Dragon, Karen E.

From: Robert.Sell@Draeger.net
Sent: Friday, May 30, 2003 11:50 AM
To: niocindocket@cdc.gov
Cc: Mary.Doane@Draeger.net;
Arnd_Kausch/AR/Luebeck/Draeger__ST/DE@Draeger_ST_DE.draeger.net;
Kirstin_Denker/AR/Luebeck/Draeger__ST/DE@Draeger_ST_DE.draeger.net;
Bodo_Heins@DRAEGER_ST_US.draeger.net;
Manfred_Krause/Z/Luebeck/Draeger__ST/DE@Draeger_ST_DE.draeger.net;
Horst_Wezurek/DR/Luebeck/Draeger__ST/DE@Draeger_ST_DE.draeger.net
Subject: Docket Reference No.: NIOSH 05

Docket Ref. #
NIOSH 05 SCSR Pu..

To Whom It May Concern:

Attached please find Draeger Safety's comments for the above mentioned docket number.

If there should be any questions, please contact me at 412-788-5685.

Regards,

Robert Sell

Robert Sell
Technical Product Mgr., Protection

(See attached file: Docket Ref. # NIOSH 05 SCSR Public Comments.doc)

Draeger Safety

Dräger

May 30, 2003

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

Subject: Docket Reference No: NIOSH 05

To Whom It May Concern:

Enclosed please find Draeger Safety's comments regarding the proposals for the above mentioned Docket Number concerning the rulemaking for Self-Contained, Self-Rescuers (SCSR's).

Please consider our comments concerning the pending changes to the certification and testing requirements. If there should be any questions concerning this matter, please do not hesitate to contact me at 412-788-5685.

Respectfully,

Robert Sell

Robert Sell
Technical Product Mgr., Protection

cc: Mary Doane – DSI
Bodo Heins – DST
Anrd Kausch – DST
Kistern Denker – DST
file

Draeger Safety, Inc.
101 Technology Drive
Pittsburgh, PA 15275-1057
Tel: (412) 787-8383
Fax: (412) 787-2207
www.draeger.net

Docket Reference # NIOSH 05
Comment on 42 CFR Part 84; (Subpart H)
Self-Contained Self-Rescuers

1. General / Introduction:

The purpose of the following comments is to improve the suitability of Self-Contained, Self-Rescuers (SCSR's) with particular attention to the robustness and reliability by means of improved or modified tests that are more adapted to the practical use of SCSR's. Special focus is put on the reproducibility and un-ambiguity of test procedures.

2. Service Life

If the aim of NIOSH / MSHA is to reduce the service life of SCSR's; i.e.: to 5 years, Draeger Safety would be in favor of this proposal, if the conditions for all manufacturers were the same.

One possible method, in order to reduce the weight and size of the SCSR may be to look at different service times. A lighter weight unit would be less cumbersome to the user and would have a reduced service life because it is man carried. Whereas, a longer duration unit, which would be larger in size could be used for a cached SCSR and have a longer service life since they would not be subjected to day-to-day carriage by man or machine.

Each of these options would implement a different series of tests.

3. Indicators

There are essential parameters that can be observed by the users if they were incorporated into the SCSR's. Indicators for reading humidity, temperature exposure, and vibration are three indicators that can be installed. Any and all indicators would need to be observed from the outside of the SCSR for ease of inspection. The use of indicators would let the user know if the SCSR has been used outside of the parameters located in the respective Instructions for Use. In addition, the indicators would also serve as an indication that the SCSR is to be removed from service

4. Registration of the devices

The manufacturers can control and trace product down to the distribution level and in some cases even down to the end users, but there are some distributors who do not like to reveal their customers to the manufacturers. There have been attempts to get SCSR's registered via warranty cards and other methods, but they do not always work.

Tracking of the SCSR's is a critical issue, and we feel that this falls more into the enforcement phase than into a standards document.

5. Classification of the devices

Draeger Safety would like to propose two categories for SCSR's and that the distinction, is how they are used in service.

Cache units:
- Devices that would be stored / cached only; i.e.: Customer warehouse, a secure Storage location whether above or below ground.
- Relatively low mechanical / environmental stress occurs and only a transport program (see 8) would be used for mechanical pre-stressing of the units.

Body-worn / Machine carried units:
- High mechanical stress occurs.
- A vibration program (See Item 6) and the drop test would be used for mechanical pre-
  Stressing of the units.

Duration / Service Time:
- Service time of the SCSR's could be classified in 10-minute increments starting from 10 minutes up to one hour.

