3M Occupational Health and Environmental Safety Division

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3M

July 8, 2004

NIOSH Docket Officer
RE: NIOSH DOCKET -010
Robert A. Taft Laboratories
M/S C34, 4676 Columbia Parkway
Cincinnati, OH 45226
NIOCINDOCKET@CDC.GOV.

RE: CBRN PAPR Concept Paper, April 1, 2004

Dear Docket Officer:

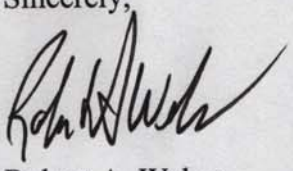
Minnesota Mining and Manufacturing Company (**3M**), through its Occupational Health and Environmental Safety (OH&ES) Division, is a major manufacturer and supplier of respiratory protective devices throughout the world. 3M has invented, developed, manufactured and sold approved respirators since 1972. 3M employs experienced engineers and technical professionals for the development of respirators. Our sales people have trained and fit tested hundreds of thousands of respirator wearers throughout the world. Our technical staff has performed basic research on the performance of respirators and their uses, presented and published this data in numerous forums and assisted customers with the development and administration of effective respirator programs. In sum, we have substantial experience in all phases and applications of respiratory protection. We are pleased to provide the National Institute for Occupational Health and Safety with our comments on the proposed Standard Concept for CBRN PAPR, dated April 1, 2004

3M supports NIOSH in its attempt to develop a standard for evaluating the effectiveness of respirators for use in atmospheres that may contain chemical, biological, radiological, and nuclear (CBRN) war agents. 3M recognizes that it is imperative that these types of products be available as soon as possible. However, thorough discussions, which consider input from all stakeholders, are necessary for developing an appropriate, effective and feasible CBRN equipment statement of standards. 3M offers the following comments and recommendations regarding scope and definitions, respirator use, hazards, general construction including battery and indicator requirements, breathing performance, and special CBRN requirements including the crisis provision and LRPL test requirements. Finally, typographical and editorial suggestions are offered. These comments and suggestions are included with this letter.

rec'd 7/19/04

We appreciate the opportunity to add our comments and knowledge to docket 010 and look forward to the promulgation of a fair, protective and useful statement of standard for CBRN PAPRs.

Sincerely,



Robert A. Weber
Technical Service Manager
3M Occupational Health & Environmental Safety Division

RAW:CEC/llb
Enclosures

3M Comments and Suggested Revisions to the April 1, 2004 CBRN PAPR Concept

Background, Para. 4

"The concept uses the same breathing machine performance requirement and test for both tight fitting and loose fitting face piece designs."

3.0 Descriptions

"Powered air-purifying respirators use a powered mechanism to draw ambient air through an air-purifying filter elements(s)…"

The use of "filter" and "element" is redundant. Air-purifying element is a term typically used by OSHA and ANSI that includes filters, cartridges and canisters. Deleting the word filter will make the use consistent with accepted definitions.

3.1 Definitions

Based on the definitions used in this draft and the omission of certain performance tests, it appears to 3M that loose fitting PAPRs have been excluded from consideration in this Concept. There is one statement, however, that implies the allowance of a loose fitting device in the Background, para. 4 (*see above*). Here it refers to one type of loose fitting respiratory inlet covering, the loose fitting facepiece. Clarification on what constitutes a loose fitting facepiece and whether loose fitting facepieces are intended to be included is needed. The following discussion on the definitions from the Concept will explain how this conclusion was reached and provides our recommended additions.

"(a) Powered air-purifying respirator (PAPR) – an air-purifying respirator that uses a powered mechanism (blower) to pass ambient air through an air-purifying element to a respiratory inlet covering."

This definition includes loose fitting devices because by using the term respirtory inlet covering, it allows all possible types of PAPRs.

"(b) Tight fitting PAPR – a PAPR, which contains a respiratory inlet covering that seals ~~tightly~~ to the face."

This definition is restricted to tight fitting respiratory inlet coverings, which are the half facepiece, full facepiece, and hoods and helmets with neck dams. While this definition includes half facepieces, all tests refer only to full facepieces and hoods and helmets with neck dams. NIOSH should be more direct if half facepieces are not to be allowed. The term "tightly" is not defined and should be removed. Whether the seal is adequate is determined by a fit test.

"(c) Neck dam PAPR – a PAPR, which contains a hood or helmet and which covers and seals ~~tightly~~ around the neck area."

While the neck dam PAPR definition allows some hoods and helmets it does not allow the loose fitting hoods and helmets, which are a type of tight fitting PAPR. In 3M's opinion these products should be included. OSHA requires fit tests for these types of respirtory inlet coverings. Again the concern on the use of "tightly" is the same as above and 3M recommends that it be removed.

"(d) Respiratory inlet covering – A facepiece, hood, helmet or some combination of these, which serves as the covering to the nose and mouth area ~~and ensures that only purified air reach these areas~~."

While definition (d) does not preclude loose fitting hoods and helmets, the lack of a definition for loose fitting PAPRs can only lead the reader to believe NIOSH is talking about the hoods and helmets with neck dams discussed in definition (c). The definition for respiratory inlet covering causes concern because as written it appears to reinforce the notion that only hoods and helmets with neck dams are allowed. The statement, "ensures that only purified air reach these areas", with no discussion as to whether the PAPR is turned on or not implies it must do this even when it is turned off. This would, in turn, allow only tight fitting devices and therefore fit testing would be required on all CBRN PAPRs. 3M believes PAPRs should only be tested while "on" because they can only be used for entry into non-IDLH atmospheres or to use NIOSH words, atmospheres from which the user can escape without the aid of a respirator.

In summary, the proposed definitions appear to exclude loose fitting facepieces, hoods and helmets from being used with the CBRN PAPR. Further, there is no loose fitting description to allow submission of these type PAPRs. It is 3M's view that these devices should be allowed and the definitions clarified accordingly.

Loose fitting respirtory inlet coverings have many benefits over tight fitting. These include being able to be worn over facial hair, accommodation of eyeglasses, and no requirement for fit testing and, especially for loose fitting facepieces, accommodation of stethoscopes. Loose fitting respiratory inlet coverings should be included in the standard and definitions for loose fitting hoods and helmets need to be provided. In addition, test for lens abrasion, fogging and field of vision do not appear to include hoods as the tests proposed are the ones used for full facepieces.

