development and implementation of its regulations.

Specific Comments:

Section 2
The options for respiratory inlet coverings are numerous and include both tight fitting and loose fitting facepieces, hoods and helmets. NIOSH should revise the terms and definition to more accurately reflect the offerings of these products in the marketplace.

Section 4.1.2.
ISEA believes that the basic requirement for a power monitor is extraneous and unnecessary for a non-CBRN PAPR device.

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Section 4.1.2.2

Manufacturers believe that the basic requirement for a low pressure indicator is unnecessary since PAPRs are intended for routine use in non-IDLH conditions. We do not support mandatory alarms as part of the device's basic construction. We acknowledge that products may include a device at the manufacturer's discretion and suggest the following language to reflect that alarms may be optional:

4.1.2.2 If a PAPR is equipped with an alarm, it shall alert the user, via an audible or visual indicator or other means, when the airflow of the PAPR falls below the manufacturer's stated minimum design flow (MMDF) for 30 or more seconds. It shall be readily detectable to the wearer during use without manipulation of the respirator. Indicators that are actuated when pressure inside the respiratory inlet covering falls below the manufacturer's stated minimum for 30 or more seconds are also acceptable.

Sections 4.1.2.6 and 4.1.2.7

The use of the term "essentially equal" is subjective and cannot be measured. It is important that NIOSH provide the STP prior to publication of this concept to permit adequate opportunity for review and comments by stakeholders.

Section 4.1.6.2

This paragraph should be deleted. Evaluating common safety and/or corrective eyewear for interference is not measurable. Interference of equipment depends on the specific eyewear and the user's facial characteristics and is best addressed during selection and fitting of the device as required by OSHA.

Section 4.1.6.5

The statement "regarding the marking of helmets not designed to offer head protection," should be removed. Marking helmets that are not impact resistant, as proposed in the concept paper, would conflict with ANSI Z89.1, which requires marking to identify compliant head protection. Cautionary language in the user instructions will tell users if the helmet does not offer head protection. The subsection should be revised to read:

Helmets designed to provide head protection shall meet the requirements of ANSI Z89.1- 2003. [NOTE: The 2003 version is undergoing revision and an updated version, designated ANSI/ISEA Z89.1 is expected in final, published form in 2008.]

Section 4.1.7.1.1

Requiring an average Visual Field Score (VFS) of 90 or greater for respiratory inlet coverings limits the ability to provide welding versions of these devices with reduced field of vision.

Section 4.1.7.2

ISEA recommends removing the statement regarding the marking of lenses that are not impact resistant. The proposal in the concept paper conflicts with ANSI Z87.1 which requires marking on compliant eye protection. Cautionary language in the user instructions indicate if the lens does not offer impact protection. The subsection should be revised to read:

Helmets designed to provide head protection shall meet the requirements of ANSI Z87.1- 2003. [NOTE: The 2003 version is undergoing revision and an updated version, designated ANSI/ISEA Z87.1 is expected in final, published form in 2008.]

Section 4.1.9
We do not believe that a low pressure indicator is needed for PAPRs. The current SCBA standard does not include the requirement for a low pressure alarm inside the respiratory inlet cover that detects when the pressure inside the RIC falls below ambient for more than twelve consecutive breaths of blower operation. This requirement is not applicable because PAPRs are not approved for IDLH atmospheres.

Section 4.1.10.3
Remove the requirement for an active low power alarm, as the low flow alarm would provide this function in a loss of power event.

4.1.12.1.3 - 5 – NIOSH needs to define what are common interferences and acceptable interferences for ESLI. What if the ESLI is reusable and part of the facepiece? Performance restrictions within the testing protocol could limit design features and technology advancements that would further protect the user.

4.1.12.3.6 – NIOSH needs to define how they want the interference identified for ESLI.

Section 4.1.14
NIOSH must provide details as to the agency's expectations for an acceptable FMEA. NIOSH should also specify qualifications for examiners.

Section 4.2.4.2
We request that NIOSH clarify the statement that "Pressure shall remain above ambient at all times during testing. Static pressure relative to external pressure may not exceed 2" of water column height for any PAPR during testing." It is unclear what is meant by "static pressure." We also question the criteria for a maximum 2" water column and request that NIOSH justify this requirement. In addition, the work rate must be stated.

Section 4.2.5.1
NIOSH should consider specifying criteria for the headform to be used. Current CO_2 testing is dramatically affected by the person mounting the respiratory inlet cover (RIC) on the test head. Considering that there are a number of test headforms currently being used, NIOSH should test the appropriate sized RIC on the appropriate sized test head.

Section 4.2.7.1.1
As currently written, this requirement prohibits a PAPR that might use three or more cartridges. NIOSH needs to indicate that either Table 3 or 4 should be used depending on the device being tested. ISEA recommends that this section be rewritten as follows:

PAPR cartridge/canisters shall first be tested as received and shall meet the minimum requirements set forth in Table 3 or 4 of this subpart for each gas/vapor for which the approval is sought using the constant required flow rate set forth in Table 2. Each tested cartridge/canister shall then be stored in an air-tight enclosure. After no less than 8 and not more than 24 hours, clean air shall be passed through the same cartridge/canisters at the same humidity, temperature and flow rate as the initial test. The gas/vapor effluent concentration shall not exceed the breakthrough concentration listed in Table 3 or 4 at any time during the desorption test. The duration of the desorption test will be the minimum allowable service life listed in Table 3 or 4 for the gas/vapor for which the approval is sought.

Section 4.2.7.7.4
ISEA believes that the maximum breakthrough concentration should be set at a concentration that can be measured reliability, similar to that for the canisters.

Section 4.2.8
Manufacturers do not believe that additional categories are needed for PAPR designation.

Section 4.2.10
ISEA reiterates its desire for NIOSH to provide specifics for the practical performance testing in the next version to allow stakeholders an opportunity to offer comment. Such protocol should include the exercises to be performed and the criteria for panel members.

Section 6.1
NIOSH has not provided any details on the requirement for flammability and heat resistance. We recommend the test method in Section 8 of standard, EN 13274-4:2001, Respiratory Protective Devices, Methods of test, Part 4, Flame tests, Single burner moving specimen test: Method 3 be incorporated, in which the requirement in the two PAPR standards states: *"No part of the device shall continue to burn after removal from the flame. The device is not required to meet the other requirements of this standard after being subjected to this test."*

Section 6.4
ISEA requests that NIOSH provide details for the hydration device testing in the next version of the concept paper to allow stakeholders an opportunity to review and comment.