

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

From: Dmitri [dima71@optushome.com.au]
Sent: Thursday, January 15, 2009 11:43 PM
To: NIOSH Docket Office (CDC)
Cc: goran.berndtsson@theseagroup.com; Graham.Powe@theseagroup.com.au
Subject: Re: NIOSH-008-A. SEA comments following the NIOSH public meeting on December 2
Attachments: Docket Office SEA_Cover Letter and Comments 16 January 2009.pdf

Dear Sir,

The S.E.A. Group would like to submit the attached comments following the NIOSH public meeting on December 2, 2008 regarding the **Powered Air-Purifying Respirator (PAPR) Standard Concept, December 21, 2007**, for your attention and consideration.

Please feel free to contact us if you have any questions or would like further information.

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*Best regards,
Dmitri Kazakov*



Docket Officer
NIOSH Docket Office
4676 Columbia Parkway
Cincinnati, OH 45226
USA

Dear Sir,

NIOSH public meeting regarding PAPR Concept, December 2, 2008

The enclosed document contains S.E.A.'s comments following the NIOSH public meeting held on 2nd December 2008. S.E.A. commends NIOSH on their progress and welcomes continuing discussion on the development of new concepts for categorizing PAPRs, a review of LRPL testing, work rates and gas and particulate filter testing.

Once again, we appreciate the opportunity to share the benefit of our extensive research, knowledge and practical experience in the field of respiratory protection. We trust our enclosed Comments will assist you further in the development of a meaningful and protective PAPR Standard.

Yours faithfully,

GRAHAM POWE
MANAGING DIRECTOR
SAFETY EQUIPMENT AUSTRALIA PTY LTD



Comments by S.E.A. on NIOSH public meeting regarding PAPR Concept, December 2, 2008.

This document contains S.E.A.'s comments subsequent to the NIOSH public meeting of December 2, 2008, in regard to the Proposed PAPR Concept.

Opinion on the concept of categorizing PAPRs as breath assisted or positive pressure devices, and on the linkage of these types with LRPL testing

S.E.A. strongly supports NIOSH's proposal for a formal distinction between positive pressure and breath assisted PAPRs. S.E.A. is in no doubt that positive pressure performance contributes greatly to improved respiratory protection, and has maintained this position publicly for some years.

Positive pressure considerations

The foundation of S.E.A.'s argument is the belief that positive pressure can greatly reduce inward leakage in real workplaces, where – despite the best efforts of regulators – good facial fit cannot be assured. Poor facial fit in the workplace is a primary reason why assigned protection factors (APFs) are so much lower than simulated workplace or laboratory protection factors.

Consider, by way of argument, OSHA's Assigned Protection Factor for three types of device:

- Full facepiece APR – APF 50
- Full facepiece PAPR – APF 1,000
- Pressure-demand SCBA – APF 10,000

The most important difference between these types of device – in terms of protection factor – is the degree to which they rely on facial fit: APRs always, PAPRs sometimes, SCBAs rarely. And the degree of reliance on facial fit is closely linked to the degree of positive pressure performance.

It would be reasonable to argue that a positive pressure PAPR with very high efficiency filters (of the order of 99.997%) would achieve an APF similar to that of a pressure-demand SCBA.

Comments on positive pressure and breath assisted categories

In regard to NIOSH's proposal for breath assisted and positive pressure categories, the division appears somewhat arbitrary. This is most apparent when one considers the 40 lpm work rate, for which there is both a breath assisted and a positive pressure category. Comparing two such devices, they have identical positive pressure requirements for work rate (i.e.: 40 lpm) yet only one is termed positive pressure. This is illogical, and can only result in confusion.

S.E.A. recommendation: To minimize confusion, there be no single work rate at which both positive pressure and breath assisted PAPRs may be certified.

S.E.A. believes that for a device to be positive pressure in real use the user must be aware of its work rate limitations. This is best achieved with a mandatory low pressure warning that is genuinely functional. It can also be achieved with warning markings.

S.E.A. recommendation: All positive pressure PAPRs shall have a low pressure warning that activates at three or fewer consecutive negative breaths. All positive pressure PAPR devices and user instructions shall be marked to indicate the work rate limitations. All breath assisted PAPRs shall be marked to indicate that positive pressure performance is not assured.