Many first receivers prefer to use loose fitting PAPRs and the guidance documents being produced for first receivers are recommending the use of loose fitting PAPRs. These documents describe conditions in which first receivers could have lower exposures than first responders at an incident site. Based on these assumptions, respirators with an APF of 1000 are recommended instead of SCBA. Specifically, PAPRs with hoods were indicated. This proposed guidance does not include PAPRs with loose fitting facepieces. NIOSH must provide a definition for "loose fitting facepiece" especially since it appears NIOSH does not use this term in the same way as the Occupational Safety and Health Administration (OSHA) and the American National Standards Institute (ANSI).

Therefore, 3M recommends that NIOSH provide the following definitions and that these devices be addressed by this Concept:

- Loose fitting PAPR – a PAPR, which utilizes a loose fitting respiratory inlet covering.

- Respiratory inlet covering - That portion of a respirator that connects the wearer's respiratory tract to an air-purifying device or respirable gas source, or both. It may be a facepiece, helmet, hood, suit, or mouthpiece/nose clamp. They are generally classified as either loose fitting or tight fitting.

- Hood - A loose fitting respiratory inlet covering that completely covers the head and neck and may cover portions of the shoulders.

- Helmet - A hood that offers head protection against impact and penetration.

- Loose fitting facepiece - A respiratory inlet covering that is designed to form a partial seal with the face, does not cover the neck and shoulders, and may or may not offer head protection against impact and penetration.

Attachment 1 shows examples of loose fitting respiratory inlet coverings.

3.2 Respirator Use

"C. The CBRN PAPR filter elements are single use filters and ~~should~~ must be discarded after use."

The term "use" needs to be defined as used in "C". Since these canisters cannot be rejuvenated, they must be discarded after use, which will either be based on the change schedule or the limitations established by NIOSH.

"D. CBRN respirators contaminated with liquid chemical warfare agents are to be disposed of after the use in which they have been contaminated."

Again "use" needs to be clearly defined. This definition should be consistent with other standards and test conditions. For example, if contaminated with a liquid chemical warfare agent, it must be discarded after two hours. If it is only vapor, it needs to be discarded after 8 hours. The limitation from the CBRN APR statement of standard reads, "15. The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours."

3.3 Hazards

"Ten chemical TRAs, plus one particulate TRA, were identified. Testing against these 11 TRAs provides protection for 139 potential respiratory hazards."

Discussion:

This statement claims that a CBRN respirator only protects against 139 potential respirtory hazards. This statement is misleading. Based on testing against cyclohexane, for example, the respirator will be at least as effective against organic vapors with a vapor pressure less than cyclohexane even if that organic vapor has not been identified as a possible chemical warfare agent. In addition this respirator will be effective against many industrial contaminants. As written, NIOSH is indicating that respirators under this approval category are not effective against these contaminants.

3M suggests rewording this statement to, "Testing against these 11 TRAs ensures that the respirator provides protection for the 139 identified potential weapons of mass destruction respiratory hazards."

5.1.3. Required Packaging Configuration: Minimum packaging configuration:

"End user: The definition of the end user is the person who will derive protection from the respirator by wearing it. It is assumed that the end user will store the respirator in a location where it will be available for immediate access and use during an emergency."

Discussion:

One of two changes needs to be made here. Either:

- delete "It is assumed that the end user will store the respirator in a location where it will be available for immediate access and use during an emergency.", or
- add storage language that also meets the requirements under 29 CFR 1910.134.

Proper storage is addressed earlier by requiring that it should be covered by the manufacturer's instructions. As such, the second sentence in the quoted statement can be eliminated. However, if it stays here, additional information needs to be provided to avoid people storing them so they are accessible but necessarily to protect the respirator.

Recommended wording is, "It is assumed that the end user will store the respirator in a location where it will be available for immediate access and use during an emergency and stored to protect it from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals."

5.2 Labels

"5.2.1 The battery part number must be prominently displayed with the part number on the respirator battery pack or other suitable location."

Discussion:

This statement is confusing. 3M submits that it should say;, "The battery part number must be prominently displayed on the respirator battery pack or other suitable location."

5.2.2 Additional cautions and limitations appropriate to CBRN PAPRs must be added as deemed necessary by NIOSH, such as "Observe low flow or pressure alarm indicators."

Issue:

3M urges NIOSH to draft all of the additional limitations and cautions and publish them before the Concept becomes a statement of standard. *See 6.14.*

5.3.1 Battery Requirements

"5.3.1.2 The indicator must be capable of monitoring the battery conditions and signaling the user when the remaining operational battery life is sufficient to sustain the desired flow rate for at least 15 minutes but not more than 25 minutes."

To summarize this section identifies four requirements related to batteries and alarms/indicators. It outlines the following:

1. Operational battery life, specified by the manufacturer
2. Indicators to show state of charge of the battery
    a. Fully charged
    b. End of operational battery life (low battery)
3. Low-flow indicator
    a. Must indicate when the **m**anufacturer's **a**cceptable **m**inimum **f**low (MAMF) is reached

A low flow indicator (alarm) would be preferred to the low battery alarm specified above because battery voltage is a function of temperature, the correlation between voltage and flow is complex, low voltage does not always correspond to low flow, and high voltage does not always correspond to adequate flow.

First, the manufacturer must determine the acceptable minimum flow based on the airflow needed to pass the breathing performance test and the LRPL test. NIOSH must specify how this flow is to be measured and explain it's rational. 3M recommends that this flow be stated as a volumetric flow rate, not mass flow. This flow then allows the manufacturer to establish the low flow indicator alarm point.

The manufacturer will also select a battery to provide an operational battery life based on what they think the market desires and what is technologically feasible. The operational battery life will be based on the desired time before the minimum acceptable flow is reached. According to the requirements of this concept, the low flow alarm would be set to go off 15 minutes prior to

reaching the MAMF. This point would determine the end of the operational battery service life (See Figure 1). The claim for an operational battery life is dependent on many things related to battery technology, especially use temperature and because of this, needs to be defined more thoroughly by NIOSH. (See Figure 2)

Background

BATTERY CHEMISTRY – USE TEMPERATURES

Battery output (volts) and battery capacity (amp-hours) vary significantly with temperature. This is true for all primary (non-rechargeable) and rechargeable battery chemistries that are normally used in PAPR systems.

Low temperatures are the greatest concern with battery performance. The battery voltage output drops as temperature drops. Some electronic control could be added to assure the voltage to the motor does not vary. This is practical given current technology but there are still limits to this technology. For a given system, electronics may be able to maintain a constant voltage down to about $-10^{\circ}C$. But beyond approximately $-15^{\circ}C$, this is no longer possible. Alternatively a system can be "over designed" to accomplish appropriate respiratory protection at low temperatures. There remains a practical limit when the "over designed" battery is still small enough and of low enough mass to be worn by the user.

