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

From:

Sent: Thursday, March 27, 2008 6:23 AM

To: Ahlers, Heinz W. (CDC/NIOSH/NPPTL); Szalajda, Jonathan V. (CDC/NIOSH/NPPTL); NIOSH Docket Office (CDC); Szalajda, Jonathan V. (CDC/NIOSH/NPPTL); Boord, Leslie F. (CDC/NIOSH/NPPTL)

Subject: Proposed PAPR Concept: PAPR Standard, Subpart P

Attachments: NIOSH Docket Officer letter with SEA Logo 27 March 08.pdf

Dear Sir,
The S.E.A. Group would like to submit the attached comments to the **Proposed PAPR Concept: Powered Air-Purifying Respirator (PAPR) Standard Subpart P, NIOSH, December 21, 2007** for your attention and consideration.
Please feel free to contact us if you have any questions or would like further information.

NIOSH Docket Officer
NIOSH U.S.A.

Dear Sir,

Proposed PAPR Concept: Powered Air-Purifying Respirator (PAPR) Standard Subpart P, NIOSH, December 21, 2007

The S.E.A. Group is an international company with offices in Europe, America and Australia. Safety Equipment Australia was established in Sydney in 1984 and in a marketplace that at the time was relatively weak in the field of personal respiratory protection, the company began a vigorous campaign to increase awareness of occupational health in general and respiratory protection in particular. Through discerning selection of only superior respiratory protection and a massive investment in an extensive knowledge base for its customers, S.E.A. has become a premier name in the field of industrial and C.B.R.N. respiratory protection.

We are the manufacturers and suppliers of the world's first high performance positive pressure demand air-purifying respirator. The company became Australian Standards Quality Endorsed/ISO9002 approved in 1993 – one of the first safety companies in Australia to achieve this status. In addition, S.E.A. has been an instrumental force in the development of Australian safety standards as an active member of the Australian Standards Committee since 1985.

Internationally, we have presented and published research papers on respiratory protection at numerous events including AIHce conferences, ISO meetings and ISRP Conferences. We have been members of the International Society for Respiratory Protection for a number of years, including representation at Board level.

We appreciate the opportunity to add the benefit of our extensive research, knowledge and practical experience in the field of respiratory protection by way of our attached comments to the latest Draft Standard. We trust they 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 Proposed PAPR Concept: Powered Air-Purifying Respirator (PAPR) Standard Subpart P, NIOSH, December 21, 2007.

This document contains S.E.A.'s comments on the Proposed PAPR Concept document, hereinafter referred to as the "draft standard". It raises S.E.A.'s issues of concern and presents our recommended solutions where appropriate.

The document is divided into two sections – *Salient Issues* and *Fundamental Issues*. While we believe all issues raised are important and should be addressed, we have grouped under the section *Salient Issues* a number of key issues that address substantial shortcomings in the draft standard that we believe are imperative to be addressed if the final standard is to achieve the aim of improving respiratory protection into the future while embracing advanced technologies. The draft standard should not be implemented without correcting the deficiencies addressed in the *Salient Issues* section. Fundamental issues must also be seriously considered prior to finalizing the standard.

Please note that while this document contains proposed solutions to the issues raised, our overriding concern is that the issues be addressed adequately, by whatever means NIOSH considers appropriate.

SALIENT ISSUES

Failure to acknowledge technology extant for more than a decade

The S.E.A. Group is astonished that NIOSH has not recognized PAPR technology that has been on the world market since 1997 and in North America since 2000.

This positive pressure, breath responsive PAPR technology provides American workers with increased protection to the level of SCBAs when used within the limitations of use of PAPRs. It also provides substantial cost savings by increasing the economy of filter use almost to the level of APRs.

This technology has been demonstrated to NIOSH on numerous occasions. It has been presented at numerous public meetings held by NIOSH.

The S.E.A. Group is not the only manufacturer with this technology. KOKEN Ltd. (Japan) presented information at the NIOSH/NPPTL meeting at Marriott Key Bridge Hotel on April 10, 2003, *"Proposal of Incorporation of a New PAPR in New NIOSH Standards"*. This presentation focused on the economic benefits of the breath responsive technology through the conservation of filters.

At the same meeting S.E.A. made a presentation entitled *"What PIAF do we need to assure Positive Pressure for 95% of First Responders?"* which focused on the performance requirements for the protection of first responders. S.E.A.'s breath

responsive technology meets these requirements. This presentation has been published on the NIOSH website since 2003.

Clause 2.8 – Definition of breath responsive PAPR

Issue

The draft definition 2.8 "Breath-response PAPR" differs significantly from the published definition (Federal Register 18336, Vol. 65, No. 68, April 7, 2000).

The draft definition refers to specific technologies, and is therefore technologically restrictive.

S.E.A. recommendation

Replace the draft definition (clause 2.8) with the definition published in the Federal Register 65(68):18336, April 7, 2000.

All usage of the term "breath-response PAPR" should be replaced by "breath responsive PAPR" to be consistent with this definition.

Proposed text for clause 2.8

> "A breath responsive powered air-purifying respirator (PAPR) is designed to deliver filtered air to the user upon demand in order to match the respiratory requirements of the user."

Rationale

The definitions contained within the new standard should be consistent with existing published definitions in order to eliminate ambiguities. We believe the definition published in the Federal Register adequately describes the concept of the breath responsive PAPR without prescribing the technologies that may be used to achieve it.

By defining a breath responsive PAPR according to its intended functionality, no restriction is placed on the means used to achieve this functionality. It is therefore less likely to exclude future technologies that may arise to improve respiratory protection.

Specifically, adjustment of the air flow can be achieved by means other than electronics or by changing the blower speed; references to these technologies should therefore be removed. Also, breath responsive control of loose-fitting PAPRs may well be possible and so should not be excluded; reference to "tight-fitting" PAPR should therefore be removed.

