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From: Sell, Robert [Robert.Sell@draeger.com]
Sent: Tuesday, September 30, 2008 1:42 PM
To: NIOSH Docket Office (CDC)
Cc: Rehak, Timothy R. (CDC/NIOSH/NPPTL)
Subject: 039-A - Subpart Q CCSCBA Concept
Attachments: CCBA Docket 039-A Comments 9-30-2008.doc

Hello:

Attached please Draeger Safety's comments on the concept document for Docket #039-A. If there are any questions concerning this information, please contact me.

Regards

Bob Sell

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September 29, 2008

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Reference: NIOSH DOCKET – 039-A: Concept Standard for Closed Circuit, Self-Contained Breathing Apparatus (SCBA)

Dear Sir/Madam:

Draeger Safety has manufactured Closed-Circuit Breathing Apparatus (CCBA) and we have sold thousands of units into various markets and applications throughout the world. Therefore we offer the following comments in response to the recently posted NIOSH Concept Standard for Closed Circuit, Self-Contained Breathing Apparatus (SCBA), dated May 28, 2008:

New Section

Draeger suggests that a "Definitions" section be added to the document and that these definitions follow those that have been either implemented by EN 132:1998 or utilize the proposed definitions as being finalized in the Draft International Standard ISO/DIS 16792 where the terms are commonly known.

Section 84.502

In reviewing the required components and attributes we find that there is no weight requirement identified. We would recommend that a weight requirement be included in this section and the following requirement be located in the document:

84.XXX Weight Requirement.

(a) The completely assembled and fully charged apparatus shall not weigh more than 16 kg. (35 pounds).

(b) Where an apparatus employs equipment which contributes materially to the wearer's comfort, e.g., a cooling system, the completed assembled and fully charged apparatus shall not weigh more than 18 kg. (40 pounds).

Section 84.502(d)

Currently we do not understand the need to test permeation resistance with the three substances that are currently identified. Permeation of substances is dependent upon the solubility, diffusion, and chemical structure. Solubility increases with higher molecular weight and diffusion decreases with higher molecular weight and hydrocarbons in the range of C7 have the maximum permeability

capacity. In reviewing the three substances being considered, we find that Kerosene consists of hydrocarbons in the range of C12 - C15, gasoline consists of hydrocarbons in the range of C5 - C12, and Toluene is a pure substance with exactly C7. From a permeation aspect, Kerosene is less critical than gasoline and Toluene and will provide no additional benefits when used for testing. Gasoline will be the more critical test than Toluene since gasoline is comprised of a mixture of different substances and we believe that the use of gasoline should be sufficient. In addition, at least the grade should be identified and if the selected grade is so specific a source or other information should also be provided in order that it can be obtained. We suggest removing the toluene and kerosene and only use gasoline.

(d) The CC-SCBA shall be constructed to be resistant to the permeation of the breathing circuit by gasoline, ~~toluene, and kerosene~~ (Identify the grade of gasoline).

Section 84.507

All of the subsections reference either the primary lens system in conjunction with an optional protective outsert lens system and we would like some clarification on what either of these lens systems could be comprised of? The intent of our question is to determine if a manually operated mechanical lens wiper that we currently use for our PSS BG4 is included in the terminology of a lens system.

Section 84.507(b)

In this section it is noted that a Visual Field Score (VFS) of 90 or greater is required at all of the temperatures for which the apparatus is intended to be used. If the test is not going to be performed at room temperatures we believe that there needs to be more clarification on what the test conditions are, how long the unit is pre-conditioned at these temperatures, and what size facepiece is to be used before being tested. In addition, we feel that there may be adverse effects to the test equipment if it is being used in the extreme temperatures which may affect the results. Until more information is available concerning this requirement we put forth the following modification:

(b) Facepiece primary lens system and any optional protective outsert lens system shall be designed and constructed to provide an adequate and non-distorted field of view and shall obtain a Visual Field Score (VFS) of 90 or greater ~~at all temperatures for which it is intended to be used~~ when tested at between 22° C +/- 3° C (72°F +/- 5° F) [Note: In lieu of referencing the temperature in this section the NIOSH Standard Test Procedure could be referenced]. The VFS score is the average of three fittings of the same respirator with a medium size facepiece on the specified head form.

