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March 17, 2006

NIOSH Docket Officer, REFERENCE: NIOSH DOCKET-008  
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**RE: November 4, 2005 (Draft for Discussion) Concept: Proposed Industrial  
Powered, Air-Purifying Respirator (PAPR) Standard Concept, Docket-008**

Dear Docket Officer:

3M 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 Industrial Powered Air-Purifying Respirator (PAPR), dated November 4, 2005.

3M supports NIOSH in its effort to develop updated standards for evaluating the effectiveness of powered air purifying respirators for use in a variety of industrial environments.

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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". The signature is written in a cursive style with a long, sweeping tail on the "e".

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

## Industrial PAPR Concept Dated November 4, 2005

**General comments:** Sections not mentioned below are supported by 3M as proposed. The Standard Testing Procedures (STP) must be linked to the test requirements in future concept papers. It is difficult to comment when they are not listed.

### 84.301 Definitions

84.301 (a): Delete "operation and" from the definition. Delete "at all times" and insert "flow" before "testing". It is necessary to have pressure below ambient for testing alarms. Neither NIOSH nor manufacturers can observe pressure when the unit is in operation. As we discuss below in our comment to 84.304 (b), it is likely that every device in use will have pressure at ambient or below at some point. We suggest the requirement be revised to read:

*(a) Powered, Air-Purifying Respirator (PAPR) - an air-purifying respirator that uses a powered mechanism (blower) to pass ambient air through an air-purifying element to a respiratory inlet covering and which maintains an air pressure above ambient during flow testing in the area of the nose and mouth*

84.301 (b): Change "seals" to "is designed to seal." We suggest the requirement be revised to read:

*(b) Tight-fitting PAPR - a PAPR which contains a respiratory inlet covering that is designed to seal to the face or neck.*

84.301 (c): Eliminate "non-tight sealing" at the start of the definition and change "non-tight sealing" to "loose-fitting" before "facepiece." These mean the same thing, and the latter is an accepted term. It was also our understanding that 'neck dam' referred to a tight-fitting inlet covering. This is based on the definition of "neck dam PAPR" in the April 1, 2004 CBRN concept. It is also implied in the LRPL test described in STP-0352. We suggest 'neck dam' be removed from this paragraph. The following revisions should also be made to subparagraphs 1-4:

(1) Hood-a **flexible** loose-fitting. . .

(2) Helmet-change "non-flexible" to "rigid." The portions of the user covered by the helmet should be stated

(3) Loose-fitting facepiece, second sentence-It does not cover the neck, **the back of the head** or shoulders.

We believe the entire revised paragraph should read:

*(c) Loose-fitting PAPR- a PAPR which contains a respiratory inlet covering that may contact but does not seal completely to the face or neck. It may consist of a hood, helmet, or loose-fitting facepiece.*

*(1) Hood - a flexible loose-fitting respiratory inlet covering that covers the head and neck. It may cover portions of the shoulders.*

*(2) Helmet - a rigid loose-fitting inlet covering that is designed to offer some degree of impact and penetration protection of the head. It covers the head and neck and may cover portions of the shoulders.*

*(3) Loose-fitting facepiece - a loose-fitting respiratory inlet covering which makes contact with but does not seal to the face. It does not cover the neck, back of the head or shoulders.*

*(4) Deleted*

84.301 (d): Delete "tight-fitting" from the definition, and change "PAPR100 filter" to "a PAPR 95 or PAPR 100 filter(s). Very few particulate hazards have IDLH values. PAPR 95 filters will be essentially 100% efficient in the workplace<sup>(1,2)</sup> and could have the advantages of longer service time or extend the battery life. We suggest the requirement be revised to read:

*(d) Gas Mask PAPR (Canister PAPR) - A PAPR which contains an appropriate canister and may contain a PAPR95 or PAPR100 filter suitable for its intended use. A tight-fitting gas mask PAPR is designed to operate in a silent mode as defined herein, and is permissible for escape from atmospheres that contain at least 19.5% oxygen to support life. A loose-fitting gas mask PAPR does not operate in the silent mode and is not permissible for escape from atmospheres that may be immediately dangerous to life or contain less than 19.5% oxygen.*

