## Miller, Diane M. (CDC/NIOSH/EID)

**From:** Sell, Robert [Robert.Sell@draeger.com]
**Sent:** Monday, February 16, 2009 10:28 AM
**To:** NIOSH Docket Office (CDC)
**Cc:** Rehak, Timothy R. (CDC/NIOSH/NPPTL); Rueck, Klaus-Michael; Drews, Wolfgang; Wezurek, Horst; Betzinger, Robert
**Subject:** Draeger Comments for Docket RIN: 0920-AA10 for 42 CFR, Pt 84
**Attachments:** Draeger CCER Comments 2-2009 - RIN-0920-AA10.doc

Hello:

Attached please find Draeger Safety's comments on the proposed standard for CCER's. If there should be any questions concerning the attached information please do not hesitate to contact me.

Regards

Bob Sell

Sr. Project Engineer - Protection

Dräger Safety, Inc.
101 Technology Drive
Pittsburgh, PA 15275
Tel: (412) 788-5685
Fax: (412) 787-2207
Mobile: (412) 996-9344
Robert.Sell@Draeger.com
www.draeger.com

Dräger. Technology for Life®

Dräger

February 9, 2009

NIOSH Docket Office
Robert A. Taft Laboratories, M/S C 34
4676 Columbia Parkway
Cincinnati, Ohio 45226

Telephone 513-533-8303, Fax 513/533-8285
Email: niocindocket@cdc.gov

Reference: RIN: 0920-AA10
Approval Tests and Standards for Closed-Circuit Escape Respirators;
Notice of Proposed Rulemaking – 42 CFR Part 84

Dear Sir / Madam:

Draeger Safety manufactures respirators for various markets and applications therefore we offer the following comments in response to the Federal Register Notice which was published on December 10, 2008 on the Notice of Proposed Rulemaking for Closed-Circuit Escape Respirators

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

**Section 84.301: Applicability to new and previously approved CCERs**

**Section 84.301(a)(2):**

Draeger Safety supports the proposed three (3) year phase in period which allows users to purchase CCERs for use and for manufacturers to provide product to the market.

**Section 84.301(b):**

Draeger Safety also agrees with the proposed six (6) year period where currently approved CCERs are available for use before their approvals are rescinded. However, we do not support the one alternative that was requested for comment of allowing CCERs to remain in service for the full service life which could allow older product to remain in the field for 13 to 18 years.

Dräger

**Section 84.303: General testing conditions and requirements**

**Section 84.303(a):**

We would like to ensure that the instructions for use are also evaluated during the testing and we would like to propose the following text changes:

(a) NIOSH will conduct capacity and performance tests on the CCER, in accordance with the manufacturer's instructions, using a breathing and metabolic simulator to provide quantitative evaluations and human subjects on a treadmill to provide qualitative evaluations.

**Section 84.303, Table 1:**

Peak Breathing Pressures:
The current wording in the draft proposal for the acceptable range operating average identifies "$_{D}P \leq 200$ mm $H_2O$" which can be interpreted as ±100 mm $H_2O$ or ±200 mm $H_2O$. We also believe that the values for inhalation and exhalation resistances should use "-" sign for inhalation and "+" sign for exhalation limits.

In general, breathing resistances are a heavy work load for CCER users and this is especially apparent for escaping individuals in a panic situation. In order to prevent the user from discarding the unit because of unacceptable breathing resistances we propose that the *Acceptable Range Operating Average* be ±100 mm $H_2O$ and the *Acceptable Range Excursion* be a maximum of ±200 mm $H_2O$.

Wet-Bulb Temperature:
We suggest that a Dry Bulb temperature be used for monitoring the temperature stressor because Dry Bulb temperatures are technically easier to measure in the laboratory or during man test situations. Also, comparing the wet bulb temperature to the users sense it in their trachea is only true for wet skin/surfaces which is not always the case during CCER use.

