Miller, Diane M. (CDC/NIOSH/EID)

From: Sell, Robert [Robert.Sell@draeger.com]
Sent: Friday, March 28, 2008 1:18 PM
To: NIOSH Docket Office (CDC)
Subject: PAPR - Docket #008
Attachments: Industrial PAPR Comments - NIOSH Docket No 008 - March 2008.doc

Hello:

Enclosed please find Draeger Safety, Inc. comments for the PAPR – Docket #008.

If there should be any questions concerning this information please do not hesitate to contact me.

Regards

Bob Sell

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March 27, 2008

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Reference: DOCKET NUMBER NIOSH - 008
Concept Paper: Proposed Industrial Powered, Air- Purifying Respirator (PAPR) Standard- December 27th, 2007

Dear Sir / Madam:

Draeger Safety manufactures respirators for various markets and applications therefore we offer the following comments in response to the NIOSH Concept Paper: Proposed Industrial Powered, Air- Purifying Respirator (PAPR) Standard posted December 21, 2007.

The following Draeger Safety comments are being submitted for consideration and we will comment step-by-step 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 not affect protection and performance.

Note: There are more than one technical means to support the wearers demand, besides low pressure monitoring. It is our intention that low flow monitoring is an alternative that works safely on all types of respiratory inlet coverings.

Section 4.1.2.6:

Where two or more cartridges, canisters or filters are used in parallel, their resistance to air flow shall be within ±5% of each other ~~essentially equal~~ when measured at 85 Lpm.

Note: A value with a tolerance should be identified.

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Section 4.1.7.3:

Lenses, including visors and shields, shall not fog as a result of low temperature operation as detailed in the Standard Test Procedure XXXX.

Question: Is the reference to this STP from the APR CBRN protocol or a new STP? We think the STP should be identified.

Section 4.1.9:

Change title to: Low pressure indicator/ low flow indicator

Section 4.1.9.1:

If A low pressure indicator ~~shall~~ is ~~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. If a low flow indicator is present it shall actively and readily indicate when the flow falls below the manufacturers specified requirements.

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: For Sections 4.1.9 to 4.1.9.3 a low flow indicator can be an acceptable alternative method to determine if the PAPR is not performing properly.

Section 4.1.11.2:

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

Note: The testing requirements need to be defined in detail.

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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 need to be defined. Our proposal is one level as used for cartridge/canister certification and a second one defined by the manufacturer.

Section 4.1.12.3.5:

Replaceable ESLI shall be designed to be easily removed and replaced ~~without special tools.~~

Note: Special tools should be considered since they can help prevent any tampering with ESLI.

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: We presume that with the ESLI being "labeled appropriately" that this could be a lot of information and may small text may be needed therefore, we propose to use a pictogram or wording "SEE USERS INSTRUCTION" which would then permit the text to be readable for the user.

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 pressure above ambient in the face area and/or the 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 head-form. If multiple power selection settings are offered they shall be clearly marked to indicate silent mode, low, moderate or high breathing rates and/or pre-selection of the appropriate respiratory inlet covering (loose or tight fitting systems).

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 dual purpose application gas/vapour and particle filtering element cartridge/canister shall be tested as received and they shall be tested at 25 ± 2.5°C and 80 % ± 2.5 % RH and meet the requirements set forth in Table 4 for canisters for the corresponding gas/vapour using the constant required flow rate set forth in Table 2.

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Note 1: If the submitted devices are for dual purpose application gas/vapour and particle filtering element for cartridge and canister applications, they should only be tested according to Table 4.

Note 2: It's not possible to desorb chemicals from a filter system that is bonded chemically. That is only possible with e.g. OV, because this is only absorbed from the surface physically. Therefore performing the tests as identified may not provide the desired results.

Note 3: Rename dual cartridge to "a dual purpose application gas/vapour and particle filtering element (cartridge/canister)". An explanation on what is intended with this system would be helpful.

Note 4: A dual purpose unit can either be used for escape or for work. It's should not be used for a work shift and then some time later for escape. So storage of a cartridge tested in accordance with Table 3 and after a period of time tested according to Table 4 doesn't make any technical sense. Our intention is to describe testing only against Table 4.

Section 4.2.7.2:

Three PAPR cartridges or canisters shall be tested at 25 ± 2.5°C and 25 ± 5% RH, and three PAPR cartridges or canisters shall be tested at 25 ± 2.5°C and 80 ± ~~5~~ 2.5 % RH for each gas and vapor for which approval is sought.

