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**Subject:** NIOSH Docket No.: 008 - Industrial Powered Air Purifying Respirators  
**Attachments:** Industrial PAPR Comments - NIOSH Docket No 008 - April 2007.doc

Hello:

Attached please find Draeger Safety's comments on the Concept Paper: Proposed Industrial Powered, Air-Purifying Respirator (PAPR) Standard dated September 19, 2006. Please forward to the appropriate party for review. If there should be any questions concerning the information, please do not hesitate to contact me.

Regards

Bob Sell

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April 17, 2007

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Reference: DOCKET NUMBER NIOSH - 008  
Concept Paper: Proposed Industrial Powered, Air- Purifying Respirator  
(PAPR) Standard – September 19, 2006

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 September 19, 2006.

The following Draeger Safety comments are being submitted for consideration and we will comment step-by-step through the draft protocol:

### **Section 1.2:**

Suggested wording change – "...additional testing that may be requesting requested by the manufacturer".

### **Section 2.4:**

We believe that the reference to escape from IDLH atmospheres should identify what the oxygen content should be and suggest the following: "...can be used for escape from atmospheres Immediately Dangerous to Life or Health (IDLH) containing a minimum of 19.5% oxygen to support life".

### **Section 2.10:**

An active ESLI as referenced could be a flashing light or an automatic ringing bell but we propose the use of the term audible alarm. We suggest the following text: "...flashing light or an automatic-ringing-bell audible alarm".

## **Section 2.11:**

Intrinsic Safety requirements and levels may vary by application or customer requirements and the reference to 30 CFR, Part 18, Subpart D 18.82 only applies to gassy mines or tunnels and implies that this is the only Intrinsic Safety approval required. We would agree that product going into these types of applications would require this specific approval but for non-mining applications we would suggest that references also include other Intrinsic Safety approvals; i.e.: UL 913, CAN CSA C22.2 157, and ATEX.

## **Section 4.1.2.1:**

We believe that this statement is design restrictive and there are suitable methods to manipulate the respirator in order for the user to see the indicator; i.e. Similar to the remote gauge on a SCBA there could be remote switch for PAPR operation which includes the indicator that the user could “pick up” to view. We suggest the following change to the wording:

“Each PAPR will have an indicator to indicate when the power is full and low. It will be readily detectable to the wearer during use without manipulation of the respirator affecting the respirator protection and performance”.

## **Section 4.1.2.2:**

The requirement for an active indicator to alarm when the pressure inside the respiratory inlet covering is not above ambient is good and we would like to see a quantifiable value to be assigned to this requirement. In addition, please refer to our comment for Section 4.1.2.1. We therefore recommend the following:

“Each PAPR will have an active indicator which alarms the user, via a readily visible light or other means, when the air pressure inside the respiratory inlet covering is not above ambient for more than three consecutive breaths. It will be readily detectable to the wearer during use without manipulation of the respirator affecting the respirator protection and performance.

## **Section 4.1.3:**

Certain applications for breathing tubes will require that these components be durable for certain environments; i.e.: CBRN, therefore we propose the following wording:

“Flexible breathing tubes will be designed and constructed, as far as practical, to prevent:

## **Section 4.1.7.3:**

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Fogging of the lenses, visors, and shields will vary depending on work rate, humidity, etc. and the use of the term “normal operation” is subjective and requires some clarification or parameters as base requirements for the respirator.

## **Section 4.1.9.1:**

A low pressure indicator is described in Section 4.1.2.2 and another indicator is referred to here. Does this permit the use of one indicator for both functions or must there be two indicators to cover both requirements? Some clarification is required for these sections. In addition, similar to our comment for Section 4.1.2.2 we put forward the following change:

“...pressure inside the respiratory inlet covering falls to below ambient pressure during blower operation”.

## **Section 4.1.9.2:**

Why not include lights as a visible notification method? The use of only sound or vibration is design restrictive. Also, in keeping with the same context of the wording for Section 4.1.9.1 and our comment to Section 4.1.2.1 we recommend the following text:

A low flow or pressure ~~Low pressure~~ indicators will be readily visible or detectable (via sound, vibration or lights) to the user without ~~manipulation of the respirator~~ affecting the respirator protection and performance”.

## **Section 4.1.9.3:**

In keeping with the same context of the wording for Section 4.1.9.1 we recommend the following text:

A low flow or pressure ~~Low pressure~~ indicators will be configured so that they may not be de-energized when the blower is energized.

