INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION ISEA

ISEA Comments to the proposed NIOSH Certification Standard for CBRN APR Presented at the NIOSH Public Meeting on June 18, 2002

ISEA supports NIOSH in its attempt to develop a standard for evaluating the effectiveness of respirators for use in atmospheres that may contain chemical, biological, radiological, and nuclear (CBRN) war agents. We recognize that it is imperative that these user needs be addressed as soon as possible. However, the formal rulemaking process, which considers input from all stakeholders, is necessary for developing appropriate CBRN equipment standards.

As NIOSH did with 42CFR Part 84 standards for particulate filters, we encourage you to develop performance-based standards for equipment that will protect first responders and resist including design restrictive specifications in the standard. Design criteria inhibits innovation and prevents new technology from being designed and incorporated into products.

Interchangeability- Section 6

The interchangeability of consumable filter cartridges and canisters was raised in the Rand Report by responders to the WTC, Pentagon, and Oklahoma City events. It is our opinion that there was an adequate supply of product supplied to these sites, however, due to confusing logistics, inadequate training and enforcement, and the lack of fit testing, the supplies were depleted prematurely or never reached the users in need.

Respirators are designed as a system. This includes the combined performance of the individual components, as well as the quality system of the individual manufacturer. Focusing on the interface of the filter element to the facepiece, will negate this systems approach.

A comparison has been made to OSHA allowing for the interchangeability of SCBA cylinders under emergency conditions. We believe that this is a faulty analogy. There currently are 3 principal manufacturers of SCBA cylinders. Their products are made to specific standards from the US Department of Transportation and the Compressed Gas Association (CGA) and operate under consistent pressures. The SCBA then transforms that pressure to a breathable rate of airflow. Nothing changes the form, fit or function of the SCBA.

In developing respirators, however, manufacturers must take into consideration the weight, size, height and positioning of the various components in the development of the system. The performance of the approved system could be negatively impacted by attaching a filter element that is heavier, larger, shaped or positioned differently, or has greater breathing resistance than the filter element originally designed for the system.

A system cannot be considered interchangeable just because it meets the performance requirements set by NIOSH, and has a military type thread some type of or adapter to accommodate that thread.

In addition, the interchangeability of respirator components is a use issue and should be addressed by OSHA. It is unclear how NIOSH would ensure user protection of interchangeable parts in a certification test. We believe that interchangeability will decrease the level of protection provided to users because any NIOSH certification test cannot ensure user protection when different parts are used in the field under any conditions.

Manufacturers are also concerned about the liability and confusion that this provision may lead to with the user community. Given the high degree of liability associated with respiratory products in the US, how can companies be held harmless for misuse, or in the case of terrorist agents, be held harmless for providing respirators that will not provide complete protection?

Who will determine the type and form of cartridge/ canister connection, and will this void the approval since NIOSH tests systems?

Recommendation: NIOSH should seek systems level approvals and not regulate the interchangeability of components. NIOSH should satisfy the Rand concerns by supporting the development of emergency logistical support, training, enforcement, and fit testing.

Misuse/Decontamination

We fear that air-purifying respirators that meet NIOSH requirements for CBRN protection will be worn in atmospheres where the concentration of the agent in unknown or is IDLH. Using APR for entry into an IDLH atmosphere goes against today's "use" practice. Does NIOSH plan to promote these devices as appropriate to use for entry into an IDLH?

It is not appropriate to provide product approvals for a liquid agent for an air-purifying device. A user should never be in an environment where a liquid exposure is present using an air-purifying device. One of the proposed test agent levels is as high as 2400X the IDLH (e.g. Phosgene). This exceeds the capabilities and use recommendations of any APR. Only full ensemble protection should be used if potential exposure to a liquid agent exists.

Because an APR should not be used in an atmosphere where there exists the potential for direct exposure to HD and GB, Section 5a testing is not necessary.

Equipment guidance on use and selection needs to be an integral part of the standard. Section 3b under the Respirator Use section provides a weak statement only and gives no real guidance to the user.

The table in Section 3 shows a need for Crisis units for 20 minutes duration. Physiological studies have shown that it is not possible to sustain a 100-liter minute volume for any length of time. The use and testing (assumed) are not realistic.

NIOSH should not rely on manufacturers for decontamination and disposal recommendations. Manufacturers do not have the proper expertise in WMD's to adequately provide this information or service

Recommendation: NIOSH needs to strongly recommend that air-purifying respirators not be used for entrance into IDLH or unknown atmospheres. SCBA's along with the appropriate protective clothing should be used.

