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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)

September 16, 2005

Dear Sir/Madam:

Draeger Safety is worldwide one of the market leader of Closed Circuit Breathing Apparatus (CCBA) and has sold many units 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 June 20, 2005:

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

Continuing our concerns submitted previously dated January 31, 2005, we would like to suggest, that 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 the continual improvement of the standard for the special requests.
Any extreme requirements additional cannot be matched with any of the units being in the actual markets. It would require complete new developments and would last several


years, what cannot be in the interests neither of NIOSH, nor of the customers. We have big concerns, that the standard is following more and more firefighter requirements including extreme environmental conditions.

Breathing resistances

<table>
<thead>
<tr>
<th>NIOSH</th>
<th>at 40 L/min (24x1.66)</th>
<th>0 - 5.1 mbar</th>
<th>at room temperature 24 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBRN</td>
<td>at 40 L/min (18x2.22)</td>
<td>0 - 20 mbar</td>
<td>at -32 °C - +71 °C</td>
</tr>
<tr>
<td></td>
<td>at 100 L/min (30x3.33)</td>
<td>0 - 20 mbar</td>
<td>at -32 °C - +71 °C</td>
</tr>
</tbody>
</table>

When both standards needs to be fulfilled, the existing units cannot match! It has to be taken into consideration, if it is really better for a user, that he has to breath uncomfortable for 4 h against a high breathing resistance, only for the unlikely event, that he has for a short time (too extreme often in the standard) needs to breath with 100 L/min

Suggestion: Take the values of the EN 145, a standard which is grown since decades following the characteristics of CCBA and is giving units state of the art. There are 3 options:
1) The unit will stay in 42CFR condition and it will be accepted that at high work rates the resistance will become timewise negativ. For that it needs to convince the firebrigades, that negative pressure does not automatically mean leakage.

2) To take out of the standard, that the 42CFR resistance § has to be performed.

3) To install a button, to switch the spring from normal to high breathing rate. Cannot be done without constructive changes.

NIOSH is still looking to the NFPA standard 1981. The different calculation factor discussed on the public meeting is decided to be 8/3 instead of $\pi$, because the breathing curve of the used Biosystem Posicheck 3 unit (because it is an available one!) in a non sinusodial curve, for which $\pi$ would be the factor. So the factor 8/3 means, that a flow rate of 103 L/min at the Posicheck is equal 255 L/min constant flow. This forces any manufacturer to buy this machine.

Service times
The service time will be determined IAW 42CFR table 4 in a man test. Which is very subjective and not reproducible for the manufacturer and should therefore be subject of a replacement by a machine test.
Again the EN 145 should be taken (NIOSH wants to be international!) to become objective and reproducible!
But note: you cannot transfer the same values to a machine test! A machine test is
much stronger and needs to have adequate values. Our experience in the past is, that a breathing minute volume of 41 L/min (24x1.66) would be close to give similar values as a man test.

If the service time will be 4 hours at room temperature, how long has it to be at -32 °C / +71 °C?

The same time will be impossible!
Follow EN 145 which is testing at a breathing machine with 30 L/min adding 1.35 L CO2 and allows less than 2 Vol% CO2, +45 °C inhalation temperature and will be run at the machine for 45 min.

How long will be tested IAW the CBRN CCBA standard at – 32 °C / +71 °C?
It would make no sense, to do it the full service time, because the unit will not last that time.
It should only be tested for less than an hour, to prove that it can do it.
Missing the service time determined at room temperature IAW table 4 must not be a fail criteria.

• CO2 breakthrough at low temperature
NIOSH -5 °C stored and tested.
also possible : -15 °C, when the unit was stored at room temperature (or i.e. +10 °C)

CBRN - 32 - + 71 °C cannot be performed with the existing units and the existing sodalime.
Possible solution (would mean different versions):
Using Draegersorb 500 from – 32 °C – 0 °C
Using Draegersorb 400 from – 5 °C - + 71 °C

In Russia i.e. they test the units 30 min stored at +10 °C and go then in a climate chamber with –40 °C and test the unit for 72 min. The PSS BG4 is approved for it.

