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From: Staubs, Amy [astaubs@tycoint.com]
Sent: Saturday, January 31, 2009 8:15 PM
To: NIOSH Docket Office (CDC)
Subject: 008-A - Powered Air-Purifying (PAPR) Discussion Topics
Attachments: 20090131 Ind PAPR Scott Comments.pdf

Please find enclosed Tyco/Scott Health & Safety's comments for the 008-A - Powered Air-Purifying (PAPR) Discussion Topics. Should there be any questions concerning this information, please do not hesitate to contact me directly.
Best regards,
Amy Staubs

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Subject: DOCKET NUMBER NIOSH - 008
Proposed Industrial Powered Air-Purifying Respirator (PAPR) Standard – Concept Paper dated 21 December 2007.

Dear Sir / Madam:

Scott Health & Safety is a manufacturer of respirators for many global markets and applications and offers the following comments in response to the proposed Industrial Powered Air Purifying Respirator (PAPR) Standard posted 21 December 2007. The following Scott comments are being submitted for consideration and will comment section by section through the draft protocol:

Section 4.1.2.2 – Each PAPR shall have an active indicator which alerts the user to low pressure/or low flow in the breathing zone. It shall be readily detectable to the wearer during use without manipulation of the respirator and no affect protection and performance.

Note: Please provide a sufficient definition of NIOSH's intention for an "active indicator." There are several means of determining low pressure/low flow that can be achieved on all types of PAPRs. Is this an either/or requirement, as it does not mandate how the manufacturer should monitor these conditions in the breathing zone?

Section 4.1.2.6 – Where two or more cartridges, canisters or filters are used in parallel, their resistance to air flow shall be **essentially equal** when measured at 85 lpm.

Note: NIOSH should determine a reasonable metric for "essentially equal" resistance, such as specifying a tolerance such as "within +/- 10% of one another." Also the resistance should be measured at the manufacturer specified flow rate of the PAPR as differences in resistance between the cartridges will change with the magnitude of resistance.

Section 4.1.2.7 – Where two or more cartridges, canisters or filters are used in parallel, the manifold system shall be designed for essentially equal air flow through each cartridge, canister or filter.

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Note: NIOSH should determine a reasonable metric for "essentially equal" air flow through each cartridge, such as specifying a tolerance such as "within +/- 10% of one another." Also it is recommended that NIOSH develop a methodology to quantitatively assess balanced flow across the manifolds presented by manufacturers.

Section 4.1.9 Low pressure indicator

Note: Requirement 4.1.2.2 aforementioned does not imply what type of method is to be used to indicate low pressure. The standard should allow for any technological solution with the affect that an indication is given to the user when there is low pressure inside the respiratory inlet covering. Also, change title to: **Low pressure indicator / low flow indicator**

Section 4.1.9.1 – A low pressure indicator shall 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.

Note: Add: **If** a low pressure indicator **is** present, it shall actively and readily…during blower operation**. If a low flow indicator is present it shall actively and readily indicate when the flow falls below the manufacturers specified requirements.**

Note: This requirement needs to be better defined. It is not clear if the intention of this requirement is that the device warns the user when they take more than twelve consecutive below ambient pressure breaths or the device warns the user that below ambient pressure has been detected multiple times over the period of time it takes a user to take twelve standard breaths. If the test designed to test the requirement is based on a standard breathing pattern it is likely that devices will be designed that meet one of but not both of the above conditions.

It is also not clear how the requirement for twelve breaths was determined. Is this for any twelve breaths or twelve breaths referenced to a specific breathing pattern? This implies that the risk of the user operating in an environment with a hazard ratio up to 10,000, but below IDLH, and taking up to twelve below ambient pressure breaths with a PAPR is acceptable to NIOSH.

Given that the manufacturer will seek an approval for the PAPR at a specified work rate, would not a low flow indicator (referenced to the specified work rate) be more practical and economical to the user? NIOSH should evaluate if a low flow indication provides a better margin of protection to the user as it would warn a user that the PAPR is not operating correctly prior to an over breathing event (twelve below ambient breaths) occurs. Is it the expectation that a user could breathe at a work rate higher than that specified by the manufacturer and approved by NIOSH? If not then a low flow indicator would be a safer and more practical alternative. It is not clear if current economical solutions can reliably meet the low pressure indication requirement if this is the case. If the component fails and there is not a low flow indicator the user will be given a false sense of security. The level of equipment required to achieve this requirement would add a significant amount of cost to the PAPR and reduce acceptance and use of PAPRs.