Figure 2 shows three battery discharge curves; two are at room temperature and the third is at a lower temperature to show the effect of low temperature on the operational battery life. The left vertical axis indicates voltage and the right vertical axis indicates airflow. An alarm voltage and the MAMF are also shown. This figure also illustrates why NIOSH does not want to require a low battery indicator. A low battery alarm, if used, may not indicate before a low flow alarm as in the case of heavy loading. A low battery alarm could also indicate before the low flow alarm if the system is used beyond the batteries' capacity e.g., low temperature. In either case, the low flow alarm alerts the user to the potentially unsafe condition; the low battery alarm does not.

There is no simple relationship between the two alarms. In the schematic, ~1.180 volts/cell is the point where the low battery indicator would alarm. As the low temperature discharge curve indicates, this indicator would alarm well before the manufacturer's acceptable minimum flow (MAMF) would be approached. Under these conditions, workers would be likely to ignore as it "cries wolf" by alarming less than half way into the operational life. Another shortcoming is that a low battery alarm may not indicate loss of flow due to filter loading.

Tying filter-loading issues to the battery voltage will result in very onerous battery packs. Instead of a low battery alarm, a low flow alarm will accommodate filter-loading issues, which has also been expressed as a concern of NIOSH.

Therefore, 3M recommends that the operational battery life be defined as:

Operational Battery Life: The time, specified by the manufacturer, between when the system is activated with a fully charged battery and when the low *flow* alarm indicates plus fifteen minutes at 70°F +/-3°F.

This addition is not thought to be limiting as a PAPR used at low temperatures provides a wind chill to the user. It is 3M's experience that it is very uncomfortable to use a PAPR at temperatures below freezing. When they are used below freezing it is typically for relatively short time periods to allow some relief to the user.

The manufacturer (applicant) should provide data to NIOSH showing that the systems being submitted meet MAMF at the usable temperature extremes. The manufacturer (applicant) should also provide data that shows the low flow alarm functions properly at the useable temperature extremes.

State of charge of the battery: 3M proposes only one indicator to show battery state of charge. This indicator should inform the user that the battery is fully charged and the operational battery life can be attained at the specified operating temperature. For rechargeable cells this indicator may be passive or active. The fully charged indication may be on the charger, battery, or blower. A tamper proof label may be applied after charging. Primary cells should be allowed to have a tamper proof label with expiration date which, as long as it has not been tampered with, indicates it is fully charged.

And for the **Low-flow indicator:** 3M recommends no 25-minute maximum requirement. 3M was led to believe at the public meeting that this is no longer being considered but wants to emphasize that this is a poor idea. First, this is a severe technical challenge as there are motor variation, battery cell variation (battery cell manufacturers routinely improve their processes to increase capacity), battery circuit component variation, flow monitoring circuit variation, and the battery changes as it ages. **It would require the manufacturer to build a system that would prematurely give a low flow indication when adequate airflow remains**. Secondly, it is highly likely that once the user has experienced this phenomenon, he/she would disregard the alarm, resulting in unsafe respirator user practices.

3M believes the low flow indicator to be the better indicator as to when to exit the area rather than a low battery indicator. This is the alarm that will alert the user that airflow may soon be reduced below acceptable levels. The Low Flow Alarm point should indicate at "15 minutes before the MAMF'.

5.3.3 Operational Controls

"CBRN PAPR units must be equipped with readily accessible switches and controls designed to prevent accidental shutoff."

Discussion:

While 3M agrees with NIOSH on the importance of this issue, NIOSH needs to explain how it proposes to test this parameter. NIOSH must develop the STP for this property before issuing the statement of standard. It is 3M's position that it will be difficult to design a reproducible test for this attribute and therefore suggests that NIOSH discard this requirement. This is a feature that needs to be determined by the user an as such will be a market driven issue. What is "immediately accessible" to one person will not necessarily be to the next person.

5.4 Breathing Performance

3M suggests the following change to this section: "CBRN Powered air-purifying respirators will…"

It is important that NIOSH indicate in the paragraphs of the Statement of Standard that these requirements apply to CBRN PAPRs and not all PAPRs at this point in time.

5.4.4 Breathing Performance Requirement

Short negative pressure excursions occur in supplied air respirator and powered air purifying respirator testing while the systems provide very high fit factors. Please see ORC study.[1] NIOSH needs to specify the equipment, test protocol, and Pass/Fail criteria in enough detail so that manufacturers can establish whether their systems meet the criteria listed in this section before submission. The tolerance range for 0 – 3.5" H_2O along with the time needs to be defined, as this will determine what is a failure. These are important issues regarding the resolution required to measure the pressure, the equipment to be used and the repeatability of the test. For example, the transducer response time is not indicated. The two machines specified have two different transducers specified between NFPA and NIOSH. The NIOSH transducer is faster than the NFPA version. The transducer needs to be specified before finalization of the Statement of Standard, because it will define many of these requirements.

1. Cohen, H.J., L.H. Hecker, D.K. Mattheis, J.S. Johnson, A.H. Biermann and K.L. Foote: Simulated Workplace Protection Factor Study of Powered Air-Purifying and Supplied Air Respirators. *AIHAJ 62*:595-604 (2001).

5.6 Respiratory Inlet Covering: Lens Material Haze, Luminous Transmittance and Abrasion Resistance

The abrasion resistance test was lifted out of the full facepiece specification and should be modified to include a different provision for hoods based on the typical materials used for hoods. This is needed for the hoods and helmets with neck dams, even if loose fitting devices are not allowed. NIOSH has done this in the CBRN APR escape hood statement of standard. This test should recognize the types of environments they are likely to be used in, i.e., first receiver environments.

5.6.4 Test Specimens:

It is not clear why NIOSH is requiring the manufacturer to provide the abraded samples. If this is to be third party testing, NIOSH or its designated representative should be abrading supplied lens samples.

5.7 Carbon Dioxide

NIOSH needs to identify the STP to be used for the carbon dioxide test.

5.9 Noise Levels

The Concept indicates that NIOSH is proposing to reduce the maximum noise level generated by the PAPR from 80 dBA to 75 dBA. Because the noise value in 42 CFR 84 is 80 dBA, Subpart KK 84.1139, this seems counter to the NIOSH position indicated in the steps to the development of the Statements of Standards. It seems the process was to:

1. use existing standards, and where they did not exist,
2. propose new ones from existing standards and where none existed
3. develop new tests.

