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From: Bodo Heins [Bodo.Heins@draeger.com]
Sent: Monday, January 31, 2005 9:56 AM
To: NIOSH Docket Office (CDC)
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Subject: Comments NIOSH Docket 039
Attachments: Comments docket Jan 31 2005.doc; InterScan_Disclaimer.txt

Dear Sir/Madame,
Please find attached our comments concerning the draft CBRN CCBA standard.

Mit freundlichen Gruessen / With friendly regards,

Bodo Heins

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Reference: NIOSH DOCKET - **039**
Concept Standard for Chemical, Biological, Radiological, and Nuclear (CBRN), Full Facepiece, Closed Circuit, Self-Contained Breathing Apparatus (SCBA)

Dear Sir/Madam:

Draeger Safety for decades has been a worldwide and well-known manufacturer of Closed Circuit Breathing Apparatus (CCBA) and has sold thousands of units into various markets and applications to the full satisfaction of the user.
Therefore we offer the following comments in response to the recently posted NIOSH Concept Standard for Chemical, Biological, Radiological, and Nuclear (CBRN), Full Facepiece, Closed Circuit, Self-Contained Breathing Apparatus (SCBA), dated October 30, 2004:

We will comment step by step through the draft protocol, but first some general recommendations:

- It would prevent further discussions, if NIOSH would follow the well-known and proven EN 145 standard (Respiratory protective devices – Self-contained closed-circuit breathing apparatus compressed oxygen or compressed oxygen-nitrogen type – Requirements, testing and marking).
  This standard is state-of-the-art for these types of respirators and has been kept current throughout the years by keeping up with the technological advances being made to CCBA's. Adopting EN 145 and incorporating only the special CBRN requirements would allow for the continual improvement of the standard.

- The requirements in the draft standard are not a minimum but extreme maximum requirements which do not pay attention to the special characteristics of a CCBA.

  The requirements currently being defined in the draft standard come from the NFPA 1984 draft document for Closed-Circuit Self-Contained Breathing Apparatus for Fire Fighters that was being developed in the mid-1990's and which was never completed. The NFPA 1984 draft was patterned after the NFPA 1981 document for Open-Circuit Self-Contained Breathing Apparatus (SCBA) for Fire and Emergency Services, which is an inherently different type of design when compared to a CCBA.
  At this time, there is not a CCBA on the worldwide market that can perform to this draft standard.

  The working principle of CCBA's is that the breathing gas of the user will be regenerated by passing through a CO_2 scrubber which removes, by a chemical reaction, the CO_2 of the exhaled breathing air:

  $$Ca(OH)_2 + CO_2 = Ca\,CO_3 + H_2O + \text{heat}\ .$$

  This process is exothermic and is creating a lot of heat, which is one of the time limiting factors for a CCBA. Because you need an additional cooling mechanism, you need to add weight and dimensions to the unit for additional cooling equipment.

  One consideration for the low temperature requirements is, that soda lime (the most commonly used CO_2 Scrubber material) is producing water during the reaction. This causes problems when high ventilation rates are used. The soda lime can be "drowned" due to water build up, which is condensed at these low temperatures even though the reaction is exothermic.
  The soda lime itself must have a moisture content of ~16 Vol-% to work properly. If this is not the case, at least at the beginning, the soda lime needs some time to start. Therefore a CO_2-peak for a limited time must be allowed.

  We recommend that all of the current requirements be reviewed and based upon scientific principles and current technologies of actual state-of-the-art CCBA's and not utilize a draft NFPA document that is meant for Open-Circuit SCBA's.

- We recommend that the performance requirements for the high work rate be lowered to 75 lpm (see EN 145). If it will be required to follow the same performance requirements at 40 L/min as at 100 L/min it would be necessary to design the unit for the higher requirements.
  This means that the user has to carry a heavier and bigger unit than necessary for the duration of the CCBA if the requirements are not realistic.

- We recommend that the performance requirements after environmental stress should be reduced. It is technically unfeasible that stressed units have to follow the same performance requirements as brand new units.

  The EN 145 also performs environmental stress, but then the units are removed from the environmental stress and is tested at ambient conditions to determine if the environmental stress tests have had any influence on the performance of the unit.

  We recommend following the same procedure.

  At least the environmental stress conditions should be changed that the unit has to have ambient temperature (+20 ± 3 °C) when started to be tested at – 20 °C (instead of -32 C) or +50 °C (instead of + 71 °C).

