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

From: cmschmidt1@mmm.com
Sent: Friday, March 28, 2008 6:08 PM
To: NIOSH Docket Office (CDC)
Cc: robert.weber@mmm.com
Subject: 3M's Comments
Attachments: 032808.pdf

Attached are 3M's comments concerning:

December 21, 2007 Proposed Concept: Powered Air-Purifying Respirator (PAPR) Standard Subpart P, Docket-008

Best regards,

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March 19, 2008

NIOSH Docket Officer, REFERENCE: NIOSH DOCKET-008
Robert A. Taft Laboratories MS-C34
PAPR – Docket #008
4676 Columbia Parkway
Cincinnati, OH 45226
NIOCINDOCKET@CDC.GOV.

RE: December 21, 2007 Proposed Concept: Powered Air-Purifying Respirator (PAPR) Standard Subpart P, Docket-008

Dear Docket Officer:

3M 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. We have developed numerous training programs, videos, computer programs and technical literature to help our customers develop and run effective respirator programs. 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 these data in numerous forums and participated in the development of the ANSI Z88 standards on respiratory protection. In sum, we have substantial experience in all phases and applications of respiratory protection. We are pleased to offer the following comments and recommendations regarding the Concept for Industrial Powered Air-Purifying Respirator (PAPR), dated December 21, 2007.

3M supports NIOSH in its effort to develop updated standards for evaluating the effectiveness of powered air purifying respirators for use in a variety of industrial environments.

We appreciate the opportunity to add our comments and knowledge to the docket and look forward to the development of a fair, protective and useful concept.

Sincerely,

Robert A. Weber
Laboratory Manager, Regulatory Affairs
3M Occupational Health & Environmental Safety Division

Industrial PAPR Concept Dated December 21, 2007

General comments: Sections not mentioned below are supported by 3M as proposed. The Standard Testing Procedures (STP) must be linked to the test requirements in future concept papers. We will reserve our comments on the STPs until they are published. The numbers at the start of each new section from the Concept are in **bold**. Recommended changes are in blue and inset.

2. Definitions

Clarification is needed to be certain that NIOSH is including all of the options for respiratory inlet coverings available today. We appreciate the use of this term by NIOSH, but the wording in the definitions does not reflect that there are both tight fitting and loose fitting facepieces, hoods and helmets. The reason for this belief should be apparent upon reviewing the specific comments on the definitions.

Specific comments

The blue type indicates our recommended changes.

2.3.3 Loose-fitting facepiece - a respiratory inlet covering which makes contact with but does not seal to the face. It ~~may~~ does not cover the neck, the back of the head or shoulders.

Comment: This change is necessary because if the respiratory inlet covering covers the neck, the back of the head or shoulders it is a hood or helmet so it is not an option for a loose fitting facepiece to cover the neck, the back of the head or shoulders, *see 2.3.1 and 2.3.2.*

2.3.4 Loose-fitting neck dam - a respiratory inlet covering which makes contact with but does not seal to the neck.

Comment: Respiratory inlet coverings use neck dams to make them tight-fitting. Without a neck dam they are loose-fitting. NIOSH's distinction is not clear is because this term has not been defined and second neck dams they are always used with hoods and helmets. They are not used on other respiratory inlet coverings. A "loose fitting" neck dam first is an anomaly as there are no loose fitting neck dams as neck dams are tight-fitting and they are not a respiratory inlet covering, but rather a component of a tight-fitting respiratory inlet covering. By manufacturer convention, they are only on tight fitting hoods and helmets. Loose fitting hoods and helmets use either a collar or bib to help build up a positive pressure in the respiratory inlet covering. The dam is used to create a seal that is a barrier and has been used on air purifying escape hoods and SCBAs. This term is also not used in the Concept so it technically should be deleted. At a minimum, this term should be redefined and placed in the definitions under "neck dam."

2.X. Neck dam – material used on helmets and hoods to provide a seal to the neck, creating a tight-fitting respiratory inlet covering.

Comment: Neck dam is also not used in the concept so it is really not needed.

