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From: cecolton@mmm.com
Sent: Monday, January 31, 2005 3:05 PM
To: NIOSH Docket Office
Subject: NIOSH DOCKET-010

01-31-05 Letter to niosh docke...

Attached files contain comments for the above referenced docket.

(See attached file: 01-31-05 Letter to niosh docket officer.doc)

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January 31, 2005

NIOSH Docket Officer, REFERENCE: NIOSH DOCKET-010
Robert A. Taft Laboratories M/S C34
4676 Columbia Parkway
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RE: October 30, 2004 (Draft for Discussion) Concept for Chemical, Biological, Radiological, and Nuclear (CBRN), Tight Fitting, Powered Air Purifying Respirator (PAPR) Docket-010

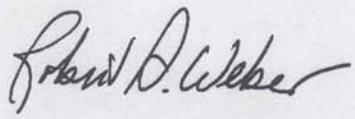
Dear Docket Officer:

Minnesota Mining and Manufacturing Company (**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 Health and Safety with our comments on the Concept for Chemical, Biological, Radiological, and Nuclear (CBRN), Tight fitting, Powered Air Purifying Respirator (PAPR), dated October 30, 2004.

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 offer the following comments and recommendations regarding the Concept for Chemical, Biological, Radiological, and Nuclear (CBRN), Tight fitting, Powered Air Purifying Respirator (PAPR), dated October 30, 2004.

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,



Robert A. Weber
Technical Service Manager
3M Occupational Health & Environmental Safety Division

RAW:CEC/llb
Enclosures

3M Comments on October 30, 2004 (Draft for Discussion) Concept for Chemical, Biological, Radiological, and Nuclear (CBRN), Tight Fitting, Powered Air Purifying Respirator (PAPR)

3M's recommended changes to this version of the CBRN PAPR Concept follows. One general comment pertains to testing in the "failure" mode. Based on the Public Hearing Presentations and Comments, this concept relies extensively on testing the PAPR in the failure mode, i.e., negative pressure. In fact, one might argue that this is a concept exclusively for a negative pressure respirator with a motor and blower attached. Requiring these PAPR products to function in a negative pressure mode because the battery might fail or fall off seems overly limiting and reduces the benefits gained from a PAPR system. This concern is not evidenced in other existing CBRN Standards where there are no provisions imposed to cover fault modes, such as straps breaking on a FF CBRN APR or requiring a CBRN SCBA to function on an empty SCBA Cylinder.

1. Purpose

Since NIOSH indicates that PAPRs approved under these requirements are intended for first responders, the title of this section should be changed to "Purpose and Scope" and the text of the first paragraph modified as follows (shown in blue upper case). As explained in section B.2.1 of the cited OSHA document, 42 CFR 84 compliant PAPRs provide the necessary level of protection and flexibility for first receivers.[1] This is consistent with NIOSH's position stated at the public meeting on December 15, 2004. At that meeting NIOSH indicated that because published papers demonstrated that crossover contamination of war agents would be low and due to the recommendations in OSHA's draft document on guidance for first receivers, first receivers would not need CBRN PAPRs. The suggested revision below would obviate the need for NIOSH to promulgate specific PAPR criteria for first receivers.

1.0 PURPOSE AND SCOPE

To develop a NIOSH NPPTL, tight-fitting, powered air-purifying respirator standard for **emergency responders** that address CBRN materials identified as inhalation and/or possible hazards from terrorist activity. PAPR APPROVED UNDER THESE REQUIREMENTS ARE NOT INTENDED FOR USE BY **FIRST RECEIVERS.** FIRST RECEIVERS ARE HOSPITAL STAFF, WORKING IN A HOSPITAL, WHO HAVE A ROLE IN RECEIVING AND TREATING CONTAMINATED VICTIMS (E.G., TRIAGE, DECONTAMINATION, MEDICAL TREATMENT, AND SECURITY) AND THOSE WHOSE ROLES SUPPORT THESE FUNCTIONS (E.G., SET UP AND PATIENT TRACKING). INHERENT TO THE DEFINITION OF *FIRST RECEIVERS*, IS AN ASSUMPTION THAT THE HOSPITAL IS NOT ITSELF THE PRIMARY INCIDENT SITE, BUT RATHER IS REMOTE FROM THE LOCATION WHERE THE HAZARDOUS SUBSTANCE RELEASE OCCURRED. THUS, THE POSSIBLE EXPOSURE OF FIRST RECEIVERS IS LIMITED TO THE QUANTITY OF SUBSTANCE ARRIVING AT THE HOSPITAL AS A CONTAMINANT ON VICTIMS AND THEIR CLOTHING OR PERSONAL EFFECTS (HORTON ET AL.,