Comments on LRPL

S.E.A. sees numerous problems with the linking of PAPR category with LRPL in the way that NIOSH has proposed.

Firstly, there is a very large step – from LRPL 250 to 10,000 – at 40 lpm. This is not consistent with the expectation that LRPL performance would increase in some sort of proportion with increasing positive pressure performance.

Secondly, and more importantly, the existing LRPL test does not take into account the effect of the different work rates. The eleven-exercise regime in the NIOSH LRPL test appears to be roughly equivalent to ISO class 2 or 3, or NIOSH Low work rate (25 lpm). High work rate devices cannot be fairly evaluated using such a low work rate regime.

S.E.A. recommendation: The LRPL exercises should be performed using exercise regimes that are representative of the nominated work rates.

Opinion on the expansion of the number of work rates where PAPRs can be submitted for approval

S.E.A. strongly supports NIOSH's initiative to establish two new high work rates. This was argued extensively in *Comments by S.E.A. on Proposed PAPR Concept*¹ dated March 27, 2008.

S.E.A. observes, however, that NIOSH has based its work rates on the ISO data for the average male of 1.84 m². In their study, *Head-and-Face Anthropometric Survey of U.S. Respirator Users*², Zhuang and Bradtmiller found that the mean height and weight of a NIOSH respirator sample male were 1.754 m and 90.4 kg respectively. Using the formula from ISO8996:2004, this equates to a surface area of 2.06 m², very close to that for the ISO large (2.11 m²) male. They also found that the NIOSH respirator sample female had mean height and weight of 1.625 m and 75.7 kg respectively, giving a calculated surface area of 1.81 m², very close to the ISO average (1.84 m²) person.

S.E.A. recommendation: ISO data for the 2.11 m² person should be used as the basis for the NIOSH work rates, considering that respirator users are represented primarily by males.

S.E.A. does not believe that the sedentary flow rate of 11 lpm should be included in the standard. ISO decided against including Class 1 because "sedentary" does not represent working conditions. S.E.A. concurs with this position.

S.E.A. recommendation: Sedentary work rate (11 lpm) should be excluded from the standard.

S.E.A. believes that a sinusoidal breathing profile is adequate for all breathing machine rates.

Opinion on the consideration of an alternate approach to gas and vapor testing

S.E.A. commends NIOSH on the progress it has made in the development of test methods for gas and particulate filters. However, the methods describe only constant flow PAPRs, and no proposals are made for the testing of breath-responsive PAPRs.

It is important that flow rates for breath-responsive PAPRs are measured directly, rather than relying on a table of flow rates derived from constant flow PAPRs. This is because significant efficiency benefits are possible with breath-responsive PAPRs, and these advantages should be recognized by the test.

It is also important for constant-flow PAPRs to use the actual measured flow through the device because devices may exceed the nominated flow rate by a significant amount; the proposed table of test flow rates would tend to underestimate the test flow rates in such cases.

S.E.A. discussed the above issues and proposed detailed test methods in *Comments by S.E.A. on Proposed PAPR Concept*¹ dated March 27, 2008; these will not be reproduced here.

S.E.A. recommendation: Filter and canister test flow rates for all PAPRs should be determined from actual PAPR air flow measured on a breathing machine.

NIOSH's proposal to measure service life at three flow rates appears to be a valid means of determining service life over a range of work rates. However, we would enquire on the extent to which accuracy has been compromised by reducing the number of tests per data point from three to one.

Opinion on the establishment of positive pressure PAPR ESLI for organic vapors and acid gases

S.E.A. commends NIOSH on the progress they have made in this area.

REFERENCES

1. Comments by S.E.A. on Proposed PAPR Concept: Powered Air-Purifying Respirator (PAPR) Standard Subpart P, NIOSH, December 21, 2007, *S.E.A., March 27, 2008.*
2. **Zhuang, Z. and Bradtmiller, B.,** Head-and-Face Anthropometric Survey of U.S. Respirator Users, *Journal of Occ. Health and Hygiene, 2: 567-576.*