2.4 Canister PAPR (Gas Mask PAPR) - A tight-fitting ~~full facepiece~~ PAPR which…

Comment: "Full facepiece" should be removed because there is no reason hoods with neck dams, i.e., tight fitting hoods, could not be used. As we read the CBRN PAPR concept these would be allowed. Therefore, "full facepiece" should be deleted from this definition as shown above. Also the statement, "Additionally, a unit may be of intrinsically safe design" should be removed as this is not unique to Canister PAPRs and also applies to other PAPR categories as well.

2.5 Chemical cartridge PAPR - A PAPR which contains an appropriate cartridge and/or filter suitable for its intended use and not intended to be used for entry into or escape from atmospheres that may be Immediately Dangerous to Life or Health Concentrations (IDLH).

Comment: This group of PAPRs needs a provision allowing it be approved with intrinsically safe design as well as gas mask PAPR. In addition, NIOSH should rewrite this statement in positive language as the rest of 42 CFR 84 is:

"2.5 Chemical cartridge PAPR - A PAPR which contains an appropriate cartridge and/or filter suitable for its intended use which are designed for use as respiratory protection during entry into or escape from atmospheres not immediately dangerous to life or health (IDLH)."

2.7 LCBRN -.A ~~loose-fitting~~ chemical cartridge PAPR that meets the additional minimum requirements defined herein for LCBRN protection.

Comment: There is no reason to limit these devices to loose fitting respiratory inlet coverings. LCBRN with hoods or helmets have the same APF as full facepiece PAPRs. The APF of PAPRs with full facepieces are higher than those of the loose fitting facepieces. The difference between CBRN PAPR and LCBRN PAPR is not the type of respiratory inlet covering, but rather whether it has canisters or cartridges, respectively.

2.13 Work rating- A PAPR air flow rating. The three ratings are Low, Moderate or High, as designated by the manufacturer.

Comment: There is no reason to certify PAPRs to a flow rate rating as the APFs and their use are all the same. In other words the APF is not dependant on the flow rate rating.

3 Descriptions

3.1 A PAPR utilizes a powered mechanism to move ambient air through an air-purifying element(s) to remove contaminants from the ambient air. It is designed for use as respiratory protection against atmospheres with particulates (solid and/or liquid contaminants), gases and/or vapors or combination of gases, vapors and/or particulates where concentrations during entry and use are not IDLH and adequate oxygen exists to support life. All are considered as positive pressure when tested by air flow testing described herein.

3.1 A PAPR utilizes a powered mechanism to move ambient air through an air-purifying element(s) to remove contaminants from the ambient air. PAPR are designed for use as respiratory protection against atmospheres with particulate contaminants (solid and/or liquid ~~contaminants~~), gases and/or vapors or combination of gases, vapors and/or particulates ~~where the concentrations~~ during entry into and use that are not IDLH with adequate oxygen to support life. All are considered as positive pressure when tested by air flow testing described herein.

3.2 Gas Mask PAPR is a tight-fitting ~~full facepiece~~ PAPR equipped with appropriate canisters.

Comment: Same comment as 2.4.

3.3 LCBRN PAPR is a ~~loose-fitting~~ PAPR meeting the additional minimum requirements for ...

Comment: Same comment as 2.7

3.4 No half-mask CBRN PAPR shall be approved for CBRN protection.

Comment: This standard should not be so design restrictive that use of a half mask LCBRN would be prevented. If NIOSH's concern is the lack of skin and eye protection or lower protection, we submit that skin and eye protection is not sufficient justification for eliminating half masks when these routes of entry or targets can be protected by other means. A full face CBRN PAPR does not protect the entire body from CBRN agent so other measures will have to be taken to totally protect the worker. The need for other means to protect the body is no different with the half mask and is why there is more to selecting a proper respirator than looking to see if it says NIOSH and CBRN. In fact, the half mask PAPR provides a higher degree of protection than the LCBRN PAPRs that NIOSH currently approves (APF of 50 vs 25).

4.1 Non-Respiratory Requirements

4.1.1 Required Components

4.1.1 Required Components. A PAPR shall, **where its design requires**[emphasis added], contain the following component parts:

Comment: Item (7) should be revised to say "low flow and/or low pressure indicator." Either can be used to warn the user when the PAPR is no longer performing at its certified performance level. Our explanation for this statement is fully explained in our comment to 4.1.2.2 below.