In addition, we believe that other terms such as "demand responsive" and "pressure demand" should not be used. "Demand responsive" has not been formally defined, but appears to be similar to "breath responsive", so its use would only lead to confusion. "Pressure demand" is a term that appears to have been carried over from supplied-air respirators and breathing apparatus. Its meaning is covered by the above definition of "breath responsive PAPR", and so should not be used.

4.1.9 – Low pressure indicator

Issue

The draft standard specifies a low pressure indicator (clause 4.1.9). However, the requirement as written does not ensure their effectiveness in real use; ineffective low pressure indicators may be misleading and potentially dangerous to users.

The performance requirement specified at twelve breaths is substantially below what is achievable with state of the art technology contained in current NIOSH approved respirators. We see no reason to reduce the standard below what is currently achievable. In view of current technology capabilities and the objective of minimizing the risk to users' health, this performance requirement is inadequate.

The wording of clause 4.1.9.1 is ambiguous. It may be read as requiring the indicator to activate at *any number* of negative breaths greater than twelve. For example, one may argue that an indicator that activates at 30 consecutive negative breaths is compliant. Such a reading would nullify the requirement.

The clause may also be read as disallowing indicators that activate at *fewer than* twelve breaths. It is imperative not to exclude indicators that exceed the requirement.

In addition, the test method for evaluating low pressure indicators is very important but has not been specified in the draft standard.

S.E.A. recommendation

In clause 4.1.9.1, change "during more than twelve consecutive breaths" to "during each of three consecutive breaths".

Alter the clause to eliminate the ambiguities. See proposed wording below.

Specify the test method for low pressure indicators. We propose a method whereby the PAPR is tested on a breathing machine at the nominated work rate; the breathing rate is then increased until negative pressures occur; the indicator must activate by the time three consecutive negative breaths have occurred.

Proposed text for clause 4.1.9.1

> "A low pressure indicator shall be present. It shall actively and readily indicate when the pressure inside the respiratory inlet covering falls below ambient pressure during each of three consecutive breaths. The indicator shall continue to activate if more than three consecutive negative breaths occur. The indicator may activate when fewer than three consecutive negative breaths occur."

Rationale

There is common understanding in the respiratory protection community that negative pressure in the breathing zone reduces the level of protection [(1)]. The inclusion of the requirement for a low pressure indicator in the draft standard is to be commended and it illustrates NIOSH's recognition of the importance of positive pressure performance.

Clause 3.1 of the draft standard states, "All (PAPRs) are considered as positive pressure when tested by air flow testing described herein." We believe this statement holds true only if the limitations of use of the PAPR work rates are defined and users are actively warned whenever their breathing rate exceeds these limitations.

We are convinced of the need for low pressure warnings on all PAPRs. For more than a decade we have manufactured PAPRs with low pressure warnings that activate after two consecutive negative breaths. We continue to see real situations where these warnings give users feedback on their rate of work, allowing them to adjust their behavior in order to remain within the limits of their respirators. It therefore aids in the correct selection and use of PAPRs by increasing user awareness of the limitations of their equipment.

The requirement as drafted does not ensure that low pressure warnings will be functional in real use. It states that a low pressure indicator must activate when more than twelve consecutive negative breaths occur. A single "short" (i.e.: non-negative) inhalation during this time will allow the count to restart. Unless the PAPR is being "out-breathed" by a large margin, occasional short inhalations will be common. It will therefore be common for users to repeatedly out-breathe the PAPR without the indicator activating.

Appendix C of this document contains samples of breathing rate data collected by S.E.A. that clearly illustrate the above condition. From the data we have collected over many years we can recommend three negative breaths as the basis for a low pressure indicator – it ensures an effective indicator and is technically feasible.

The weakness of the draft clause is of great concern because users will reasonably expect a low pressure warning to activate whenever low pressure occurs, but in reality there may be no warning during repeated negative pressure excursions. A defective low pressure indicator is *less safe* than no indicator at all because it instills in the user a false sense of security.

Furthermore, it can reasonably be argued that the condition where a low pressure indicator with the defined function of detecting low pressure in the breathing zone fails to do so should be considered a Major A defect, defined in 42 CFR 84.41 as "a defect that reduces respiratory protection and is not detectable by the user". This is clearly unacceptable.

It is perplexing that the draft clause requires PAPRs to detect negative pressure but not to activate the indicator immediately upon detection. A device able to detect and count twelve consecutive negative breaths is inherently able to detect and count three.

By activating the warning at three consecutive negative breaths, the effect of occasional short inhalations will be greatly diminished and will result in truly functional low pressure warnings.

Clause 4.2.4 – Work rates

Issue 1

The current draft specifies PAPR performance at work rates up to 57 lpm, but does not address higher work rates known to occur in certain situations [2,3,4].

S.E.A. recommendation

Include an additional Very High work rate of 86 lpm. Very High work rate PAPRs should provide full performance for a duration of approximately 2 hours. We propose that PAPRs certified to Very High work rate should first be certified to High work rate.

We also propose an additional Extremely High work rate of 103 lpm. Extremely High work rate PAPRs should provide full performance for a duration of approximately 30 minutes. PAPRs certified to Extremely High work rate should first be certified to High work rate.

The proposed new work rates would have additional requirements for positive pressure breathing rates, gas/vapor service life, particulate efficiency and battery life. Proposed criteria are set out in Appendix A.

Rationale

The NIOSH draft work rates Low, Moderate and High appear to be broadly similar to the work classes 2 (Light), 3 (Moderate) and 5 (Very heavy) defined in specification ISO/TS 16976-1:2005. These ISO classes are considered to be valid for repeated activities during work shifts in everyday occupational exposure.