Note: The purpose of this comment is to harmonize the different values in this concept paper. See 5.1.5.2, where 2.5 % is the accepted tolerance, this should be used in general. For tests at humidity levels of 25% ± 2.5 and 80 % ± 2.5 the required lifetimes should be divided by the factor of two because the charcoals on the market have been developed to this specific issue and this has been the NIOSH specification for years.

Section 4. 2.7.3:

Continuous airflow rates required for testing are given in Table 2 depending on the type of respirator and the work rating of the respirator. For PAPR with two or more canisters, canister tests shall be performed at the required flow divided by the number of cartridges/canisters. The gas performance efficiency shall be tested at the highest flow rate the blower can be set for.

Note: See remarks in chapter to Table 2 and 4.2.8.5.

Table 2:

Note 1: The given test regime in Table 2 refers only to manufacturer's systems operating at rates identified. When the maximum work rate specified by the manufacturer differs from Table 2 (higher rates than the ones in table 2), testing should be done according to those stated flow rates.

Note 2: According to EN-Standards the blower with the filtering devices is tested for the flow rate of a given combination first and after that the configuration is tested according to that evaluated flow.

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Table 4:

Gas/Vapor	Test Concentration (ppm)	Maximum Break Through (ppm)	Minimum Allowable Service Life (min)
Hydrogen Chloride	5000	5	6@ ~~85~~ 80 % RH 12@ 25 % RH

Note: After discussion with NIOSH personnel there are some discrepancies between Table 4 in the draft dated 21.12.2007 and the version NIOSH was working with during our discussions. Please address this discrepancy in the next concept.

Section 4.2.7.4:

4.2.7.4 Carbon Monoxide Canister/Cartridges testing

4.2.7.4.1 Service Life

CO-Canister/Cartridges shall be classified according to their nominal service life, that will be classified by a test with an artificial lung after testing at 30 L/min with 20 strokes per minute at 1.5 L/strike at 0.25 Vol %, 0.5 Vol % and 1.0 Vol % CO.

Class 20: breakthrough time minimum 20 min;
Class 60: breakthrough time minimum 60 min;
Class 180: breakthrough time minimum 180 min

4.2.7.4.2 Test procedure

The canister/filters shall be connected via a connection piece with an inhalation and exhalation valve onto the artificial lung.

The testing chamber shall be provided with a flow with of at least 100 l/min humidified air.

The CO concentration of 0.25, 0.5, 1.0 Vol % CO shall be lead into the chamber via regulation valve or flow meter.

Humidity (in test-chamber): 20.7 g/m³;

Temp. : 23°C to 25°C.

4.2.7.4.3 Break-through-criteria

The inhaled moving average value for CO in the inhaled air shall not succeed 200 ml/m³ (calculated as moving average in any five minutes interval) during the stated nominal service live. (0. to 5th Minute, 1st to 6th Minute, 2nd to 7th Minute and so on). The last interval starts 5

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minutes before end of nominal service life. The inhaled air shall not succeed more than 200 mL CO during the nominal service life.

Note: This proposed method has been taken from the national German standard DIN 58620.

Section 4.2.7.7:

Cartridge test conditions, with the exception of Sections 4.2.7.5 and 4.2.7.6 shall be determined as follows: …

Note: The last two sub-sections do not apply to the test conditions and could lead a misunderstanding.

Section 4.2.7.8:

Canister test conditions with the exception of Sections 4.2.7.5 and 4.2.7.6 shall be determined as follows: …

Note: See comment to Section 4.2.7.7.

Section 4.2.10.1:

The measured LRPL according to STPRCT/CBRN/APR/ASR/STP0352 shall be determined for each PAPR. Required LRPL values are listed in Table 5.

Note: The STP needs to be identified.

Table 5:

Table 5: LRPL-values	
Type of PAPR	**LRPL – minimum-value ~~(%)~~**
Half-mask	100 (blower on)
Loose-fitting Face-piece	10,000 (blower on)
Tight-fitting Face-piece Including Hoods and Helmets	10,000 (blower on)
Tight-fitting Face-piece Including Hoods and Helmets	2000 (blower off)

Note: Test conditions are clearly identified.

Section 5.1.1.2:

…..* End user: The definition of the end user is the person who will derive protection from the respirator by wearing it. It is assumed that the end user will store the respirator and its required

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components in a location where it will be available for immediate access and use during an emergency.