Section 84.507(c)

As noted above under Section 84.507 we would like to be able to confirm that a manually operated mechanical wiper is permitted to be used to clear the fog from the lens and if an anti-fog solution is also permitted to be applied to the lens to verify its suitability for use.

Also, why is a low temperature being specified? We feel that the manufacturer should specify the low temperature rating for the device and then the test is conducted at that specified temperature. Since preconditioning and low temperature use can affect the performance of the scrubber will the test subject's respiratory parameters (CO₂ and O₂ levels) be monitored and used as pass/fail

criteria for this test to determine "undue discomfort"? We therefore propose the following change to this section:

The CC-SCBA shall be cold soaked and tested in an environmental chamber at the low temperature specified by the manufacturer ~~minus 21°C ± 2°C (-5.8°F ± 3.6°F)~~ for four (4) hours. The wearer shall not experience undue discomfort because of restrictions to breathing or other physical or chemical changes to the respirator.

Section 84.508

The current requirement for the breathing gas requirements is very vague and we believe that more information is needed. We suggest the following for when oxygen is used as the breathing gas:

- (a) Oxygen, including liquid oxygen, shall be of medical grade or better and shall not contain less than 99.0%, by volume, of pure O₂, not more than 0.03%, by volume, carbon dioxide, and not more than 0.001%, by volume, carbon monoxide. Methods for making these determinations can be found the United States Pharmacopoeia (USP).

Section 84.510(c)

As a part of the verification for this requirement, will a gauge accuracy test be performed? We suggest the following be added to this sub-section:

Section 84.510(c)(1) Dial indicating gauges shall be reliable to within ±5 percent of full scale when tested both up and down the scale at each of five equal intervals.

Section 84.511

There may be many possible solutions to this requirement and we would like to know what possible test methods may be used to determine compliance with this requirement. In addition, will a capacity gauge accuracy test be performed?

Section 84.516(a)

As noted in our comment Section 84.502(d) for we do not understand the need to test permeation resistance with the three substances that is currently identified. This requirement also seems to be geared for a four hour rated capacity and there is always the possibility that an approval could be granted for a system with a shorter capacity. Therefore, we also suggest that the test be performed for twice the rated capacity. We propose the following wording for this section:

- (a) *Three (3) CC-SCBA units shall be tested in ~~three separate~~ the contaminated atmospheres at a room temperature of 22 +/- 3°C 24°- 30°C (75° - 86°F) for a period of twice the rated capacity eight hours each; one unit in a gasoline (Grade to be identified) saturated atmosphere, one unit in a kerosene saturated atmosphere, and one unit in a toluene saturated atmosphere.*

Section 84.516(c)

In keeping with our comments noted above the change we also put forward the following:

(c) The breathing air in the CC-SCBA shall not contain more than 100 parts per million (ppm) of gasoline vapor, ~~14 ppm of kerosene vapor, and 50 ppm of toluene vapor~~ at the conclusion of each of the respective tests.

Section 84.518(a)

The section specifies that four tests to be performed for this requirement but sub-section (4) also accounts for units being used in coal mines and requires two additional tests. This causes some confusion and we offer the following:

(a) NIOSH will conduct the Capacity test ~~a total of four times~~ on the CC-SCBA submitted for approval, as follows:

Section 84.518(a)(2)

The previous CCBA concept document had specified a 12 hour storage requirement for this test and the NFPA 1981 document also utilizes a 12 requirement. We propose that this requirement be maintained instead of using the 24 hour storage that is currently identified.

(2) The CC-SCBA shall be tested on an ABMS at the cold-temperature limit recommended by the applicant under § 84.502(e)(8) of this subpart after it has been stored for a minimum of 24 12 hours at this limit.

Section 84.518(a)(3)

It is not clear on what the test specification is for the activities or ventilation rate is to be performed while the subject is being tested to this requirement on the treadmill. We would recommend that this information be identified.

Section 84.518(d)

This section is identifying two conditions that have not been defined:

1. "User of average weight": Please identify what NIOSH has determined to be the average weight of a person.
2. "Moderately high work rate": We believe that this term needs to be defined. NIOSH Technical Report (Publication No. 76-189) covers a medium heavy work rate of 40 Lpm and a heavy work rate at 59.5. ISO 16976 Part 1 identifies 35 Lpm as a medium heavy work rate and a heavy or high work rate of 50 Lpm. We suggest that a "Moderately high work" rate be defined as 57 Lpm.