## **Section 4.10.10.4:**

Why not include lights as a visible notification method? The use of only sound or vibration is design restrictive. Also, in keeping with the same context of the wording for Section 4.1.9.1 and our comment to Section 4.1.2.1 we recommend the following text:

Low power indicators will be readily visible or detectable (via sound, vibration or lights) to the user without ~~manipulation of the respirator~~ affecting the respirator protection and performance”.

## **Section 4.10.10.5:**

We advocate an alternative text with the same meaning to what is currently written.

~~Low power indicators will be configured so that they may not be de-energized when the blower is energized. As long as the blower is in the operational mode, the low power indicator must not be configured to be switched off.~~

## **Section 4.1.11.2:**

The influence of filter resistance on battery life is dependent upon the blower / fan technology being used and we feel that this current section could be design restrictive to limit this technology and we put forward the following text:

The PAPR system will be operated fully assembled on a head form with the ~~lowest resistance filtering elements~~ filter element which gives the highest power consumption.

## **Section 4.12.1.2:**

This sentence needs some clarification as to which impregnation is meant (charcoal or indicator). Any impregnation used in the indicator will not be absorbed by the charcoal and the indicator itself can react or be used up by a test agent. We offer no suggestions.

## **Section 4.12.1.3:**

This statement is too far ranging and we propose the following:

Effects of industrial interferences as identified by the manufacturer, which are commonly found in workplaces where it is anticipated that a given respirator will be used.

## **Section 4.12.1.4:**

We would like to add some clarification to the statement and recommend the following:

The effects on the ESLI of any reaction products produced in the reaction between the sorbent and the contaminant gases and/or vapours against which it is designed to protect.

## **Section 4.12.1.6:**

We believe that some clarification is needed to include the concentration of the gas/vapour being requested for certification and therefore we suggest reducing the additional requirement for data to one.

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 the given contaminant level used for cartridge/canister certification and one additional ~~two~~ contaminant levels selected by the manufacturer.

### **Section 4.12.3.3:**

We feel that this is a subjective evaluation and that anything that is mounted and visible in the facepiece interferes with the line of sight and we advocate the following text.

~~The ESLI will not interfere with required lines of sight.~~ If the ESLI is mask mounted it shall not significantly interfere with the line of sight.

### **Section 4.1.13.1:**

We wonder why do only the "Special" storage requirements are to be included in the user instructions and believe that any and all such requirements are to be identified and we advocate removing the term "Special" from the text.

~~"Special Shelf (storage) life requirements..."~~

### **Section 4.1.15.1 and 4.1.15.2:**

Remove both sections and incorporate the following requirement on FMEA from ISO RPD draft performance requirement (February 2007) - clause 5.2.33. We believe that this would help to harmonize documents that are currently being created.

Section 4.1.15.1      Manufacturers shall demonstrate that reliability is assessed and controlled by conducting a system failure modes and effect analysis (FMEA) on their device or component.

Section 4.1.15.2      The manufacturer shall provide a written declaration that the FMEA was completed.

Section 4.1.15.3      The manufacturer shall maintain a copy of the FMEA in their records.

### **Section 4.2.3.2:**

Further clarification is need on where the static reference point is between the inhalation and exhalation breaths. Is it the mid-point between the two values or is it on the lower end or upper end of the ranges?

## **Section 4.2.4.2.5:**

We are not sure of why the term “desired” is used when it is not needed and there may be a typographical error with the use of the term “Moderate” being used twice. We propose the following changes.

“...while breathing at either ~~Moderate~~ or Moderate or High rates, depending on desired rating.”

## **Section 4.2.4.2.9:**

We wonder why the flow rating should be different for Loose Fitting PAPR versus Breath Responsive PAPR and feel that the minimum requirements for both should be the same. If the manufacturer specifies additional flow ratings then these will be tested in addition to the minimum requirements. We recommend the following wording.

“...while breathing at each ~~of the desired~~ either of the Low, Moderate, or High rates, depending on rating while on a head form. Other rates specified by the manufacturer shall also meet this requirement”.

## **Section 4.2.5.7:**

After reviewing this section we conjure up the vision of only a two size mask (Small / Medium and Medium / Large) and are curious as to how to interpret the test requirement. Could it be expected that the statement “whichever is greater” will be used and four masks (two of each size) would be tested? Please clarify.

## **Section 4.2.6.3:**

We believe that the air flow rate is missing in this section and put forward the following wording.

“...the highest resistance combination cartridges, canisters, and / or filters are tested at the air flow rates specified for the PAPR design”.

## **Section 4.2.7.1:**

The number of cartridges being tested and what the temperature / pressure parameters are for the term “as received” need to be included in this section. In keeping with Sections 4.2.7.2 and 4.2.7.3 it implies that three PAPR cartridges and canisters will be tested. We recommend the following:

“Three PAPR cartridges and canisters will be tested as received (25 ± 2.5°C and 50% +/- 5% RH)...”