Section 4.1.9.2 - Low pressure/**Low flow** indicators shall be readily visible (via light) or detectable (via sound or vibration) to the user without manipulation of the respirator and shall not affect respirator protection and performance.

Section 4.1.9.3 - Low pressure/**low flow** indicators shall be configured so that they may not be de-energized when the blower is energized.

Note: As aforementioned, a low flow indicator would be an acceptable alternative to achieve the user's intent to determine if the PAPR is not performing properly.

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Section 4.1.10.1 – Power for PAPR can be supplied by local battery or external power supply. PAPR using an external power supply that can be used for emergency escape must have a battery with a minimum life of 15 minutes. The switch from external power to emergency battery shall restore minimum required operating conditions within 15 seconds.

Note: Are minimum required operating conditions under emergency power to be the same as that approved for the PAPR? For example if a PAPR approved for a high work rate loses main power and switches over to emergency power is it acceptable that the minimum operating condition only meet requirements for a low work rate?

Section 4.1.11.2 – Battery life times shall be such that batteries shall perform properly and meet testing requirements for the entire battery operational service time at the lowest recommended operating temperature specified by the applicant.

Note: How will this requirement be tested? Will the entire PAPR unit be flow tested at these conditions or would battery discharge data at multiple temperatures be a sufficient substitute? This test methodology should be described in detail.

Section 4.1.11.4 – The PAPR system shall be operated fully assembled on a headform using a breathing machine as described in section 4.2. The breathing machine shall be set at the manufacturer's requested work rate an the pressure shall remain above ambient when measured in the nose/mouth area.

Note: Standards for work rates should be referenced here, perhaps the 3 different levels of work rate, low, moderate, and high such as outlined in Table 1, Section 4.2.4.1 so breathing machine tidal volume and respiration rates can be properly adjusted and utilized.

Section 4.1.12 – ESLI criteria

Note: As stated in the NIOSH Public Stakeholder's Meeting in December, 2008, NIOSH is considering the establishment of a performance requirement for an End of Service Life Indicator (ESLI) for PAPRs submitted for approval against Organic Vapors and Acid Gases for PAPRs in the positive pressure category. These ESLI would be evaluated using the criteria that are defined in the December 21, 2007 concept paper. We support criteria for ESLI as defined in the Concept Paper for PAPR, so long as the following comments are addressed:

Section 4.1.12.1 – Approval submittals for PAPR which utilize cartridges or canisters with an ESLI shall provide the following data:
Section 4.1.12.1.1 – Demonstration that the ESLI is at its end point (e.g., color change is complete, warning signal activates, etc.), when the cartridge or canister has at least 10% of its service life remaining.

Note: 10% of remaining service life for a particular contaminant challenge to the ESLI as a demonstration of end point may not be sufficient warning to give the user enough time to egress from the area and do a proper cartridge change-out, particularly with multi-purpose approval canisters or cartridges. We suggest increasing time remaining indication to at least 25%.

Section 4.1.12.1.2 - Desorption of any impregnating agents used in the indicator.

Note: This requirement should be better defined – as a volatilization rate or desorption rate at specific test conditions or concentration of the indicator impregnating agents in a clean air stream.

Section 4.1.12.1.3 – Chemicals or other interferences that could cause ESLI to malfunction, if they are commonly found in workplaces where it is anticipated that a given ESLI shall be used.

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Note: More direction must be provided by NIOSH to manufacturers regarding types of interferents encountered in the workplaces due to their variability, by nature. A multitude of chemical gases, vapors, and fumes exist in workplaces. For example a list is defined within the government identifying common battlefield contaminants. Chemical interferents and their concentration causing the ESLI to false alarm, often reversibly, or the ESLI's poisoning are two very different outcomes and guidance is required here as well. It is recommended that NIOSH consider the creation of a set of environmental conditions and standard contaminants related to chemical families for interference testing.

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

Note: There should be no potentially hazardous exposures resulting from the reaction of the ESLI to challenge gases and/or vapors for use in an air-purifying respirator.

Section 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.

Note: The contaminant levels should be defined here, for example at one-half the contaminants' PEL and twice the PEL.

Section 4.1.12.3.3 – If the ESLI is mask mounted, it shall not significantly interfere with required lines of sight.

Note: It is recommended that passing the general respirator requirement for a VFS > 90 with the ESLI device be accepted as satisfying this requirement.

Section 4.1.12.3.4 - Any ESLI that is not discarded with the cartridge or canister shall withstand cleaning.

Note: Suggest adding the verbiage "or be removable for cleaning."

Section 4.1.12.3.5 - Replaceable ESLI shall be designed to be easily removed and replaced without special tools.

