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Sent: Monday, April 16, 2001 3:32 PM
To: NIOCINDOCKET@CDC.GOV
Subject: Comments on WMD Respiratory Protection

Based on our firm's experience in operation of a chemical warfare agent (CWA) surety laboratory, and mobile laboratories in support of Army chemical warfare materiel (CWM) operations at Deseret Army Depot and Dugway Proving Ground, and our research and development of protective systems for WMD applications, we have seven comments regarding the use of NIOSH approved respirators in WMD operations.

1. Protection Factors

Currently respirator Protection Factors (PF) are assigned by regulation. Our experience demonstrates that there are wide differences between approved respirators performance in this area as represented by Fit Factors. Full face masks that have APFs of 100 for example may range in performance over one or even two orders of magnitude. After internal testing of competing brands we have selected full face masks with measured Fit Factors of between 10,000 and 100,000. Without purchasing many different masks and testing as we did it is currently impossible to differentiate between masks as we did.

NIOSH could improve the ability of consumers to select better quality masks by publishing the results of Fit Factor testing of masks on human fit test panels. Placing this product information into the approval documentation as public information would offer incentive to manufacturers to improve the performance of the masks.

I also believe it would be appropriate to allow the use of respirators that offer better fit in higher concentrations of threat. For example, a respirator that consistently offered a Fit Factor of ten times the current limit should be allowed to be used in a ten times higher concentration.

2. Donning

Currently there are no criteria for quick donning and repeatability in donning of respirators. Many respirators cannot be donned quickly and/or require extensive adjustment and readjustment especially of straps to achieve a seal. This is a special problem when air purifying masks are used for escape. The only way for purchasers to determine this is to buy different masks and conduct their own testing.

To address this I suggest that the NIOSH human fit test panels add a manufacturer-voluntary criteria for quick donning. Fit factors should be tested 10 seconds after donning 10 different times for each subject. These numbers would be published with appropriate statistics to allow the purchaser to compare the masks tested performance.

3. Durability

Masks are currently available that are widely different in price. For full face APRs, the range may be \$50 to \$500. Purchasers have no way except by buying multiple masks to conduct their own tests to determine the differences in durability that may or may not be related to cost. We have purchased a reputable manufacturer's full face masks based on price. Our use showed that their lower price mask had straps that stretched out after only a few uses, and plastic parts and cartridges that fell apart when the mask was dropped. We discarded the masks at considerable expense. Later testing of their more expensive mask showed much greater and adequate durability.

I suggest that a voluntary test be available at NIOSH to allow manufacturers to offer data to purchasers that showed their masks were designed for rough use. This could include multiple donning and doffing as well as vibration table, drop tests, etc. The NFPA SCBA standard could be used as a starting point, recognizing that the included durability tests were derived from MILSTD 882 methods. Alternately, NIOSH and the Army could determine which MILSTD 882 test methods could be used to indicate the higher level of performance that military masks provide and use this as a guideline for testing of the approved masks.

4. Chemical Resistance

There is clearly the need to offer manufacturers the ability to perform testing of their masks for various chemicals. This is a special problem with SCBAs that are currently in use for protection from IDLH exposures to ANY chemical with no documentation of protection offered by the lens, surround, hoses, etc. Firefighters in particular have this issue in immediate response without Level A suits. This could be a problem for some chemicals and materials, for example, liquid mustard agent readily permeates silicone polymer parts.

Army SOPs should be combined with ASTM procedures to allow testing. A baseline for guidance methodology could be NFPA 1994 with different baselines for respiratory exposure levels.

5. Designs

There are respirator designs that are available worldwide and in CEN that are not represented in NIOSH approvals. Three specific areas are air purifying chemical/biological and/or smoke escape hoods, PAPR hoods with neck seals, and positive pressure demand PAPRs (i.e. not just positive flow). An analysis of new types of certifications that should be allowed should be done based on the performance of these designs. Duration should be included in this analysis. For example, use of a PAPR with a shorter duration than currently allowed should be allowed.

6. Filters etc.

Current canister and cartridge regulations are limiting in the fact that durations and concentrations of testing are design-limiting. This is a particular problem with the particulate test based on silica dust but also is an issue for chemicals vapors. Users should be allowed to determine the duration of their mission and purchase products based on the projected threat concentrations. To assist in this a complete analysis of world standards and requirements for use should be made for filters. Included in this should be the issue of carcinogenicity based on long-term exposure versus acute exposures in such scenarios as emergency response and escape.

For example, mustard agent is a suspect carcinogen, and as such requires the use of an SCBA. But there are filter and masks systems that provide equal protection to an SCBA. In particular, the Army standard for PAPRs is an APF of 10,000. Respirators meeting these standards should be allowed for use with carcinogens, especially for such applications as medical use.

7. Medical Respirators

Current CDC Guidelines appear to allow use of respirators with an APF of 10 and PAPR hoods with APFs of 50 with any pathogens, even those that are considered BSL-4 (ebola, etc.). These Guidelines appear to be based on TB/HIV Guidelines. These APFs are totally inadequate as these organisms are deadly and have no means of treatment or prophylaxis.

I suggest that the Army Guidelines for PAPRs of APF of 10,000 be adopted for respirators used with unknown pathogens and pathogens rated BSL-3 and 4.

8. Passthroughs

Our testing of Level A suit breathing air passthroughs demonstrates that some NIOSH approved passthroughs when tested external to the suit with liquid sarin allow rapid permeation into the breathing air at lethal levels. This effect may be suit dependent, i.e. the interface with different suit materials may dramatically effect the performance of the passthrough. Current NIOSH testing of breathing hoses with gasoline does not address this or the repeatability of the installation of the passthrough into the suit and the effect on the breathing airstream.

We suggest that the regulations be upgraded to address these issues in that each passthrough must be certified with each suit, the procedures for suit installation must be demonstrated to be repeatable, and that the external interfaces (hose/coupling, coupling/gasket, etc.) all be tested with liquid gasoline or equal.

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