- It can be interpreted that all testing is to be performed in accordance with Section 3.1 Breathing Gas Performance after each of the special tests, It is not rational to perform a full service time (~4 hours), to see if the unit has been affected.
  A reduced time period of 1 hour is recommended.

- The Automated Breathing and Metabolic Simulator (ABMS) will become an essential part of the requirements and it is very complex device!
  If it is not described in detail in the standard, everybody who tries to perform the required tests will come to different results and a detailed technical description needs to be provided. Not only the details of the machine itself, but also its handling will influence the results. This is the worst case situation for the manufacturer ! We suggest, that a comparative test be performed between the manufacturer's simulator and the ABMS to compare their own test results with the NPPTL test-results.

  It is doubtful, that a fullface piece mask can be sealed on a dummy head, which is also very important for this unit because of positive pressure (service time).
  It would be preferable to connect the unit direct to the connector of the breathing machine (without mask).

  The location and connection of the ABMS is very important for the breathing resistances during testing. For the cold chamber test i.e. it is impossible to place the ABMS in the climate chamber, because it contains water. That means, that the dummy head (or direct connector) has to be put through the environmental chamber by a tube/hose. Other tests (environmental high temperature, heat / flame, Live Agent, etc.) also needs to be considered in that a correction factor may need to be applied because of the distance/ deadspace.

The volume of the sample gas taken out of the unit has to be defined (or taken into consideration), because it affects the service time if it is not brought back into the breathing circuit.

The accuracy of the measuring instruments used with the ABMS has to be clearly described.

The waveform of the ABMS lung should be changed into sinusoidal waveform.

- It has to be considered that a negative pressure inside a tight fitting full facepiece mask does not constitute that there is a leak in the facepiece/system.
  A negative pressure value can also indicate the system has been mechanically stressed beyond the limits of the components.
  Negative pressure CCBA is still an approved system worldwide and is still in use.

  The Laboratory Respirator Protection Level (LRPL) test is being used to determine the fitness of the mask to the user and has been a requirement for all of the CBRN standards developed.

- The Fire Service currently has limited stress exposure to CCBA's whereas they are well trained from the beginning of their careers with Open-Circuit SCBA's which they use on a daily basis.
  A CCBA will be used less often and is a respirator that requires more extensive training, maintenance, cleaning and disinfecting to ensure that it is in proper working condition.
  We recommend that the standard include information to this effect in order that the differences can be understood to the First Responders.

- Currently within the NFPA 1981 standard a surrogate cylinder is used during the vibration test. This was implemented due to safety considerations of the lab and its personnel if there should be a sudden catastrophic failure of a cylinder and valve assembly that contained compressed air. (We believe there was a cylinder / valve failure during NFPA 1981 testing which is the reason a surrogate cylinder was implemented.)
  We would recommend that a similar surrogate cylinder be implemented for the CCBA vibration test. Once the test has been completed then a fully charged cylinder is reinstalled on the CCBA and performance testing can continue.

Recommendations to the CBRN CCBA Standard by section:

1.0) Purpose

The purpose of this standard shall be to specify minimum requirements to determine the effectiveness of the CBRN CCBA.....used during entry into.....
We recommend that it should be supplemented with **"and escape from".**

2.0) Title 42 Code of Federal Regulations (CFR), Part 84

The requirements of the 42 CFR, Part 84 can only be fulfilled if the performance requirements of the CBRN CCBA are be changed. See our recommendations below. In addition, there are "Special or Critical User's Instructions" that apply to 42 CFR, Part 84 that would cause the CCBA NIOSH certification to be void when used in the conditions detailed in the current CBRN CCBA draft. Some examples of these conditions are:

1. The manufacturer, for safe operation of the respirator, defines the low temperature of the respirator. The low temperature currently being specified in the CCBA CBRN draft would cause the CCBA to void the certification.

2. If the CCBA is a pressure demand apparatus, 42 CFR, Part 84 requires additional "Warnings and Limitations". One of these is, that the respirator is not to be used where there is direct exposure to open flames or high radiant heat.
   The CCBA CBRN draft allows this occurrence which in turn would lead the First Responder to consider that this is an approved use of the CCBA when actually it is an unapproved condition.

3. Special Requirements for CBRN Use:

3.1 Breathing gas performance

We recommend that the ambient temperature be decreased to 20 °C + 3 °C (68 °F + 5 °F) to prevent too high heat treatment of the unit in accordance to the required low inhalation temperature.