2003). PAPRs THAT COMPLY WITH THE APPLICABLE PARAGRAPHS OF Title 42 CFR, Part 84 ARE CONSIDERED ACCEPTABLE FOR FIRST RECEIVERS. FOR SPECIFIC GUIDANCE REFER TO *OSHA BEST PRACTICES FOR HOSPITAL-BASED FIRST RECEIVERS OF VICTIMS FROM MASS CASUALTY INCIDENTS INVOLVING THE RELEASE OF HAZARDOUS SUBSTANCES (DECEMBER 2004).*[1]

1. OSHA Best Practices for Hospital-based First Receivers. USDOL/OSHA. December 2004. page 7.

TIGHT FITTING CBRN PAPRs must meet the minimum requirements identified in the following paragraphs:

- Paragraph ~~4.0~~3.0 Requirements specified in Title 42 CFR, Part 84 applicable paragraphs
- Paragraph ~~5.0~~4.0 Requirements based on existing national and international standards
- Paragraph ~~6.0~~5.0, Special Requirements for CBRN

1. Purpose, fourth paragraph:

NIOSH must add an explanation of the anticipated uses for moderate and high work rate PAPRs. The fact that these are two well-recognized test criteria is not a justification for having two types of PAPRs. Unless NIOSH is aware of data that demonstrate a difference in protection or comfort between PAPRs with the specified flow rates, there is no point in making the distinction. In reality, the PAPRs will operate over a wide range of flows, similar to industrial PAPRs today. Thus, the difference in airflow between some moderate and high airflow PAPRs will be small. A moderate work rate PAPR with flow characteristics slightly under the high work rate requirement would be indistinguishable to the user regardless of the evaluation criteria used. It would make more sense to choose a single test flow rate for all PAPRs.

This paragraph also states, "The CBRN Tight-Fitting PAPR concept specifies requirements for breathing performance [3M's emphasis] based on the ability of the respirator to maintain a positive pressure in the breathing zone when tested with a breathing machine." Change "breathing performance" to "air flow performance" as one cannot measure the ability of a PAPR to breathe.

2.1 Respirator Use

A. In line 2, change "recommended exposure level (REL)" to "permissible exposure limit (PEL)," which is the OSHA established limit. Using the REL would be the equivalent of changing an OSHA standard without rulemaking.
B. Change: "Crisis (Panic/Demand)" to "Emergency Egress Mode." The former term is in appropriate since all responders must be (and have been) trained to remain calm (not panic and think clearly) in the event of an emergency.

4.1.1. Required Packaging Configuration: (Minimum Packaging Configuration)

The spelled out form of the acronym, MPC, was omitted, so the following change is recommended: "The CBRN Tight Fitting PAPR and the required components will be subjected to the environmental and transportation portions of the durability conditioning in the manufacturer specified ~~MPC~~ MINIMUM PACKAGING CONFIGURATION (MPC)."

4.2 Labels

It is not clear if "labels" refers to the Approval Label or other labels that may be used by the manufacturer. If the following statements are referring to the approval label, the title of this section should be changed to reflect that point, i.e., "LABEL."

In addition to the requirements of Paragraph 43.2, the following paragraphs apply:

4.2.1 The battery part number must be prominently displayed with the part number on the respirator battery pack or other suitable location.

For clarity, 4.2.1 should be changed to: "The battery part number must be prominently displayed on the battery AND ON THE PAPR BLOWER or other suitable location." This would allow the user to match the PAPR with the correct battery pack.

4.2.2 Additional cautions and limitations appropriate to CBRN Tight Fitting PAPRs must be added as deemed necessary by NIOSH, such as "Observe low flow or pressure alarm indicators."

3M suggests that 4.2.2 be moved to section 5.16.

