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From: cecolton@mmm.com
Sent: Thursday, January 15, 2009 6:02 PM
To: NIOSH Docket Office (CDC)
Cc: Szalajda, Jonathan V. (CDC/NIOSH/NPPTL)
Subject: PAPR – Docket #008 A – Powered Air-Purifying Respirators

Attachments: Written comments for Industrial PAPR Jan15 09.pdf

Written comments for Industria...

Please find attached, comments for the docket on powered air purifying respirators.

(See attached file: Written comments for Industrial PAPR Jan15 09.pdf)

Thanks,

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January 15, 2009

NIOSH Docket Officer, REFERENCE: NIOSH DOCKET-008
Robert A. Taft Laboratories MS-C34
PAPR – Docket #008 A – Powered Air-Purifying Respirators
4676 Columbia Parkway
Cincinnati, OH 45226
NIOCINDOCKET@CDC.GOV.

RE: December 2, 2008 Public Meeting on Concepts for Powered Air-Purifying Respirator (PAPR) Standard, Docket-008A

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 these 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 Public Meeting on the Concept for Powered Air-Purifying Respirators (PAPR), held on December 2, 2008.

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.

We appreciate the opportunity to add our comments and knowledge to the docket and look forward to the development of a fair, protective and useful concept.

Sincerely,

Robert A. Weber
Laboratory Manager, Regulatory Affairs
3M Occupational Health & Environmental Safety Division

Public Meeting on PAPR Concept held December 2, 2008

While we appreciate the opportunity to comment on NIOSH's considerations for change to the December 21, 2007 Industrial PAPR Concept, it is difficult to make comments based only on bullet points contained in a slide presentation because they lack the detail of a published concept. Unfortunately, NIOSH has indicated its next step is to publish the "slide show" concept as a proposed rule. We disagree with that approach and think it is imperative that NIOSH publish a revised draft concept in order for interested parties to provide meaningful comment. Without a revised draft, commenters will have difficulty trying to understand NIOSH's intent or its reasoning due to the cryptic nature of presentation slides. This may result in the development of an unsatisfactory proposed rule and result in greater comments or challenges to the final rule, significantly delaying the rulemaking process.

General comments: Because many of the Standard Testing Procedures (STP) mentioned in the Concept have not been linked to the test requirements and because NIOSH is planning the next step to be a proposed rule, our comments may appear to be more critical than perhaps required if the STPs had been provided. It is indeed impossible to comment on the STPs when they are not listed. NIOSH also solicited comment on the following items:

1. Opinions on the concept of categorizing PAPRs as breath assisted or positive pressure devices.
2. Opinions on the expansion of the number of work rates where PAPRs can be submitted for approval.
3. Opinions on the linkage of breath assisted PAPRs and positive pressure PAPRs with LRPL testing.
4. Opinions on the consideration of an alternate approach to gas and vapor testing.
5. Opinions on the establishment of positive pressure PAPR ESLI for organic vapors and acid gases.

We are commenting on the first four requests.

1. Opinions on the concept of categorizing PAPRs as breath assisted or positive pressure devices.

At the December 2008 public meeting NIOSH introduced the idea of having PAPRs divided into two classes. NIOSH suggested dividing all of the flow rates into two categories: Breath Assisted and Positive Pressure Monitored. This is one of those areas, alluded to above, where it is not clear what NIOSH means. The use of the word "Monitored" could mean these devices will be required to have pressure monitors for "positive pressure". This doesn't make sense because the earlier concept indicated every PAPR would have a pressure monitor. Perhaps NIOSH changed the concept and

has not mentioned it. We can not tell because we have not seen a revised draft. On the other hand, this could mean that during testing, these products would have to maintain a positive pressure on the breathing machine at the identified rates. A revised concept would make this clear and 3M encourages NIOSH to produce one.

If this later case is what NIOSH means, then, in our view, NIOSH is incorrectly writing this as a design standard instead of a performance standard. Devices that are tested at the "breathing assist" rates may also be able to be designed to pass the positive pressure requirement.

If devices are going to be classified as positive pressure, "positive pressure" needs to be defined. Presently NIOSH does not certify any PAPR or supplied air respirator (SAR) as positive pressure. It does certify some respirators as pressure demand. This designation is based on a specified test that the respirator must pass. "Positive pressure", however, has never been defined by NIOSH. The definition is needed because positive pressure can mean different things to different people. To some it means positive pressure at all times, even though the literature indicates high performance PAPRs or SARs are not in positive pressure under all situations. Maintaining a positive pressure is very dependent upon the measurement method and equipment. Intuitively it is obvious that all PAPRs and SARs are positive pressure. If they were not positive pressure, the Assigned Protection Factor (APF) for PAPRs and SARs with a loose fitting respiratory inlet covering would have to be 1, meaning no protection. This is not the case as demonstrated by workplace protection factor studies showing existing devices provide very high protection levels (APFs of 1000).