The adoption of these widely accepted work rates is clear evidence that NIOSH is committed to establishing performance criteria commensurate with the physiological needs of users. We wholeheartedly support NIOSH's efforts in this regard.

However, we are greatly concerned that the needs of users at even higher work rates – as evidenced by widespread research – have not been addressed.

In their paper "Workplace Breathing Rates: Defining Anticipated Values and Ranges for Respirator Certification Testing" – based on an extensive literature review – Caretti *et al.* [(2)] stated, in regard to minute volumes:

> "An analysis of the measured and estimated minute volumes indicated a range from about 8 to 162 $L.min^{-1}$ for unencumbered ventilation and work activities that spanned from mild to exhaustive. The mean minute volume of the distribution was 38.5 ± 16.6 $L.min^{-1}$ and the median was 33.6 $L.min^{-1}$... However, a higher cyclic flow rate may be necessary to account for a greater percentage of ventilation rates that occur in the workplace as the 95th percentile for minute volume was 73.3 $L.min^{-1}$. If the desire is to encompass a higher percentage of possible ventilation rates independent of the workplace, the recommendation would be to use the maximum minute volume of 114 ± 23 $L.min^{-1}$ measured by Blackie *et al.* [(15)] for 20 to 29 year old males during maximal exercise."

Further, they stated, in regard to peak inspiratory flow rates (PIF):

> "The anticipated range of PIF rates for the 95th percentile minute volume is between 182 $L.min^{-1}$ and 295 $L.min^{-1}$. Thus, a PIF of approximately 300 $L.min^{-1}$ would adequately represent 95% of the peaks occurring during occupational task performance."

Holmér *et al.* 2007 [(3)] and Kaufman & Hastings, 2005 [(4)] have reported similar work rates.

Clearly the current draft High work rate of 57 lpm does not encompass the flow rates recommended by Caretti *et al.*, above. However, it would seem that the flow rates 86 lpm and 103 lpm contained in the previous (September 19, 2006) draft standard are broadly equivalent to the Caretti *et al.* recommendations of 73.3 lpm (95th percentile) and 114 lpm (maximum).

These research findings are recognized in ISO/TC 16987-1:2005 which specifies additional classes 6 (Very, very heavy), 7 (Extremely heavy) and 8 (Maximal), associated with activities at higher work rates that are sustainable only for shorter durations.

The rationale behind NIOSH's Low, Moderate and High work rate classes logically must be applied also to the higher work rates if users are to be adequately protected in all situations. Requirements must be included which ensure adequate positive pressure performance, breathing resistance, gas/vapor service life, particulate efficiency and battery life at the higher work rates and for the expected durations.

Therefore we propose two additional work rates, Very High and Extremely High. It is imperative that the standard contains provision for the higher work rates known to occur in the workplace in order to ensure adequate protection for all users.

Issue 2

The draft does not specify any limitations on use of respirators classified to different work rates.

S.E.A. recommendation

Specify limitations on use based on work rate classification. All other Cautions and Limitations should also be specified.

Rationale

Without use limitations, work rate classifications have limited meaning in practical terms. Without use limitations, manufacturers have an incentive to submit respirators at Low or Moderate Work Rate, where higher capacity classes can be achieved.

4.2.3 – Exhalation resistance

Issue

Clause 4.2.3 specifies exhalation resistance with respect to ambient pressure. The exhalation resistance for positive pressure respirators such as PAPRs, supplied-air and SCBAs should be specified with respect to the static pressure in the breathing zone, as required in 42 CFR clauses 84.157 and 84.91.

S.E.A. recommendation

Change the wording in clause 4.2.3.2 from "63.5 mm (2.5") water column height above ambient at any flow rate" to "51 mm (2") water column height above static pressure at 85 lpm".

Rationale

It is recognized that the resistance to breathing perceived by the user is related to the static pressure in the breathing zone rather than to the ambient pressure. It is for this reason that 42 CFR specifies breathing resistance limits for pressure-demand supplied-air respirators and breathing apparatus relative to static pressure. The same approach should also be applied to PAPRs that include pressure-demand regulator valves.

We propose that the 42 CFR exhalation resistance requirement for Type C pressure-demand supplied-air respirators (clause 84.157) and pressure-demand open-circuit breathing apparatus (clause 84.91) be used for PAPR breathing resistance also.

Clause 84.157 (c) states: "The exhalation resistance... at 85 lpm shall not exceed the static pressure in the facepiece by more than 51 mm water column height."

It is important to note that breath responsive PAPRs currently certified under 42 CFR are tested to 84.157. This requirement is specified in RCT-APR-STP-0065, a test protocol created by NIOSH in 2000 to address 42 CFR's shortcomings in this area. To include this requirement in the new standard would be consistent with current practice.

Clause 4.2.7.3 – Flow rates for cartridge/canister service life testing

Issue

The flow rates for cartridge/canister service life testing specified in Table 2 of the draft standard make no allowance for the more efficient use of air achievable by breath responsive PAPRs. As a result, capacity classes for breath responsive PAPRs – which may consume up to 50% less air than equivalent conventional PAPRs – are likely to be underestimated. In this regard the standard fails to encourage manufacturers to develop more efficient PAPRs which benefit users through reduced running costs, increased operating time and/or reduced weight; indeed, it fails even to recognize the performance benefits of breath responsive devices currently approved by NIOSH.

In addition, the actual flow rates through conventional (steady flow) PAPRs may be significantly greater than the test flow rates specified in Table 2 of the draft standard, when tested at the nominated work rates. This will occur when a PAPR delivers a flow rate greater than the specified minimum – a likely occurrence because manufacturers must include a safety margin. It would also occur if a manufacturer chose to nominate a lower work rate than a PAPR could achieve in order to gain a higher gas capacity class. Such overrating of capacity class would be misleading and potentially dangerous to users as it would result in earlier breakthrough and increased risk of exposure to breathing hazards. While this may be considered an issue of use rather than certification, addressing the issue in the standard may potentially circumvent this "real world" health and practical use problem.

