

**Dragon, Karen E.**

**From:** Rich Stein [qmask9@yahoo.com]  
**Sent:** Thursday, July 03, 2003 1:30 PM  
**To:** niocindocket@cdc.gov  
**Cc:** Monahan, Mike; Szalajda, John; Boord, Les  
**Subject:** NIOSH 002 CBRN Escape Hooded Respirators

Please find attached comments related to the June 15, 2003 "Concept for CBRN Escape Respirator Standard"

July 1, 2003

NIOSH Docket Officer  
Robert Taft Laboratories, M/S C34  
4676 Columbia Parkway  
Cincinnati, OH 45226

RE: CBRN Escape Respirator Standard Development Effort

Docket Officer:

Please find the following comments related to NIOSH's development of a standard for CBRN Escape Respirators below. These comments are based upon review of the June 15, 2003 draft titled "Concept for CBRN Escape Respirator Standard" and the review meeting held by NIOSH in Pittsburgh on June 25, 2003.

1. **Section 4(a):** Escape respirators approved for use in CBRN should not have any time category below 15 minutes. There is good reason to suspect that a user may be trapped in an area for some time, may be directed to a location for a short time, may need some time for decontamination procedures, etc. This is also true for self-contained devices used in the "high" category. Allowing a 3, 5, 8 min. etc. CBRN escape respirator is not beneficial to the user.
2. **Section 4(c):** The requirement written in the June 15 document specifies a P100 filter. Since this product is a one-time use escape respirator it should be permissible to utilize a R100 particulate filter. This would allow manufacturers some design choice related to reduced inhalation resistance as compared to a P100. A reduced resistance is to the benefit of the end user, especially to those with reduced lung capacity or breathing ailment. The R100 provides the same protection as the P100 given the escape situation.
3. **Section 6 (c):** Data developed when testing the carbon dioxide levels of current escape hoods indicates that meeting the proposed levels will be a challenge. A reasonable trade-off to meet the proposed CO<sub>2</sub> levels would be to allow a slightly higher exhalation resistance. This would allow manufacturers to reduce the dead space leading to the exhalation valve and thus reduce the re-breathed carbon dioxide. Raising the allowable resistance to 25 mm would match values that have been used by NIOSH for many years. Raising the resistance to this level will have little effect physiologically, but it would provide the users with reduced carbon dioxide levels and ensure that the oxygen levels remain high.
4. **Section 6(d):** Use of human test subjects is inappropriate to test for carbon dioxide. NIOSH has extensive experience in using test subjects to evaluate breathing

equipment and understands that such testing is subject to the vagaries and differences inherent in each test subject. Testing of breathing apparatus wherein a particular device can “pass” or “fail” the carbon dioxide test according to the person wearing the device is not in the best interest of NIOSH, the manufacturer or the end user. NIOSH has tested for carbon dioxide for more than 30 years with a simple machine. We are unaware of any major problem with using this machine. This machine and test setup is available to all manufacturers. NIOSH can use this machine to test at work rates equivalent to those specified in paragraph 6(d) but in a repeatable fashion. Further, manufacturers can also perform these same tests and design escape respirators to meet the standard. NIOSH must keep in mind that overall testing and certification costs for this new module is in the range of \$93,000 per submittal and that testing can take as long as 3 months. It is not reasonable, given these costs and time issues, that NIOSH require human subject tests for such a sensitive criteria as CO<sub>2</sub> wherein tests at a manufacturing facility show a “pass” but at NIOSH show a “fail” because of the vagaries of human subjects. The purpose of the tests (to ensure that carbon dioxide is minimized and oxygen is maintained) is legitimate; the test method of using human subjects is not.

The levels of carbon dioxide allowed should vary with service life, as NIOSH is suggesting. However, we believe the level suggested are unnecessarily too low for the purpose of the escape hoods. It is known that escape can be made with the given duration of 15-60 minutes at levels slightly above the NIOSH table and not have any undue user hardship. On the other hand, slightly upwardly revised values would provide for possibility of smaller size package, lighter weight and more user comfort (comfort is important related to reducing fear of wearing and removal due to claustrophobia). We suggest that NIOSH consider the following table (the values chosen allow for escape with no major increased physiological effects compared to those carbon dioxide levels suggested by NIOSH in the June 15 document):

Service Time	Carbon Dioxide Allowed
Not more than 30 minutes	3.0 %
60 minutes	2.5%

5. **Section 6 (f) and (g):** Manufacturers provide instructions related to these issues. NIOSH should include within these tests the proviso that manufacturers’ instructions are to be followed.
  