Note: Filters and cartridges or canisters should be stored in there original packing to prevent ingress of dirt, debris and protection from ageing by humidity.

Section 5.1.4.1 Table 7:

* Vapour challenge concentration generation shall…

Note: Please review notes for the Table 7 and Table 8 for consistency between content.

Section 5.1.4.1 Table 8:

Note- Add a new column to be consistent with Table 7:

Breathing Machine Airflow Rate (L/min) = 40 L/min

Section 5.2. Table 11:

Note: Add a new column for the following:

Breathing Machine Airflow Rate (L/min) = 40 L/min

‡ Three consecutive sequential test data points at or exceeding 0.044 or 0.30 mg/m³ shall collectively constitute a failure where each test value is based on a detector sample time of approximately 2 minutes.

Section 6.1:

Note- Insert following proposed wording:

No part of the respirator shall continue to burn after removal from the flame. Test shall be performed with a single burner, at 850° ± 50°C. The sample shall be moved into the flame at a speed of 60 mm/min. The distance between flame and sample shall be 20 mm.

Section 6.2:

If this section only pertains to those PAPRs that are intended for CBRN applications, then this complete section and subparts should be relocated to Section 5. Draeger Safety feels that a silent mode of operation could be an option for any tight fitting full facepiece PAPR and would recommend testing requirements for this enhanced mode of operation.

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Section 6.2.1:

~~Tight-fitting full facepiece CBRN respirators shall meet and the for CBRN air-purifying respirator (APR) to be granted approval for use in silent (non-powered) as well as normal (powered) mode.~~

Note: Delete this subpart and renumber the remaining subparts accordingly. See comments to Section 6.2.

Section 6.2.2:

~~For approval~~ When tested in a silent mode, initial resistance to airflow shall additionally be measured inside the respiratory inlet covering of a completely assembled PAPR with the blower not operating.

Section 6.2.3:

When tested in a silent mode, the maximum allowable resistance requirements with the blower not operating, mounted on a test fixture, and air flowing at a continuous rate of 85 liters per minute, are as follows:

Table 13: Maximum Allowable Resistance for Silent Mode PAPR Operation

Type of Protection	Initial Inhalation Resistance	Initial Exhalation Resistance
Particulate Only	45 mm H20	20 mm H20
Gas/Vapor cartridge Only	50 mm H20	20 mm H20
Gas/vapor cartridge/ particulate	60 mm H20	20 mm H20
Gas/vapor canister Only	50 mm H20	20 mm H20
Gas/vapor canister/ particulate	75 mm H20	20 mm H20

Note: Table 13 - It is very unlikely to meet the Initial Inhalation resistance values for the canister or particulate values for a PAPR in silent mode as noted. The values proposed in that table are identical to the APR standard without accounting for any resistance due to the blower system and distances from the filtering elements. The given values of Table 13 have to be increased by 10 mm H_2O accordingly to take the system resistance into account.

Section 6.3:

Delete this section. Further information or examples of what may cause this additional evaluation is necessary.

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Section 6.5.1:

Units to be identified as intrinsically safe on NIOSH-approved labels must be certified as intrinsically safe prior to submission to NIOSH. Certification must be through a recognized authority such as ~~the National Fire Protection Agency (NFPA)~~, Factory Mutual (FM), Underwriters Laboratories (UL), ~~or the~~ Mine Safety and Health Administration (MSHA), Canadian Standards Association (CSA), or the ATEX Directive 94/9/EC.

Note 1: The NFPA only develops standards and they are not a certifying authority and should not be listed as such.

Note 2: Some regions throughout out the world do specify NIOSH certified respirators but would also require specific Intrinsic Safety approvals other than what is listed in the concept document. For example, the Canadian Federal Government requires NIOSH certified equipment (if available) but requires electronic components to meet the Intrinsic Safety requirements of CSA. In addition, some specific market applications would only accept specific Intrinsic Safety certifications; i.e.: Mining requires MSHA Intrinsic Safety for Methane-Air Atmospheres.

Draeger Safety thanks NIOSH for the opportunity to provide comments. Please consider our comments concerning the ongoing changes to the standard.

If there should be any questions concerning this matter, please do not hesitate to contact me at 412-788-5685 or via e-mail at Robert.Sell@Draeger.com.

Respectfully,

Robert Sell

Robert Sell
Sr. Project Engineer

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