S.E.A. recommendations

Implement a PAPR flow rate test at the nominated work rate to determine the appropriate flow rate for testing of cartridge/canister service life. The air flow through the PAPR filters would be measured while running on a breathing machine at the nominated work rate. The flow rate for cartridge/canister tests would be derived from this.

A possible method is described in Appendix B. This method is given for guidance only.

In addition, implement a verification test at the peak flow rate measured in the PAPR flow test, to ensure that cartridges/canisters have sufficient adsorbent bed depth to perform at the expected peak flow rates.

Rationale

The method we have proposed would result in the fair assessment of capacity class for all types of PAPR whilst removing any incentive for manufacturers to nominate lower work rates to gain artificially high capacity classes.

It should be noted that while capacity classes currently apply to cartridges and canisters on their own, our proposed method would require that they be applied to entire respirator systems (PAPR with cartridges/canisters). This is entirely logical – the real capacity of cartridges and canisters is dependent on the behavior of the respirators they are used with – and must be taken into account by the standard.

Because the peak flows may be significantly higher than the average flows used for service life testing – and particularly so for breath responsive PAPRs – a verification test should be implemented to ensure that cartridges/canisters have sufficient bed depth to prevent breakthrough at the peak flows. This test may use a single representative gas.

Clause 4.2.8 – Particulate filter efficiency level determination

Issue

PAPR100 minimum filter efficiency of 99.97% is inadequate for PAPRs that must provide laboratory protection factors of at least 10,000.

PAPR95 minimum filter efficiency of 95% is totally inadequate for such PAPRs. Despite this inadequacy and the absence of a DOP loading requirement for PAPR95 filters, there are no restrictions on use applicable to PAPR95 filters.

S.E.A. recommendation

Replace PAPR100 with a new filter classification whose efficiency is of the order of 99.997%.

Remove the PAPR95 specification from the standard.

Rationale

A steady flow PAPR fitted with PAPR100 filters whose efficiency is exactly 99.97% (or penetration 0.03%) at the nominated test flow rate delivers air to the breathing zone with contamination level of the order of 0.03%. Ignoring other sources of inward leakage, this would equate to a nominal LRPL of 3,300. This "thumb-nail" calculation is very approximate but it illustrates clearly that the PAPR100 requirement is inadequate for PAPRs intended to maintain LRPL of at least 10,000.

All filters to be submitted by manufacturers for certification to the new standard will exceed the PAPR100 requirement by a considerable margin. This is because manufacturers need to ensure an efficiency of *at least* 99.997% to give sufficient margin to pass LRPL comfortably. It is well known that NIOSH LRPL test results of greater than 100,000 are common; these results can be achieved only with filters of very high efficiency.

The filter efficiency requirement is important to ensure ongoing production performance of filters in the absence of a production LRPL test. To meet this objective the required efficiency should be at least ten times higher than PAPR100 when tested at the nominated test flow rate.

Using the same "thumb-nail" calculation, the nominal LRPL of a PAPR with "on the limit" PAPR95 filters would be of the order of 20. It is self-evident that the PAPR95

specification has no place in the new PAPR standard. We are astounded that NIOSH has proposed such a requirement.

Clause 4.2.8.5 – Flow rates for particulate filter efficiency testing

Issue

The flow rates specified in Table 2 of the draft standard for testing particulate filter efficiency for tight-fitting PAPRs are lower than will occur when PAPRs are operating at the nominated work rates. The reasons for this are discussed in the section on clause 4.2.7.3, above. Particulate efficiency testing at non-representative flow rates cannot assure adequate particulate protection for users.

S.E.A. recommendation

Use the PAPR flow rate test proposed in discussion of clause 4.2.7.3 to determine the average flow rate through the PAPR filters when running on a breathing machine at the nominated work rate. Use this flow rate for testing of particulate filter efficiency.

In addition, implement a verification test at the peak flow rate measured in the PAPR flow test, to ensure that filters have adequate efficiency at the expected peak flow rates.

Rationale

Because particulate filter efficiency varies with flow rate, filters must be tested at the actual PAPR flow rates that occur when operating at the nominated work rates. It has been discussed in the section on clause 4.2.7.3 that the actual PAPR flow rates can be significantly higher than the test flow rates currently specified in Table 2 of the draft standard. For this reason the filter efficiency testing may yield optimistic results.

It is imperative that filter efficiency testing is done at representative flow rates. Use of the proposed PAPR flow rate test would ensure test flow rates are representative.

Because the peak flows may be significantly higher than the average flows used for filter efficiency testing – and particularly so for breath responsive PAPRs – a verification test should be implemented to ensure that filters have adequate efficiency at the peak flows.

6.2 – Exhalation resistance in Silent Mode

Issue

The requirement for silent mode (power-off) exhalation resistance requirement of 20 mm water column height at 85 lpm is not achievable with breath-responsive PAPRs using today's technologies.

S.E.A. recommendation

The silent mode (non-powered) exhalation resistance requirement should be changed to 51 mm water column height at 85 lpm. This is equivalent to the requirement for powered exhalation resistance proposed above.

Rationale

The draft requirement for all APRs and PAPRs of 20 mm water column height at 85 lpm – and taken directly from 42 CFR – is achievable with simple non-biased exhalation valves.

In contrast, breath-responsive PAPRs may employ an exhalation valve that either: 1) is biased (i.e.: pre-loaded), or 2) is controlled by a demand valve. Both of these configurations increase the exhalation resistance when the blower is off. In order to accommodate such respirators, the maximum power-off exhalation resistance requirement must be increased significantly.