(e) Delete 'tight fitting' from the definition, and indicate only tight-fitting devices can be designed to operate in silent mode. We suggest the paragraph be revised to read as follows:

*(e) Chemical cartridge and/or filter PAPR - A PAPR which contains an appropriate cartridge and/or PAPR filter suitable for its intended use. Devices with tight-fitting inlet coverings may optionally be designed to operate in a silent mode as defined herein.*

### **84.302 Description**

84.302 (b): Change "PAPR 100 filters" to "a PAPR 95 or PAPR 100 filter(s). Very few particulate hazards have IDLH values. As noted in our comment to 84.301 (d), PAPR 95 filters will be essentially 100% efficient in the workplace, and could have the advantages of longer service time or extend the battery life. We suggest the requirement be revised to read:

*(b) Gas Mask PAPRs are equipped with appropriate canisters and may also contain PAPR95 or PAPR100 filters. Devices with tight-fitting inlet coverings are designed to operate in a silent mode as defined herein. Devices with tight-fitting inlet coverings may be used for escape from hazardous atmospheres containing a minimum of 19.5% oxygen to support life.*

### **84.303 Required Components**

Item (a)(7) should be revised to say “low flow or low pressure indicator.” Either can be used to warn the user when the PAPR is no longer performing at its “certified performance level.” Our logic for this statement is fully explained in our comment to 84.304 (b) below.

### **84.304 General Construction**

a) This paragraph should be revised to indicate that a full charge indicator need not be located on the battery itself. For example, the full charge indicator can be located on the charger. We suggest the requirement be revised to read:

*(a) Each PAPR system shall have an indicator to indicate when the battery is fully charged and at low charge. The low charge indicator shall be readily detectable to the wearer during use without manipulation of the respirator.*

84.304 (b) Since PAPRs are intended for use in atmospheres that are not IDLH, there is no compelling reason to require alarms; they should be optional at the manufacturer’s discretion. The statement should also be revised to indicate that if an alarm is used, it may actuate based on either low flow or low pressure. The two are inter-related; pressure in the inlet covering is maintained by providing appropriate air flow. Further, it is known that most, if not all, positive pressure respirators can be drawn into momentary negative pressure excursions in actual use. There are laboratory studies<sup>(2,3)</sup> and field studies<sup>(4)</sup> that have measured these excursions. When the data from these studies are analyzed, it is easily seen that the occasional negative pressure excursions that occur in positive pressure respirators have negligible effect on protection, even during periods of heavy work. Campbell et al.<sup>(3)</sup> demonstrated this with a mathematical model; Cohen et al.<sup>(2)</sup> measured simulated workplace protection factors (equivalent to LRPL) far in excess of 10,000 for all but one device. Therefore, an alarm that actuates after one or a few momentary negative pressure excursions is not useful. It does not tell the user he or she may be at risk of possible reduced protection because of declining PAPR function. The permissible response time for the low pressure indicator must be specified to prevent spurious alarming. To provide PAPR wears useful information, we suggest an alarm that actuates when airflow falls below the manufacturer’s stated minimum for 30 seconds. This would address several failure modes, including clogged filters, low battery and motor degradation. We suggest the requirement be revised to read:

*(b) If a PAPR is equipped with an alarm, it shall alert the user, via a readily visible light or other means, when the airflow of the PAPR falls below the manufacturer’s stated minimum flow for 30 or more seconds. It shall be readily detectable to the wearer during use without manipulation of the respirator. Indicators that are actuated when pressure inside the respiratory inlet covering falls below the manufacturer’s stated minimum for 30 or more seconds are also acceptable.*

84.304 (d): Insert "gas mask" after "tight-fitting." Cartridge PAPRs and gas mask PAPRs with loose-fitting inlet coverings are limited to non-IDLH environments. If the blower fails, respiratory protection is not necessary to leave the work environment. We suggest the sentence be revised to read:

*(d) Each tight-fitting gas mask PAPR shall be designed to prevent unpurified air from entering the system if the blower function stops*

84.304 (e) Delete the phrase "or most recent version;" the sentence should be ended after "2003." If Z88.7 is revised, NIOSH can choose to incorporate it (or not) with appropriate public notice. We suggest the sentence be revised to read:

*(e) Color coding of cartridges and canisters shall be per the ANSI Z88.7 -2003.*

#### **84.306 Body Harness**

These provisions, when applicable, are vague and ambiguous. They should be deleted.