Table 1—Performance requirements

Parameter	Requirement	Suggestions
CO 2 concentration of dry breathing gas during inhalation	≤2% by volume	• 2 Vol-% to be an average value over the whole test period. • A peak of 4 Vol-% to be allowed during the high work rate breathing tests and at the end of the service time.
O 2 concentration of dry breathing gas during inhalation	≥19.5% by volume	
Wet-bulb temperature of breathing gas during inhalation	≤45 °C	= ≤45 °C at 40 L/min and = ≤50 °C at 100 L/min
Maximum breathing gas pressure	≤89 mm, w.g.	= ≤ 8.7 mbar at 40 L/min = ≤12 mbar for 100 L/min
Minimum breathing gas pressure	≥0 mm, w.g.	= ≥ 0 mbar at 40 L/min = ≥- 8 mbar at 100 L/min

Table 2.—Test regimen

Table 2.a.—Parameters

Parameter	Work load A	Work load B	Suggestions
Ventilation rate, [liters/min] at T lung , P local and 100% RH	100	40	Workload A to be reduced to 75 L/min (30 stroke x 2.5 L) following table 1 performance requirements add 100 L/min with performance requirement "breathable"
Respiratory frequency, [breaths/min]	30.0	24.0	The wave form should be sinusoidal to prevent tests that may only be possible on the ABMS
Oxygen consumption rate, [liters/min], STPD	3.2	1.6	
Carbon dioxide production rate, [liters/min], STPD	3.4	1.6	Value equal oxygen consumption (3.2 L/min)

Table 2.b.—Protocol

Apparatus rated period	Work load	Starting time (minutes)	Duration (minutes)	Suggestions
Hour 1	A	0	12	Do not start with workload A. Normal use of the CCBA does not indicate that this is a realistic situation. Normally other low work rate activities are performed by personnel before physical exertion occurs
	B	12	43	
	A	55	5	
Hour 2	B	60	25	
	A	85	5	
	B	90	25	
	A	115	5	
Hour 3	B	120	25	
	A	145	5	
	B	150	30	
Hour 4 and beyond	B	180	60	Are there any requirements for a minimum service time? How will the rated service time be determined (This was previously determined by the table 4 man test in 42 CFR, Part 84) ?

3.2) Environmental Temperature Operational Performance Requirement

3.2.1) The performance requirements should be different for work load A and work load B. The 100 lpm work load is too excessive for a CCBA, possibly consider a work load of 75 lpm. Also, even at the 75 lpm recommended work load a negative breathing resistance should be permitted.

3.2.2) The unit shall be in the environmental chamber, but the ABMS cannot be in the chamber because it contains water and other temperature sensitive components. It is therefore important that the necessary changes to the ABMS points of measurements are part of the standard and are traceable available to the manufacturer. The dead space within the ABMS should also be defined and limited.

3.2.3) Temperature conditions are too extreme and fall out of the use requirements specified by Draeger for both high and low temperature.
This would then cause the unit to fall out of the approved ranges and conflict with the certification of the demand unit.

Table 3.—Environmental test conditions

Environment	Temperature	Test duration	Test procedure	Suggestions
Cold	-32 °C ± 1 °C (-25 °F ± 2 °F)	Cold soak for a minimum of 12 hours	Perform test at -32 °C ± 5 °C (-25 ± 10 °F)	IAW the characteristics of a CCBA the test temperature should be decreased to – 20 °C ± 2 °C (- 4 °F ± 1.8 °F). For the performance testing the CCBA should be at room temperature of 20 + 3 °C (68 °F + 5.4 °F) With current technology for scrubber materials the CO_2 levels would be exceeded from the beginning Test duration : 1 hour CO2 peak at the beginning should be allowed. The manufacturer specifies the conditions of use. Draeger specifies (required by MSHA) that no ice at temperatures below 0°C is permitted. Therefore, during the performance testing this needs to be considered. Accessories for the environmental tests are possible and their installation and removal needs to be considered. Visibility through the lens should not limit the service time.
Hot	71 °C ± 1 °C (160 °F ± 2 °F)	Hot soak for a minimum of 12 hours	Perform test at 71 °C ± 5 °C (160 °F ± 10 °F)	IAW the character of a CCBA the ambient test temperature should be decreased to + 50 °C ± 2 °C (122 °F ± 3.6 °F). For the performance testing the CCBA should be at room temperature of 20 + 3 °C (68 °F + 5.4 °F) Test duration : 1 hour Increased inhalation temperatures should not limit the service time of the unit. A statement in the standard should note, that under such extreme conditions the values identified in 42