2. Opinions on the expansion of the number of work rates where PAPRs can be submitted for approval.

NIOSH needs to decide if this standard is to be a performance specification or a design specification. 3M recommends NIOSH develop a performance specification. Specifying a minimum flow rate (i.e., 115, 170 or 235 Lpm) for the PAPR for various work rates is a design specification. Requiring the PAPR to meet a positive pressure, or other performance requirement, at an identified work rate regardless of the PAPRs flow rate is performance oriented. Our primary concern here is that this proposal indicates NIOSH believes only flow rate is important for maintaining positive pressure when in reality it is a combination of both flow rate and the respiratory inlet covering.

This NIOSH proposal expands the list of work rates for which PAPR approval may be sought beyond those described in the December 21, 2007 draft of the proposed PAPR Concept Paper. The work rates identified in the December 21, 2007 draft corresponding to the minute volume breathing rates of 25, 40 and 57 Lpm would be retained. NIOSH indicated that these work rates should cover the majority of sustainable user activities. We agree with this statement. NIOSH stated that the 11, 78 and 99 Lpm rates currently being considered are based on the Draft International Standard ISO/TS 16976-1:2005, Classes 1, 7 and 8 for the ISO standard man (body surface of 1.8m2).

NIOSH has erred in stating that these flow rates are from an ISO standard and hence justification for their use. These flow rates are from an ISO technical specification (see "TS" in the above reference). As a technical specification, these flow rates are identified for consideration for those writing the ISO standards. To date, they have not been included in a standard. NIOSH needs to reveal its justification why these flow rates should be added.

NIOSH intends to retain the complete definitions of the 25, 40, and 57 Lpm work rates as presented in Table 1 of the December 21, 2007 draft. This includes the defined tidal volumes and respiration rates as well as a sinusoidal ventilation profile. The proposed sedentary rate of 11 Lpm would have a sinusoidal profile as well. An appropriate ventilation profile has not yet been defined to represent the proposed high work rates of 78 and 99 Lpm. This proposal would result in six classes of PAPRs before the respiratory inlet covering distinctions are added. This is too many classes, and as demonstrated by the multiple classes of non-powered particulate filters, will continue to confuse respirator users.

3M believes there is no reason for the sedentary rate of 11 Lpm when NIOSH is requiring a minimum flow rate of 115 Lpm for the device. Without change, this could allow PAPRs in the market with poorly designed respiratory inlet coverings. In addition, it is 3M's experience that a work rate as low as 11 Lpm is not common in workplaces where respirators are used.

The alternative high flow rates of 78 and 99 Lpm are also not justified by NIOSH. Presently, ISO is restricting these work rates to SCBAs only as these two work rates can only be maintained for extremely short periods of time, e.g., less than 5 minutes. According to ISO, these flow rates are examples of metabolic rates associated with temporary activities of an escape and rescue nature and cover work associated with firefighting and rescue work of a one time nature. This can be verified by talking with the Administrator or Technical Chairman for the ISO/TC94/SC15 US Technical Advisory group.

Finally, this proposal could make six categories of PAPRs for which OSHA has already identified the APFs. PAPRs with various identified work rates and the same APFs only confuse the selection process, complicating their use.

3. Opinions on the linkage of breath assisted PAPRs and positive pressure PAPRs with LRPL testing.

At the December 2008 Public Meeting, NIOSH proposed that a "breath assisted" device should meet an LRPL of 250 and a "positive pressure" PAPR should meet an LRPL of 10,000. This proposed requirement indicates that the flow rate, not the respiratory inlet covering, is what determines how well the respirator protects an individual. There are no data indicating any linkage between LRPL and air flow rate or positive pressure with protection. It appears NIOSH is using LRPL testing as an indicator of protection. This is in error because respirator workplace data clearly demonstrate that the level of

protection provided by the respirator is mainly determined by the type of respiratory inlet covering rather than the air flow as implied by NIOSH.