#### **84.307 Head Harness**

84.307 (a) and (b): It is possible that not all devices will have a head harness. We suggest the sentence be revised to read:

*(a) If the respiratory inlet covering is equipped with a head harness, it shall be designed and constructed to hold the unit properly in place, provide adequate tension during use, and provide even distribution of pressure over the entire area in contact with the head or face*

*(b) Each head harnesses shall be adjustable and replaceable where necessary.*

#### **84.308 Respiratory Inlet Coverings**

84.308 (e) Delete the phrase "or most recent version;" the sentence should be ended after "2003." If Z89.1 is revised, NIOSH can choose to incorporate it (or not) with appropriate public notice. We believe the revised sentence should read:

*(e) Helmets designed for head protection shall meet the requirements of ANSI Z89.1-2003 Type I or Type II. Helmets not designed to provide head protection shall be prominently and permanently labeled to indicate that they are not impact and penetration resistant.*

#### **84.309 Lenses of Respiratory Inlet Coverings**

84.309 (b) and (c): These requirements are vague and the measurement criteria must be defined and explained.

84.309 (d) Delete the phrase “or most recent version;” the sentence should be ended after “2003.” If Z87.1 is revised, NIOSH can choose to incorporate it (or not) with appropriate public notice. We also believe that marking lenses that are not impact resistant would conflict with Z87.1, which requires marking to identify compliant eye and face protection. Cautionary language in the user instructions will tell users if the lens does not offer eye or face protection. We believe the revised sentence should read:

*(d) Lenses designed to provide eye and/or face protection shall meet the requirements of ANSI Z87.1- 2003.*

#### **84.313 Air Pressure Determination for Maintaining Positive Pressure**

84.313 (a): “Positive” is redundant and should be deleted. Change “during operation” to “during the test” for the reason noted under 84.301 (a) comment. The phrase “be designed to maintain” should be inserted after “shall.” We believe the revised sentence should read:

*(a) All PAPRs shall be designed to maintain a pressure above ambient inside the inlet covering during testing described in this paragraph.*

84.313 (d): Definition of permissible uses for PAPR with different flow ratings must be provided. The assigned protection factors must be stated here, because 84.316 (d)(2) relies on APF for gas/vapor test concentration. If the different flow rates are to have different APFs, valid data must be used to set them. At this time there is no published data that would support different APFs for different flow rates. The data NIOSH plans to use to set APFs must be made available for evaluation prior to setting APFs. In addition, the breathing machine(s) that will be used must be specified.

#### **84.314 Air Flow Determination for Testing Cartridges, Canisters, and/or Filters at a Constant Flow and for Machine Breathing Gas Testing**

84.314 (a): The flow rate of a PAPR system can change significantly when different inlet coverings are used. Thus, multiple “systems” may need to be specified for the same basic unit. An example of the range of airflow rates as a function of the air purifying element and inlet covering for an actual PAPR system is presented in Attachment A. The sentence should be revised as follows to acknowledge this variability:

*(a) The manufacturer shall specify a maximum and minimum average constant flow rate of the PAPR system(s) on which the cartridges, canister or filters will be used.*

84.314 (b): Flow rates can be significantly different for different combinations of air purifying element and inlet covering. It is logical to test each air purifying element at the highest airflow it will actually encounter in use. We believe the paragraph should be revised as follows:

*(b) Average constant air flow for each cartridge, canister and/or filter shall be determined on a headform by testing three PAPR systems (as defined in section 84.301 (a)) equipped with the cartridges, canisters, and/or filters. When there are multiple combinations of inlet coverings and cartridges, canisters and/or filters within one PAPR system, air flow must be determined for each approved combination separately.*