To the best of 3M's knowledge, there have not been complaints based on noise from current PAPRs sold into industry; therefore, there is no reason to reduce the noise level from existing tests. Furthermore, these PAPRs may require higher flow resulting in more noise as a result of meeting these new performance standards.

6.2 Canister Capacity

3M recommends that NIOSH delete the reference to ppm-min as this will confuse most people reading this standard and does not provide any useful information to the concept.

Constant Flow/Demand Flow (Table 3 canister tests)

The terms "constant flow" and "demand flow" are not defined, yet they appear in Table 3 with different test flow rate requirements. It is both unnecessary and inappropriate to identify these two airflow types and to list separate approval tests. A single test for moderate breathing rate and another for high breathing rate is sufficient. 3M recommends a constant flow rate of 115 L/min for Moderate Breathing Rate and 300 L/min for High Breathing Rate Performance. Since the test concentrations are three times the IDLH concentration, they are many times higher than the concentrations in which the canisters are permitted to be used. They do not represent how long a canister would last in actual use; this is why a change schedule will still need to be calculated by the end users. The Table 3 tests only assure the canisters contain carbon in sufficient quantity and quality to pass a specific test. If NIOSH believes that it is necessary to run the tests at higher flow rates, the same rates should be used for all CBRN PAPR canisters.

This canister testing system would assure that, as appropriate, all respirators that pass a given test would have equal status regardless of their mode of operation. Resulting approval language

should designate only "Moderate Breathing Rate PAPR" or "High Breathing Rate PAPR". The terms "continuous flow" and "demand flow" (or pressure demand) should not be included. This would eliminate the confusion created by the terms "continuous flow" and "pressure demand or other positive pressure mode" historically used by both NIOSH and OSHA. NIOSH has previously used an approach similar to that recommended here, i.e., continuous flow supplied air respirators (SAR) have been granted pressure demand approvals when they are subjected to the same tests as pressure demand SAR (Attachment 2, page 2). Based on 3M's experience, this has caused immense confusion in the field. There is also no reason for this designation as no difference in performance and protection level is expected to be provided as a result of meeting the requirements of this concept.

However, if NIOSH elects to keep the proposed Table 3 language, it needs to fully explain and justify this position before 3M can comment.

NIOSH also needs to clarify the development and release of the test procedure based on STP-0012 as noted on Page 9, paragraph under Table 3.

6.2 Stacking

Under the April 1 proposed CBRN PAPR Concept, manufacturers may choose to have their PAPR tested at a moderate or high work rate. There is much disagreement as to what test flow rates would be appropriate for these work levels. It would be equally difficult to explain to end users how these flow rates were derived and which may be applicable for their application. However, the ability to stack chemical families to different levels may be even more confusing. Customers (and manufacturers) need to understand that the Cap rating is only meaningful for NIOSH testing. Customers are required to establish canister change schedules based on service life estimates prior to use. It is quite feasible that a Cap 1 canister could be used for hours depending upon the contaminant and concentration. In other words, the Cap designations give a rough idea of performance capability for comparison, but service life calculations will determine how long the canister may actually be worn. Therefore, there seems to be little benefit for stacking of specific additional chemicals.

NIOSH has stated that the TRAs represent 6 chemical families in this standard and that capacities could be stacked for families. If we assume 6 different chemical families from the ten test gases, 6 capacities and 2 flow rates; the number of possible combinations is (6^6) X 2 or 93,312 possible combinations. This is beyond comprehension for all involved. Customers are still having difficulty understanding how to choose between nine different types of negative pressure particulate filters. It is much simpler from an end user, design and manufacturing perspective to only have the Cap 1, 2, etc. rating for the entire canister. Stacking will only determine the size of the canister and not tell the customer how long it can be used. They will still have to establish a change schedule. Scenarios can be run prior to purchase using tools such as the NIOSH developed software that is on the OSHA website or that furnished by manufacturers to determine which one will last longer, if that is an issue.

Canister Uniformity

3M proposes that NIOSH obtain data to examine veracity of a change so that the pressure drop range of supplied sample canisters conform with European NORM EN 12941/12942 calculated pressure drop Range/Average ≤ 0.2. Minimum canister lifetimes could be increased by 20% to account for extremes of this range, i.e., 15% for canister variation and 5% for manifold variation. 3M believes test data will confirm that these values are reasonable or enable definition of appropriate values.

6.3 Particulate/Aerosol Canister

Most of these requirements are identical to those published in 42 CFR 84 for P100 filters. NIOSH should just reference those requirements. As proposed, however, a particulate filter that passes these requirements is not a P100 because the test requirements, especially the airflow rate, are not identical to that of the P100. Calling a filter P100 that is not will only add confusion. This filter is also not a high efficiency filter as defined by NIOSH as the test for high efficiency does not include filter loading.

"6.3.3 When the canisters do not have separable holders and gaskets, the exhalation valves shall be blocked to ensure that valve leakage, if present, is not included in the filter efficiency level evaluation."

PAPR filters and canisters do not generally have valves on them. Any valves present are on the facepiece.

P100 filter rating and DOP testing

Section 6.3.4 should be revised to read: "A single PAPR canister will be tested at a continuous flow rate of 85 L/min." Delete the rest of the paragraph.

Justification: Data has not been presented to justify the complex test protocol NIOSH has proposed. The cost of introducing new test equipment to test complete filters at higher flow rates than used now would need to be justified by a measurable benefit to the end user. In addition, the time necessary to develop, validate and produce filter test equipment capable of the high proposed flow rates would significantly delay the approval process. It is important to recognize that no data suggests that current PAPR HEPA media provide inadequate wearer protection. Furthermore, no information has suggested that higher certification test flow rates would improve protection. Because the DOP test aerosol NIOSH proposes to use lies in the "most penetrating" size range of approximately 0.3 μm, performance will be better against aerosols of both smaller and larger size than that indicated by the certification test. This well-known filtration principle has been described often in the literature. Several references describe this and other fundamental filtration principles:

1. Hinds, W.C., 1982. Aerosol technology; Properties, behavior and measurement of airborne particles. New York: John Wiley and Sons. pp.164-186.

2. Brown, R.C. 1993. Air Filtration: An integrated approach to the theory and applications of fibrous filters. Oxford: Pergamon Press. pp.73-116.
3. Japuntich, D.A.: Respiratory particulate filtration. JISRP 2(1):137-169 (1984).