4.3 General Construction Requirements

4.3.1 Battery Requirements

The word "charge" in the second to last sentence in this section should be changed to "charger."

Change with Comment: 4.3.1.1 User Instructions: User instructions will provide adequate information on the function and operation of THE battery chargeR.

It is also not clear what NIOSH means when they state "information regarding operational battery life in typical climates." "Typical" is dependent on the user's location. The wording should read, "THE MANUFACTURER SHOULD PROVIDE INFORMATION ON HOW THE BATTERY FUNCTIONS AT DIFFERENT TEMPERATURES, I.E., OPERATING TEMPERATURE RANGE AND EXPECTED DURATION."

4.3.1.2 Low Battery Indicator:

The low temperature requirements will require batteries to be "oversized" and also may limit the manufacturer's choices in battery chemistry. The operational temperature of a battery affects the voltage that the cells are capable of delivering (the voltage is reduced at lower temperatures and affects the airflow directly). This means that one will need to add additional cells to a battery pack and would likely require voltage control. The CBRN PAPR Standard should allow the manufacturer to specify the minimum operating temperature for the unit and the testing should be done at this temperature. The user should then select an appropriate PAPR unit with an operating temperature that meets their application.

4.3.2 Low Flow Indicator

4.3.2.1: Change "insure" to "ensure"

4.3.2.2, sixth line: Change "maintaining positive pressure in the breathing zone" to "must not allow pressure in the breathing zone to fall below atmospheric pressure." This language is equivalent to Sec. 84.157 of 42 CFR regarding pressure demand supplied air respirators and 4.4.4 of this document. In addition, Clause 7.1.1 of NFPA Standard 1981 (2002) uses similar language in its airflow performance test. The change is particularly necessary for tight fitting hoods, which may operate at lower positive pressure than tight fitting facepieces.

In addition "alarm" should be changed to "indicator" to be consistent with the title of this section. The low flow ~~alarm~~ INDICATOR may be audible, visual, or vibratory.

4.4.2 and 4.4.3 Breathing Rate Performance Tests

See above comment (Purpose, fourth paragraph): More than likely it will only be necessary to describe one test.

If current 4.4.3 language is retained, insert CBRN before PAPRs. "4.4.3 High Breathing Rate Performance: CBRN PAPRs designated for the high breathing…"

4.4.4 Breathing Performance Requirement, second line

Paragraph references should be ~~5~~ 4.2.2 and ~~5~~ 4.2.3 if both paragraphs are retained.

4.7.2 Human Subject Breathing Gas Testing:

Based on the Public Hearing, NIOSH needs to clearly define if this test is conducted once with the power on and once with the power off. If the testing in

the "off" mode is to support a failure mode of the PAPR, then the CO_2 level should be raised to 2.5% as in the CBRN escape APR standard.

5.0 Special CBRN Requirements

5.2 Canister Capacity

Table 3

See previous comments on "breathing rate" performance. More than likely it will only be necessary to describe one test. Also, a definition must be provided for "Demand Responsive PAPR." This is a new term proposed by NIOSH. In the *Federal Register* on April 7, 2000 NIOSH created the new term "breath responsive powered air-purifying respirators" which was a PAPR that met the pressure demand requirements of supplied air respirators.[1] Are these two terms the same? NIOSH needs to define these terms clearly in order to prevent confusion among users. It is easy to envision improper selection being made if confusing terms are used. "Constant flow PAPR" has also never been defined, but use of this term may be inherent.

1. Breath Responsive Powered Air-Purifying Respirators (PAPRs): Notice of Acceptance and Evaluation. NIOSH. *Federal Register* 65(68): 18336 April 7, 2000.

5.2 also states, "Where multiple canisters are used, the canister capacity airflow rate will be divided by the number of canister elements used on the CBRN Tight Fitting PAPR." This wording is confusing and should be amended as follows, "Where multiple canisters are used, the PAPR airflow rate will be divided by the number of canister elements used on the CBRN Tight Fitting PAPR."

5.3 Particulate/Aerosol Canister

Change title to "Aerosol Filter". The canister is the container and has both aerosol and gas/vapor removing capabilities. This makes it sound like there are different canisters. Update paragraph references in 5.3.1.1 and 5.3.4. In the second line of 5.3.3: change 6 to 5. Insert "valve" before leakage, for clarity.

