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Sent: Friday, March 26, 2010 5:43 AM
To: NIOSH Docket Office (CDC)
Cc: Heyer, Harald; Drews, Wolfgang; Froesch, Mirco; Ammann, Klaus; Hodson, David
Subject: HHS RIN 0920-AA33 42 CFR part 84
Attachments: Comment to docket TIL RIN 0920-AA33-March2010.doc

Dear Sir/Madam,

enclosed please receive comments from Dräger Safety AG & Co. KG aA in Lübeck, Germany for the TIL Requirements for Respirators

Mit freundlichen Grüßen/Yours sincerely

Klaus-Michael Rück
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Approvals

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KMR-TIL-Comments March 2010

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CC: Harald Heyer; Mirko Frösch, Wolfgang Drews; Klaus Ammann
Robert Sell, Dave Hodson

Dear Sir/Madam,

Draeger Safety manufactures respirators for various markets and applications therefore we offer the following comments in response to the publication of the proposed rule in the Federal Register 42 CFR 84 RIN 0920-AA33 Total Inward Leakage October 30, 2009.

We agree to the concept in principle, and we think that the chosen method based on testing with NaCl particles gives excellent repeatable and reliable results during certification. We agree to use the described panels preferably the PCA panel, because it is based on the scanning of world user population.

The following Draeger Safety comments are being submitted for consideration:

§84.175 Half mask facepieces, full face pieces, hood, helmets and mouth pieces

1.) The title gives the impression that not a complete system is involved, but facepieces on its own, which would indicate that the testing is an inward leakage test of the facepieces. Since the term TIL is used means Total Inward Leakage, the test refers to a system of facepieces including filters. We therefore propose to change the title in "§84.175 Half mask facepieces, full face pieces, hood, helmets and mouth pieces including its filter(s)"

2.) The headline misses the filtering facepiece which are in the scope of

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this proposal. We therefor propose to add the filtering facepieces to the proposed title above. The new full title should be:

"§84.175 Filtering facepiece, Half mask facepieces, full face pieces, hood, helmets and mouth pieces including its filter(s)"

3.) Total Inward leakage is a part of the approval test to verify the performance of a respirator during certification. Fit testing is the part of the selection process of an adequate and suitable respirator at the workplace. The third level of testing is given by the user's seal check after donning. It is our strong recommendation to differentiate these levels and clearly identify by using the right terms in the title for this clause.

Proposal:

"§84.175 Filtering facepiece, Half mask facepieces, full face pieces, hood, helmets and mouth pieces including its filter(s); ~~fit and~~ total inward leakage (TIL) minimum requirements"

Rational: Even though the fit test at the workplace might use the same procedure or test method it should not be part of the certification. Fit tests still needs to be performed by the responsible person at the workplace. Adding the wording fit into the title might lead to misinterpretation by the user, and might release the responsible person to perform these essentially required tests.

4.) It is our strong believe to harmonize a TIL level for all the respirator types addressed in the title will be a conflict in principle.

Rational: the proposed sodium chloride challenge with a size range defined in 84.175 (6) with 0,02 - 0,06 μm is the most penetrating range for particle filters based on electrical charged material. The N95 respirators allow a penetration up to 5 % for the filtering media. The definition of total inward leakage includes filter penetration and face seal leakage. The pass fail value stated in 84.175 (3) of 1 % is very unlikely to achieve by this types of respirators. Which means a very well established and widely used product class will be eliminated from the market. We presume that the pass fail value of 1% requested in 84.175 (3) is based on the given OSHA value for full face masks (APF 50), multiplied by a safety factor of 2, means a protection level of 100.

Proposal: We recommend to specify individual TIL levels for the different classes of respirator types, reflecting the assigned protection factors as stated in the OSHA regulation 29 CFR 1910.134 with a certain safety factor.

5.) Test Panel Comments

We are concerned that a panel which utilizes 35 test subjects with a requirement that 26 subjects must pass the test criteria will prolong the testing process for certification at NIOSH. Draeger's experience with the CBRN Laboratory Respirator Protection Level (LRPL) testing has shown that there are significant delays in getting these tests

completed due to the availability of tests subjects according the proposed panels. In addition we are convinced that the actual practice to verify the correct mask for a user over a fit test performed at the workplace with the users gives more accurate safety to the user then an approval of masks under the purpose to use a "statistically" screening. Any test panel chosen wouldn't succeed in 100 % safety for the user.

Today's practice for certification of PPE is to verify that the minimum performance requirements passed by the device. It is not the intention of a certification process to validate engineering output, where statistics comes into focus.

For verification typical sample size is two or three tests per requirement. We see TIL as a requirement, and since we deal with different head sizes we have to take into account a higher number than the typical; as stated below with sample sizes of 16.