Section 84.520(a)

In looking at the requirements for this section there is no pre-conditioning identified. We propose the following:

- (a) NIOSH will conduct the Wearability test three times at ambient and once in a cold chamber at the lowest temperature recommended for use by the applicant. Three human subjects (two (2) males and one (1) female), will perform the tests at ambient temperature. The three subjects will range in height and weight as follows: one subject of height ≥ 174 centimeters*

(cm) (68.5 inches (in)) and weight ≥ 90 kilograms (kg) (198.4 pounds (lb)); one subject of either 163 cm (64.2 in) \leq height < 174 cm (68.5 in), regardless of weight, or of 72 kg (158.7 lb) \leq weight < 90 kg (198.4 lb) regardless of height; and one subject of height < 163 cm (64.2 in) and weight < 72 kg (158.7 lb). All CC-SCBA tested shall be pre-conditioned for 12 hours at the specified temperature and meet all conditions specified in this section to receive approval. A human subject of any weight and height can be used in the cold wearability test.

Table 4

Section 84.520 identifies Table 4 as the regimen and we are wondering there are any concerns with the test equipment for the low temperature tests? Will the test be performed at low temperature with the test equipment in the chamber or will the unit be pre-conditioned first and then the test is performed at ambient temperature specified?

Section 84.522

Negative inhalation pressures do not always constitute a leak but it can reflect what occurs in the system at higher ventilation rates. In order to verify that the system is leak tight and we suggest adding a quantitative leak test with the following requirements taken from NIOSH RCT-CBRN-STP-0200, 0201.

(e) NIOSH will perform a quantitative leak test on the apparatus submitted for approval. At the greatest negative pressure exhibited by the apparatus in the Performance test, the leak rate into the breathing circuit shall not exceed 0 ml/min a maximum penetration of 0.001%.

Table 5

In keeping with the above recommendation (Section 84.522) and our rationale for Table 6 and Table 6b we suggest that the acceptable excursion requirement for the Peak Inhalation Pressure be changed to -30 mm H₂O once it has been determined that the system is leak tight.

Table 6

In the NIOSH SAR concept document (Released 7-2008) NIOSH has defined in Section 4.2.8 Table 2 an approved breathing rate of 57 Lpm as a high work rate. To accommodate this high work rate Draeger proposes to have three levels of work defined in Table 6: 40 Lpm as a baseline rate, 57 Lpm has a high work rate, and 100 Lpm as an extremely high rate. It is our understanding that a majority of the work that is handed during a mission occurs within the range of 40 – 57 Lpm. The 100 Lpm work rate is an extreme work and should be accommodated with performance criteria that does not contribute significantly to the use during a typical operating period.

Parameter	Work load A	Work load B	Work load C
Ventilation rate, liters/min, absolute volume displacement	100	57	40
Respiratory frequency, breaths/min	30	29.1	18
Oxygen consumption rate, liters/min, * STPD	4.0	3.0	1.35
Carbon dioxide production rate, liters/min, * STPD	3.9	2.9	1.15

Table 6b

As noted in our comment for Table 6 above, Draeger proposes a similar amendment to Table 6b which would test more at the 57 Lpm high work rate with excursions to the extreme work rate of 100 Lpm for short periods only. During the extreme work rate excursions the CCBA is still fully functional even if the mask cavity dips to negative pressure for brief periods with a recommended minimum excursion of -30 mm H₂O. Coupled with our comment for Section 84.522 above when the quantitative leak test is performed with the requirement of a maximum penetration of 0.001% a negative excursion would not constitute a leak and therefore there would be no consequence to the system.

Starting time (minutes)	Work load	Duration (minutes)
0	A	12
12	C	43
55	B	5
60	C	25
85	B	5
90	C	25
115	B	5
120	C	25
145	A	5
150	C	30
180	C	60

Section 84.526

As noted in our comment for Section 84.516(a) this seems to favour a four hour rated capacity and there is always the possibility that an approval could be granted for a system with a shorter capacity. Therefore, we also suggest that the test be performed for 1.5 times the rated capacity. We propose the following wording for this section:

84.526 Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) and Sarin (GB) Agent Test Requirement for CBRN Use. The CC-SCBA, including all components and accessories, shall resist the permeation and penetration of distilled sulfur mustard (HD) and Sarin (GB) chemical agents for 1.5 times the rated capacity by meeting the requirements and test conditions specified in Table 8 for HD and Table 9 for GB.