(7) Low flow and/or low pressure indicator

4.1.2 General Considerations

Comment: Many of the paragraphs in this section contradict the statement in 4.1.1 "where its design requires" because there are many cases where PAPRs do not need to be designed with all of the indicators listed. There are many places where users have purchased PAPRs for exposures either below the occupational exposure limits (OEL) or just above the OEL where a low APF is appropriate. PAPR selection will be made on the basis of cost and other features it provide, generally comfort related, e.g., air flow, eye protection and perhaps hard hat features built into one device. Alarms are not needed in cases where respirator use is not required and will drive up the cost needlessly and may result in denying these workers respiratory protection or certainly this high level of respiratory protection. Certainly NIOSH would not want to issue regulations that would diminish the likelihood of workers receiving respiratory protection.

In addition, PAPRs are only allowed to be used to enter into atmospheres in which the worker can escape without the aid of the respirator (non-IDLH atmospheres). Certainly in environments where you can exit without the respirator, alarms may not be required. In addition, the importance of the Time Weighted Average concept cannot be disregarded when considering this topic. We do believe there will be situations where alarms will be desired but this discretion needs to be left to the user.

4.1.2.1 Each PAPR, where necessary, shall have a monitor to indicate the condition of the power source. It... or "Each PAPR with ~~shall have~~ a monitor to indicate the condition of the power source, ~~It~~ the monitor shall be readily ...

4.1.2.2 Each PAPR shall have an active indicator which alerts the user to low pressure in the breathing zone.

Comment: 4.1.2.2: PAPRs should not be treated as SCBA. Since PAPRs are intended for routine use in atmospheres that are not IDLH, there is no compelling reason to require alarms; they should be optional at the manufacturer's discretion. The statement should also be revised to indicate that if an alarm is used, it may actuate based on either low flow or low pressure. The two are inter-related; pressure in the inlet covering

is maintained by providing appropriate air flow. Further, it is known that most, if not all, positive pressure respirators can be drawn into momentary negative pressure excursions in actual use. There are laboratory studies[1,2] and field studies[3] that have measured these excursions. When the data from these studies are analyzed, it is readily seen that the occasional negative pressure excursions that occur in positive pressure respirators have negligible effect on protection, even during periods of heavy work. Campbell et al.[3] demonstrated this with a mathematical model; Cohen et al.[2] measured simulated workplace protection factors (equivalent to LRPL) far in excess of 10,000 for all but one device. Therefore, an alarm that actuates after one or a few momentary negative pressure excursions is not useful. It does not tell the user he or she may be at risk of possible reduced protection because of declining PAPR function. The permissible response time for the low pressure indicator must be specified to prevent spurious alarming. Spurious alarming may result in one ignoring the alarm or disconnecting it. To provide PAPR wearers useful information, we suggest an alarm that actuates when airflow falls below the manufacturer's stated minimum for 30 seconds. This would address several failure modes, including clogged filters, low battery and motor degradation. We suggest the requirement be revised to read:

> *4.1.2.2 If a PAPR is equipped with an alarm, it shall alert the user, via a readily visible light or other means, when the airflow of the PAPR falls below the manufacturer's stated minimum design flow (MMDF) for 30 or more seconds. It shall be readily detectable to the wearer during use without manipulation of the respirator. Indicators that are actuated when pressure inside the respiratory inlet covering falls below the manufacturer's stated minimum for 30 or more seconds are also acceptable.*

4.1.2.5 Color coding of cartridges and canisters shall be as per the ANSI Z88.7-2003 standard where applicable.

Comment: This requirement causes some confusion. ANSI Z88.7 has color code requirements for particle filters as well as gas and vapor filters. It is not clear if NIOSH intends this statement to include the particle filter color codes as well. Presently, 42 CFR 84 Subpart K requires a color code for only one filter type and that is for the P100 filter. The P100 is required to be magenta and the other filters must be some color other than magenta. We suggest the addition of the following sentence:

> *Purple (Munsell Notation 7.5P 4/8) color shall be used to identify PAPR 100 filters.*

We have used this language from ANSI Z88.7 over the magenta color designation currently used by NIOSH because the color called out for P100 filters in Subpart K is from a now obsolete National Bureau of Standards color-code. This old color, however, matches Munsell Notation 7.5P 4/8.