Our proposed requirement for exhalation resistance during powered operation (see section *Exhalation Resistance*, above) can be adapted to non-powered operation simply by considering the static pressure to be zero. As already discussed, the *effective* exhalation resistance of 51 mm water column height was taken from 42 CFR clause 84.157 for Type C pressure-demand supplied-air respirators.

Future demand responsive technologies may obviate the need for biased exhalation valves or demand valves, but it is fundamental that the standard embraces existing demand responsive technologies.

FUNDAMENTAL ISSUES

Clause 1.1 – Relevant requirements of 42 CFR

Issue

Clause 1.1 states that PAPRs shall meet the requirements of 42 CFR subparts A, B, F and G, but not subparts D (Approval and Disapproval) and E (Quality Control).

S.E.A. recommendation

Add subparts D and E to this requirement.

Rationale

42 CFR subparts D and E are relevant to this standard.

Clause 2.1 – Definition of PAPR

Issue

Clause 2.1 defines a PAPR based only on the components of which it is comprised. The intended functionality of a PAPR is not defined. The definition is therefore technologically restrictive and fails to adequately define the functionality of the device.

S.E.A. recommendation

Clause 2.1 should be rewritten to define a PAPR according to its intended functionality and to remove references to specific components. We do not intend to propose an alternative wording, but would suggest that a PAPR's function is essentially to deliver purified ambient air to the breathing zone of the user under positive pressure at flow rates up to a specified work rate.

Rationale

By defining a PAPR according to its intended functionality, no restriction is placed on the means used to achieve this functionality. It is therefore less likely to exclude future technologies that may arise to improve respiratory protection.

Clause 3 – Descriptions

Issue

Descriptions of devices contained within this section supplement the definition of those devices. As such there is potential for the descriptions to contradict the definitions.

S.E.A. recommendation

Clause 3 should be deleted, and relevant content transferred to Clause 2, Definitions, as appropriate.

Rationale

A case in point is the definition of PAPR. The description in clause 3.1 would appear to be more accurate a definition than the existing draft definition in clause 2.8.

Clause 4.1.8 – Noise levels

Issue

The term "maximum average constant airflow specified by the manufacturer" cannot be applied to breath responsive PAPRs which do not generate constant airflow. It is therefore impossible to test breath responsive PAPRs to this requirement in its current form. Also, the requirement does not state whether human subjects are to be used.

S.E.A. recommendation

The statement should be reworded to include breath responsive PAPRs.

The existing test protocol for noise level testing, RCT-APR-STP-0030, specifies the use of human subjects. We assume human subjects will be used to test the new requirement, so we propose that this be stated in the requirement.

Proposed text for clause 4.1.8

> "Noise levels generated by any PAPR shall be measured at each ear location, and shall not exceed 80 dBA. Where the PAPR has manual airflow settings, the maximum setting shall be selected. Testing shall be performed when PAPRs are fitted to three human subjects."

Clause 4.1.10.3 – Low power warning

Issue

The phrase "additional adequate power to properly power the unit" is not defined.

The phrase "at the highest flow attainable" is not defined.

S.E.A. recommendation

Change "additional adequate power to properly power the unit" to "additional adequate power to maintain positive pressure inside the respiratory inlet covering when tested on a breathing machine at the nominated work rate".

Delete the text "and at the highest flow attainable" and replace with the sentence "Where the PAPR has manual airflow settings, the maximum setting shall be selected."

Proposed text for clause 4.1.10.3

> "Each PAPR equipped with a local battery shall have an active low power warning. This warning indicator shall signal when the battery can no longer provide the unit with 15 minutes of additional adequate power to maintain positive pressure inside the respiratory inlet covering when tested on a breathing machine at the nominated work rate and at the lowest recommended operating temperature. Where the PAPR has manual airflow settings, the maximum setting shall be selected. A PAPR with emergency battery power only does not require a low battery warning indicator."

Rationale

We believe strongly that a PAPR should maintain rated positive pressure performance until it shuts down due to low battery power. Users would reasonably expect the level of protection to remain unchanged while the blower is running. For this reason we argue that the requirement to maintain positive pressure be added to the clause.

The phrase "at the highest flow attainable" is applicable to conventional PAPRs, which may have multiple speed settings, but is meaningless when used in reference to breath responsive PAPRs, which deliver air flow only in response to users' demands. By performing the test on a breathing machine, all PAPR types are accommodated.

Note that this test can be done conveniently, for all PAPR types, simultaneously with the battery duration test.

Clause 4.2.4.1.2 – Breathing machine for work rate testing

Issue

The breathing profile of the breathing machine is not specified.

S.E.A. recommendation

A sinusoidal breathing profile should be specified.

Proposed text for clause 4.2.4.1.2

> "A breathing machine with sinusoidal profile shall be used to meet the work rates as described in Table 1."

Clause 4.2.7.1.1 – Dual cartridge/canisters

Issue

"PAPR dual cartridge/canister" is not defined.

S.E.A. recommendation

Include a definition of "PAPR dual cartridge/canister" in clause 2, Definitions.

Clause 4.2.10 – Non-powered LRPL performance

Issue

Clause 4.2.10 Table 5 is ambiguous. The term "Tight-fitting facepiece including hoods and helmets with blower off (Silent Operation)" indicates that the requirement applies only to respirators approved for Silent Operation.

In addition, the categories described in Table 5 are ambiguous. Hoods and helmets are included with tight-fitting facepieces, which contradicts the definitions stated in Clause 2.

S.E.A. recommendation

Remove the text "(Silent Operation)" from this clause.

In Table 5, "Loose-fitting Facepiece" should be changed to "Loose-fitting Facepiece Including Hoods and Helmets", and "Tight-fitting Facepiece Including Hoods and Helmets" should be changed to "Tight-fitting Facepiece".