Note: Special tools will prohibit disabling, removing or tampering with ESLI devices installed on filtration elements or masks.

Section 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.

Note: ESLI devices are prone to miniaturization and adequate information required to properly inform the user of use conditions and any situations that could cause the ESLI to respond inappropriately may not be feasible for a physical label. It may be necessary for manufacturers to direct the users to the User Instructions via a label on the device only, so this may be accomplished.

Section 4.1.13.1 – Shelf (storage) life requirements for filters, cartridges, canisters, batteries and other applicable components shall be addressed in the User's Instructions if applicable.

Note: Add ESLI "...canisters, ESLI, batteries and..."

Section 4.1.14 FMEA

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Note: Provision of a system Failure Mode and Effects Analysis (FMEA) for devices or components may require that manufacturers disclose highly confidential and/or proprietary information that must, if provided, be held in the strictest of confidences. Scott agrees that the FMEA declaration be provided and the FMEA kept on file and the tool is typically employed as a part of the design process. This may be alternately handled via an audit of the manufacturer's quality system for reliability processes/procedures and record-keeping for ISO certification.

Section 4.2.4.1 – The manufacturer shall specify the highest work rate from Table 1 for the intended use of the PAPR system. The PAPR must maintain positive pressure above ambient in the face area and/or hood area around the neck during the manufacturer's minimum battery life time while breathing at each of the rates desired while properly mounted on a headform.

Table 1: NIOSH Approved Work Rates

Work Rate	Minute Volume	Tidal Volume and Respirations
Low	25 Lpm	1.30 liters @ 19.2 respirations per minute
Moderate	40 Lpm	1.67 liters @ 24 respirations per minute
High	57 Lpm	1.95 liters @ 29.1 respirations per minute

Note:

NIOSH's consideration at the December 2008 Public Stakeholder's included a redefinition of PAPR performance into categories of devices that are breath assisted and those that maintain positive pressure. PAPRs in the breath assisted category would be tested per the manufacturer's request at work rates of 11 Lpm, 25 Lpm, or 40 Lpm. PAPRs in the positive pressure category would be tested per the manufacturer's request at 40 Lpm, 57 Lpm, 78 Lpm, or 99 Lpm.

There is some concern that the sedentary rate (11 Lpm) may lead to wide variation of result and be below the lower detection limit of devices used in the laboratory to maintain this measurement at a to-be-defined tidal volume and respiration rate. This sedentary rate may be highly unrealistic for any ergonomic task other than sleep.

The higher workrates identified by NIOSH during the Public Meeting (78 Lpm, 99 Lpm) will sustain peak inhalation airflows (PIAFs) of up to 230 lpm and this seems to be a very realistic representation of heavy work cycles performed at higher metabolic rates for workers during short duration, heavy exertion tasks, such as nurses lifting heaving patients in triage or rescue workers removing debris from a search and rescue scene. The duration of may be something that will have to be woven into the methodology of this requirement for dynamic breathing performance as well as gas capacity of the cartridges/canisters/filter elements.

Following the Draft International Standard ISO/TS 16976-1:2005, Classes 1, 7 and 8 for the ISO standard man (body surface of 1.8m2) cited in the Public Meeting is a bit concerning. In ISO 8996, a "Fit" man of 1.8 m^2 and 2.2 m^2 surface area is considered. Our civilian worker population is not all in a fit condition. The work rate derivation may need to be re-scoped to include an accurate representation of fitness levels, gender/ethnic/geographic bias, etc. For example, the ISO (8) rate assumes a tidal volume of 3.0 liters, on a sinusoidal breathing machine, at a work rate of 700 Watts, average airflow of 135 lpm, 45.0 respirations/minute for a duration of 5 minutes. This level of output and duration considered for a fit individual may not be a safe work practice for an unfit worker performing the same task.

Ventilation profiles (sinusoidal, trapezoidal, etc.) and metabolic workrate studies need further investigation to accommodate the civilian worker population. Further clarification is needed here, not arbitrary rates.

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Section 4.2.6.1 - Service time recommendations for batteries and any other applicable components shall be listed in the User's Instructions.

Note: Shall we be more specific here and require a minimum service time?

Table 2: PAPR Bench Test Constant Airflow Requirements			
Respirator Type	**Low Work Rate**	**Moderate Work Rate**	**High Work Rate**
Tight-fitting	Not Applicable	115 Lpm	170 Lpm
Loose-fitting	115 Lpm	170 Lpm	235 Lpm

Note: See comments to **Section 4.2.4.1** addressing newly proposed workrates at the NIOSH Public Meeting in December, 2008.

