



July 7, 2003

NIOSH Docket Officer
Robert A. Taft Laboratories, M/S C34
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RE: Docket 0002, Comments on the May 15, 2003 Concept for CBRN (Chemical Biological Radiological Nuclear) Escape Respirator Standard

Dear Docket Officer:

3M, through its Occupational Health and Environmental Safety (OH&ES) Division, is a major manufacturer and supplier of respiratory protective devices throughout the world. 3M has invented, developed, manufactured and sold approved respirators since 1972. We have developed numerous training programs, videos, computer programs and technical literature to help our customers develop and run effective respirator programs. Our sales people have trained and fit tested hundreds of thousands of respirator wearers throughout the world. Our technical staff has performed basic research on the performance of respirators and their uses, presented and published this data in numerous forums and participated in the development of the ANSI Z88 standards on respiratory protection. In sum, we have substantial experience in all phases and applications of respiratory protection. We are pleased to provide the National Institute for Occupational Safety and Health with our comments on the May 15 version of the CBRN Escape Respirator Concept.

3M 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 types of products be available as soon as possible. However, the formal rulemaking process, which considers input from all stakeholders, is necessary for developing appropriate CBRN equipment standards. We offer the following comments and recommendations regarding hazard categories, respirator use, gas life test requirements, environmental conditioning requirements, performance requirements, design considerations, training, and cautions and limitations.

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We appreciate the opportunity to add our comments and knowledge to the rulemaking record and look forward to the promulgation of a fair, protective and useful standard.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael L. Runge", followed by a short horizontal line.

Michael L. Runge
Technical Director
3M Occupational Health & Environmental Safety Division

Enclosures

3M Comments on the May 15, 2003 Draft Concept for CBRN Air-Purifying Escape Respirator

2. Hazard Categories

2(a) Category vs. Hazard vs. Escape Respirator Type

The May 15, 2003 Concept provides for many types of escape respirators. In general, this may encumber rather than benefit the selection process for the user. Considering the options for the “specific” gases, carbon monoxide, communication and service life ratings, there are infinite possible approvals in the Specific Category. The potential market for many of these combinations will be very low. It is also worth noting that a “general” approval with a longer duration rating may be roughly equivalent to a “specific” approval with a shorter duration rating. Therefore, the specific category may lead to no differentiated products and result in end user confusion when it comes to selection. Therefore, we recommend that the specific category as proposed be eliminated, since escape respirators currently exist for different industrial chemicals.

2(b) Escape Respirator multi Gas/Vapor/Particulate Requirements LOW (General)

The test concentrations for cyclohexane and cyanogen chloride doubled in the May 15th version of the Concept. Justification for the 1300 ppm cyclohexane and 150 ppm cyanogen chloride was given at the April 29th meeting. We recommend that the levels stay as presented at the April 29th meeting.

The doubling of the organic vapor requirement – to the level of the October 15 draft - takes us back to the requirement for a larger filter, which is not as acceptable to users based on our research. Cyclohexane is a critical test agent in determining carbon volume. We have conducted a number of experiments that shows the necessary carbon volume needed to pass a variety of cyclohexane challenge concentrations and times. Figure 1 predicts the volumes for service lives for a 3M carbon that is utilized in one of our products. It illustrates that at a 15-minute, 1300 ppm challenge/10 ppm breakthrough an approximate carbon volume of 127 cc is needed, compared to 162 cc with a 2600-ppm challenge with all other conditions the same. Table 1 outlines the predictive relationships between carbon volumes and a 1300-ppm and 2600 ppm challenge.

Raising the challenge to 2600 ppm will require larger filter housings than current products use. As noted above, however, these larger products are undesirable by the majority of end users. We understand that some users may require a higher volume of carbon capacity for their expected hazard. Devices with a higher volume can be selected by choosing one having a longer duration rating. We suggest that by having

a 1300 ppm challenge at four duration ratings of 15, 30, 46 and 60 minutes, end users will have the capability of using products with carbon volumes ranging from approximately 125cc to 330 cc. This recommendation permits current technology to be used in an acceptable cartridge size.

The permitted breakthrough concentrations in the escape hood standard are in some cases higher than in the air purifying full facepiece respirator standard. For example, 150-ppm ammonia may not be tolerable by some wearers.