It is also likely that PAPRs tested under this module will have two or three filters, which would make the suggested test equivalent to a PAPR flow rate of 170 or 255 L/min, respectively. Combined with the DOP loading test included in the proposal, appropriate filter efficiency is assured.

It should also be noted that the proposed testing of filters with DOP will assure performance against all aerosols, including biological materials. The efficiency of respirator filters in removing bioaerosols has been studied extensively over the last decade. Results of these studies have been published in the peer-reviewed literature. A summary of this work was presented at the first public meeting on the CBRN full facepiece air-purifying respirator, June 18, 2002. The studies confirm that bioaerosols obey the same laws of aerosol physics as non-biological materials. They are removed with equivalent efficiency by the same filtration mechanisms. The authors invariably conclude that it is appropriate to use a non-biological aerosol to measure the performance of filters to be used against biological materials. References supporting the performance of filters against biological aerosols include the following:

1. Chen, S.-K., Vesley, D., Brosseau, L.M., and J.H. Vincent. Evaluation of single-use masks and respirators for protection of health care workers against mycobacterial aerosols. Am. J. Infect. Control 22:65-74; 1994
2. Brosseau, L.M., McCullough, N.V. and D. Vesley. Mycobacterial aerosol collection efficiency of respirator and surgical mask filters under varying conditions of flow and humidity. Appl. Occup. Environ. Hyg. 12(6):435-445; 1997
3. McCullough, N.V., Brosseau, L.M. and D. Vesley. Collection of three bacterial aerosols by respirator and surgical mask filters under varying conditions of flow and relative humidity. Ann. Occup. Hyg. 41(6):677-690; 1997.
4. Qian, Y., Willeke, K., Grinshpun, S.A., Donnelly, J. and C.C. Coffey. Performance of N95 respirators: Filtration efficiency for airborne microbial and inert particles. AIHA Journal 59:128-132; 1998
5. Willeke, K., Qian, Y., Donnelly, J., Grinshpun, S.A. and V. Ulevicius. Penetration of airborne microorganisms through a surgical mask and a dust/mist respirator. AIHA Journal 57:348-355; 1996

6.4 Crisis (Panic Demand) Provision

"Constant Flow PAPR and Pressure Demand PAPR canister capacity shall be evaluated using a constant flow rate of 430 L/min for 5 minutes."

The Crisis (Panic Demand) Provision test specified in section 6.4 is not a reasonable test for canister capacity and should be deleted. A flow rate of 430 L/min represents a peak inhalation rate that could be attained by few workers working at maximum capacity. This work rate would be sustainable for only several minutes, with peak flow rates occurring for tenths of a second per

breath. During normal PAPR operation, these peaks would be superimposed onto the PAPR flow through the canister(s), and would have negligible effect on canister bed loading. The canister tests at a minimum flow rate of 115 L/min or 300 L/min are the appropriate tests for canister capacity. If NIOSH feels it necessary to have a five minute test at the maximum possible work rate, a breathing machine with a sinusoidal pattern, a Ve of 114 L/min and a peak flow rate of ~360 L/min should be used.

No explanation was offered as to why the "panic mode" for CBRN PAPRs should be different than that in the CBRN full facepiece APR statement of standard. In addition, in the APR statement of standard the flow rate used is 100 liters per minute, 50±5 percent relative humidity and 25±5° C for each of the gases/vapors tested against.

6.6 Communications

The communication test proposed by NIOSH is a direct carryover from the CBRN, Full-Facepiece Air Purifying Respirators (APR) Statement of Standard. It does not consider the fact that there will be four CBRN PAPRs running at the same time in the test room. 3M does not believe the negative pressure full facepiece communications test is transferable to the PAPR Concept, without modifications.

In the APR standard, the speakers are 'trained' to speak at 75-85dBA. Their speaking volume is measured with a digital sound meter placed in front of the speaker. This test could present a demanding challenge based on the fact that in addition to the pink noise background, the noise from 4 PAPR units running in a closed environment will be adding to the background noise in the test chamber and the speakers could be speaking at the same level as the PAPR noise. The additional noise from the PAPRs should be included in the steady background noise of 60 dBA consisting of a broadband "pink" noise.

3M tested four Breathe Easy PAPRs running in a room separated by a distance of 10 feet to simulate the noise generated from 4 PAPRs running in a room. The PAPR running alone generated approximately 70 dBA and the combination of four produced almost 76 dBA. If the device is a hood, there will be additional noise from the movement of the test subjects inside the hooded PAPR, which will also add to the background noise. The CBRN PAPR will probably be operating at higher pressure and flow than current industrial PAPRs to meet the other requirements of the proposed CBRN Standard, thus presenting even higher noise levels than the standard industrial PAPR.

The exact details of the test need to be defrined in an STP that must be completed before the Concept is finalized.

6.7 Chemical Agent Permeation and Penetration Resistance against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement

No mention is made during this test whether the CBRN PAPR is running or not. If the PAPR is off, the proposed test airflow rate seems to be appropriate for the moderate breathing rate PAPR,

but not the high breathing rate PAPR. Because the higher flow rate could affect vapor permeation, this PAPR should be tested at a higher airflow rate during the distilled sulfur mustard (HD) and Sarin (GB) chemical agents tests.

6.8 Laboratory Respiratory Protection Level (LRPL) Test Requirement:

LRPL test requires an APF of 10,000 and is excessive. The justification appears to be that because these devices are expected to provide an APF of 1000 that an LRPL number ten times greater than that should be obtained, hence, 10,000. This implies that loose fitting facepieces perform at the same level of loose fitting hoods and helmets, i.e., 1000 where the world outside of NIOSH expects an APF of 25. In fact, NIOSH recommends an APF of 25 for all hoods and helmets so this pass value appears to be set extremely high.

The proposed LRPL test appears to be designed for tight-fitting respirtory inlet coverings only, i.e., full facepieces, and hoods and helmets with neck dams. A required LRPL of 10,000 could eliminate hoods without a neck dam. 3M is one of the leaders in providing respiratory protection to healthcare and our marketing information indicates that first receivers (hospital personnel) prefer loose fitting hoods. It appears since this concept seems to eliminate these devices; the needs of the first receivers are not being addressed.

The proposed test does not address loose fitting hoods and helmets. No mention is made as to how they would be fitted to the LRPL test panel. Loose fitting hoods and helmets will most likely be provided in just one size. This requirement needs to address the panel requirements when the respirator is provided in only one size.