"5.3.3 When the canisters do not have separable holders and gaskets, the exhalation valves will be blocked to ensure that VALVE leakage, if present, is not included in the filter efficiency level evaluation."

It is also important to point out that these are not P100 filters if they are not tested at 85 lpm or one-half this rate if there are two filters or one-third this value if there are three filters.

5.4 Crisis (Panic Demand) Provision

Change title to Emergency Egress Mode for reasons stated previously under 2.1 Respirator Use. EMERGENCY EGRESS MODE **or Crisis ~~(Panic Demand)~~ Provision**

This provision is to be evaluated by a method "to be determined." This statement replaces a contentious high flow test requirement of 430 liters per minute for five minutes. It is very important that there be another draft concept paper that describes the proposed test before the final version is published. It would not be acceptable to have a test condition inserted without the possibility of comment and would clearly defeat the purpose of the public meetings.

The following histogram is presented in anticipation of that discussion. It represents data collected on the "worst-case" subject in a recently completed respiration physiology study at 3M. The histogram summarizes two minutes of data collected at 80% of the subject's VO_2 max, comprised of approximately 12,000 data points. The frequency bars represent maximum peak flow rates from 80 breaths during that period, i.e., each occurrence is 0.01 second duration. The salient point is the maximum peak airflow rate that has been the subject of recent debate occurs only once, for 0.01 second. The mean (340 L/min) or mode (344 L/min) is a much more reasonable indicator of an individual's maximum airflow requirement than is a single maximum peak.

More importantly, since all the peaks in the histogram add up to only 0.8 seconds (out of two minutes) it is clear that an "Emergency Egress Provision" test should not be based on peak airflow rates at all. In our study the 95th percentile minute volume for 15 subjects (nine men and six women) was 110 L/min at 80% VO_2 max. This is close to the 114 L/min minute volume suggested as a reasonable estimate for occupational activities by Caretti.[1] Both values are in general agreement with Kaufman and Hastings' study of respiratory demands of respirator users at very high work rates (mean minute volume 96.4 L/min).[2] In all cases the data indicate the 100 L/min flow rate NIOSH already uses for CBRN Full Facepiece APR "panic" testing is appropriate. Since requirements later in this concept paper address PAPR use in a negative pressure mode, it is logical that the 100 L/min total crisis flow rate of the CBRN-APR specification be adopted, divided by the number of filters on the PAPR. This requirement would be technically defensible as well as assuring consistency among regulations.

References:

1. Caretti, D. "Workplace Breathing Rates: Defining Anticipated Values Defining Anticipated Values and Ranges." Presentation at NIOSH public meeting, Canonsburg, PA, May 4, 2004.

2. Kaufman, J.W. and S. Hastings: Respiratory demand during rigorous physical work in a chemical protective ensemble. *J Occup Environ Hyg*: 2:98-110, 2004.