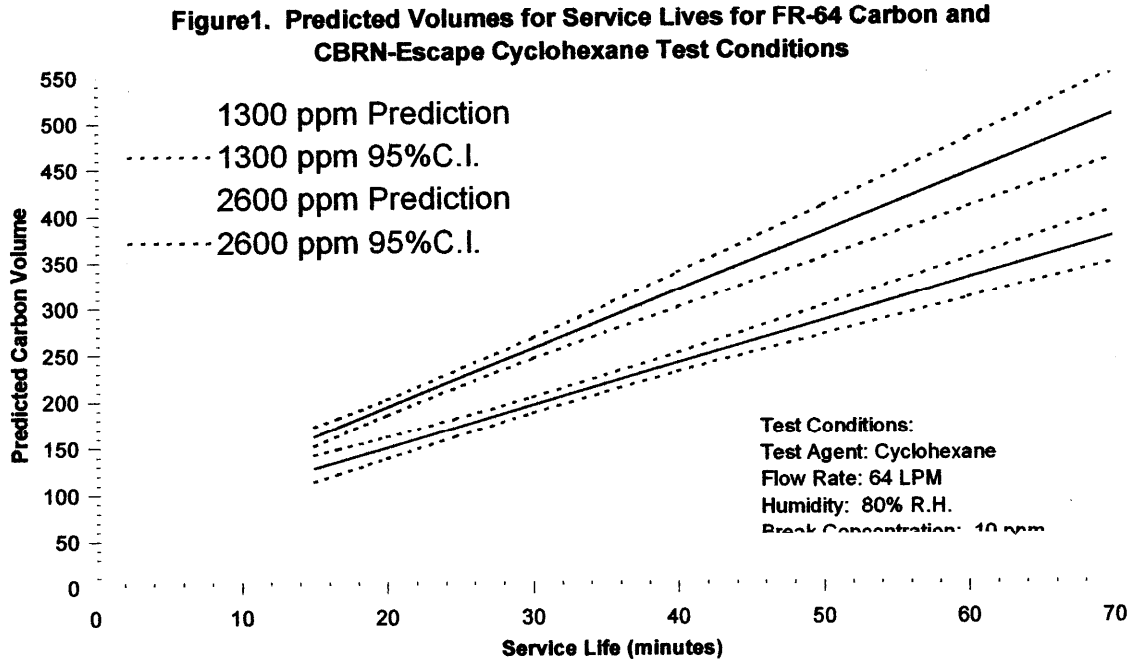


Table 1. Required Carbon volumes for 1300 ppm and 2600 ppm Cyclohexane Challenges

Required Time Minutes	Carbon Volume (cc) for indicated test conc.	
	1300 ppm	2600 ppm
15	128	152
20	150	185
30	195	245
40	240	300
50	285	353
60	330	406
70	375	505

2(d) Escape Respirator multi Gas/Vapor/Particulate Plus CWA Requirements SPECIFIC category

2)d)2. Breakthrough Concentration for Specific Category

The breakthrough concentration for the specific category in the May 15 version is a major change from the April 15 version of the Concept, which defined SPECIFIC test concentrations as double those of the LOW category with the same breakthrough levels. The lack of defined challenge limits in the May 15 version will create confusion for end users. For example, the LOW-test concentration for ammonia as proposed in the May 15th version is 1250 ppm. As written, a manufacturer could make a claim of a SPECIFIC capability for ammonia by testing at 1251 ppm. Such a definition of the SPECIFIC level may lead to unjustified expectations from the user. Since the SPECIFIC concentrations are not specified in the Concept, a manufacturer could actually make claims for a SPECIFIC approval with concentrations below the LOW-test concentrations.

If NIOSH chooses to keep the SPECIFIC category, the best recommendation would be to keep the requirement for the full range of LOW test gases at the LOW concentrations, and add SPECIFIC test gases at double the requirement as per the April 15 version.

3. Respirator Use

3(a) Escape Only

As escape only respirators, they are not intended to be worn during shelter in-place events. Shelter in-place is a non-respirator escape strategy. If an escape strategy is desired and a respirator is to be used, then respirator selection needs to be made based on the expected hazard. “Shelter-in-place” is an engineering control used for responding to a chemical attack.

It is inappropriate to include “Shelter in Place” with the escape respirator criteria. The term “emergency escape” must refer only to the act of leaving the hazardous area as quickly as practical. Shutdown procedures, rescue, and “sheltering in place” are not a part of emergency escape. If affected personnel are required to shelter in place, it is unlikely that the duration of sheltering will be predictable. As such, issues of service time, communication and other human factors have significance beyond that required for escape only.

Air purifying respiratory protection approved for entry into CBRN contaminated atmospheres should apply to shelter in place activities. These criteria are applied to entry versus escape conditions for other industrial hazards. As the CBRN proposal is currently written, an employer might develop criteria for their office workers for escape from CBRN hazards that conflict with existing procedures for escape respirator use in their plant.