These descriptions contain a mixture of singular and plural, which should be rectified.

Rationale

We believe that all PAPRs should have rated non-powered performance to assure continued protection during escape. This agrees with the intent of the standard, as stated in clause 4.1.2.4, "Each tight-fitting PAPR shall be designed to prevent unpurified air from entering the system if the blower function stops."

A user should reasonably expect a tight-fitting PAPR to continue to function as an APR if the blower stops. Existing APR inward leakage performance (LRPL 2,000) should be mandatory for all tight-fitting PAPRs.

Clause 4.2.2 – Exhalation valve leakage

Issue

Clause 4.2.2 implies that *each* exhalation valve shall have a leakage not exceeding 30 ml/min. No provision is made for PAPRs with multiple exhalation valves.

S.E.A. recommendation

Clause 4.2.2.2 should be reworded to accommodate multiple exhalation valves.

Proposed text for clause 4.2.2.2

> "Leakage between the valve(s) and valve seat(s) shall not exceed a total of 30 milliliters per minute."

Clause 5.2.1 – LCBRN LRPL requirement

Issue

Clause 5.2.1 states that the requirement in this clause "exceeds the general requirement for a loose-fitting PAPR. This is not correct – it is 10,000 in both cases.

S.E.A. recommendation

If the LRPL values in the draft standard are correct, the above statement must be removed from clause 5.2.1.

Clause 6.2.3 – Silent Operation

Issue

The intent of clause 6.2.3 is to limit the breathing resistance in silent mode to an acceptable level. Therefore, single limits may be specified for inhalation resistance and exhalation resistance.

S.E.A. recommendation

Replace the inhalation resistance limits listed in Table 13 with a single requirement of 65 mm water column height at 85 lpm.

Rationale

The inhalation resistance acceptable to a user does not vary depending on the type of filters fitted to the PAPR. If inhalation resistance of 65 mm water column height is acceptable when canister/particulate filters are fitted, is should also be acceptable when particulate-only filters are fitted.

In practice, the resistances of the various types of filter will inherently be much different, regardless of whether specific limits exist. The presence of the specific limits is therefore of no benefit to users.

PAPRs with manual settings

Issue

The draft standard makes no allowance for classification of PAPRs with manual settings, including speed settings. The draft does not state how such devices will be set during testing.

S.E.A. recommendation

Provision should be made to clarify how manual settings shall be set during testing. This is necessary wherever manual settings may affect the outcome of the test.

APPENDIX A – Proposed performance criteria for Very High and Extremely High work rate PAPRs

S.E.A. has proposed two additional work rate classes – Very High and Extremely High – to address the respiratory requirements of users at higher work rates than the proposed High work rate.

Table 1 contains suggested possible performance criteria for these work rate classes. Such PAPRs should first meet all the requirements for High work rate.

Table 1 - Suggested performance criteria for higher work rates

	High	Very High	Extremely High
Minute flow lpm	57	86	103
Peak flow lpm	179	270	324
Exhalation resistance	As proposed in this document	As per "High"	As per "High"
Gas/vapor service life	Cap 1, 2, 3, etc. tested at flow rate derived from BM test at 57 lpm	UI to advise of 50% reduction in capacity at Very High work rate	UI to advise of 50% reduction in capacity at Extremely High work rate
Low power warning	15 min	15 min	5 min (or no requirement)

APPENDIX B – Proposed methods for determining flow rates for cartridge/canister service life testing

To measure the average flow rate through the PAPR cartridges/canisters/filters – hereinafter referred to as "filters" – the PAPR must be operated on a breathing machine running at the nominated work rate (Low, Moderate or High). PAPR flow rate is measured by recording the pressure drop across the filters.

Tests should be performed for highest and lowest resistance filter combinations, and at highest and lowest performance configurations, as determined by NIOSH with the assistance of the manufacturer.

A method is described below.

Method for measuring PAPR flow rate

The proposed procedure is divided into three steps:

1. Filters characterization – Determine the flow/pressure characteristic of the filters when fitted to the PAPR by measuring pressure drop across the filters and flow rate at a series of steady flows.
2. Air flow measurement – Use the characterized filters as a flow meter to measure the average flow rate through the PAPR when tested on a breathing machine at the nominated work rate.
3. From the measured average flow through the PAPR, determine an appropriate test flow rate for cartridges/canisters service life testing.

The PAPR's filters should be used as a flow meter because the alternative – attaching an external flow meter to the filters – would affect the flow readings due to the resistance of the flow meter itself.

For Step 1 (filters characterization), the blower unit would be connected directly to the flow meter and suction device via a special breathing hose/adapter (supplied by manufacturer with NIOSH-specified interface). In this way face seal leakage – which would affect the accuracy of the characterization – is eliminated. The test would be done with the PAPR blower off.

For Step 2 (air flow measurement), the complete PAPR would be mounted on a dummy head and breathing machine. A facepiece fit test for tight-fitting PAPRs would be necessary because any face seal leakage would add to the measured flow rate through the filters.

Step 1 – Determine pressure/flow characteristic of set of filters

1. Set up the configuration per Figure 1, with the following components:
   - Set of filters fitted to blower unit via adapters with test ports to measure pressure immediately downstream of filters. Connect the test ports via tee connector(s) to a pressure transducer, connected in turn to a data acquisition system. Pressure tubing should be configured so that the pressures from all filters are averaged
   - Breathing hose/adapter connected at one end to blower unit. The outlet end of the adapter would meet NIOSH spec. to allow connection to test flow meter
   - Flow meter
   - Vacuum device
   - The PAPR blower remains off throughout the test.
2. Record the pressure at zero flow.
3. Start the vacuum device. Record the pressure and flow rate readings at a series of flow rates up to the maximum peak flow rate that will occur at the nominated work rate. All flow rate readings must be corrected to standard pressure and temperature of the flow meter.
4. Tabulate the flow/pressure data on a spreadsheet, plot the points on a graph, create a best-fit curve and determine the formula. This is the flow/pressure characteristic of the set of filters. These calculations can be done easily with MS Excel or LabView software.