On another point of the LRPL test, if the user instructions are required to clearly and accurately explain how users choose appropriate sizes of respirtory inlet coverings, then NIOSH must ensure that they follow those instructions during the testing with personnel having the same degree of commitment as the end user will have.

This section does not mention what happens if the Low Flow Alarm indicates during the LRPL. It is 3M's recommendation that the LRPL test be discontinued and the user exit the test chamber. The LRPL test should not be performed with the respirator being used in a manner inconsistent with the manufacturer's user instructions.

6.9 Durability Conditioning

NIOSH needs to rewrite the following statement in plain English; "Batteries Exposed to Durability Conditioning must not render the PAPR in-operable and must result in self –reporting of functionality." 3M believes NIOSH should say; "After durability conditioning the battery must be able to power the PAPR."

In Section 6.9, clarify the battery functionality, i.e., fully charged, not broken, etc.

6.12 Practical Performance

NIOSH needs to define "acceptable practical performance" and how they will assess when it has been attained. The inability to accidentally turn off the respirator is subjective and could be very dependent upon the test subjects chosen. The effect of "the inability for hoses and electrical wires to tangle, causing the respirator position on the wearer to move to an improper position, such as the respirator facepiece or hood being removed from the wearer's head" will be captured during the LRPL test. The removal of the respiratory inlet covering during the LRPL test will lower the LRPL value and therefore is not needed here. As a result, NIOSH should delete this requirement from the Concept. Furthermore, before NIOSH finalizes this concept, the other factors NIOSH plans to evaluate under "practical performance" must be identified. Many items of practical performance relate to issues the purchaser evaluates when selecting a device. In 3M's view, NIOSH should allow CBRN PAPR customers are unable to decide for themselves what operating features are important to them.

6.14 Cautions and Limitations

"To Be Determined"

These cautions and limitations need to be decided before the Statement of Standard is published instead of being finalized as NIOSH is accepting submissions.

Suggested cautions and limitations:

A- Not for use in atmospheres containing less than 19.5 percent oxygen.
J- Failure to properly use and maintain this product could result in injury or death.
L- Follow the manufacturer's User's Instructions for changing cartridges, canister and/or filters.
M-All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
O-Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
S- Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

CBRN CAUTIONS AND LIMITATIONS
R- Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.
T- Direct contact with CBRN agents requires proper handling of the respirator after each use and between multiple entries during the same use. Decontamination and disposal procedures must be followed. If contaminated with liquid chemical warfare agents, dispose of the respirator after decontamination.
V- Not for entry into atmospheres immediately dangerous to life and health or where hazards have not been fully characterized.
W-Use replacement parts in the configuration as specified by the applicable regulations and guidance.

X- Consult manufacturer's *User* Instructions for information on the use, storage, and maintenance of these respirators at various temperatures.
Y- This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.
Z- If during use, an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air.
HH- Follow established canister change out schedules or observe End of Service Life Indicators to ensure that canisters are replaced before breakthrough occurs.
QQ-Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained.
UU- The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours.

Suggested Typo and Editorial Changes

Background

Hot Zone: This zone is also referred to as the exclusion zone, red zone or restricted zone in other documents (EPA Standard Operating Safety Guidelines, OSHA 29 CFR 1910.120, and NFPA 472).

Para. 4

The CBRN PAPR Concept addresses major performance issues for flow, hazard protection, filter capacity and particulate filter efficiency. The Concept addresses each of these respirator issues with performance-based requirements. The CBRN PAPR Concept specifies requirements for breathing performance based on the ability of the respirator to maintain a positive pressure in the breathing zone when tested with a breathing machine. The concept further allows for performance evaluation and approval at a moderate or high work rate. Breathing machines operating at 40 liters per minute (L/min) and 103 L/min volume work rates are used to establish conformance with the requirement. These breathing machine rates are well-recognized criteria used to evaluate self-contained breathing apparatus. Using this Concept a CBRN PAPR approval would be issued for either a moderate work rate or high work rate.

• 99.97% particulate filter efficiency and

The minimum filter canister capacity is defined using a test time of 15 minutes at gas concentrations based on three times immediately dangerous to life or health (IDLH) concentrations.

Filter capacity and particulate filter efficiency testing is done at flow rates determined by the maximum flow rate of the respirator.

In addition to flow, filter capacity, work rate and particulate filter efficiency…

2.0 Purpose

Develop a NIOSH, NPPTL, powered air-purifying respirator standard that addresses chemical…

3.1 Definitions

(b) Tight fitting PAPR – a PAPR, which contains a respiratory inlet covering that seals ~~tightly~~ to the face.

c) Neck dam PAPR – a PAPR, which contains a hood or helmet and which covers and seals ~~tightly~~ around the neck area.

d) Respiratory inlet covering – A facepiece, hood, helmet or some combination of these, which serves as the covering to the nose and mouth area ~~and ensures that only purified air reach these areas~~.

3.2 Respirator Use

A. Warm Zone/Cold Zone Use: Concentrations above acceptable exposure limits, but less than IDLH concentrations, to NIOSH Recommended Exposure Limit (REL).

B. Crisis (Panic/Demand) Provision Mode: Egress and escape from above IDLH concentrations where oxygen concentration is greater than 19.5%, high physiological (flow) demand possible; contingency for unforeseen factors such as secondary devise or pockets of entrapped hazard.

5.1.3. Required Packaging Configuration: Minimum packaging configuration:

Examples of common Minimum Packaging Configurations are mask carriers, clamshell containers, draw~~l~~ (change to draw) string plastic bags, hermetically sealed canister bags or nothing at all.

5.3.1.3. The user instructions shall also provide the specific indicator location and method of indication in a ~~manor~~ manner that the user can understand.

Section 5.4.2 / 5.4.3

3M suggest the following change in the wording in this section: CBRN Powered air-purifying respirators will…

5.6.3 Abrasion Resistance: After the residue is removed from the test specimens, the test specimens shall not exhibit an increase of haze greater than 4% and a decrease of luminous transmittance greater than 4%.

5.9 Noise Levels

Noise levels generated by the PAPR measured at each ear location shall not exceed 75 dBA. In the case of respiratory inlet coverings that cover the ear, the noise level will be measured inside the respiratory inlet covering.

6.2 Canister Capacity

"Three canisters will be tested at each specified humidity for each gas."

Table 3

The wording for adjusting the flow rate based on the number of air purifying elements is more complex than needed. We suggest: "The filter canister capacity airflow rate shall be divided by the number of filter elements used on the PAPR."