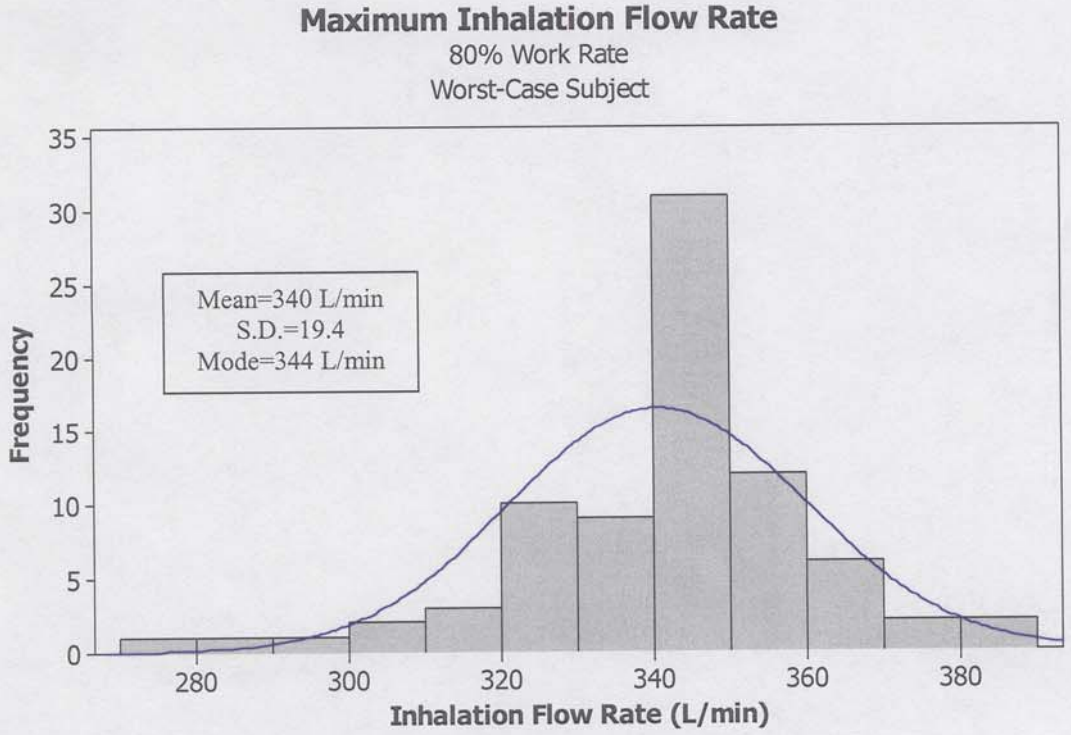


Table 4 and 5, footnote @

At this footnote, NIOSH introduces another term that has not been defined as it relates to PAPRs. It may have been an oversight if copied from the CBRN SCBA Concept where "pressure demand" has meaning.

Therefore change "pressure demand" to "demand responsive" as used in Table 3 (or define it if it means something different; breath responsive?). The same comment applies to Table 5 footnote @.

5.5 Canisters in Parallel Resistance

This requirement states, "…when two or more canisters are used in parallel, their resistance will be uniform within the population when tested at a 85 liters per minute continuous airflow…" This requirement is far too vague. NIOSH needs to define "uniform within the population" in this context. While NIOSH acknowledged this at the Public Meeting acceptance criteria, it must be applied to paper and discussed in a subsequent draft.

5.10 Laboratory Respiratory Protection Level (LRPL) Test Requirement

The word "trails" in the fourth line should be changed to "trials."

The concept indicates that facial grimace will be one of the LRPL exercises. This is consistent with past concepts. The concern is how NIOSH plans to handle the results

from this exercise. Based on the CBRN SCBA concept it is believed that NIOSH intends to use the results from the grimace exercise in the calculation of the overall fit factor. It is 3M's opinion, however, that the reason for the addition of this exercise to test protocols has been lost with time. Historically, it was never expected that the respirator would not leak during this exercise. In fact, it was expected to leak grossly during this exercise. This exercise was performed prior to the second normal breathing exercise to see if when the face seal was broken, it would re-seat to a level comparable to the first normal breathing. The results were never to be used in the final calculation and should not be so used here.[1,2]

1. Lowry, P.L., L.D. Wheat, and J.M. Bustos: Quantitative fit-test method for powered air-purifying respirators. *Am. Ind. Hyg Assoc. J. 40*:291-299 (1979).

2. Respirator Studies for the National Institute for Occupational Safety and Health, July 1, 1974-June 30, 1975. LA-6386-PR. August 1976. p. 39

As NIOSH develops the STP for the LRPL, NIOSH should resolve this issue and remove the grimace result from the calculation. This would be consistent with OSHA procedures where NIOSH indicates that "The LRPL test consists of a set of eleven standard exercises that use eight (8) basic US Department of Labor, Occupational Safety and Health Administration (OSHA) Quantitative Fit Test (QNFT) ..." OSHA does not use the results of the grimace exercise in the calculations of the overall fit factor.

5.14 Practical Performance

This section states, "Should 95 percent of the practical performance test trials not be acceptable, one additional run of test trials of paragraph 5.10 or paragraph 4.7.2, may be performed to increase the total number of trials." Words of clarity and intent are missing and should be added as follows: "Should LESS THAN 95 percent of the practical performance test trials not be acceptable, one additional run of test trials of paragraph 5.10 or paragraph 4.7.2, may be performed to increase the total number of trials."