				CFR, Part 84 are exceeded. The high temperature test would cause the coolant system to be ineffective and high inhalation temperatures would be exceeded from the beginning. The cooling system can be replenished throughout the test and this should be considered. Accessories for the environmental tests are possible and their installation and removal needs to be considered.
Cold temperature shock	71 °C ± 1 °C (160 °F ± 2 °F) transferred to -32 °C ± 1 °C (-25 °F ± 2 °F); Test temperature shall be -32 °C ± 5 °C (-25 °F ± 10 °F)	Hot soak for a minimum of 12 hours; initiate test within 3 minutes in cold chamber	Initiate test within 3 minutes after transferring apparatus to cold chamber	See EN 145 § 7.14. No performance tests at the stress temperatures but at room temperature. Accessories for the environmental tests are possible and their installation and removal needs to be considered.
Hot temperature shock	-32 °C ± 1 °C (-25 ± 2 °F) transferred to 71 °C ± 1 °C (160 °F ± 2 °F); Test temperature shall be 71 °C ± 5 °C (160 °F ± 10 °F)	Cold soak for a minimum of 12 hours; initiate test within 3 minutes in hot chamber	Initiate test within 3 minutes after transferring apparatus to hold chamber	See EN 145 § 7.14. No performance tests at the stress temperatures but at room temperature. Accessories for the environmental tests are possible and their installation and removal needs to be considered.

3.3) Vibration Endurance Requirement

Consider using a surrogate cylinder during the vibration time period. This would be similar to what is done in NFPA 1981. There are safety concerns if the cylinder valve should fail during this test.

We believe there was a cylinder / valve failure during NFPA 1981 testing which is the reason a surrogate cylinder was implemented.

Limit test duration to one hour.

3.7) Accelerated Corrosion Resistance Requirement
This test seems to be redundant. The function of a CCBA cannot be affected and the appearance is a marketing aspect, a matter between customer and manufacturer. This test would unnecessarily increase the number of units needed for approval .

Limit test duration to one hour if really being tested.

3.8) Particulate Resistance Requirement
This test seems to be redundant. The function of a CCBA cannot be affected. This test would unnecessarily increase the number of units needed for approval .

Limit test duration to one hour if really being tested.

3.11) Heat and Flame Resistance Performance Requirement
If the CCBA is a pressure demand apparatus, 42 CFR, Part 84 requires additional "Warnings and Limitations". One of these is that the respirator is not to be used where there is direct exposure to open flames or high radiant heat. The CCBA CBRN draft allows this occurrence which in turn would lead the First Responder to consider that this is an approved use of the CCBA when actually it is an unapproved condition.

3.12) Chemical Agent Permeation and Penetration Resistance Against Distilled Mustard (HD) and Sarin (GB) Agent Test Requirement
It should be mentioned in the standard that the CCBA being tested is in the configuration as specified by the manufacturer.

We recommend the compressed oxygen cylinder not be included as part of the test and that the set-up be similar to what is being used for the SCBA CBRN protocol where only the cylinder valve is subjected to the chemical agent.

Comment:

1. There are concerns over the affect of two agents and their exposure to pure oxygen.

2. There are concerns over the use of the ABMS in the chemical agent atmosphere and how it is to be protected. Two concerns in this area is if there is breakthrough in the CCBA that it contaminate the ABMS and the other is if there is breakthrough in the ABMS that it could contaminate the CCBA.

3.12.1) The cumulative Ct including all peak excursions points must not be exceeded for the duration of the rated service time of the unit.

3.13) Laboratory Respiratory Protection Level (LRPL) Test Requirement
We recommend that the number of units to be submitted for the LRPL testing be kept to a minimum level. It is understood that based upon previous CBRN experience that this will be an expensive project for the manufacturer and this is one area that the costs can be limited.

It also needs to be considered that CCBA is to be disassembled, cleaned / disinfected, assembled (scrubber and the cooling system recharged), and tested prior to the next use.
This usually requires training by the manufacturer, which can be done on site or at the manufacturer's facility for the lab personnel.

An alternative to this would be to have the manufacturer perform this service. Another option that would help speed up the LRPL tests, if there were many test subjects available, is a turn-around kit that would contain the required fresh components that could be readily installed. We feel that the oxygen cylinder contains enough volume that the same cylinder can be reused for multiple tests.

Training also needs to be considered for the test subjects in the operation of the CCBA during the LRPL test. This also presents additional issues because not only do the subjects have be trained in the proper donning of the facepiece they also need to be trained in the proper operation of the CCBA.
Therefore the normal LRPL training period with practice sessions will need to increase from the current 30 minute period to approximately one hour or more.

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 011 49 451 882 2678.

Respectfully,
Bodo Heins

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