**Section 84.304: Capacity test requirements**

**Section 84.304(e):**

Draeger Safety would like to suggest that when the capacity rating is assigned for the CCER that it is based upon the average of the seven units tested and not on the least value achieved by the seven units when tested. The prerequisite for this determination must also include that all of the values obtained need to be within the given capacity rating that is being requested. If the lowest value is not within the requested capacity rating then the capacity rating is to be assigned based upon the lowest value. For examples:

Dräger

1. The following values are obtained after testing the seven units: 89, 86, 85, 87, 86, 85 and 80 which results in an average of 85.4. These units would then be certified as a CAP 3/85 due to the nearest lower value 5 L increment of the average and not 80 as proposed for the least value.

2. The following values are obtained after testing the seven units: 85, 83, 84, 83, 86, 82 and 78 which results in an average of 83. Because one of the values obtained was not within the requested Capacity 3 range the units would be certified as a CAP 2/75 due to the nearest lower value 5 L increment of the average. If this is the case, then the units would need to be retested to the Capacity 2 requirements

3. The following values are obtained after testing the seven units: 85, 83, 84, 83, 86, 82 and 80 which results in an average of 83.3. Because all of the values are within the requested Capacity 3 range the units would be certified as a CAP 3/80 due to the nearest lower value 5 L increment of the average.

We therefore propose the following text:

(e) NIOSH will document ~~the~~ all of the ~~least value~~ values achieved by the seven units tested using the breathing and metabolic simulator and calculate the average. NIOSH will quantify this average value of achieved capacity within an increment of 5 liters, rounding intermediate values to the nearest lower 5 liter increment. All values obtained shall be within the capacity range requested by the applicant in order to be certified.

**Section 84.304, Table 2**

We would like to propose adding two additional capacity ratings and modifying the Cap 3 oxygen capacity and offer the following:

| Capacity Rating | Capacity (L of $O_2$) | $VO_2$ (L/min) | $VCO_2$ (L/min) | Ve (L/min) | RF (Breaths/min) |
|---|---|---|---|---|---|
| 1 | 20 ≤L ≤59 | 2.50 | 2.50 | 55 | 22 |
| 2 | 60 ≤L ≤79 | 2.00 | 1.80 | 44 | 20 |
| 3 | 80 ≤L ≤89 | 1.35 | 1.15 | 30 | 30 |
| 4 | 90 ≤L ≤99 | 1.35 | 1.15 | 30 | 30 |
| 5 | L ≥100 | 1.35 | 1.15 | 30 | 30 |

It is our opinion that the oxygen capacity on the high end could be have further categories for mining applications and that the other parameters could remain the same. In addition, we would also like to suggest that the capacity rating is to be identified on the device itself to make it easier for the user see the information clearly without having to go through the product literature or the instructions for use which may not always be available to the user.

**Section 84.305: Performance test requirements**

**Section 84.305(a) (3):**

We would like to suggest that the rate of speed be identified for the how the treadmill is to be operated. Also we can only assume that the treadmill in question is a horizontal treadmill to be used for the purpose of walking or running and the text should also help clarify this too.

**Section 84.305(c):**

Draeger would like to propose an additional requirement to this section. The continuation of testing of a unit which is exhausted before the test sequence is finalized is only to be permitted if the entire 5 minute initial peak flow test was completed successfully. A unit which does not complete the 5 minute peak flow test is not to be certified and we propose the following text:

(c) Testing of CCERs with less than 50 liters of capacity, as determined by the capacity testing under § 84.304, will require the submission of additional test units to fully apply the work-rate test sequence and requirements specified in Table 3. The testing of each individual unit will complete the cycle specified in Table 3 until the breathing supply of the initial test unit is exhausted. This initial test unit is required to complete the entire cycle of the peak flow test sequence and will then be replaced by a second unit, which will continue the test cycle, beginning at the work rate in the cycle at which the initial unit was exhausted, and completing the full period specified in Table 3 for that work rate before proceeding to the subsequent work rate, if any, specified in Table 3. Each initial testing unit will be replaced as many times as necessary to complete the cycle, not to exceed two replacement units per initial test unit.