84.314 (d): As noted in our comments to the two previous paragraphs, the airflows for different combinations of inlet covering/air purifying element (i.e., systems) can vary significantly. We believe the paragraph should be revised as follows to indicate this is the case:

*(d) The determined average constant air flow values shall fall within the specified maximum and minimum values provided by the manufacturer for each PAPR system.*

84.314 (e) Same comment and logic as above. We suggest the paragraph be revised as follows:

*(e) Cartridge, canister and/or filter testing (84.315 and 84.316) will be done at the maximum specified air flow rate for the PAPR system using the specific cartridge, canister and/or filter being tested.*

84.314 (f): Same comment and logic as above. We suggest the paragraph be revised as follows:

*(f) The breathing gas: carbon dioxide (CO<sub>2</sub>), machine-generated test (84.321) will be done at the minimum specified flow rate for the PAPR system using the specific respiratory inlet covering.*

#### **84.315 PAPR 100 and PAPR 95 Particulate Filter Efficiency Level Determination**

(d) This requirement must be clarified as follows:

*(d) Particulate filters shall be tested at the system's maximum average constant flow rate specified by the manufacturer, divided by the number of filters on the unit.*

#### **84.316 Chemical Cartridge/Canister Gas/Vapor Removing Effectiveness**

(b) For clarity, this paragraph should be revised as follows:

*(b) Cartridges and canisters shall be tested at the system's maximum average constant flow rate specified by the manufacturer, divided by the number of cartridges or canisters on the unit.*



84.316 (d)(2): As noted under 84.313 (d) comment, the APFs that will be used must be identified for all flow rate classes of PAPR. The basis for setting the APFs must be explained and agreed upon by NIOSH and manufacturers.

84.316 (d)(3): The IDLH values NIOSH will use to make this determination must be specified by a reference. We suggest the revised sentence read as follows:

*(3) For gases under this paragraph (d) the canister test concentration calculation shall generally be set at the IDLH concentration listed in NIOSH Publication No. 2005-149 multiplied by 100. Where this is not achievable or can not be done safely in the laboratory, time and concentrations may be proportionally adjusted.*

84.316 (e): "Floating" test requirements based on exposure limits are not fair to manufacturers or end users. It would be more appropriate to set a percentage of the challenge concentration rather than an REL or PEL, both of which can change. This approach would also conform to the way that laboratory test data are typically reported. It would also minimize the misconception of some end users that the bench tests are related to exposure limits. We believe the requirement should be deleted or revised to read:

*(e) Allowable breakthrough concentrations for all testing for which approval is sought shall be set at 1% of the challenge concentration.*

#### **84.317: Laboratory Respiratory Protection Level (LRPL)**

Subject selection must be specified.

84.317 (a): To eliminate variability in probe location during LRPL testing, 3M suggests deleting the statement about sampling location in the breathing zone of the respirator. It should be replaced with a description of the sampling probe location as specified in STP CBRN 0552.

84.317 (e): Exercise duration must be specified. 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 <sup>(5,6)</sup>

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. 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-fitting hoods, it is not required.

#### **84.318 Field of View**

The test method must be specified.

#### **84.319 Low Temperature Fogging**

The test method must be specified.

#### **84.323 Low Pressure Indicator**

As described in detail in our comment to 84.304 (b), a suitable alarm can be actuated by either low pressure or low flow. For that reason the title of this section should be changed to:

#### ***84.323 Low Flow or Low Pressure Indicator***

84.323 (a), (b) and (c) Again, for the reasons described in our comment to 84.304 (b), we believe these requirements should be revised to read:

*a) Low flow or low pressure indicators, if present, shall readily indicate when the air flow or pressure inside the respiratory inlet covering falls below the manufacturer's specified minimum for a period of thirty seconds during blower operation.*

*(b) Low flow or low pressure indicators, if present, shall be readily visible or detectable to the user without manipulation of the respirator.*

*(c) Low flow or low pressure indicators, if present, shall be configured so that they may not be de-energized when the blower is energized.*

#### **84.324 Full and low battery power indicator**

As noted in our comment to 84.304 (a), this paragraph should be revised to indicate that a full charge indicator need not be located on the battery itself. For example, the full charge indicator can be located on the charger. We suggest the requirement be revised to read:

*(a) Each PAPR system equipped with a battery shall contain an indicator to show when the battery is fully charged.*

### **84.325 Battery Life**

84.325 (b): It is not appropriate to test the PAPR with no filtering elements since the unit will never be used in this configuration. We believe the sentence should be revised read:

*(b) The PAPR system shall be operated fully assembled on a headform using the combination of air purifying elements and inlet covering specified by the manufacturer to maximize the severity of the challenge to the battery.*

84.325 (d): This paragraph implies that “stated battery life” is the battery life at the lowest recommended operating temperature. Manufacturers should be required to advise the user on the battery life at lowest operating temperature, but also to advise the user at room temperature and at highest operating temperature in the user instructions. That is, “battery life” might be stated at multiple temperatures. However, if only one battery life value is required, it must be at room temperature (or a stated temperature, e.g., 20°C). Users would be misled if only the low temperature service time were stated. We suggest the sentence be revised to read:

*(d) The PAPR system shall be tested at the lowest recommended operating temperature specified by the manufacturer. It shall operate for the battery life stated for that temperature plus 15 minutes.*

84.325 (e): It is not necessary for a PAPR to maintain positive pressure 15 minutes beyond the stated battery life. Negative pressure excursions during the last 15 minutes would pose essentially no risk to the user if the respirator has been properly selected, maintained and used. We suggest the requirement be revised as follows:

*(e) At no time shall the pressure, when measured in the nose/mouth area drop below ambient before the last 15 minutes of testing when connected to a breathing machine.*

### **84.326 End of Service Life (ESLI) Criteria**

84.326 (a)(2): Change “adsorption” to “desorption.” We suggest the requirement be revised as follows:

*(2) On desorption of any impregnating agents used in the indicator.*

84.326(b)(1) It may be necessary to perform some repositioning of the PAPR to allow the user to clearly see the ESLI. For example, a belt-mounted PAPR may need to be repositioned on the user’s waist. So long as these minor movements would not compromise the PAPR function or user protection, they should be permitted. We suggest the requirement be revised to read:

*(b)(1) A passive ESLI shall be situated on the respirator so that it is readily visible by the wearer without manipulation of either the respirator or the indicator that would affect the protection of the user or interfere with PAPR function.*

84.326(b)(2) It may not be possible to anticipate all possible color blindness combinations potential users may have. Manufacturers should be required to screen for the common color blindness conditions (red-green and yellow-blue) if their ESLI might present a problem for individuals with these conditions. Potential problems can be listed in the user instructions. We suggest the requirement be revised to read:

*(b)(2) If the passive ESLI relies on a color change that may be hard to detect by individuals with the most common forms of color blindness (red-green and yellow-blue), the manufacturer shall include an appropriate warning in the user instructions.*

84.326 (b)(3): The requirement for the initial color of ESLI is not necessary and should be deleted. It does nothing to help the user determine when service life has been reached. NIOSH has previously waived this requirement for mercury vapor cartridges (12-29-05 memo from Doris Walter of NPPTL to Martha Nelson of 3M). We suggest the sentence be revised to read:

*(3) If the passive indicator utilizes color change, the reference color for the final (end point) color of the indicator shall be placed adjacent to the indicator.*

84.326 (c)(4): This requirement needs clarification. ESLI are not designed for cleaning, a fact which can be stated in the user instructions. We suggest the requirement be revised as follows:

*(4) Any ESLI that is permanently installed shall withstand a drop from a six-foot height onto concrete.*

#### **84.327 Service time limitations**

84.327 (a) Battery service life can vary considerably with environmental temperature. In order to provide useful information to users, service time recommendations for batteries should be listed over the range of specified operating temperatures. We suggest the requirement be revised as follows:

*(a) Service time recommendations for batteries and any other applicable components as a function of temperature shall be listed in the user instructions. At a minimum, battery life shall be specified at 20°C and at the manufacturer's lowest and highest recommended operating temperatures.*

84.327 (c) This requirement appears to repeat what is already stated in 84.325. We suggest it be deleted.

#### **84.332 Additional Label Requirements Specific to PAPRs**