4.1.2.6 Where two or more cartridges, canisters or filters are used in parallel, their resistance to air flow shall be essentially equal when measured at 85 Lpm.

4.1.2.7 Where two or more cartridges, canisters or filters are used in parallel, the manifold system shall be designed for essentially equal air flow through each cartridge, canister or filter.

Comment: Both of the above paragraphs used the phrase "essentially equal." This is a subjective term and simply not suitable. NIOSH must provide the STP prior to publication of this concept in order to receive comments.

4.1.4.1 Each respirator shall, where necessary, be equipped with a suitable harness designed and constructed to hold the components of the respirator in position against the wearer's body.

Comment: The wording of this paragraph is very specification oriented and should be written in a more performance oriented manner. We suggest the following:

4.1.4.1 Each respirator shall, where necessary, be equipped with a ~~suitable harness designed and constructed~~ **mechanism** to hold the components of the respirator in position against the wearer's body and will be evaluated during the practical performance test.

4.1.6.2 Common safety and/or corrective eyewear shall not interfere with the fit of half-mask facepieces.

Comment: This requirement is not measurable nor enforceable and should therefore, be deleted. Interference of equipment depends on the specific eyewear and the user's facial characteristics and is best addressed during selection and fitting of the device as required by OSHA. NIOSH has no control over what happens in the workplace.

~~4.1.6.2 Common safety and/or corrective eyewear shall not interfere with the fit of half-mask facepieces.~~

4.1.6.4 Hoods, helmets, and loose-fitting facepieces shall be designed and constructed to fit persons with various head sizes, allow for the optional use of corrective eyewear, and insure against any restriction of movement or vision by the wearer.

Comment: This requirement is not measurable and unenforceable and should therefore, be deleted. Interference of equipment depends on the specific eyewear and the user's facial characteristics and is best addressed during selection and fitting of the device as required by OSHA.

4.1.6.5 Helmets designed for head protection shall meet the requirements of ANSI Z89.1-2003 Type I or Type II protective cap standards. Helmets not designed to provide head protection shall be prominently and permanently labeled to indicate that they are not impact and penetration resistant.

Comment: This standard is for respiratory protection devices. NIOSH should not set requirements for head protection in a respiratory protection device standard Additionally referencing this specific ANSI standard is in conflict with OSHA's Proposed Rule on PPE Designs. Preferably, this requirement should be deleted in its entirety.

Deleted: .

Respirator Type	Low Work Rate	Moderate Work	Rate High Work Rate
Tight-fitting	~~Not Applicable~~115 Lpm	115 Lpm	170 Lpm
Loose-fitting	115 Lpm	170 Lpm	235 Lpm

4.2.4.2 Pressure shall remain above ambient at all times during testing. Static pressure relative to external pressure may not exceed 2" of water column height for any PAPR during testing.

Comment: This statement needs to clearly define what is desired by NIOSH. It is not clear what NIOSH means by Static pressure here and appears to conflict with other statements in the standard.

4.2.5 Breathing gas: Carbon dioxide (CO_2) machine tests

Comment: There should be only one CO_2 test and it should be the one performed with the breathing machine.

4.2.5.8 The maximum allowable average carbon dioxide concentration during the "inhalation" cycle, determined by subtracting the blank run average CO_2 level measured during the "inhalation" phase from the average CO_2 level measured during the "inhalation" phase with the respirator properly mounted on the headform, shall not exceed 1.0 % for one of the three donnings.

Comment: The last sentence is unclear. It says in effect that CO_2 could exceed 1% for 2 donnings-this is probably not what NIOSH meant to say.

4.2.7.1.1 PAPR dual cartridge/canisters shall first be tested as received and shall meet the minimum requirements set forth in Table 3 of this subpart for each gas/vapor for which approval is sought using the constant required flow rate set forth in Table 2. Each tested dual cartridge/canister element shall then be stored in an air-tight enclosure. After no less than eight and not more than twenty four hours, the same dual cartridge/canisters shall then be tested at the same humidity and temperature as the initial test and meet the requirements set forth in Table 4 of this subpart for the corresponding gas/vapor using the constant required flow rate set forth in Table 2.