## **Section 4.2.7.2:**

Are the cartridges and canisters to be pre-conditioned for these tests or are they to be tested as received to these conditions? If pre-conditioning is going to be performed, please identify these requirements.

## **Section 4.2.7.3:**

Typographical error

"...canisters will be tests will be performed at..."

## **Table 1.1:**

There is a discrepancy for the "Constant Flow: High" rates as compared to the text in Section 4.2.4.2.4 and Section 4.2.4.2.8 and this table. Section 4.2.4.2.4 states 250 Lpm vs. Table 1.1 at 270 LPM for Tight-fitting and Section 4.2.4.2.8 states 370 Lpm vs. Table 1.1 at 325 Lpm. Please identify the correct values.

## **Table 1 Cartridge Bench Test versus Table 2 Canister Bench Test Requirements:**

Test concentrations for Methylamine for both categories have remained the same and we are wondering if this is typographical error since the test concentrations for cartridges are typically lower when the two tables are compared.

In comparing the two tables, it is also noted that Hydrogen Chloride and Hydrogen Fluoride are also missing from Table 2 (Canister Bench Tests) and we are wondering if this was intentional or an over sight?

In our experience for Ethylene Oxide as compared with the concentration, maximum breakthrough and service life especially under humid conditions may lead to very huge canisters. The requirements should be reconsidered.

Finally, the note following the two tables identifies that either the cartridge and canister will be approved for tear gas if desired by the applicant once they meet the requirements for Cyclohexane and PAPR P100 and we are wondering if this is the case since the two concentrations are different or does this only apply to the requirements of Table 2 (PAPR Canisters)?

## **Section 4.2.7.5.1:**

We believe that the specific class / family for the additional gases and vapors be identified and recommend that an Appendix section be included in the standard that identifies these other gases and vapors that are qualified. This would prevent any

confusion between the customer and manufacturer if there is something identified by NIOSH in conjunction with the standard.

## **Section 4.2.7.5.2:**

Please provide some clarification for this statement. Would NIOSH conduct additional testing to these additional gases or vapors? Would 3<sup>rd</sup> party or manufacturer test data be sufficient for NIOSH to qualify the cartridge or canister? Would NIOSH accept independent data at all in order to make these claims?

## **Section 4.2.7.7:**

What previous sections is this statement referring to? It can be considered to apply to the complete Section 4.2.7, but it seems only to apply to Section 4.2.7.6. We therefore suggest that this be renumbered as Section 4.2.7.6.1 and this would only then pertain to the manufacturer's additional request for other gases or vapors.

## **Section 4.2.7.8:**

Reference our comment to Section 4.2.7.7. We suggest that this be renumbered as Section 4.2.7.6.2 and this would only then pertain to the manufacturer's additional request for other gases or vapors.

## **Section 4.2.7.8.5:**

This section references a paragraph that is not in the document and we propose the following:

Test time for cartridges for which approval is sought under ~~this paragraph (d)~~ Section 4.2.7.5 and Section 4.2.7.6 will generally be set at 50 minutes. Where this is not achievable or can not be done safely in the laboratory, time and concentrations may be proportionally adjusted.

## **Section 4.2.7.9.5:**

This section references a paragraph that is not in the document and we propose the following:

Test time for cartridges for which approval is sought under ~~this paragraph (d)~~ Section 4.2.7.5 and Section 4.2.7.6 will generally be set at 60 minutes. Where this is not achievable or can not be done safely in the laboratory, time and concentrations may be proportionally adjusted.

## **Section 4.2.7.9.6:**

Is it normal practice to select the lower value and what is the basis or governing rule for this requirement? We would think that the health and safety of the user is paramount and would consider the higher values. If this section remains, we would propose that following:

Allowable breakthrough concentrations for all testing for which approval is sought will be based on the NIOSH REL (recommended exposure limit) or OSHA PEL (permissible exposure limit) in effect at the time of testing by NIOSH, whichever is lower. Where this is not achievable or can not be readily detected in the laboratory the concentrations may be proportionally adjusted.

## **General Comment for Section 4.2.7.5 through Section 4.2.7.9:**

Since these sections apparently relate to additional gases and vapors not addressed in this document we suggest that these section be combined into their own section and put forward the following:

Section 4.2.8            Chemical cartridges and canisters: Additional gases and vapors;  
Requirements

## **Section 4.2.8.5:**

Please identify the test equipment that would be used for this section. Currently, our investigations have revealed that there is no test equipment available which is able to monitor the aerosol concentration at very high flow rates (> 95 Lpm) that could be specified.