Tables 8 and 9

As noted in our comment for Section 84.526 this seems to favour a four hour rated capacity and there is always the possibility that an approval could be granted for a system with a shorter capacity. Therefore, we also suggest that the test be performed for 1.5 times the rated capacity and that the tables be modified accordingly. In addition, we also suggest that the respiratory rate also be included with the "Breathing machine airflow rate" as 40 L/min @ 36 respirations/min.

Section 84.527 Heat/Flame, Fabric Flame, Fabric Heat, and Thread Resistance

It is our opinion that this requirement should not be an optional but mandatory in order to meet the needs of the Fire Service. Even though there is a current prohibition on the use of oxygen systems in high radiant heat and open flames the systems can be still qualified and utilized as a special test similar to the other CBRN standards that have been generated by NIOSH in order to determine their suitability for use in this environment. In addition, it is our opinion that Sections 84.529 through 84.531 could be mandatory requirements. We therefore recommend the following text:

84.527 Firefighter Protection Requirements for CBRN Use (Optional and in addition to Section § 84.521 through § 84.526 of Subpart Q). NIOSH CBRN Certification rationale remains the same A NIOSH prohibition limitation exists which states:

“When using closed circuit positive pressure breathing apparatus for extended duration in high radiant heat and exposed flames it must be ensured that the equipment is fully tested and functional as required by the manufacturer and that the wearer has a correctly fitted facepiece.

Failure to ensure the above may cause the equipment to support burning in and around any leaking area including the head-facepiece interface.”

~~as stated in Federal Register (Vol. 50, No. 222, pages 47456—47457 dated Monday, November 18, 1985), for entry into high radiant heat and open flame environments while wearing a pure oxygen positive pressure CC-SCBA. However, optional testing may be obtained. In the event that this prohibition is lifted sometime in the future, approval could then be granted without additional testing. Sections § 84.527 through § 84.531 specifies minimum requirements to ensure that the CC-SCBA possesses some features of high radiant heat and open flame resistance characteristics. These requirements are not meant to sanction its use in high radiant heat and open flame environments unless NIOSH repeals the prohibition.~~

Section 84.528(a)(1)

In keeping with our recommendation noted in Section 84.522 and Table 5 above we propose the following:

(1) The peak exhalation pressure shall be ≤ 200 mm H₂O and the peak inhalation pressure ≥ 0 mm H₂O with an acceptable peak excursion limit requirement of -30 mm H₂O when measured as described in § 84.517(a).

Sections 84.528(b)

The current wording for this section implies that NIOSH has control over the NFPA standards process and in keeping with the text in section 84.525(b) we suggest the following wording:

(b) As described in § 84.525(b), NIOSH will make the determination whether to revise this document when the next Edition of NFPA 1981 is available to test the performance requirement stated in § 84.528(a)

Sections 84.529(b)

The current wording for this section implies that NIOSH has control over the NFPA standards process and in keeping with the text in section 84.525(b) we suggest the following wording:

(b) As described in § 84.525(b), NIOSH will make the determination whether to revise this document when the next Edition of NFPA 1981 is available to test the performance requirement stated in § 84.529(a).

Sections 84.530(b)

The current wording for this section implies that NIOSH has control over the NFPA standards process and in keeping with the text in section 84.525(b) we suggest the following wording:

(b) As described in § 84.525(b), NIOSH will make the determination whether to revise this document when the next Edition of NFPA 1981 is available to test the performance requirement stated in § 84.330(a)

Sections 84.531(b)

The current wording for this section implies that NIOSH has control over the NFPA standards process and in keeping with the text in section 84.525(b) we suggest the following wording:

(c) As described in § 84.525(b), NIOSH will make the determination whether to revise this document when the next Edition of NFPA 1981 is available to test the performance requirement stated in § 84.331(a).

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
Senior Project Engineer

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