"In addition to this, as per manufacturer request,…"

6.3 Particulate/Aerosol Canister

6.3.3 When the canisters do not have separable holders and gaskets, the exhalation valves shall be blocked to ensure that valve leakage, if present, is not included in the filter efficiency level evaluation.

6.5 Low Temperature/Fogging

"The CBRN PAPR respiratory inlet covering shall demonstrate and average Visual Acuity Score (VAS) of greater than or equal to 75 points…"

6.12 Practical Performance

"The Practical Performance of the CBRN powered air-purifying respirator…"

Figure 1

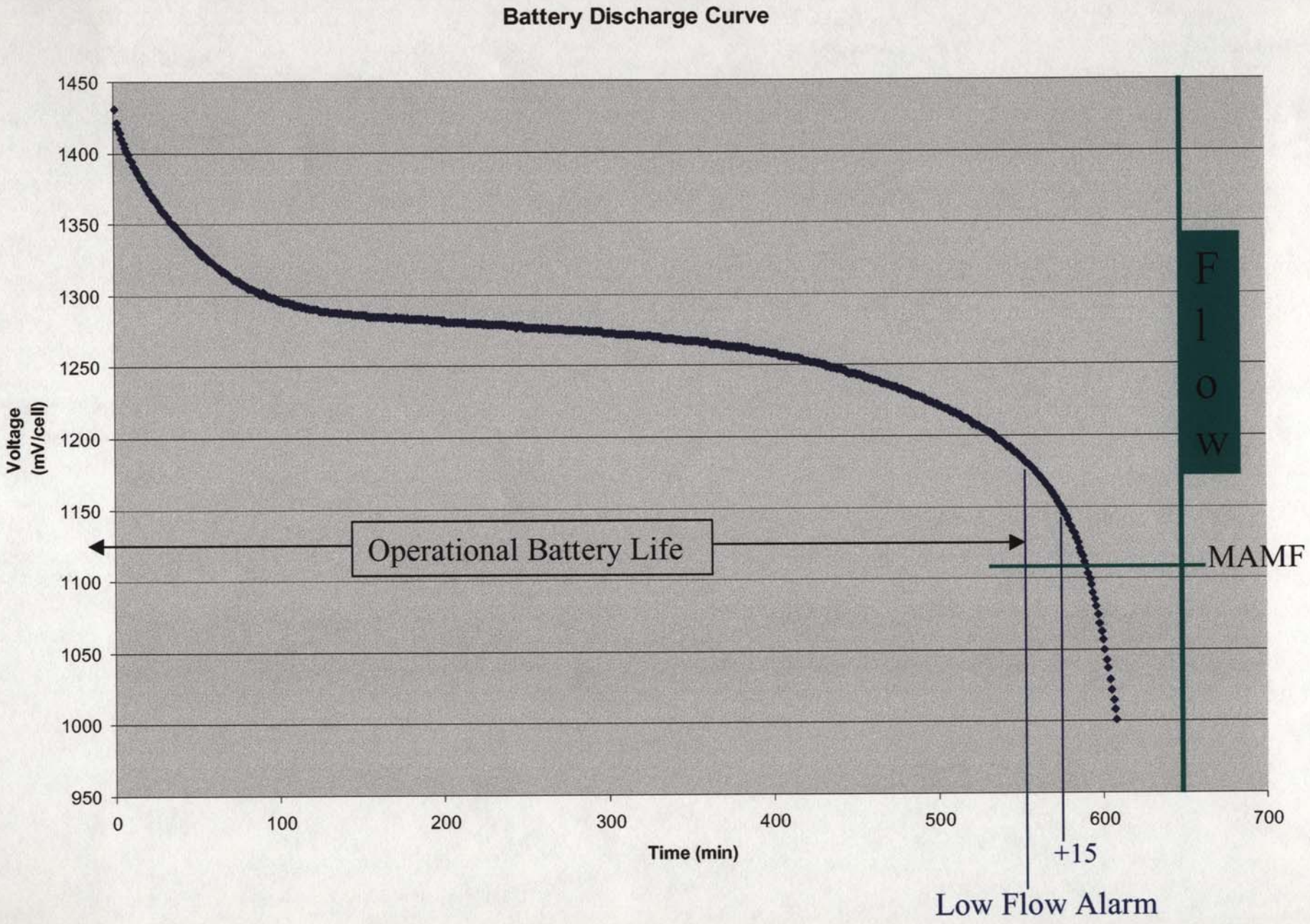
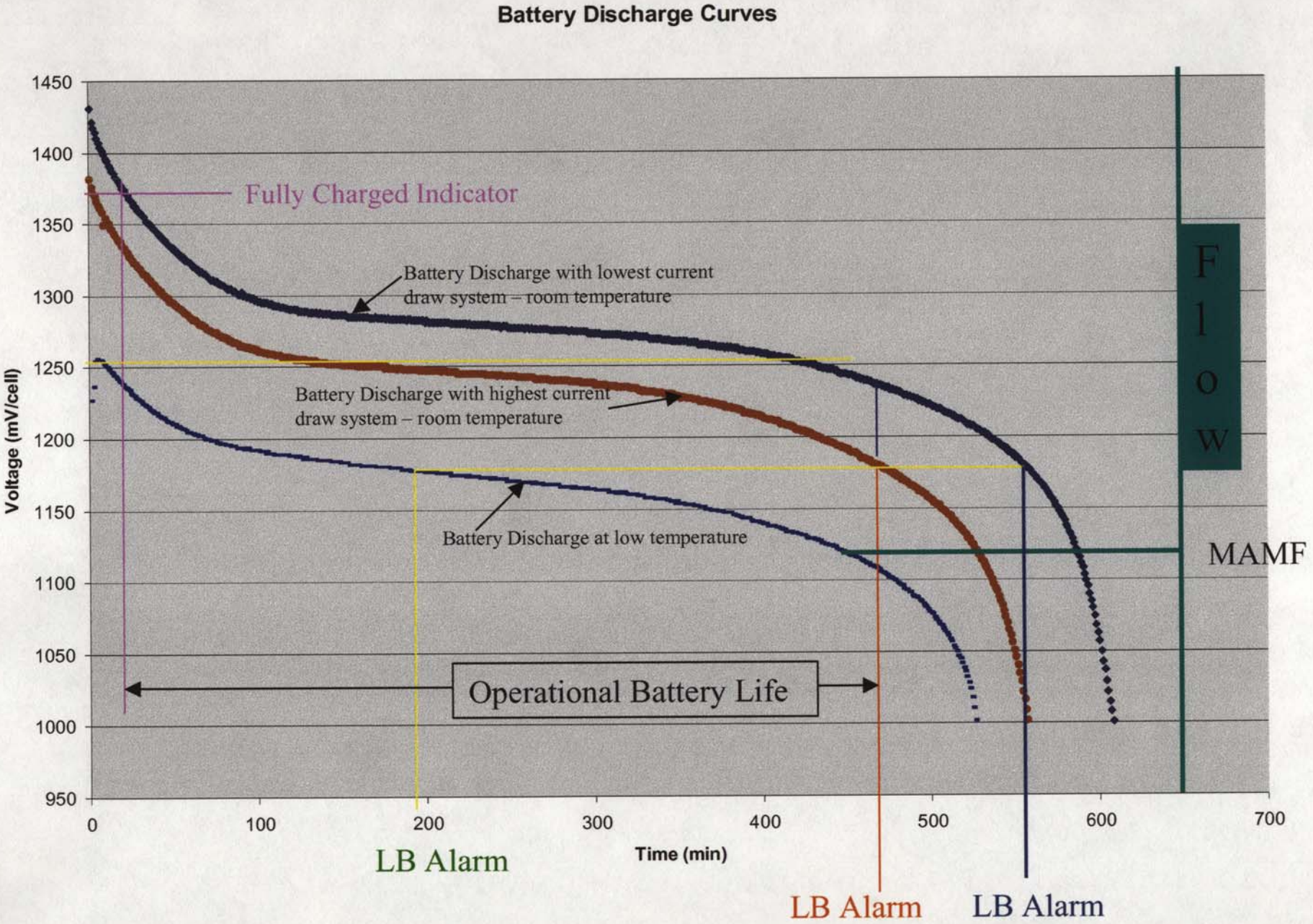