4. Gas Life Test Requirements

4(b) Gas Life

There appears to be some redundancy in humidity testing (e.g. low humidity for organics, and high humidity for acid and alkaline gases). Redundant tests should be eliminated.

5. Environmental Conditioning Requirements

The environmental conditioning tests should reflect anticipated storage conditions for these respirators. Based on our research, it is anticipated that these respirators will be stored under a variety of environmental conditions ranging from the top drawer of a desk, to the trunk of a motor vehicle. Therefore we agree with the need to have a robust test that will challenge these respirators under a variety of conditions.

6. Performance Requirements

6(a) Chemical Agent Permeation and Penetration Resistance

NIOSH has stated that intended users of the escape hood respirators would primarily be office workers and possibly first responders. In either case, it is assumed that the user would not necessarily be wearing any other PPE for skin protection. Therefore, it seems unreasonable that the escape hood respirator be required to demonstrate resistance against liquid agents. Vapor resistance testing should be sufficient given the lack of skin protection on the rest of the body. The escape respirator should not be expected to be any more resistant to chemical permeation than the clothing that is expected to be worn (i.e., street clothes) by the people at the time of escape. This would result in over designing the product, which could lead to increased donning time and make the respirator less user acceptable. Additionally we believe the presence of this test in the standard will imply full protection against liquid agents, and therefore could mislead the end user.

6(d) Breathing Gas

There are two areas concerning CO₂ that we would like to address in this section; first the test methodology and second the inhaled CO₂ content of 1.5%. With respect to testing, this section requires two different tests for CO₂ and O₂ during use: human tests and ones on an Automated Breathing Metabolic Simulator (ABMS). NIOSH's own data does not indicate a relationship between the two. Given the cost of the ABMS and lack of understanding what ABMS data mean, it seems premature to require this testing. Testing on humans appears to be the most representative of performance during use and should be the only required test.

Next, this section states, “Inhaled CO₂ concentration shall be less than 1.5% by volume ...” We believe this value should be increased to 2.5% by volume. This increase reflects current guidance that has been developed in other standards. This is an acceptable level since use of this device is designed for short-term duration use pattern. The ACGIH TLV-STEL for CO₂ is 30,000 ppm (3.0%). The Documentation of the TLV¹ states, “in light of the short-term exposure, physical exercise studies by Sinclair and associates, in which carbon dioxide exposure concentrations of 27,000 to 39,500 ppm produced increased pulmonary ventilation rates, a TLV-STEL of 30,000 ppm is considered appropriate.” The American National Standards Institute is currently developing a new Air-Purifying Respirator Protective Smoke Escape Standard (ANSI 110-200x)², and in section 7.1.1 under Carbon Dioxide Inhalation it states: RPED shall be tested for CO₂ levels in the inspired airstreams as specified in Section 9.1, Carbon Dioxide Testing and shall not contain CO₂ concentration levels that exceed 2.5%. In July 2000 the US Army Soldier Biological Chemical Command in Edgewood published a document titled, “Test Guidelines and Performance Criteria for the Evaluation of Chemical/Biological Escape Hood Respirators” [(EHR) *sic*]. The criterion for CO₂ in this human performance test states, “The CO₂ content of the inhalation air of the EHR shall not exceed an average of 2.5% by volume. Based on these three references and the limited duration of use of an escape device, we submit that the inhaled CO₂ content should be increased to 2.5%.

6(e) Communications (Speech Intelligibility)

This test is described as an optional feature. Our belief is that speech intelligibility is not a major factor for an effective escape activity. To imply that it is, may give the impression that stopping to do other things as one escapes is okay such as rendering first aid or using a fire extinguisher with the respirator. These also are not escape activities. In this venue if a user desires speech intelligibility, they will need to evaluate escape devices on their own thus making this a market issue and not a certification issue.

This communication/speech provision also clearly discriminates against possible escape systems that use a mouthpiece inlet breathing device. It would be virtually impossible to communicate while a mouthpiece is engaged for respiratory protection. Thus this test could prevent a proven escape design i.e., a mouthpiece, from being certified. Personnel employed in environments where escape systems may be employed must be directed and trained to leave the affected area as quickly as practical. For these reasons this provision should be deleted.

