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**From:** Rueck, Klaus-Michael [Klaus-Michael.Rueck@draeger.com]
**Sent:** Friday, February 11, 2011 10:30 AM
**To:** NIOSH Docket Office (CDC)
**Cc:** Sell, Robert; Hodson, David; Drews, Wolfgang; Nesch, Volker; Schultz, Christian; Blenkiron, Stuart; Donaldson, Angus; Bahr, Axel; Ammann, Klaus
**Subject:** Comments on Commbined Respirator Units RFI Docket 82-A
**Attachments:** Draeger RFI CRU Comments Feb-11-2011.pdf

Good Morning,

enclosed please find comments from Dräger Safety GmbH & Co KGaA in Lübeck Germany, Dräger Saftey Ltd in Blyth UK and Dräger Safety Inc in Pittsburgh USA on the Request for Information for the development of NIOSH CBRN – CRU docket 82A.

If there are any questions reagarding our comments please don't hesitate to contact us.

Mit freundlichen Grüßen/Yours sincerely

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Docket 82-A
CBRN Combination Respirator Units RFI

11. Februar 2011

Dear Sir / Madam,

Draeger Safety manufactures respirators for various markets and applications therefore we offer the following comments in response to the NIOSH notice issued in November 2010.

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

**Title: Chemical Biological, Radiological and Nuclear (CBRN) Combination Respirator Unit.**

We fully support the development of a standard that would allow for the certification of a Combination Respirator Unit but we highly recommend that the proposed standard is created to also allow for industrial applications and not solely for CBRN only applications. From our point of view a new standard should not only be based upon performance but also upon its application and intended use

A CRU-Standard should cover, e.g.

APR/PAPR (tight fit)
APR/Airline (tight fit)
PAPR/Airline (loose fit or tight fit)
APR/SCBA (tight fit; open or closed circuit devices)
PAPR/SCBA (tight fit; open or closed circuit devices)
APR/PAPR/SCBA (tight fit; open or closed circuit devices)

In addition, all these tight fitting variants can be designed for CBRN protection and the CBRN requirements would then be listed in the standard under a separate chapter "Optional CBRN Requirements" or "Enhanced Performance Requirements".

The following comments pertain to the paper issued for CBRN–CRU:

## NOMENCLATURE OF THE CRU:

The nomenclature Combination Respirator Unit (CRU) is acceptable.

## TOPICS OF DISCUSSION:

1. The CRU should have multiple classifications/approvals including IDLH which would be dependent upon the mode in use as long as the CRU meets the performance requirements for each mode of operation. This would also pertain to the required protection factors when the mode is switched. It should also be considered to increase the protection factor testing as it was done for the APR CBRN standard.

2. Automatic Switching should be allowed, but this shouldn't be defined as a mandatory requirement. Detection of hazardous IDLH substances is pretty much dependant on the substances of concern. There is no single method to cover 100% of the possible substances to detect today. A mandatory automatic switching, wouldn't fit to the different wearers applications as they were discussed at the December 2010 stakeholder meeting where two of the presenters preferred that the mode used is dictated by the "Authority Having Jurisdiction". Therefore, manual switching or automatic switching should be permitted. From a safety perspective switching modes needs be a task that the wearer is instructed to do, is done knowingly or in the case of automatic switching the mode change is made known to the wearer.

Example for possible automatic switch operation: An automatic switching from an air-purifying mode to a supplied-air mode based on the hazard level of the atmosphere by the CRU should be allowed, but the wearer has to have the opportunity to take over control by himself. An automatic switching back to a lower protection level based on a detection component has to be possible to override by the wearer.

3. To verify manual switching, units should be evaluated to determine if switching might happen by chance, due to movement during practical performance testing, and even through some type of environmental conditioning or mechanical stress; i.e.: vibration. A mode of operation indicator shall be included (if it is optical it should be within the field of

vision). The user's instruction should contain clear instructions how to switch from one mode to the other or back again.

Switching should be possible by single hand operation, even with gloves, depending on the intended use for the units.

Switching should be allowed in both directions, from one mode to the other and back, or to another mode. Rational: It depends on the tasks of the wearer groups. It is possible that from a threat the scene changes the wearer's exposure of substances. In this case entering would be e.g. in APR or PAPR mode and under exposure to substances the wearer switches to SCBA. Another scenario would be to enter in SCBA mode due to unknown exposure, after clearing the scene and verify the atmosphere he wearer can switch back to a lower level of protection.

## HUMAN FACTOR / TRAINING REQUIREMENT:

1. All CRU units should be labeled with „S" Special Cautions and Limitations because of their special design, mode operations and requirements. These Special Cautions and Limitation, as it is currently done, need to be explained in the wearer's instruction. Due to the multiple modes, basic training should not be permitted and a more enhanced training program needs to be established to ensure that the wearer fully understands the operation and performance of the CRU. For wearers who may be quite familiar with a SCBA and the ease of breathing on the unit could become nervous when operating in a negative pressure mode because of the increased breathing resistance. An example of an enhanced training program would be what the National Fire Protection Association (NFPA) Technical Committee on Fire Service Training has developed in their NFPA 1400 Series of standards.

2. Based on the upcoming new ISO Standard for Respiratory Protective Devices (RPD) we recommend to use the defined three workrate levels (W1; W2; W3):

W1 to be tested at 35 l/min dynamic/110 l/min constant flow;
W2 to be tested at 65 l/min dynamic/180 l/min constant flow;
W3 to be tested at 135 l/min dynamic/ 340 l/min constant flow;

The work rate classes are seen to be the minimum conditions. Manufacturer might claim a flow performance wich is above the minimum level of the three classes for PAPR devices. For such cases the canister/cartridge performance has to be tested at the claimed flow rates.