Note: The filter characteristic can be represented by a second order polynomial best-fit curve. This can be determined using only three data points, including the zero point. However it is recommended to use more data points to ensure high accuracy.

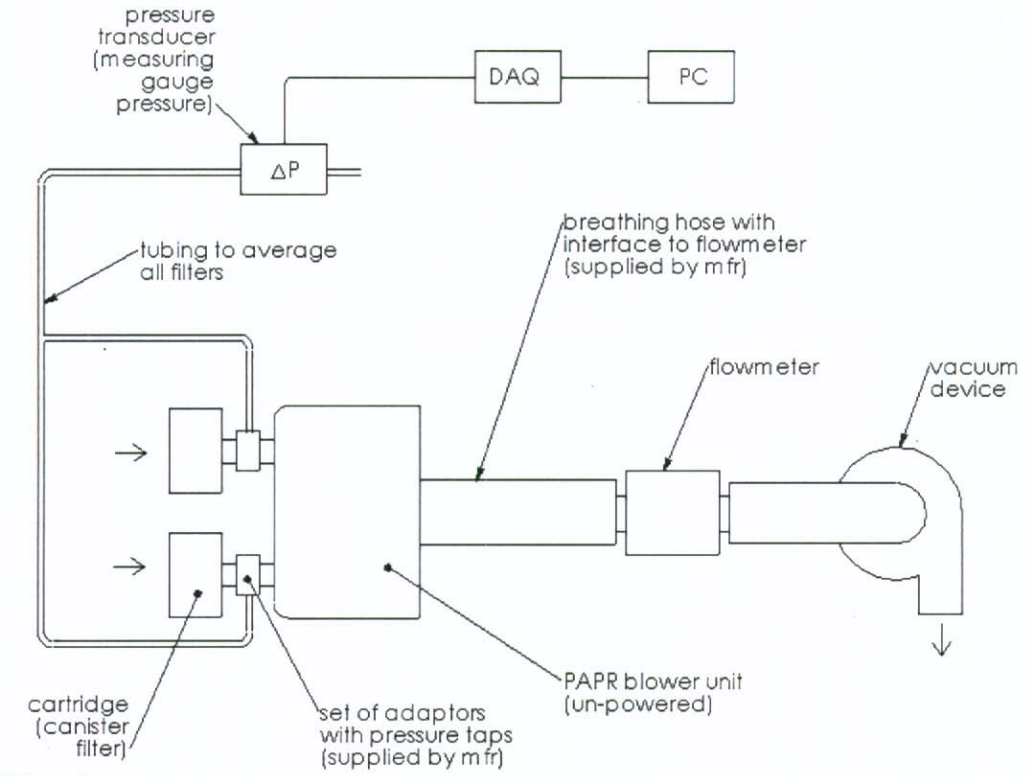


Figure 1

Step 2 – Measure PAPR air flow at required breathing rate

1. Assemble the complete PAPR including facepiece. The adapters should be fitted downstream of the filters as in Step 1. It is essential that the pressure tubing configuration is identical to that used in Step 1.
2. Mount the PAPR facepiece on the dummy head and tighten the head harness.
3. Set the breathing machine to operate at the nominated work rate.
4. Perform a quantitative facepiece fit test with PAPR blower off.
5. Start the PAPR and wait for blower speed to stabilize (allow at least one minute).
6. Make a recording of pressure using the DAQ. (minimum duration 2 minutes, minimum sampling rate 50 Hz).
7. Using analysis software, calculate the flow rate through the PAPR filters for each pressure data point using the characteristic formula determined above. This can be easily done using MS Excel or LabView software.
8. Calculate the average PAPR flow rate in liters per minute.
9. Divide the result by the number of filters to give the measured average flow rate through each filter.

Note: It is important to calculate each flow rate and then average the flow rate values. If the pressure values are averaged and then converted to a flow rate, errors will result if the pressure/flow characteristic is non-linear (normally the case for carbon filters).

Note: Ideally the sample should include a number of full breathing cycles only (i.e.: the starting and finishing points should be at the same point on the breathing curve) in order to eliminate end effects. If a partial breath is included, an error will result. The longer the duration, the less this potential error will be. For duration of 2 minutes and 30 breaths per minute the maximum error would be less than 1%.

Step 3 – Determine appropriate flow rate for cartridge/canister service life testing

It is important to add a contingency factor to the flow rate measured in Step 2 when determining the actual test flow rate for service life testing. This is needed to avoid unnecessary retesting of service life in any future extensions of approval.

This is best illustrated by example. Consider an initial PAPR certification where service life testing was done at the exact flow rate as measured by the above method. The manufacturer then submits a slightly different configuration for extension of approval. If the PAPR flow rate test yields a slightly higher result than the original test – whether due to minor variations in the configuration or random production variations – the service life testing would need to be repeated at the higher flow rate.

This issue can be mitigated either by adding a contingency factor to the test flow rate at initial certification, or by specifying in the standard a series of flow rate groups, each with an allocated test flow rate, in a similar way to Table 2 of the present draft standard. Future extensions to approval would require only a PAPR flow rate test to verify it is within the original range.

We do not intend to propose any such methods at this time.