Decontamination and disposal should be handled by the on-site response/hazmat personnel.

Surrogate Test Agents

Because this is the second NIOSH proposed standard for equipment to protect against CBRN challenges, we must again strongly urge NIOSH to focus their effort on developing surrogate test agents. This would allow manufacturers of all PPE to test products in their labs prior to submitting them for approval. It would also significantly reduce the cost of approval. This is an urgent need that is necessary for equipment development, testing, design and equipment refinement.

Recommendation: NIOSH should continue to seek surrogate test agents that can be used for product development testing, as well as product approval testing before establishing a final standard for CBRN APRs.

Certification Tests

The current NIOSH and OSHA APF for Full Facepiece respirators is 50. The Sarin Vapor Test features a challenge concentration of 2000 mg/m3 and a maximum peak excursion of 0.087 mg/m3. That equates to a Protection Factor of 22,989. The allowable permeation/penetration ratio during testing should be within the APF of the given respirator.

The rough handling requirements in section 6b are far in excess of what is required of a non-military apparatus. There is nothing in this type of APR that can be adversely affected by any of these tests, except perhaps drop and vibration. These tests only add to the cost and duration of testing without any benefit to the user. Again there is no need for permeation testing.

The full facepiece fogging test in section 6b is a new concept that is not easily addressed or eliminated. This seems to be a very extensive, expensive and subjective test. NIOSH should consider a more routine steam generator and light transmission test.

NIOSH proposes visual acuity testing and fogging testing yet there is no field of vision test in the proposal. We suggest that NIOSH use EN 136, the European full face mask standard, for field of vision requirements, and to evaluate the facepiece, using bench tests, for definition, refractive power, etc., including any preconditioning. This would be less subjective than performing a vision test on a wearer.

ISEA would like NIOSH to address the following questions regarding certification tests.

Does NIOSH have any concerns with organic compounds that have a low boiling point <65 C?

Why is NIOSH considering the use of both Cyclohexane and Carbon Tetrachloride for organic vapor qualification? Cyclohexane was developed in Europe as a surrogate for Carbon Tetrachloride due to the lack of availability of Carbon Tetrachloride. There is significant documentation that demonstrates the relationship between Carbon Tetrachloride and Cyclohexane service life so there is no need to test both.

Chromium containing carbon is used in military canisters as an effective impregnating agent for acid gases. However, NIOSH currently bans chromium-containing carbons for industrial cartridges. Will this ban apply to CBRN cartridges?

Approval Issues

It is proposed that the approvals be released in two phases. The First "half" step is scheduled to be released in October, the second step in 2003. Given the length of time required for manufacturers to develop a product and gain NIOSH certification, there could be overlap and possibly conflict between the two phases.

Recommendation: NIOSH should allow for grandfathering of approvals or eliminate the phased approval approach.

Cost

Based on the testing fees associated with the CBRN SCBA standard, one APR model undergoing ten or twelve permeation tests, conditioned and not, 13 basic service life tests and a particulate test plus service lives after five different conditioning and required man tests, including fit, speech, fogging, etc, puts the estimated approval cost at $250,000.00 per respirator/filter/cartridge combination.

The total cost of running through all the tests is 100 times the costs of a regular industrial respirator. If the certification costs are prohibitive, they will serve as a deterrent to manufacturers to develop these much needed products, and for those manufacturers willing to make the huge investment in certification testing, they will be forced to pass those costs onto end users.

ISEA appreciates the opportunity to present our views today. Thank you for your consideration of these very important issues.

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Specific Questions for Written Submission to the NIOSH Docket

1. The goal as stated is to develop 4 respirator categories, yet the table indicates 8 levels of use (section 3). It is unclear how these relate. Illustrative, indicated service life times are given in a chart for the 4 filter types and the type of use. Are these the service life minimum life requirements? If these times are not the minimum test times, what are the minimum test times?

2. How will NIOSH address protection factors with the various devices? SBCCOM has a performance standard for Chemical, Biological Escape Hood Respirators (CBEHR) and Specifically how will NIOSH escape hoods will be handled and how will protection factors be assigned to these devices as they may vary greatly for different designs.
Does NIOSH have a full ensemble approval for CBRN planned?

3. NIOSH does not provide specific details about the pre-conditioning of the cartridges, what type of breathing machine will be used, and temperature and relative humidity of the test air. These parameters are vital to the test protocol and should be included in any final draft proposal.