6(g) Donning

The donning test appears to be a new certification test for NIOSH. It is very subjective and is solely dependent on the ability of the test panel. It will be very hard for manufacturers to produce test results for pre-submission with any confidence that

the results will be similar to the NIOSH test. 3M knows of no objective criteria for selecting a panel of test personnel for use in submission testing for this requirement. We believe this feature is best left to the market to decide. Personal preference and experience will determine how fast donning is for a specific packaging design and the user will be able to select the design they prefer. We recommend removing this performance criterion because it lacks clear definition of the attributes for the test panel. If it is determined that donning will be included, the section must contain additional information regarding the need for the panel members to be properly trained according the manufacturers guidelines. The NIOSH standard test procedure (STP) must be completed and released to stakeholders for comment prior to accepting approval submissions in this category.

6(h) Fogging

It is important that this test evaluate respirator resistance to fogging and not be penalized for test subjects with poor vision. The participants must not have poor visual acuity before participating in the test. Test participants, not wearing the hood, should first demonstrate an average VAS of 95 points without the use of glasses. This will assure that the test evaluates the fogging of the face shield and not the natural sight ability of the test participant or the quality of their glasses and any treatments the glasses may have received.

With regards to the described test, the concept does not specify how long the respirator is at the “resting” temperature before going into the test environments. This is a critical requirement for this test and could greatly affect the outcome. Therefore, it is important to specify this time. It is also important to specify how long the test participant will remain in the 72° F chamber before exiting to the either of the extreme temperature chambers. The time the test participant remains in the extreme temperature environments before the test is administered must be specified as well.

6(i) Flammability and Heat Resistance (applicable to respirators approved for carbon monoxide protection)

We agree that this test is only applicable to those respirators approved for carbon monoxide and the paragraph title should reflect this. Therefore, we recommend the title be changed to: Flammability and Heat Resistance (applicable **only** to respirators approved for carbon monoxide protection). To not do so may give the user a false sense of security for fire resistance, forgetting about the limitation of the flammability of their clothing or believing that it will protect against carbon monoxide.

The Concept indicates that after the flame test the breathing protection cannot be compromised by the flame conditioning. While visual check determine drip, melt, a visible hole, damage in any other manner that compromises the breathing protection

may not be visible. No post-flame performance test for breathing protection is included. We believe the phrase “damage in any manner that compromises the breathing protection provided by the respirator” be deleted from this paragraph.

The test specified for flammability and heat resistance is EN 136, 1998 edition. Whether it is Class 1 or Class 2,3 of the standard is not listed. Class 2,3 uses a six-burner test with each flame at 950 C. Given that it is assumed that no additional protective gear is worn by the user, exposure to this type of heat would be detrimental beyond capabilities of the escape respirator. 3M believes that Class 1, with a single burner at 800 C is the proper choice in EN136 if a full-system conditioning is to be applied.

6(k) Laboratory Respirator Protection Level

This paragraph requires a LRPL of 2000 for the escape hood. This is the same as that in the Full Facepiece APR for CBRN. This implies the same performance as the CBRN full facepiece APR. Since these are negative pressure devices, 2000 does not seem to be an appropriate LRPL (not even for the full facepiece CBRN APR). The 500 required for SCBA seems more appropriate.

There are several concerns about performing LRPL testing and the message this sends to the user. Using criteria established by ANSI and OSHA the performance of the LRPL test and the pass level of 2000 implies an assigned protection factor (APF) of 200. 3M does not know of any data to support this implication for performance. This is a bad precedent and goes against current acceptable practices.

ANSI Z88.2-1992 indicates APFs are not applicable for escape respirators.³ In the NIOSH Respirator Decision Logic it states, “Escape devices have a single function: to allow a person working in a normally safe environment sufficient time to escape from suddenly occurring respiratory hazards.”⁴

Secondly, the test may indicate fit is important and the need to fit test prior to use of the respirator. We do not believe this is the purpose of the test, but rather to ensure manufacturers make models that accommodate a wide variety of head sizes. If NIOSH is to perform the LRPL test, it should clarify the objective of the test.

If this test is included in the standard, several test criteria need to be identified. The May 15th Concept does not indicate where the in-respirator sampling would be performed. Sampling in or outside the nose cup or mouth bit could provide different results. Full comment on this requirement cannot be made until this fundamental question is answered. NIOSH does not indicate what exercises will be used during this test. 3M does not believe the same exercises used in the past are necessarily appropriate for these devices, (e.g. talking, grimacing, sighting a rifle). As a minimum, these exercises should be eliminated if NIOSH decides to keep this test.

NIOSH should specify that LRPL test participants should be trained in proper donning of the hood and follow all manufacturers' instructions before entering the LRPL test chamber. If the manufacturer has specified a method for evaluating proper fit, then those individuals that are identified (during the training) as having unacceptable fit should be excluded from the LRPL panel.

