3M Occupational Health and Environmental Safety Division

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January 12, 2006

NIOSH Docket Officer, REFERENCE: NIOSH DOCKET-010
Robert A. Taft Laboratories M/S C34
4676 Columbia Parkway
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NIOCINDOCKET@CDC.GOV.

RE: November 4, 2005 (Draft for Discussion) Chemical, Biological, Radiological, and Nuclear (CBRN) Powered Air Purifying Respirator (PAPR) Concept, 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 offer the following comments and recommendations regarding the Concept for Chemical, Biological, Radiological, and Nuclear (CBRN) Powered Air Purifying Respirator (PAPR), dated November 4, 2005.

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 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,

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

Chemical Biological Radiological Nuclear (CBRN) Powered Air-Purifying Respirator (PAPR) Concept dated November 4, 2005

The introductory section states that the CBRN PAPR obtaining NIOSH 42 CFR Part 84 approval and the second is passing CBRN PAPR approval. 3M suggests that it may be more efficient and clearer to any one seeking or dealing with the approval process for NIOSH to consider combing these two stages into one step.

2.0 Chemical Agent Permeation and Penetration against Distilled Sulfur Mustard (HD) and Sarin (GB)

2.1: Two PAPR systems for each test agent are called out in the text of this paragraph. Tables 2 and 3, however, specify three systems for each agent. The text in paragraph 2.1 should be revised to call out six systems, and explain that two systems will be used for preliminary screening.

Table 2, footnote ††: To help insure uniformity of test conditions, the second sentence should be modified to state: "All live agent testing shall be run on supplemental electrical power provided by the test agency. The manufacturer shall supply voltage and current requirements and a connecting cable".

Table 3, footnote †: The second sentence should also be revised as suggested above for Table 2 footnote ††.

3.0 Laboratory Respiratory Protection Level (LRPL) Test Requirement – (all Respirators, Reference STP CBRN 0552)

3.1 and 3.2: To eliminate variability in probe location during LRPL testing, 3M suggests deleting the statement about sampling location in the breathing zone of the respirator. Replace it with a description of the sampling probe location as specified in STP CBRN 0552.

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 when testing full facepiece respirators. 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 of full facepiece respirators. 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.

In addition, a statement should be added that because the grimace exercise does not produce facial conditions that could lead to leakage for loose fitting respirators and tight-fittting hoods, it is not required.

4.0 Canister Test Challenge and Test Breakthrough Concentrations– Reference STPs CBRN – 0501, 0502, 0503, 0504, 0505, 0506, 0507, 0508, 0509, 0510)

The following revisions to section 4.0 are suggested so that these provisions are consistent with past NIOSH approvals and limitations, and provide the most flexibility for both manufacturers and end users.

First, the title to section 4 should be amended by inserting "and Cartridge" after "Canister" in accordance with the comment to 4.2.1 below.

4.1: As currently written this section includes half and full facepieces, and excludes tight-fitting hoods. We believe NIOSH intended to include tight-fitting hoods and suggest the title of 4.1 be changed to "Canisters".

4.2: As discussed in greater detail below, this section deals primarily with chemical cartridges and therefore, the title should be changed from "Losse-fitting facepiece" to Cartridges".

4.2.1. This section is actually defining chemical cartridges rather than canisters. It limits the capacity of "canisters" used on PAPR's with loose-fitting inlet coverings (Table 5) to half the capacity of those used on PAPR's with tight-fitting inlet coverings (Table 4). 3M submits that it is not appropriate to link the capacity of the air purifying element to the type of inlet covering on the PAPR. The reasoning put forth at the public meeting that loose-fitting PAPRs shouldn't be used in high physiological demand situations is not supported in the literature and is contrary to sound logic. Airflow for loose-fitting PAPRs is typically higher than for tight-fitting devices, and the larger dead volume makes them harder to overbreathe (i.e., draw into negative pressure). In addition, users of loose-

fitting devices may be better prepared for unscheduled events requiring respiratory protection since fit testing is not required for these devices.

Table 5: To be consistent with the above alterations, change "Canister" to "Cartridge" in the title.

4.3: Revise terminology throughout to include cartridges as well as canisters. Using this approach, all canisters would carry the TC-14G approval. This change would require the second sentence of Table 2 footnote † to be revised to state that the liquid challenge is required for all inlet coverings to be used on PAPRs with canisters. Further, a limitation would be added to the TC-14G approval label, stating that the PAPR is only approved for escape from IDLH atmospheres when a tight-fitting facepiece or tight-fitting hood is used. All cartridges would carry the TC-23C approval. Consistent with existing limitations, cartridges would not be acceptable for escape from IDLH atmospheres.

In sum, these changes would make the decision logic for CBRN cartridges and canisters consistent with current practice. End users would not have to learn a new decision logic based on the type of inlet covering used. In addition, responder and receiver organizations would have more options in PAPR configurations. Each organization could select the device that best fits its specific needs.

5.2: Requiring the use of authorized technicians for retrofit procedures does not make sense for PAPR systems. These systems do not have the level of complexity or need for fine adjustment such as needed for SCBA. User instructions can be written in such detail that individuals making repairs or upgrades do not need to have special training by the respirator manufacturer. 3M suggests this requirement be deleted.

5.3: The provisions in this section appear to be a carryover from the CBRN SCBA standard. Specifically, PAPRs do not have serial numbers, nor should they be required to have them. We are not aware of any reasons for the need to track them. The requirement for tracking upgraded PAPRs should be deleted.

5.5: The definition for "heavy use" needs more specificity and clarity. The paragraph should be revised to state that manufacturers must specify model numbers and product age limit for devices eligible for upgrade.