NIOSH requires the same minimum air flow for all tight fitting PAPRs. These PAPRs have one of two types of respiratory inlet coverings: a half facepiece or a full facepiece. Even though they are required to provide the same air flow, the half facepiece PAPR has an APF of 50 while the full facepiece PAPR has an APF of 1000. After extensive review of available respirator performance data from the past 20 years on NIOSH certified PAPRs, OSHA recognized this in publishing its APF standard. This is also true for PAPRs with loose fitting respiratory inlet coverings where NIOSH requires the same minimum airflow for different respiratory inlet coverings: loose fitting facepieces have an APF of 25 and a loose fitting helmet or hood typically has an APF of 1000. A simulated workplace protection factor study performed at Lawrence Livermore Laboratories indicated that one hood design with the same minimum airflow as all of the other SARs with hoods did not achieve the same level of performance. All of this evidence shows the design of the respiratory inlet covering is the primary factor determining how the PAPR will perform in the LRPL test.

We understand that NIOSH has traditionally relied on air flow as the primary factor determining protection since 1986[1]. This position, however, has been proven wrong. Respirator experts on the ANSI standard (Z88.2-1992)[2], OSHA regulation (29 CFR 1910.134)[3] and the Canadian Standard (CSA Z94.4-02)[4] have considered the type of respiratory inlet covering as the primary factor influencing protection.

We believe that NIOSH chose the LRPL of 250 based on the NIOSH Respirator Decision Logic[1] that assigns an APF of 25 to all loose fitting respiratory inlet coverings based on the minimum airflow and the 10,000 level is derived from the APF of 1000 for tight fitting full facepieces. This means NIOSH is using a factor of 10 to account for differences between workplace protection and the laboratory testing. People may wrongly interpret this as NIOSH setting the APFs for these devices which conflicts with OSHA's values. OSHA set the APFs based on respiratory inlet covering design.

There is no reason to certify PAPRs to a flow rate rating because the APFs for PAPRs with the same style of respiratory inlet covering and hence their use as regulated by OSHA are all the same.

4. Opinions on the consideration of an alternate approach to gas and vapor testing.

We support the removal of the pre-humidification requirement, and the change to cyclohexane from carbon tetrachloride as the organic vapor test agent. We encourage NIOSH to extend these two changes to the negative pressure gas mask and chemical cartridge tests as soon as possible.

The gas test concentrations and durations shown on slides at the December 2008 public meeting are different from what are used now and from what was published in the

December 2007 draft. It would be useful to have the complete list of gases covered and their requirements to comment more fully and we encourage NIOSH to make this information available.

This slide also proposed an allowance for testing unlisted compounds. For Unlisted Contaminants NIOSH suggested testing them at four times the immediately dangerous to life or health (IDLH) concentration and using the NIOSH REL for the breakthrough concentration.

Unfortunately this may not be possible for some chemicals because they do not have an IDLH level or REL. The December 2007 draft notes that other limits as defined by NIOSH can be used. NIOSH needs to identify what the preferred sources would be.

The "4 x IDLH" test concentration requirement also makes for an interesting issue in that the greater the hazard of the product (and lower IDLH), the lower the filter capacity required. For example, a company could get an approval for Sarin with a really tiny filter as the IDLH is very low (30 ppb). NIOSH should obviously consider placing limits for approval. Please note that the December 2007 document has a canister requirement for unlisted contaminants of 5000 ppm, regardless of IDLH.

Because an unlisted contaminant may be a low-boiling organic vapor or gas, where there is the possibility of desorption, NIOSH should also consider introducing a desorption test or requiring limitations of use to ensure that low-boiling point compounds which might readily migrate through the filter do not introduce a hazard. EN14387 "SX" test requirements provide a model for a desorption test, which is to adsorb under the standard test conditions for half the required time, let stand three days and then desorb with clean humidified air at standard test conditions and monitor the effluent concentration for two hours. It must not exceed a minimum breakthrough requirement.

For historical accuracy, we wish to point out that Wheeler apparently never published the "Wheeler" equation. It appears to have been first published in a paper "The Kinetics of Adsorption of Carbon Tetrachloride and Chloroform from Air Mixtures by Activated Carbon", L.A. Jonas, and W.J. Svirbely, *Journal of Catalysis* 1972 24 pp. 446-459 (See slide used at public meeting, December 2008) It is more properly called the "Wheeler-Jonas" equation and is otherwise known as the "Reaction-Kinetic" equation.

The *J. Phys. Chem* reference given here does not include this equation but relates to calculation of sorption affinities based on sorbate polarizability. In fact, what is shown here is a simplified version of the equation in which all factors that are the same for a specific sorbent bed/sorbate combination have been grouped into constants A and B. A more precise form of the equation uses C_0-C_x in place of C_0 in the numerator above.