Section 4.2.7 Chemical cartridge/canister gas/vapor removal effectiveness

Note: NIOSH is considering an alternate approach for gas and vapor testing as of the NIOSH Public Stakeholder's Meeting in December, 2008, which uses the Wheeler relationship to address assessment of capacity and efficiency at multiple flow rates. Three canisters or cartridges would be tested as received (no preconditioning) at two challenge levels, 25% and 80% relative humidity. Each of the three canisters could be performed at a different flow and conducted until the maximum allowed test penetration. Regression analysis of the resulting service life versus reciprocal test flow rate gives a linear relationship applicable to all flow rates pertinent to the approvals sought.

Some theory and experimentation in peer reviewed journals recently on the impact of increased volumetric flowrate on chemical vapor filter service life have demonstrated general adsorbent breakthrough trends. Starting with the Reaction Kinetic Equation (i.e. service life = equilibrium time – mass transfer limitation) there are two effects of air flow rate on service life. The first is the effect on equilibrium time which is inverse with air flow, Q such that te ~ 1/Q. This is simply based on the fact that at a constant concentration the capacity of a volume of carbon is fixed and the flowrate only impacts the mass rate of material loaded onto the carbon. The second effect is more subtle and trickier to deal with, mass transfer, k which has the impact of 1 – 1/k. Mass transfer itself is proportional to flowrate but not always linearly. As flow rate increases so does mass transfer which reduces the critical bed depth and increases service life. The end result of both effects is that as flow increases service life decreases (linearly for non water soluble organics and acid gases and non linearly for water soluble organics and weakly adsorbed, reactive gases like SO2 and NH3).

Making the assumption that a linear relationship may exist between flowrate and resulting service life may prove to be a dangerous one without sufficient corrections to the Wheeler equation model employed.

Section 4.2.7.1.1 – PAPR dual cartridge/canisters shall first be tested as received and shall meet the minimum requirements set forth in Table 3 of this subpart for each gas/vapor for which approval is sought using the constant required flow rate set forth in Table 2. Each tested dual cartridge/canister element shall then be stored in an air-tight enclosure. After no less than eight and not more than twenty four hours, the same dual cartridge/canisters shall then be tested at the same humidity and temperature as the initial test and meet the requirements set forth in Table 4 of this subpart for the corresponding gas/vapor using the constant required flow rate set forth in Table 2.

Note: Wording is unclear in this section. Are dual purpose cartridges/canisters tested at 25 +/- 2.5 deg C and 80% +/- 2.5% RH only, as-received? Is the first test a cartridge level test (Table 3), followed by a period for desorption (8-24 hours) and then a test for canister level capacity (Table 4) at the appropriate flow conditions defined in Table 2? Is this a desorption test or a filter that is tested to cartridge conditions and then canister conditions? It should be noted by NIOSH that chemical species removed via chemisorption cannot be readily desorbed and will result in diminished capacity for

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canister level tests. Physically adsorbed species can be desorbed and for those, this test is possible. There is also concern as to whether the canister level testing will demonstrate suitability for work, or just escape. This section needs extensive rewording for clarification and further comment.

Table 4: PAPR Canister Gas/Vapor Bench Tests and Requirements

Protection Type	PAPR Canister (ppm-min)	Canister 42 CFR 84 subpart I table 6 (ppm-min)	Canister 42 CFR 84 subpart I table 5 (ppm-min)
AM	**60,000**	60,000	360,000
CL	**60,000**	60,000	240,000
CD	**60,000**	-	
C6H12	156,000	60,000	240,000
FM	**30,000**	-	
HC	**30,000**	-	
HF	**60,000**	-	
HS	300,000	-	
MA	**60,000**	-	
SD	**90,000**	60,000	240,000
CK	**18,000**	-	
EO	300,000	-	
AC	56,400	-	
NO2	**12,000**	-	
CG	**15,000**	-	
PH	**18,000**	-	

Note: The above table is a comparison of table 4 to existing 42 CFR 84 canister requirements on a ppm – min basis (obtained by multiplying the feed concentration to the minimum allowable service life). It is a gross measure of required canister capacity.

It is observed that the capacity requirements for OV (C6H12), HS, EO, and AC appear to be excessive compared to the existing 42 CFR 84 subpart I standard and CBRN APR CAP 1 requirements. It is also noted that the capacity

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requirements for these compounds are excessive when compared to analogous compounds in the same standard. Please explain the justification for these values as they would have a serious impact on canister design.

Section 4.2.7.4 – Carbon monoxide testing - TBD

Note: Nothing proposed for CO testing. When will this requirement be added or will it be included in the standard?

