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Sent: Thursday, March 31, 2011 4:32 PM
To: NIOSH Docket Office (CDC)
Subject: 221 - NIOSH Regulatory Agenda for updating 42 CFR Part 84
Attachments: Draeger 42 CFR 84 Comments 03-2011.doc

Dear Sirs or Madam,

please find enclosed comments from Draeger Safety Approval Office for PPE in Lübeck Germany.

Mit freundlichen Grüßen/Yours sincerely

Klaus-Michael Rück
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Docket 221
NIOSH Regulatory Agenda for updating 42 CFR Part 841

1. April 2011

Dear Sir / Madam,

Herewith we offer some comments taken into consideration in response to the NIOSH notice issued in November 2010.

Please find following comments regarding the regulation, based on experiences out of many approvals we submitted in regions all over the world and based on standardization work done by our standardization committee members.

We fully support the update of regulation 42 CFR 84.

The regulation 42 CFR 84 released 1995 offered good descriptions and specifications to verify functionality and safe use for respirators in the past. Due to new developments, production methods and tests and analytical methods we are convinced that an update of this standard would support NIOSH to remain or keep close to be an accepted institute in product certification and evaluation for PPE worldwide.

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Dräger Safety Verwaltungs AG:
Prof. Dr. Dieter Henning Feddersen
Vorstand:

Test improvement and production methods today allow excellent control over product capabilities directly in production processes. Machinery testing today ensures high repeatability of test during evaluation.

A significant weakness from our point of view in 42 CFR 84, are the mantests #1 to #6 as described in the in subpart H. We don't oppose mantesting, we think practical performance tests are quite necessary during product evaluation and certification and certain mantests should remain mandatory as practical performance tests. But such tests shouldn't be used as the performance or efficiency evaluation tests for e.g. duration at high or low workrates. The use from test subject to subject isn't controlable reproducable. For this man tests should only be to evaluate ergonomic capabilities, donning procedures, doffing procedures, maintenance instruction, user instruction check, handling and TIL testings for the complete respirator system.

We strongly recommend adopting test methods and specifications as they are under development in the ISO TC 94 SC 15. These methods and specifications pay respect to the experiences done over the past 20 years worldwide. The development of an updated 42 CFR 84 will run in parallel to the ISO Standard development and it is very likely that ISO Standards for Respiratory Protective Devices and new 42 CFR 84 might be issued in a timeframe near to each other.

The ISO Standard doesn't describe special designs, but it is clearly performance related. This is a very strong argument, to cover even new designs, which are not covered with the actual standard (e.g. no smoke escape specification for industrial or hotel escape today; no combination units like APR/SCBA or APR/PAPR/SCBA certification possible today). Performance specifications release the certification body, to rule over a certain design or to restrict a design.

NIOSH has given lots of inputs to the mentioned standardization committee and it would be logic consequence to follow that approach in the 42 CFR 84 regulation.

Yours sincerely

Klaus-Michael Rück

Klaus-Michael Rück
st-rd-ppe Approvals

Anlage