The standard needs to identify the criteria to be used in determining if an escape hood model "passes" the LRPL of 2000. If the objective is to ensure that the product will consistently provide a LRPL of 2000 for the population at large, then the appropriate statistical parameter (5% percentile, average, etc.) needs to be identified. A justification should be included as to how the number of subjects was selected. In our experience, 25 subjects are minimal for meaningful statistics in quantitative respirator fit tests. The number of subjects should be determined based on the objective of the LRPL test and the statistical methods used to evaluate the LRPL.

It is very important to specify where the neck should be measured. This is not done in the May 15th concept. If the neck sizes listed in the May 15, 2003 Concept for neck circumferences measured at the Adam's Apple (infrathyroid landmark, then the size range should be increased, so that the small starts at 292 mm (11.5 inches) which is approximately the 5% of women's neck circumference and the large ends at 413 mm (16.25 inches) which is 95% of men's neck circumference when measured at the Adam's Apple.⁵ This results in the distribution shown below.

Table 1. Neck Sizes

	Small	Medium	Large
Neck size (mm)	292-350	351-375	376-413
	Percent of population (%)		
Women	5-98	98-100	
Men	0-6	7-43	44-95

If one assumes that the user population is equally distributed between men and women, then this distribution means that approximately 50% of the total population is represented by the "small" category, 25% by the "medium" category and 25% by the "large" category. The subjects should be distributed accordingly (i.e. 12 subjects in small, 7 in medium and 6 in large, for a total of 25). If there are different assumptions about the population then these should be stated.

7. Design Considerations

7(c) Respiratory Protection System

This paragraph requires that the unit consist of a nose cup or mouthpiece. This is a design specification and should be removed from the standard. The purpose of this

would seem to be to control breathing and CO₂ levels and to protect the eyes. There are other ways to do this. The standard already has performance requirements for these parameters. If eye protection is important and goggles are used, for example, there are ways to sample behind them to see if they meet the standard. Making the standard design specific limits the use of future design improvement based on new technology.

10 Training

This provision should state practice in the donning of the respirator is a required part of training. Training can be accomplished by either using one of the respirator systems or a training model provided by the manufacturer. This may assist users in complying with the training requirements under the OSHA standard. However, if a training model is available, it should be identical to the approved device in appearance, packaging, human factors (weight, breathing resistance, etc.), and design with the exception of labeling. If opening the packaging is an important step in donning, then having a training model does not provide an advantage during training if the packaging is not reusable. Since the respirator is not designed for reusability, the packaging would not be expected to be either. Whether manufacturers provide training models or recommend real product should be left to the manufacturer.

11 Cautions and Limitations

New cautions and limitations statements that NIOSH should include for this device are:

- *Not for use for shelter in place scenarios.*
- Not for use in atmospheres containing less than 19.5 percent oxygen.
- Not for entry into atmospheres immediately dangerous to life and health.
- This respirator helps reduce exposures against inhalation of radiological and nuclear dust particles.
- Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained.
- Direct contact with CBRN agents requires proper handling of the respirator after each use. Decontamination and disposal procedures must be followed. If contaminated with liquid chemical warfare agents, dispose of the respirator after decontamination.
- The respirator has finite permeation resistance to liquid chemical warfare agents. Avoid liquids if possible. If liquid exposure is encountered, the respirator should be removed, decontaminated and discarded as soon as it is safe to do so.

References

1. **American Conference of Governmental Industrial Hygienists:** *Documentation of the Threshold Limit Values and Biological Exposure Indices, 7th ed.* Cincinnati, OH: American Conference of Governmental Industrial Hygienists, 2002.
2. **American National Standards Institute:** *American National Standard for Air-Purifying Respirator Protective Smoke Escape Standard (ISEA/ANSI 110-200x).* Arlington, VA: International Safety Equipment Organization (Draft).
3. **American National Standards Institute:** *American National Standard for Respiratory Protection (Z88.2-1992).* New York: American National Standards Institute, Inc. 1992.
4. **National Institute for Occupational Safety and Health:** *NIOSH Respirator Decision Logic (Pub. No. 87-108).* Washington, D. C.: U.S. Department of Health and Human Services/National Institute for Occupational Safety and Health, 1987.
5. **Gordon CC, Bradtmiller B, Clauser CE, Churchill T, McConville JT, Tebbetts I, and Walker RA:** *1987-1988 Anthropometric Survey of U.S. Army Personnel: Methods and Summary Statistics.* Technical Report (TR-89-044). U.S. Army Natick Research, Development and Engineering Center, Natick, MA. 1989.