**Section 84.305(d)**

It is our understanding that during this testing that NIOSH wants to evaluate the units for their susceptibility to hypoxia. Therefore if the units are operated in accordance with the instructions for use, which we commented on above under Section 84.303(a), this could not accomplished for units that provide an initial oxygen supply by means of a "starter". We would like to amend the wording for this section to allow for the hypoxia test but

Dräger

after this has been completed the "starter" is then to be activated. Our suggested text follows:

(d) The performance test will begin with two exhalations into the unit at the specified ventilation rate to determine the design's susceptibility to hypoxia. Upon completion of this cycle if an oxygen assisted supply is provided it shall be activated and the testing cycle will be completed.

**Section 84.305, Table 3:**

In the beginning of an escape it is reasonable to believe that the user will reach the peak values but during a long duration escape of 30 minutes or more this work load will decrease and the work rates would be within the high and low rates. We therefore suggest that table be adjusted so the repeating cycles only test to the high and low work rates. Our suggested modification to Table 3 is:

| Work-rate test sequence | Duration per cycle (min) | $VO_2$ (L/min) | $VCO_2$ (L/min) | Ve (L/min) | RF (breaths/min) |
|---|---|---|---|---|---|
| 1. Peak | 5 | 3.00 | 3.20 | 65.0 | 25 |
| 2. High | 15 | 2.00 | 1.80 | 44.0 | 20 |
| 3. Low | 10 | 0.50 | 0.40 | 20.0 | 12 |
| 4. High | 15 | 2.00 | 1.80 | 44.0 | 25 |
| 5. Low | 15 | 0.50 | 0.40 | 20.0 | 12 |

**Section 84.306: Wearability test requirements**

**Section 84.306(a)**

Training in the use of a CCER is a Mine Safety and Health Administration requirement (30 CFR, Part 75.1504) and training should also apply to the test subjects performing the tests identified in this section. We propose that wording be included to ensure that the subjects have been trained in the use of the CCER before testing.

(a) NIOSH will conduct the wearability test on a total of units submitted for approval. The human subjects (two (2) males and one (1) female), one subject per unit, will be trained in the use of the CCER prior to conducting the test. The three subjects will…

Dräger

**Section 84.307: Environmental treatments**

**Section 84.307(b)**

This section does not identify if this preconditioning is evaluating temperature shock by going from one extreme to the other immediately or if the units are permitted to be returned to room temperature before the next cycle. We suggest that prior to the next temperature cycle and after completion temperature exposure that the units are permitted to return to room temperature prior to the next steps. We propose the following change to the text for this section:

(b)(1) Upon completion of each temperature cycle the units shall be conditioned to room temperature (22 ± 2° C / 72 ± 3° F) for four (4) hours.

**Section 84.307(c)**

We would like to suggest that a diagram or some other method be included in the document to define the six (6) different sides that are to be tested. The text currently used in the document is ambiguous and does not accurately define these positions.

**Section 84.307(d)**

We do not feel that vibration testing to high frequencies above 500 Hz is relevant for these devices if they are properly stored or worn on the body. We suggest that the third test sequence identified in Table 5 is removed and replaced with another shock test that would account for heavy bumps, drops, and shock that is seen during normal use. We suggest that the additional shock test (BS EN 60068-2-29 or equal) use the following parameters:

- Number of shocks/bumps = 12,000 (2,000 in both axis directions)
- Acceleration = 40 g
- Duration of shock/bump = 6 ms

**Section 84.310: Post certification testing**

**Section 84.310(g)**

We agree with the intent of this section, but what is to happen in the event that the manufacturer decides to discontinue production of the product due to a newer product being approved? Is the manufacturer required to still adhere to this requirement for the older CCER? Currently, manufacturers do not inform NIOSH when a product is going to be discontinued and if they are to meet the requirement specified here this would cause additional costs for the manufacturer. For a device with a service life of 10 years the manufacturer would potentially be required to provide an additional 1000 units which would either be produced or stocked as inventory for the ten years or to reopen production capability to produce new units to ensure that this requirement is met. We

Dräger

suggest that a "phase-out" plan be considered in order to address equipment that is no longer being offered for sale.

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
Sr. Project Engineer

cc: W. Drews – DST
K. Rueck – DST
H. Wezurek – DST
R. Betzinger – DST