We request that the usage of the breakthrough time/inverse flow estimates derived from the Wheeler-Jonas equation be clarified by NIOSH because we do not know if it was just for information in the presentation or for submissions to provide data to feed into this model.

We encourage NIOSH to consider introducing an approval for general low-boiling point organic compounds (boiling point <65°C). Models for this exist in other standards domains, and it addresses a specific need in the market. This might include a desorption test as described above.

The following comments were comments submitted on the December 21, 2007 Concept but are missing from our comments in the docket. For reasons not known, these comments were not included and are therefore being resubmitted with this comment. Blue ink indicates our recommended change. Please see the earlier comments for further explanation of the formatting of our comments.

4.1.6.6 Neck seal designs shall provide a seal around the neck without causing discomfort to the user and permit easy donning and doffing.

Comment: This requirement is not measurable and unenforceable and should therefore, be deleted. Discomfort and easy donning/doffing are subjective determinations and re morel likely to be addressed in the market place. If they do not meet the customers' definitions of comfort and easy donning/doffing, they will not be purchased. Interference of equipment depends on the specific eyewear and the user's facial characteristics and is best addressed during selection and fitting of the device as required by OSHA.

~~4.1.6.6 Neck seal designs shall provide a seal around the neck without causing discomfort to the user and permit easy donning and doffing.~~

4.1.7.2 Lenses of respiratory inlet coverings shall meet optical requirements of ANSI Z87.1-2003.

Comment: This statement aids in preventing the respirator from becoming a safety hazard for the wearer and is acceptable for NIOSH to specify.

4.1.7.4 Lenses shall meet the requirements of the impact and penetration sections of ANSI Z87.1-2003 or the lenses shall be prominently and permanently labeled to indicate that they are not impact resistant.

Comment: This standard is for respiratory protection devices. NIOSH should not set requirements for eye and face protection in a respiratory protection device standard. They do not add to the respiratory protection provided. This requirement means the manufacturer is marking all lenses and will most likely have Z87.1 in the marking. This will be confusing as users may not take time to read the marking closely and may assume it indicates Z87.1 compliance. Markings would be either:

1. "Meets Z87.1 – 2003" or
2. "Does not meet Z87.1 – 2003"

It is current practice for users and OSHA compliance officers to just look for Z87.1. In addition, marking lenses that are not impact resistant would conflict with Z87.1, which

requires marking to identify compliant eye and face protection. NIOSH would be making manufactures violate the ANSI standard just to get NIOSH approval. Cautionary language in the user instructions will tell users if the lens does not offer eye or face protection.

If NIOSH insists on retaining this requirement, the revised sentence should read:

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

4.1.9 Optional Low pressure indicator

Comment: This heading should be retitled **4.1.9 Low Flow or Low Pressure Indicator** since either should be permissible. We made this comment on the previous version of this Concept and if the title does not change after this time, NIOSH needs to explain their reasoning for not doing so.

4.1.9.1 A low pressure or low flow indicator, ~~shall~~ if ~~be~~ present~~, It~~ shall actively and readily indicate when pressure inside the respiratory inlet covering falls below ambient pressure ~~during more than twelve consecutive breaths during blower operation~~, or when airflow is lower than the MMDF (Manufacturer's Minimum Design Flow) for 30 seconds or more, as tested in the flow determination test. See 4.2.4.

4.1.10 ~~Optional Power~~ Indicators

4.1.10.2 Each PAPR shall have an indicator to monitor the condition and source (battery or external, if applicable) of the power.

Comment: This has been previously addressed and can be deleted here. There is no need for this monitor. A low flow alarm would cover a loss of power condition.

4.1.10.3 Each PAPR equipped with a local battery may have an active low power warning. If present, this warning indicator shall signal when the battery can no longer provide the unit with 15 minutes of additional adequate power to properly power the unit at the highest power consumption ~~lowest recommended operating temperature and at the highest flow attainable~~. A PAPR with emergency battery power only does not require a low battery warning indicator.

Comment: There is no need for a low power alarm. A low flow alarm would cover a loss of power condition.

4.1.10.4 ~~All power~~ Failure mode indicators shall be readily visible (via light) or detectable (via sound or vibration) to the user without manipulation of the respirator and without affecting protection and performance.

Comment: The wording needs to be changed as power indicators are not necessary where failure mode indicators are present.