It is necessary that the manufacturer designates for each mode of operation the relevant workrate class (e.g. for a APR/PAPR/SCBA W1/W2/W3).

Another factor to be considered is the weight requirement of the combined system. When looking at a SCBA/PAPR/APR combination the weight may be exceeded over the current 35 pound limit as noted in 42 CFR, Part 84, Section 84.89. This in turn would increase the work rate of the wearer just during normal activities particularly when the CRU was in a negative pressure mode. Another area for consideration would be how the multiple

respirator components are configured. Does the unit cause undue stress or fatigue to the neck?

Compatibility to other personal protective equipment should be taken into consideration. Since the CRU most likely will be designed and configured for a specific application then this may be the time that NIOSH starts to consider looking at the complete ensemble and the interface between the wearer.

## STAKEHOLDER INPUT

1. We think it would be reasonable to change 42 CFR 84, Section 84.63b to allow a CRU to be worn in IDLH, if the wearer ensures to be in the correct mode to do so. Example: PAPR/SCBA before entering an unknown atmosphere that may be IDLH needs to be in the SCBA mode but once the atmosphere has been assessed then the CRU can be switched to the most suitable mode.

2. Today there is no such detection system available, which is portable and reliable to detect all TIC, CWA, Bio-Organics and Dust or Powder in a simple manner. So a mandatory full automatic switch based on a detected substance would prevent CRU development. This seems to be design restrictive. The way of switching should be open for different options. Automatic switching is possible also in different design levels. (A fully automatic switch actuated by pressing a button willingly by the wearer or a fully automatic switch by the system itself, after a measurement of substances, or others). We believe a mode change not actuated by the wearer himself might cause the wearer to become irritated because of the switch over or in worst case panic if the SCBA set switches in supposed IDLH atmosphere back to APR or PAPR mode. So we think it would be better if the task of switching modes should always be performed by the CRU wearer.

The use of gas detection instruments can be incorporated as an option carried "onboard" respirators and depending upon the instrument it is possible to detect up to a various number of substances (Oxygen, Carbon Monoxide, explosives/flammable gases, specific gases, etc.) but there is a size limitation that needs be considered. In addition, Intrinsic Safety certifications would also need to be addressed in the standard.

3. In addition to the conflicts identified in the concept request for information, NIOSH will need to reconsider the man-date that requires electronic components to be certified by MSHA as Intrinsically Safe in Methane-Air atmospheres in accordance with 30 CFR. There may be applications where the CRU would be used in mining, but many other applications would also be above ground and therefore other Intrinsic Certifications need to be included in the CRU standard.

4. We do not believe that there are concerns or conflict when it comes to the NFPA and their standards due to the working relationship that has been developed between NIOSH and the various NFPA Technical Committees (TCs). Currently, the NFPA TC for Respiratory Protection Equipment is looking at the possibility of including performance and design requirements for SCBAs for other Emergency Services in order to suit their needs. Also, since the NFPA reviews and revises their documents on a 5 year cycle the

development of a CRU standard and the needs of Emergency Services personnel can be reviewed and addressed in future revisions. In addition, the NFPA also has mechanisms to address emerging changes and standards in order to protect their targeted groups.

5. CRU should be separate subchapters of the 42 CFR 84 or NFPA 1981. In following the current methodology that NIOSH has been working in by reviewing and revising 42 CFR as a modular concept should continue to be adhered to. We propose to address some of the concerns discussed in this concept that NIOSH should consider developing new respirator classes.

6.1 A rewording of that chapter 42 CFR 84.63 or an amendment to this should be taken into consideration.

6.2 The use of the by-pass and its color does not need to be changed for the CRU if it is incorporated into the SCBA portion of the CRU. Currently, when a similar system whether it is locking or non-locking is used for a combination Escape SCBA/SAR the terminology used is denoted as "purge valve". There may need to be some clarifications or terminology and/or definitions created in order to address some of these concerns.

6.3 Due to the fact that the intended use for a CRU is strongly dependant on the wearer's tasks and demand, we would oppose to define a mandatory NFPA 1981 compliance. We absolutely agree with NFPA 1981 compliance if the CRU should be a part of Emergency Services Personnel equipment where flash fire might occur but this should be a decision of the wearer and their intended application.

6.4 As noted above, the CRU should also be developed to allow for industrial applications. If the application is intended to be used by the Fire Service and other Emergency Services Personnel then NFPA certifications need to be mandatory. If the CRU is intended for industrial applications, NIOSH should consider other enhanced requirements to be included for those devices.

6.5 If the manufacturer doesn't seek NFPA approval, then stress tests as they are defined in IEC 60721 environmental mechanical stress (vibration) and shock performance according to IEC 60068-2-29 or other relevant performance tests should be taken into consideration.

6.6 As mentioned in our comment to 6.5 the stress tests might be taken from IEC 60068-2-29 and IEC 60721. There are many standards and test procedures throughout the world that can be utilized and NIOSH have incorporated some of these procedures in the development of other standards that have been released over the years and this approach should be continued.

6.7 NIOSH currently has a list of substances identified in 42 CFR that can be used plus with the development of the APR CBRN and the PAPR concept the approaches used in the development of these document can still be utilized.

6.8 We recommend that a new subchapter for 42 CFR 84 and respirator classifications be defined for the CRU requirements. This subchapter should pay attention to the different application and should define different levels of performance (basic unit, basic unit + CBRN, basic unit + NFPA +CBRN....)

Yours sincerely

Klaus-Michael Rück
st-rd-ppe Approvals

Anlage