Miller, Diane M.

From: Dmitri Kazakov [dima11@optushome.com.au]
Sent: Friday, May 27, 2005 2:24 AM
To: NIOSH Docket Office; Szalajda, Jonathan V.
Cc: goran@sea.com.au; Graham.Powe@seasafe.com.au; Bruce.Daniel@seasafe.com.au; Andrew.Smith@seasafe.com.au
Subject: SEA proposition for NIOSH draft PAPR standard 30 March 2005.


March 2005 NIOSH draft questio...


March 2005 NIOSH draft questio...

→ Same document; 2 different formats

Dear Sirs

I have to apologise for sending this e-mail second time. In my previous e-mail I forgot to remove the disclaimer.

The S.E.A. team would like to present the attached document (MS Word and PDF versions) for your attention. We believe it may help you further in the PAPR standard development.

--
Best regards,
Dmitri **mailto:dima11@optushome.com.au**

1. Background

NIOSH is developing a new standard, currently entitled *CBRN PAPR Concept Paper* in draft form, to specify requirements for PAPRs for CBRN applications. The SEA team want to express some concerns and comments to latest standard draft revision

The current draft of the NIOSH CBRN spec is 30 March 2005 (see attachment), which will be quoted and referred below.

Q:\Projects\Project Files\02003 NIOSH DI

7.3 Required NIOSH corrections/clarifications:

7.3.1 Section 1, Paragraph 5:
Multiple requirements information (requirements of 99.97%) at the Section 1, §5, Section 5.3 and Section 5.3.9. We would recommend to NOSH to have the requirement above in one place and in other places refer to it.

7.3.2 Section 1, Paragraph 6:
"Canister capacity and particulate efficiency testing is done at flow rate determined by the maximum flow rate of the respirator" is contradict to Section 5.2. Table 3: "Filter canister tests are performed"... "Class capacity #" .... "At constant flow of 300l/min"

7.3.3 Section 4.2
Reference to Section 4.2 should refer to Section 4.1

7.3.4 Section 4.3.1.2:

a. "The indicator shall also be able of alerting the user ***prior*** to the negative pressure condition". There is no method to predict the negative pressure as the breath pattern has the random nature. NIOSH's last sentence sounds more like a negative mask pressure warning requirement than a low temperature low battery warning requirement. We recommend to change this paragraph to: "The Low battery Indicator must be capable of monitoring the battery conditions and signaling the user when the remaining operational battery capacity is no longer sufficient to sustain the desired flow rate when evaluated at the manufacturer's lowest specified operating temperature, at this temperature there is no minimum time limit or maximum time limit."
b. If the clause is intended to refer to battery warning, we propose that a negative mask pressure warning clause be added to clause 4.3.2.

7.3.5 Section 4.3.2 and 4.3.2.2, row 5 in the table at 5.11:
The "Low Flow indicator" is not what the user concern about. It is important to maintain the positive pressure inside the mask (as also mentioned at NOSH draft on Section 4.3.1.2). We recommend to replace it with "Low Flow/Pressure indicator". We propose the following

wording of the first sentence: "Each CBRN tight fitting PAPR shall have an indicator to alert the user when the airflow in the breathing zone reaches the minimum flow required to maintain positive pressure in the breathing zone."
SEA objects to the clause: "...must be capable of maintaining positive pressure in the breathing zone ***until*** the low flow alarm signals the user." As stated above (see 7.3.4, paragraph a), there is no method to predict negative mask pressure events.

7.3.6 Section 4.4.5 "The Breathing Performance Test Time"

a. It would be an advantage to specify the temperature as the battery capacity very from the temperature and it would affect the battery performance.
b. There was confusion about plus 20 minutes requirements. It will be a benefit to clearly define that it is just recording time and it does not mean that unit should perform during these extra 20 minutes. SEA assume that the unit may stop any time during this period or after it.

7.3.7 Section 4.7.2 "Human Subject Breathing Gas testing"

a. The STP does not describe the method for distinguishing the inhalation portion of the breathing cycle. Please provide this.
b. SEA *assumes* that the test is running with PAPR motor ON condition.