Battery Discharge Curve
Voltage (mV/cell)
1450
1400
1350
1300
1250
1200
1150
1100
1050
1000
950
0
100
200
300
400
500
600
700
Time (min)
Operational Battery Life
MAMF
Flow
+15
Low Flow Alarm

Figure 2


Battery Discharge Curves
Voltage (mV/cell)
1450
1400
1350
1300
1250
1200
1150
1100
1050
1000
950
0
100
200
300
400
500
600
700
Time (min)
Fully Charged Indicator
Battery Discharge with lowest current draw system – room temperature
Battery Discharge with highest current draw system – room temperature
Battery Discharge at low temperature
Operational Battery Life
F l o w
MAMF
LB Alarm
LB Alarm
LB Alarm

Attachment 1 Examples of Loose fitting Respiratory Inlet Coverings

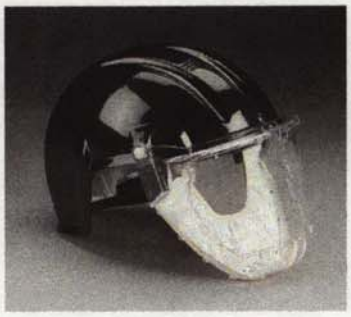
Loose-fitting facepieces (APF 25)

BE-Headcover

L-70X

L-50X

AirCrown



AS/R-Headgear

Hoods (APF – 1000)

H-Series

R-Series

Helmets (APF – 1000)

L-90X

W-8100(B)

Attachment 2

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health - ALOSH
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July 30, 1996

Mr. Larry Jassen, CIH
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OH & ES Division
Technical Service Specialist
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St. Paul, Minnesota 55144-1000

Dear Mr. Jassen:

This reply is in reference to your letter of July 10, 1996, regarding the use of the term, "positive pressure" as it applies to supplied air respirators.

You are correct that a continuous flow class respirator is not approved as a pressure-demand class respirator. The term "positive pressure" as used in the NIOSH Respirator Users Notice dated May 23, 1996, did not intend to imply that pressure-demand or positive pressure were two distinct approval classes of respirators. These are both pressure-demand class approvals. These are designed differently in that one uses a pressure-demand valve while the other operates in the continuous flow mode. Although, these designs are different, both meet the pressure-demand class requirements.

There is only one class approval for a pressure-demand respirator as listed in the Regulations, and that is as a pressure-demand approval. In fact the approval label heading will always list a pressure-demand respirator as an approved pressure-demand class approval without exception. Any other class listed on the approval label, such as, demand or continuous flow classes are not considered positive pressure respirators nor approved as a pressure-demand class respirator.

The apparent conflict which you detail between the paragraphs 84.157 and 84.162 (b) are set for different reasons, but only one is specific to a pressure-demand class approval while the second is specific to continuous flow class approval. The paragraph 84.157(b) is a test for a pressure-demand class respirator. This is a quantitative test in that it is reproducible since the test is performed with a breathing machine at measured peak air flows of 115 liters per minute. Also, the preceding paragraph 84.157 (a) must be met during this pressure-demand class test. That is, the respirator must maintain a static pressure not to exceed 1.5 inches of water column height, which is set to assure that the pressure in the facepiece will not fall below ambient during the breathing cycle. The paragraph 84.162 (b) is a qualitative fit test using a test subject wearing a continuous flow

class respirator. There is no requirement for a static pressure in the facepiece, which by design is intended to keep the facepiece pressure positive during the operation of the pressure-demand valve through the breathing cycle and respiratory frequency. This minimum flow rate is that which results from the lowest air pressure requested by the manufacturer. The breathing cycle would then be expected to remain positive simply because the wearer is not working at a high work rate while performing the simple walk and pump tests.

A "positive pressure" tight fitting full face piece respirator is one which operates in the continuous flow mode by design, but was submitted to NIOSH for a pressure-demand class approval, has been tested under the applicable requirements for that class, and meets all the requirements for a pressure-demand class approval.

This permits respirators regardless of design to be approved for use at a high protection factor (PF) if it meets all the applicable tests for the appropriate class.

The recommendation of a PF of 1000 for a "positive pressure" half-mask respirator would be for a respirator which has a pressure-demand approval as evidenced for the class approval as listed in the heading of the approval label. This would include a respirator with a pressure-demand valve or one which is designed to operate in a continuous flow mode, but was submitted for and tested as a pressure-demand class respirator. Any respirator approved by NIOSH is assigned an approval number which is unique to that respirator design and approval class. The same approval number is not assigned to a respirator in two different classes.

I hope that this response answers your questions, and if you would like to discuss this further, please call Sam Terry or me at (304) 285-5907.

Sincerely yours,

Richard W. Metzler, Chief
Certification and Quality
Assurance Branch
Division of Safety Research