6. Environmental Testing for "body-worn / machine carried units"

6.a Vibration

In order to achieve reproducible results for the mechanical tests (vibration/shock) we suggest that the mechanical tests (vibration/shock) be performed on an electromechanical vibrating table instead of using the current RoTap tests. We recommend that the SCSR's be divided into weight classifications and that test programs be allocated to the weight classes because SCSR's heavier 2 kg are subject to a lower vibration stresses.

The recommended classifications are shown below:

Recommended sinusoidal vibration test:

Device group	Frequency range with related vibration amplitude	Test period with sliding frequency per axis in min.	Cycle times in min. for frequency range 5-200-5 Hz	Load alternation per cycle
devices of up to 2 kg	5-9 Hz with 10 mm 9-32 Hz with 3 g	180	12	$3{,}8 \times 10^4$

	32-60 Hz with 0,75 mm 60-200 Hz with 10 g			
devices of up to 2-5 kg	5-9 Hz with 7,5 mm 9-37 Hz with 2,5 g 37-52 Hz with 0,46 mm 52-200 Hz with 5 g	180	12	$3,8 \times 10^4$

Recommended semi-sine permanent shock testing:

Device group	Shock acceleration in		Shock period in	No. of shocks per	Total no. of
	m/s^2	g_n	ms	direction	shocks
devices of up to 2 kg	392	40	6	4000	24000
devices of up to 2-5 kg	392	40	6	2000	12000

The specified tests have proven to be useful considering the practical use.

The marginal conditions for the sinusoidal vibration test and the semi-sine permanent shock testing are as follows:

- The devices must be **firmly** clamped onto the vibrating table, so that they cannot make any relative movements in the direction of the table.
- Vibration and shock programs are performed one after the other with the same clamping force (device axis).
- Three device axes are tested.
- The order of the axes to be tested is not defined.
- During the subsequent (machine) breathing test the devices must still meet the breathing reference values of the manufacturer (i.e. CO_2 inhalation concentration, inhalation/exhalation resistance, operating period, inhalation temperature).

6.b Shock (Impact Test)

In order to test the shock resistance of the device it must be dropped onto a concrete floor from a height of 1.5 m in three different positions.

Remarks concerning this test: This test originates from the testing of hazardous goods. The devices are only evaluated according to the criterion, that no hazardous substances (hazardous goods) may be released from the device.

We also recommend to perform an orientation drop test during which the device is dropped onto a concrete floor six times (once on each side) from a height of approx. 1.1 m. Afterwards, the unit must be fully functional, i.e. the referenced values of the manufacturer must be reached.

7. Environmental Testing for cache units

7.a Transport program

Recommended sinusoidal vibration test:

Frequency ranges with respective vibration amplitude	Test period with sliding frequency per axis in min.	Cycle times in min. for the frequency range 5-200-5 Hz	Load alternation per cycle
5-8 Hz with 7,5 mm	156	12	$3,8 \times 10^4$
8-200 Hz with 2 g			

Recommended semi-sine permanent shock testing:

Shock acceleration in		Shock period in ms	No. of shocks per direction	Total no. of shocks
m/s^2	g_n			
245	25	6	1000	6000

The specified tests have proven to be useful considering the practical use.

The marginal conditions for the sinusoidal vibration test and the semi-sine permanent shock testing are as follows:

- The devices must be **firmly** clamped onto the vibrating table, so that they cannot make any relative movements in the direction of the table.
- Vibration and shock programs are performed one after the other with the same clamping force (device axis).
- Three device axes are tested.
- The order of the axes to be tested is not defined.
- During the subsequent (machine) breathing test the devices must still meet the breathing reference values of the manufacturer (i.e. CO_2 inhalation concentration, inhalation/exhalation resistance, operating period, inhalation temperature).

8. Corrosion test

We recommend performing a corrosion test with a defined salt spraying test.

9. LTFE: new devices/body-worn / machine carried units

The **new device** must meet the complete required test program of the standard. Apart from the service time (operating time until breathing bag is empty) for which the device is approved also the parameters of the standard such as CO2 concentration, inhalation air temperature, breathing resistance must be met without limitations.