## **Section 4.2.8.6.2:**

With this current test requirement of the PAPR P100 filter being challenged to minimum efficiency or until  $1000 \pm 50$  mg, we estimate that this test would have a long duration (X 20 filters) and this value should be reconsidered.

## **Section 4.2.10.1:**

It is suggested in Section 4.2.10.6 that the PAPR will be functioning with the blower on but there is nothing clearly stated. If this is the case, we propose the following wording:

The measured Total Inward Leakage (TIL) will be determined for each PAPR design equipped with the heaviest available cartridges, canisters, and accessories while the PAPR blower is operating.

## Table 5:

The TIL value for a Tight-fitting Facepiece is identified as 10,000 and we suggest aligning this with the current EN 12942:1998 requirement of 2,000 with the blower operating and a TIL of 1,000 with the blower off. We also propose that the higher TIL value (10,000) be utilized in the CBRN Application Specific Requirements.

## Section 4.10.2.4:

The temperature identified in this section should be referenced in SI values; i.e.: 21° ± 2.5° C. This would be consistent with the rest of the document.

## Section 5.1:

This section does not coincide with the existing requirements as compared with the current **Statement of Standard for Chemical, Biological, Radiological, and Nuclear (CBRN) Powered Air-Purifying Respirators (PAPR)** dated October 6, 2006. We prefer to see the format for the requirements as described in Sections 1.1.1 and 1.1.2 of that document and therefore propose the following.

### 5.1.1 Durability conditioning (CBRN tight-fitting PAPR only) (Reference STP CBRN-0311)

#### 5.1.1.1 Respirator containers; minimum requirements

##### 5.1.1.1.1 Required packaging configuration: (minimum packaging configuration): The CBRN tight-fitting PAPR and the required components shall be subjected to the environmental and transportation portions of the durability conditioning in the manufacturer specified minimum packaging

configuration. The canisters shall also be subjected to an additional rough handling drop test in its designated minimum packaging configuration.

##### 5.1.1.1.2.1 The minimum packaging configuration is the protective packaging configuration that the end user\* shall store or maintain the CBRN tight-fitting PAPR and the required components inside after it has been issued for immediate use. The user's instructions (UI) shall identify the minimum packaging configuration and shall direct the end user how to store or maintain the CBRN tight-fitting PAPR and the required components inside the manufacturer specified minimum packaging configuration while in the possession of the end user. The same minimum packaging configuration identified in the UI shall encase the CBRN tight-fitting PAPR and the components when NIOSH performs the durability conditioning. The type of the minimum packaging configuration, if any, is left to the discretion of the

manufacturer. Examples of common minimum packaging configurations are mask carriers, clamshell containers, draw string plastic bags, hermetically-sealed canister bags or nothing at all.

If over cases, packaging, or shipping containers are provided by the applicant over and above the minimum packaging configuration, these additional packaging levels may not be a substitute for the minimum packaging configuration and will not be used by NIOSH in the durability conditioning of the application

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

5.1.1.1.3 Durability conditioning shall be performed in accordance with Table X (Table X is the current table as described in the document)

## **Section 5.1.2:**

We believe there is a typographical error in this statement and suggest the following.

5.1.2 Tight-fitting full facepiece respirator with impact resistant and scratch resistant lenses that shall meet the requirements of ANSI Z87.1- 2003.

## **Section 5.1.6.1:**

Why is there a discrepancy between Table 2 in this section and the table in Section 4.2.7.1 for the test concentration and breakthrough concentration for Hydrogen Sulphide?

Section Reference	Test Concentration	Breakthrough Concentration
Section 4.2.7.1	5000	5
Section 5.1.6.1	1000	5

It appears as if the cartridge value from Table 1 in Section 4.2.7.1 was is used instead of the canister values from Table 2.

## **Section 5.11.1:**

We recommend the following modification to the wording of this section.

Positive pressure PAPR will maintain a pressure above ambient inside the facepiece during operation.

According to the definition in chapter 2.1:

*2.1 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 as determined by pressure measurements during air flow testing described herein when measured in the area of the nose and mouth.*

According the definition, all PAPR are positive pressure. The silent mode should be mentioned as exception though.

### **Section 5.13:**

Why should Field of View be held as an application specific requirement? We believe that this should be one of the base requirements for PAPRs.

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](mailto:Robert.Sell@Draeger.com).

Respectfully,

*Robert Sell*

Robert Sell  
Sr. Project Engineer

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