Suggestion again, follow the EN 145
One other solution would be, to store the unit at ambient temperature (approx.+10 to 24 °C) before the extreme temperature tests will be performed.

• Inhalation temperature
+ 50 °C will be ok for normal ambient temperatures. For + 71 °C you would need a permanent exchange of the cooling substance.
How long will the + 71 °C test be performed?

• Oxygen content
The revised oxygen content of >15% should be allowed for short times only, not permanent.
At this time we would like to recommend to withdraw from the 42CFR requirement to have at least 1.5 L/min oxygen flow.
This is a requirement from previous days, when in addition to a constant flow, no LDV function was included. Our suggestion is, to change this requirement into 1.5 L/min ± 0.3 L/min, when additional to the constant flow a LDV function would guarantee that the user will get at any time enough oxygen. This would help to perform the maximum service time and to prevent excessive oxygen running out the unit at times with low working rates. This reduces the possible but unlikely danger of fire.

**Mask performance at low temperature**
If the mask would be stored 12 h at – 32 °C and then used, the visor would be fogging immediately and no chemical could prevent it. Any anti-fog solution is based on the function, to prevent the built up droplets of water and create i.e. a water film, but still water, which freezes immediately.

Possible solution:
1) The mask will be put on at room temperature and then enter the climate chamber
2) Recommended solution: The unit as well as the mask has to be stored at room temperature (down to + 10 °C) and then perform the – 32 °C test for a limited time.

EN 145 is giving 2 classes only (following the characteristic of CCBA’s):
   - 6 °C and – 15 °C, for approval it will be tested for 30 min.
3) In Russia is requested, to store the unit at + 10 °C and then be used at – 40 °C for 72 minutes.

We suggest a storage at room temperature (solution 2) should be performed.

**Use in extreme temperatures**
At – 32 °C also the circuit valves have to be protected against freezing on their seat. This could be done with an isolation, which means a special version of the unit, which has to be removed/ replaced at the high temperature testing/use.

As well the complete unit must be covered with an isolation against deep temperatures, which also has to be removed under normal conditions.

It would be necessary to submit a basic unit for approval with several accessories to be fit on or of for the different extreme requirements. A unit prepared for deep temperatures would not pass the requirements for high temperatures and reverse.

**Flame resistance**
This would require a protective cover over the hoses, but it has to be taken in consideration, that it effects the inhalation temperature, if it has to be on the whole time (see above).

**Testing time with LAT**
The required test time as service time + 1 hour is not possible at this type of unit.
When the service time is at the end, the unit has to be taken out of service, because the oxygen ( and the capacity of the sodalime ) is out then and no breathing is possible any longer. The end of service indicator forces the user long before, to leave the contaminated area.

The unit has to be tested with the lid covering the unit.

For PAPR the test conditions shall become similar to the SCBA requirements, which means that that approx. 36 L/min will be put into the hot chamber and rinse the agent at the time when the challenge is switched off. This should become similar here!

We suggest, to approve variations.
To fulfill the specific requirements, different solutions / designs are necessary to perform:
Basic unit plus either
1) for cold temperature (0°C/ -32°C) = isolation+CO₂ Cartridge with DrägerSorb 500
2) hot temperature (-5°C until + 71°C) with CO₂ Cartridge with DrägerSorb 400
3) flame isolation (CO₂ Cartridge with DrägerSorb 500 or 400)
4) chemical protection(CO₂ Cartridge with DrägerSorb 500 or 400)
   or if the unit is stored under ambient room temperature, only DrägerSorb 400 would be enough.
To fulfil all extreme conditions with one unit, without specific accessories, is not possible!

Thank you for the opportunity to provide comments on this document and if there should be any questions concerning these comments, please do not hesitate to contact me at +49 451 882 2678 or via e-mail at Bodo.Heins@draeger.com

Respectfully,

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