Proposal:

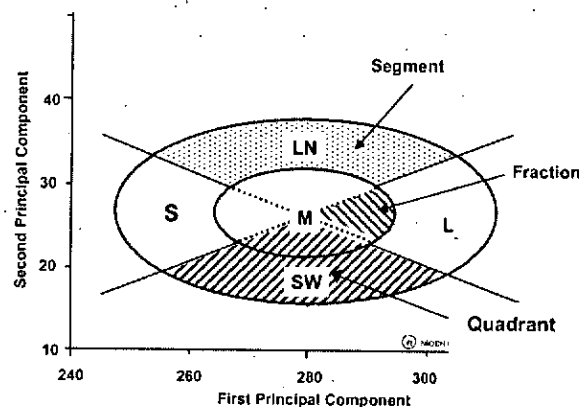
For a complete panel we propose 16 test subjects as a maximum. The complete test panel should be taken from the graphic PCA analysis distribution below, which shows five segments. These are called:

S- for small
SW-for short wide
M- for medium
LN- for long narrow
L- for large

a.) For products claimed to cover all five segments a distribution of four subjects for each of the 4 Quadrants shall be tested.

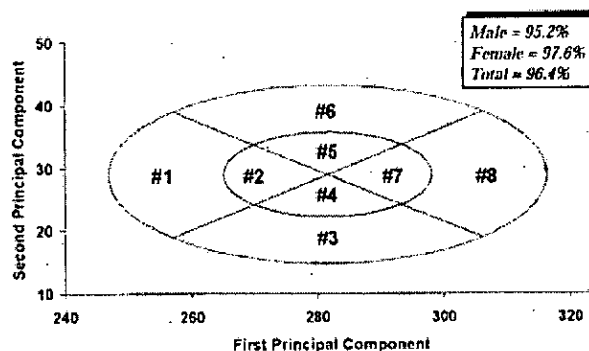
A quadrant consists out of the segments and the relevant fraction of the related M segment. The distribution of the four subjects will be 2 for the segment and 2 for the fraction.

Overall: 16 subjects = 8 from the segment M and 2 subjects from each segment S, LN, L, SW.



- b.) For products claimed to cover the center segment M, all 16 subjects shall be taken from the segment M. For each of the fractions 4 subjects shall be allocated.
- c.) For products claimed to cover one of the outer segments S, SW, LN and L all 16 shall be taken of the relevant quadrant (segment + fraction), with the distribution 14 of the segment and 2 of the relevant fraction.
- d.) For products claimed to cover two of the outer segments S/SW, SW/L, L/LN, LN/S all 16 shall be taken of the two relevant quadrant (segment + fraction), with the distribution 6 of the two segment and 2 of the relevant fraction.
- e.) For products claimed to cover the center segment and one of the the outer segments M/S, M/SW, M/LN, M/L all 16 shall be taken of the two relevant segments, with the distribution 12 of the center and 4 of the relevant outer segments.
- f.) For products claimed to cover three of the outer segments S/SW/L, SW/L/LN, L/LN/S, all 16 shall be taken of the three relevant quadrant (segment + fraction), with the distribution 3 of the three segment and 2 of each outer fraction and 3 from the relevant inner fraction.
- g.) For products claimed to cover two of the outer segments and the center segment M/S/SW, M/SW/L, M/L/LN, M/LN/S, all 16 shall be taken of the three relevant quadrant (segment + fraction), with the distribution 8 of the center (two for each fraction) and 4 subjects of the two relevant outer segments.
- h.) For products claimed to cover four of the outer segments S/SW/L/LN all 16 shall be taken of the four relevant segments, with the distribution 3 of the four segments and 1 of each inner fraction.
- g.) For products claimed to cover three of the outer segments and the center segment M/S/SW/L or M/SW/L/LN or M/L/LN/S, all 16 shall be taken of the four segments, with the distribution 3 of each of the outer segments and 1 for each fraction of the center segment. Additionally one sample from the center fraction enveloped by the outer claimed sections.

This selection model a. to g. can be transferred to the cell numbers allocated in the NIOSH PCA Panel out of the presentation "Anthropometric research to develop respirator fit test panels"



6. § 84.175 (11) (ii) states a NaCl particle size range of "...0.02 to 0.06 µm (mass median aerodynamic diameter)". This is very likely to be the wrong diameter.

Rational:

- 1) a condensation nucleus counter (CNC) can only measure counts (no mass)
- 2) a mass median diameter of 0.02 to 0.06 µm corresponds to a count median diameter in the range of 0.005 to 0.020 µm (depending on the standard deviation of the aerosol distribution). Only a few CNCs are able to measure such particles as small as 0.005 µm.
- 3) a mixing up happened (the wrong diameter is used) - it should mean count median diameter, because in the existing CFR a NaCl particle size distribution is used which is described in Section 84.181 *Non powered air-purifying particulate filter efficiency level determination* as

(g) The sodium chloride test aerosol shall have a particle size distribution with count median diameter of 0.075 \pm 0.020 micrometer and a standard geometric deviation not exceeding 1.86 at the specified test conditions as determined with a scanning mobility particle sizer or equivalent.

Proposal:

Correct the § 84.175 (11) (ii) to:

Measure only the concentrations of sodium chloride challenge aerosol in the approximate size range with count median diameter of ~~0.02 to 0.06 µm (mass median aerodynamic diameter)~~ 0.075 \pm 0.020 micrometer and a standard geometric deviation not exceeding 1.86 at the specified test conditions; and....

Draeger Safety AG & CO KGaA 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 +49-451-882-4513 or via e-mail at klaus-michael.rueck@draeger.com.

Respectfully,

Klaus-M. Rück

PPE Approval Officer