7.3.8 Section 4.9 "Noise level"

a. Is it measured on Human or manikin head? If on human subjects, what work rate? If on manikin, what BM parameters? This is important for breath responsive PAPRs because the noise level varies with motor speed, which in turn depends on work rate.
b. We believe that the speech amplification equipment should be turned off

7.3.9 Section 5.2 "Canister Capacity"

a. Demand responsive PAPRs consume less air than constant flow PAPRs because demand responsive devices conserve air during exhalation, as do SCBAs. For this reason, SEA believes the existing draft NIOSH CBRN PAPR requirement for gas capacity (300 l/min constant flow test for high breathing rate performance) unfairly disadvantages demand responsive PAPRs. This imbalance should be addressed.
b. SEA believes the most accurate method of testing gas capacity is on a sinusoidal breathing machine. For high breathing rate performance, the BM would be set at 103 litres minute volume (PIAF 324 l/min).
c. While the above method may be suitable for certification testing, SEA is very concerned that for ongoing production it would be prohibitively expensive as it consumes many more filters and much more test gas. For this reason, SEA asks that NIOSH considers allowing equivalent constant flow, single canister gas tests in production. The test flow rate should be determined by measuring the minute volume through the filters (interactive flow volume) when running on a BM set at 103 litres minute volume.
d. Alternatively, gas capacity tests for both certification and production could be performed at a constant flow rate, as described above.

7.3.10 Section 5.3.1.1 "Additional aerosol efficiency test after cyclohexane"

a. The Paragraph 6.1 is mentioned. The draft does not have such paragraph. We assume that it is the reference to the paragraph 5.1. We also **assume** that the pass/fail criteria are the same as for the new filters.
b. Section 5.3.1.1 and 5.3.1 calls for 60 and 6 canisters, but 5.11 test sequence calls for ***sets*** of canisters.

7.3.11 Section 5.3.4

a. The Paragraph 6.2 is mentioned. The draft does not have such paragraph. We assume that it is the reference to the paragraph 5.2.
b. Is this paragraph referring to 6 canisters Additional from cyclohexane test (Section 5.3.1.1)? If not (It is applicable to 20 canisters) the next sentence "The twenty production canisters will be tested at 85 l/min" contradict to previous flow rate requirement reference to the Paragraph 6.2. Does it mean that these 20 canisters will be tested second time at 85 l/min or it will be another set of 20 canisters? At the moment SEA read that "The twenty production canisters will be tested at 85 l/min ..." will be replaced with "The six canisters from cyclohexane test will be tested at 85 l/min ..."

7.3.12 Section 5.3.9 "Additional aerosol efficiency test after cyclohexane"
We are assuming the 99.97% criteria applicable to 20 canisters and additional 6 canisters. See comments 7.3.11. It would be a benefit to have a reference as stated at 7.3.1

7.3.13 Section 5.4
All the arguments given in section 7.3.9 for canister capacity apply to Crisis (Panic Demand) Provision, except that the flow rates must be higher, and the duration is 5 minutes minimum.

7.3.14 Section 5.5.2 "System service test"
The capacity tests described above (on breathing machine) already account for the flow uniformity through the filters due to the system manifold effect. Breakthrough will occur when the highest flow or weakest canister breaks through We believe there is no need for this test.

7.3.15 Section 5.6 "Low temperature fogging test"
The test specifies -21C for 4 hours soaking for the respirator. We are assuming that it is not applied to the battery as we are not testing the battery.

7.3.16 Section 5.10 "Durability conditioning "
Table 7, last row specifies the Drop test for canisters at *individual* packaging container, however the Section 4.1.1 stated that "The canisters shall also be subject to an Rough Handing Drop Test in its designed Minimum Packaging Configuration. The discrepancy above should be resolved and method clearly defined. SEA strongly believes that the canister should be tested in the minimum *sealed* packaging of canister or canisters. So if canisters were individually sealed then bundled together, they should be unbundled before drop testing.

7.3.17 Section 5.11 "Test sequence "

1. The Table. "Particle Canister Degradation" is the same as "Service Life time". We believe that the row 7 for Particulate Canister Degradation should be replaced with "Service Life Test Less Cyclohexane" to "Service Life Test with Cyclohexane".

2. Is the "Efficiency Particulate Canisters" the same as the "Particle Canister Degradation"? It would be an advantage to have some clarification for the difference and purpose.

7.3.18 Section 4.4.4 "Breathing performance requirements"
SEA assumes that NIOSH in paragraph 4.3.1.3 means that at the minimum temperature unit operational duration should not less than 40 or 35% required duration at 25°C. However the way it is written could be understood that the unit should maintain positive pressure more than 40 or 35% of all battery duration time. (I.e. include the time when unit go negative if Breathing Machine can over-breathing the unit). If it is wrong interpretation please add some clarification to the paragraph so to prevent uncertainty.

7.3.19 Section 5.14 "Failure Mode and Effect analysis"
This does not make sense. FMEA is a tool for identifying the most important problems in a design, not a tool to produce zero failure equipment. I would remind NIOSH that NASA and the FAA both work hard to achieve this and have not achieved the desired result.
FMEA can minimize failures but not eliminate them completely

7.3.20 Section 5.9 "LRPL test requirements"
SEA expects that NIOSH will discount the effect on LRPL results of harmless particles given off by the fan unit.