4.1.10.5 As long as the blower is in the operational mode, the ~~low power~~ failure mode indicator must not be configured to be switched off.

4.1.12 ESLI criteria

NIOSH appears to have ignored our comment from last time on this section, but our position has not changed as NIOSH has not indicated any reasoning to support their position.

The criteria seem to indicate the ESLIs are to be designed for a specific contaminant. It is disappointing that it appears NIOSH has not considered having "universal" or "near universal" ESLI.

4.1.12.1.4 Any potentially hazardous exposures resulting from ~~the~~ chemical reaction of the ESLI ~~and~~ with the gases and/or vapors the air purifying element is designed to remove.

4.1.12.1.6 Flow-temperature results at minimum and maximum recommended flows and temperatures of the PAPR system, at 25% and 80% relative humidity (RH), and at two contaminant levels.

The two contaminant levels **must** be specified, and allowance made for ESLI that might be used for more than one contaminant. We recommend the following revision:

> *4.1.12.1.6: The data will include flow-temperature results at minimum and maximum recommended flows and temperatures of the PAPR system, at 25% and 80% RH, and at two contaminant levels including the occupational exposure limit.*

4.1.12.2.2 If the passive ESLI relies on color change, the change shall be detectable to people with physical impairments such as color blindness (Example- light color to dark color).

Comment: Color Blindness, or Color Vision Deficiency, is an eye condition where a person is not able to distinguish certain colors or shades of colors to some degree. **Color Blindness** does not mean that a person can only see black and white. A person with color blindness is able to see different colors; however, they are not able to see some colors due to deficiencies in the eyes. So we find it difficult to determine what NIOSH is talking about when they give an example of "light color to dark color." Based on the above information, it may not be possible to anticipate all possible color blindness combinations potential users may have. Manufacturers should be required to determine if common color blindness conditions (red-green and yellow-blue) might be a contraindication for use of their particular ESLI. The FEMA is where this may be

resolved. Potential problems can be listed in the user instructions. It is the end-user employer's responsibility to determine via the medical evaluation program which employees should not wear respirators with specific ESLI because of color blindness. In fact, this may not be as big of a problem where an ESLI includes the end point color because they see shades and the important issue is if the two match. It seems NIOSH is doing their best to keep ESLI's off respirators. To encourage their development, we suggest the requirement be revised to read:

> *4.1.12.2.2 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.*

4.1.12.2.3 If the passive indicator utilizes color change, reference colors for the initial color of the indicator and the final (end point) color of the indicator shall be placed adjacent to the indicator.

Comment: The requirement for the initial reference 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, *submitted with previous comments*). Therefore this requirement is not consistent with NIOSH policy. One reason for not requiring an initial color is that the indicators are typically made in batch operations and result from mixing chemicals together that, among other things, gives the initial color of the indicator. The color can vary slightly from batch to batch, while the reaction of the contaminant with the indicator always gives the same color. If we were required to have the initial color on the cartridge, we would probably stop making the ESLI because neither NIOSH nor OSHA require it; a change schedule can be established instead. NIOSH, however, has stated that a survey indicated 20% of the change schedules are determined by the employees (see IOM review of NIOSH PPT meeting presentations). It seems NIOSH would want to encourage the use of ESLI rather than discourage their development. As indicated above, the initial color does nothing to help the user determine when service life has been reached. We suggest the sentence be revised to read:

> *4.1.12.2.3 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.*

4.1.12.3.6 PAPR with an ESLI shall be labeled appropriately to adequately inform the user of use conditions and of any situations that could cause the ESLI to fail to respond properly to the contaminant(s) for which it shall be used or to improperly respond to the presence of chemicals for which its use is not intended.

Comment: It is not clear what is meant by "respond to properly." If properly means meeting the requirements above, it should refer to those paragraphs or other requirements that define properly.

References

1. National Institute for Occupational Safety and Health: *NIOSH Respirator Decision Logic* (DHHS/NIOSH Pub. No. 87-108). Washington, D.C.: US Department of Health and Human Services/National Institute for Occupational Safety and Health, 1987.

2. American National Standards Institute: *American National Standard Practices for Respiratory Protection* (ANSI Z88.2-1992). New York: American National Standards Institute, Inc. 1992.

3. "Respiratory Protection," *Code of Federal Regulations* Title 29, Part 1910.134. 2008. pp.419-445.

4. Canadian Standards Association: *Selection, Use, and Care of Respirators* (Z94.4-02). Mississauga, Ontario, Canada: Canadian Standards Association, 2002.