6. **Section 6(h):** The main purpose of air-purifying escape hooded respirators is for protection from chemical attacks or accidents. However, there is another type of escape respirator that is used for protection from smoke. These have carbon monoxide protective capabilities. It would make sense to have a flame test on those CBRN escape respirators for which manufacturers seek NIOSH approval for CO. CBRN escape respirators without carbon monoxide protection do not need to have flame testing. This will allow for a wider choice in use of protective fabrics to better provide added chemical protection. Furthermore, the flame test chosen is unclear but it appears to be a 6-burner test that is designed for a full facepiece and is not

appropriate for hoods. NIOSH needs to clarify that the test will utilize a single burner per En136.

7. **Section 6(i):** The stated value of pass/fail for the laboratory respiratory protection level (LRPL) is 2000. It is unclear how the raw measurement data is to be converted (and we assume that the sample probe is in the breathing zone and not somewhere else in the hood). Assuming that the LRPL is a 95% requirement, then the chosen value of 2000 is extremely high. If it is on the basis that each person must achieve this, then it becomes even more difficult. We do not believe that, given the state-of-art of escape hoods, this will be achieved. Testing on several occasions by SBCCOM on the Quick2000 have shown the extreme variability in test-to-test results. The test results are only rough indications of protection. To establish pass/fail on the basis of human subject testing with the pass at a 95% LPFL of 2000 is unreasonable. It would be far more reasonable to have a requirement for LRPL average of about 500. This should be calculated by taking the average LRPL over all test subjects (add all values and divide by number of test subjects). It is not the classical manner of calculating PF, but the test is so variable that this method allows for this variability and still provides some method to eliminate truly ill designed products. It is interesting to note that the military requirement for 5 sizes of masks with well-trained persons is only 1667. This is based on experience of what is truly doable over a wide range of tests with different subjects using the same mask. The number of test subjects and the cost and time constraints for this test are considerable. It is critically important that NIOSH understand that the nature of these tests is extremely variable and that this test subjects manufacturers to facing a staggering bill for a test that has been shown on at least one escape hood to be quite variable. It is not reasonable for manufacturers to face this without NIOSH conducting significantly more testing on hoods (many tests using the same subjects many times as well as many test panels on the same hood to verify that the proposed test is repeatable.) As noted above, the Quick2000 has been subjected to two different panels and the results varied widely.
8. **Section 7(b):** This section requires that the escape respirator be designed as a hooded device. This is critically important and should not be modified. Protection from chemical warfare agents must include both the ears and the head. Penetration of liquid into the ears could be fatal, especially for a person with damaged eardrums. Further, the head has many capillaries near the skin surface for heat removal. It is easier for permeation in this area of the body. Further, hair tends to hold the liquid or vapor. Hoods have progressed to the stage whereby it would be a disservice to the end user if this requirement were loosened to allow anything less. For example, a respirator with just a mouth bit and eye protection goggles or a respirator with full facepiece do not offer the protection needed for the unique issue of escape by workers who normally do not wear respirators. Suppose the worker has glasses? Suppose the worker has a beard? Suppose the worker has hair in the sealing surface?

**Other:**

- NIOSH should require that manufactures verify the function of the hood is such that decontamination can take place. Compatible decontamination materials should be specified. Further, users may be on stretchers and the hood filters should be designed such that decontamination fluids do not unduly interfere with the operation of the escape hood.

- To date NIOSH has provided concepts. NIOSH has not yet published any complete ‘standard’ The June 15 document is itself only a further concept paper. Moreover it is only partially completed (perhaps 80-90%) and has errors that NIOSH acknowledged at the June 25 public meeting. While most of the concepts are specified, it would be of great value for NIOSH to publish on the Internet a complete copy of the “standard” at least 30 days before it become “final.” This will provide the public with a final review to see if there are any issues. These issues could be covered via Internet back to NIOSH. It would allow NIOSH itself to have some review so that no obvious errors become part of the standard when they could have easily been corrected if noted by the public.

Please contact me if you have any questions.

Sincerely yours,

Richard Stein, Ph.D.