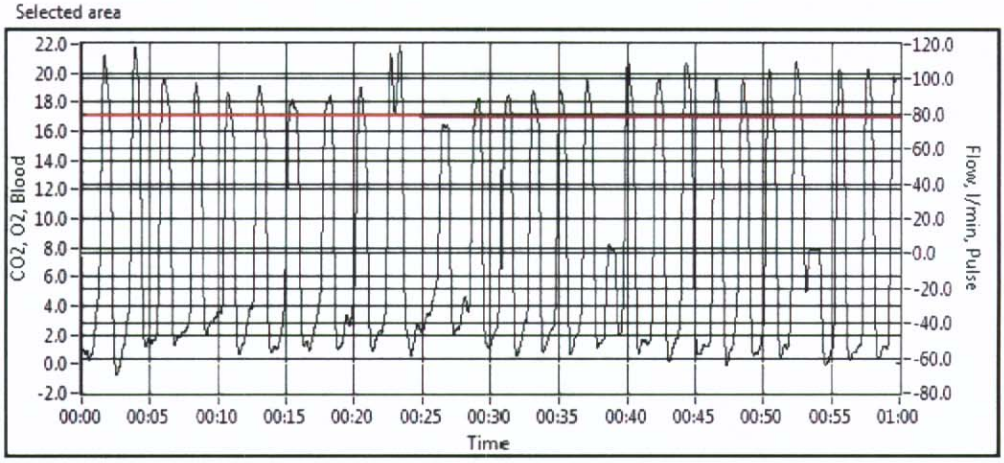
APPENDIX C – S.E.A. breathing rate data

In June 2006, S.E.A. carried out breathing rate testing on human subjects at various work rates on an exercise bicycle. Subjects were fitted with a low breathing resistance APR facepiece configured as a flowmeter.

Three sample graphs taken from the results are presented below. Each of the three tests was done at a work rate close to one of the NIOSH work rates. On each graph the red line marks the peak inspiratory flow rate (PIF) equivalent to the NIOSH work rate.

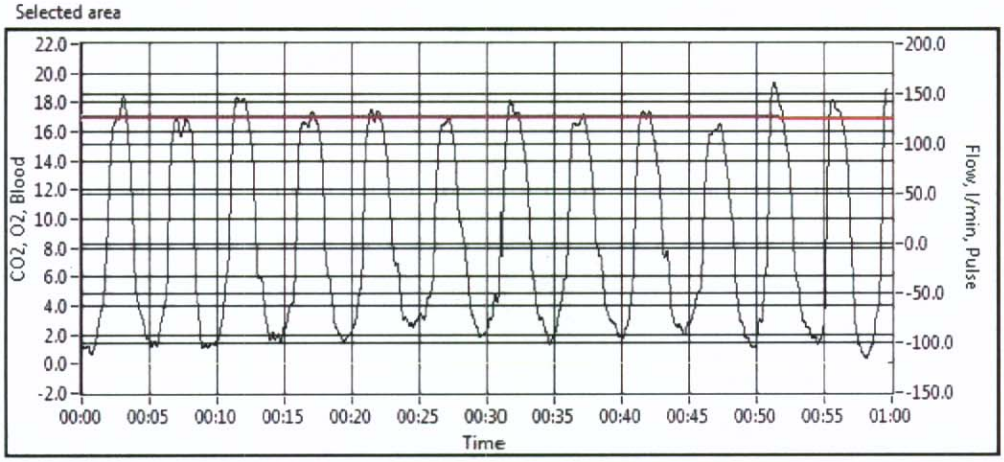
Test 1 – Low work rate

Female subject. Work rate 27.8 lpm, close to the NIOSH Low work rate of 25 lpm, nominal PIF 79 lpm. It can be seen that 25 (or 89%) of the 28 breaths exceed the nominal PIF.



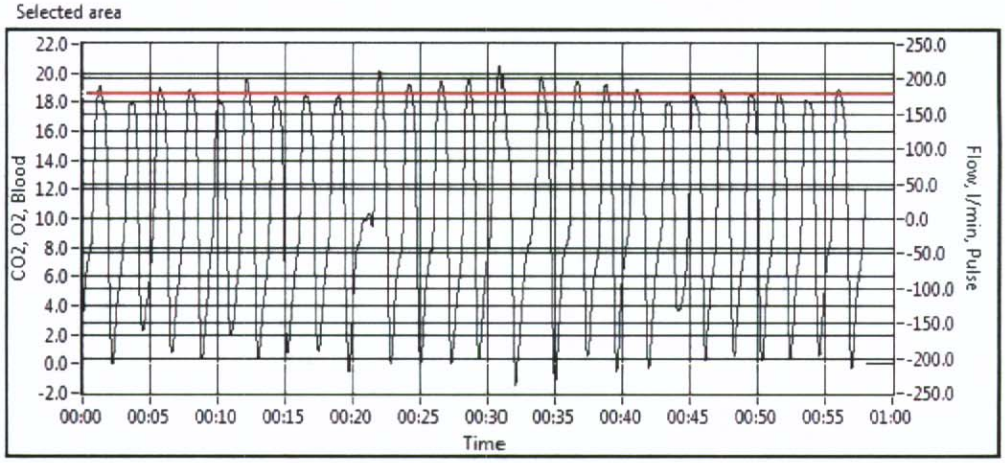
Test 2 – Moderate work rate

Male subject. Work rate 42.5 lpm, close to the NIOSH Moderate work rate of 40 lpm, nominal PIF 126 lpm. It can be seen that 11 (85%) of the 13 breaths exceed the nominal PIF.



Test 3 – High work rate

Male subject. Work rate 60.7 lpm, close to the NIOSH High work rate of 57 lpm, nominal PIF 179 lpm. It can be seen that 8 (32%) of the 25 breaths exceed the nominal PIF.



If these subjects were wearing PAPRs delivering the NIOSH flow rates, and had low pressure indicators set to activate after 12 consecutive negative breaths, the indicators would not activate during these tests, despite negative breaths occurring repeatedly.

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