Section 4.2.7.7.2 – If an IDLH does not exist, another exposure limit shall be used as selected by NIOSH.
AND
Section 4.2.7.7.5 – If the REL does not exist, another exposure limit shall be used as selected by NIOSH.

Note: Exposure limits if IDLH / REL levels do not exist: to be chosen by NIOSH. This section needs definition and a rationale how exposure limits will be determined as they pertain to cartridge test conditions and challenge concentration determination.

Section 4.2.7.7.1 – The test concentration for cartridges shall be the IDLH multiplied by four (4).
AND
Section 4.2.7.8.1 - The test concentration for canisters shall be 5000ppm.

Note: Cartridges: IDLH x 4 (Variable according to the gas tested), Canisters: 5000 ppm (Same for all gases). Is the rationale for keeping cartridge levels variable and canisters constant the intended use, working vs. escape, respectively?

Table 4 gives various canister test concentrations according to the gas, such as ammonia 2500 ppm. 4.2.7.8 indicates that test concentration for canisters shall be 5000 ppm. Is 5000 ppm for all gases? Is this inconsistent?

Section 4.2.8 - PAPR95 and PAPR100 particulate filter efficiency level determination

Note: Creation of a new particulate class designation will create confusion amongst users. What is the equivalent oil resistance for these designations? It appears based on test conditions that the PAPR100 is equivalent to the P100 designation but based on PAPR flow rates. The PAPR95 test condition with an initial penetration challenge requirement only using DOP would allow for electro-statically charged and non oil resistant synthetic media to pass. This in effect equates to a N95/R95 designation as loading testing equivalent to 4.2.8.6.2 for PAPR100 is not done. It is not clear that users would understand the difference and make improper media selections.

Section 4.2.10 – Laboratory Respirator Protection Level (LRPL)

Note: NIOSH is also considering linking the work rate performance of the breath assisted and positive pressure categories to performance criteria in the laboratory respiratory protection level (LRPL) testing. Devices in the breath assisted category would need to meet an LRPL value of 250. Devices in the positive pressure category would need to meet an LRPL value of 10,000.

NIOSH's proposed methodology linking work rate performance and performance criteria in the LRPL testing requires further investigation for breath assisted and positive pressure categories and cannot be accepted without validation of assumptions.

Tables 7 Vapor-Liquid Sequential Challenge with HD

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Table 7: Vapor-Liquid Sequential Challenge with HD

Agent	Challenge Concentration	Duration of Challenge (min)	Breathing Machine Airflow Rate (L/min)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough-Ct ($mg\text{-}min/m^3$)	Number of Systems Tested	Min. Test Time (hours)
HD-	50 mg/m^3*	30	40	0.30‡	3.0§	3	8††

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AND

Table 8 Vapor Challenge with GB

Table 8: Vapor challenge with GB

Challenge Agent	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Maximum Peak Excursion mg/m^3	Maximum Breakthrough-Ct ($mg\text{-}min/m^3$)	Number of Systems Tested	Min. Test Time (hours)
GB	210*	30	0.044‡	1.05§	3	8†

Note: Full Level CBRN and Table 11 Low Level CBRN: The Vapor challenge with GB or HD is the same. Is this correct?

Table 11: Vapor Challenge with Chemical Warfare Agent

Challenge Concentration	Vapor Concentration (mg/m^3)	Vapor Challenge Time (minutes)	Maximum Peak Excursion (mg/m^3)	Maximum Breakthrough -Ct ($mg\text{-}min/m^3$)	Number of Systems Tested	Min. Test Time (hours)
GB	210*	30	0.044‡	1.05§	3	8†
HD	50	30	0.30‡	3.0§	3	8††

Section 5.1.5.2 – Canister Capacity. The applicant shall specify the canister capacity as indicated in Table 10. Canister capacity tests shall be performed at room temperature, 25º C +/- 2.5ºC; 25% +/-2.5% relative humidity and 80% +/- 2.5% relative humidity. Three canisters shall be tested at each humidity specified.

Note: Please confirm that these tests will be done with as-received (AR) filters.

Section 5.2.4 - Cartridge Capacity. The applicant shall specify the **canister** capacity as indicated in Table 9. Cartridge capacity tests shall be performed at room temperature, 25º C +/- 2.5ºC; 25% +/-2.5% relative humidity and 80% +/- 2.5% relative humidity. Three **canisters** shall be tested at each humidity specified.

Note – there are typographical errors. First sentence; change "canister" to "cartridge", last sentence; change "canisters" to "cartridges." Also, change "table 9" to "table 10".

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