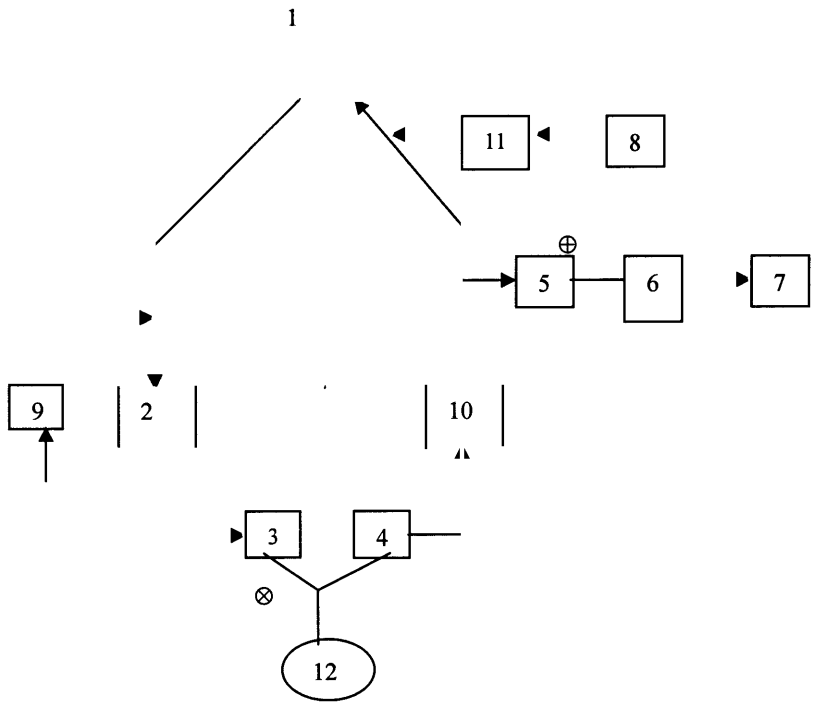
Body-worn units
For body-worn units no limitation of the service life (operating time until breathing bag is empty) for which the device is approved shall be allowed. However, we suggest allowing a deviation in per cent; i.e.: Inhalation resistance, in order to allow a certain limit value per year of being carried.

10. Breathing test (using breathing machine)

Here an exact definition of the lung simulator is to be used (schematic drawing from EN) is required in order to obtain reproducible and comparable data. (See attachment #2)

The breathing simulator test is meant for the measurement of the nominal service time as well as the basic breathing performance of the SCSR device.

The definition of the breathing simulator shall comprise a basic functional scheme of the test equipment, as follows:



1	artificial lung (main circuit)	10	heat exchanger (cooler)
2	humidifier	12	SCSR to be tested
3 + 4	magnetic valve		
5 + 11	non return valve		
6	auxiliary lung (sample gas)		
7	CO2 + O2 analyzer		
8	CO2 dosage		
9	CO2 analyzer		

For the standard performance test using the breathing simulator, the following parameters with references to the ambient conditions shall be defined:

	frequency	**Volume per stroke in main circuit**	**volume per stroke in sample gas flow**	**CO2 dosage**
unit	per minute	liters	liters	grams/minute
remarks/ parameters	deviation max 0,2 /min	behind valve 3:⊗ ≥ 95 % r.H. 37 °C ± 2	behind valve 5:⊕ volume acc. to dosage of CO2	controlled by mass flow meter
example: standard performance test	20	1,75	0,0745	2,72

Accuracy of test equipment used in breathing simulator test device shall be defined:

	CO2 analyzer	**O2 analyzer**	**Temperature**	**Breathing resistance**
unit	Vol %	Vol %	°C	hPa
remarks/ parameters	range 0 - 10 accuracy 0,05	range 0 - 100 accuracy 0,5	measured by Ni-CrNi thermocouple, diameter of weld max. 0,2 mm	diff. pressure indicator, 0 →30 hPa in t_{90} < 0,5 s

The nominal service time test using the breathing simulator shall be performed at room temperature (23 °C ± 2). The desired performance of the SCSR shall be defined by:

	CO2 conc., inhal.	**CO2 conc., inhal. for a limited period of time**	**O2 conc., inhal.**	**breathing resistance, inhal.**	**breathing resistance, exhal.**	**temperature, inhal.**
	mean	max.	min.	max.	max.	max.
example	≤ 1,5 [Vol%] during nominal service time	3 [Vol%] for 2 minutes	17 [Vol%] during nominal service time	- 10 hPa	+ 10 hPa	75 ° C

In addition exact and generally applicable parameters to be set in relation to their ambient conditions must be defined.

The breathing machine test is used to determine the operating period of the devices as well as CO2 content, inhalation temperature and inhalation / exhalation resistances.

The man test is to be regarded as an additional practical performance test and is used to evaluate the ergonomic interface; i.e.: donning, wearing characteristics, handling and wearing comfort of the units during simulated operations.