Comment: This is very puzzling. Table 3 is for cartridges and Table 4 is for canisters. The air purifying elements should be tested as one or the other, not both. Also, retesting after storage only makes sense for particle filters. The loading with a gas or vapor is cumulative-retesting as currently specified, amounts to a dramatic increase in the

capacity required (more than doubling if you make cartridges pass the canister test after storage). If the desire is to test for desorption, NIOSH should use clean air.

Also, as written this paragraph prohibits PAPR's that might use three or more cartridges.

It is unclear why Table 2 cannot have a Low Work Rate for tight fitting PAPR. NIOSH needs to explain this point. Put in 115 Lpm if this is the lowest flow acceptable.

4.2.7.1.1 PAPR ~~dual~~ cartridge/canisters shall first be tested as received and shall meet the minimum requirements set forth in Table 3 or Table 4 respectively, of this subpart for each gas/vapor for which approval is sought using the constant required flow rate set forth in Table 2. Each tested ~~dual~~ cartridge/canister element shall then be stored in an air-tight enclosure. After no less than eight and not more than twenty four hours, the same ~~dual~~ cartridge/canisters shall then be tested at the same humidity and temperature as the initial test using clean air flowing through the cartridge or canister and meet the same breakthrough requirements set forth in Table3/Table 4, respectively, of this subpart for the corresponding gas/vapor using the constant required flow rate set forth in Table 2.

4.2.7.3.1 Manifold testing may be performed based on an engineering analysis of system.

Comment: NIOSH needs to define what is meant by manifold testing and engineering analysis.

4.2.7.7.1 The test concentration for cartridges shall be the IDLH multiplied by four (4).

Comment: It is unclear why NIOSH would use a test concentration of 5000 ppm for canisters and then use a multiple of the IDLH for cartridges. It would be better to be consistent: either list a concentration for both (e.g., 1000 ppm for cartridges) or multiples of the IDLH for both. If the IDLH values are used, they must be specified by a reference. There are currently two sets of NIOSH IDLH values in use: OSHA uses those last published in 1990 and; there are the values referred to below. It is our position that a concentration of 4 times the IDLH is too high. A multiple of 1.5 seems sufficient especially because cartridges can not be used in IDLH environments. We suggest the revised sentence read as follows:

> *4.2.7.8.1 For gases under this paragraph (d) the canister test concentration calculation shall generally be set at the IDLH concentration listed in NIOSH Publication No. 2005-149 multiplied by 1.5.*

4.2.7.7.4 The maximum breakthrough concentration shall be the NIOSH recommended exposure limit (REL).

Comment: The maximum breakthrough concentration should not be set using the REL. The NIOSH RELs do not consider feasibility in measuring the number which could result in setting a breakthrough concentration for which there is no way to measure it. NIOSH should set a concentration (ppm) that they know can be measured reliably. NIOSH has done this for the canisters and should do it for cartridges.

4.2.7.8 Canister test conditions shall be determined as follows:

4.2.7.8.1 The test concentration for canisters shall be 5000ppm.

The test conditions in this paragraph are identified much more simply and clearly than in 4.2.7.7.1 We suggest changing 4.2.7.7.1 to "The test concentration for cartridges shall be 500 ppm."

4.2.8.1 Twenty filters or filter assemblies of each powered air-purifying particulate respirator model shall be tested for filter efficiency against a DOP ~~or equivalent liquid particle~~ aerosol. ~~deemed to meet the requirements of this section.~~

Comment: Alternatives to DOP may be acceptable, but NIOSH must specify all the test aerosols they intend to use and understand that properties of oils are different; therefore the performance of filters will not be the same from one oil to the next. If NIOSH feels compelled to add another oil we suggest they reference paraffin oil which is used in EN standards.

Deleted: .

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

Comment: There is no exhalation valve here.

4.2.8.6.1 A neat, cold-nebulized DOP ~~or equivalent~~ aerosol at 25 ± 5 °C that has been neutralized to the Boltzmann equilibrium state shall be used. Each PAPR100 and PAPR95 filter shall be challenged with a concentration not exceeding 200 mg/m3.

Comment: Alternatives to DOP may be acceptable, but NIOSH must specify all the test aerosols they intend to use. NIOSH also needs to understand that properties of oils are different; therefore the performance of filters will not be the same from one oil to the next. If NIOSH feels compelled to add another oil we suggest they reference paraffin oil which is used in EN standards.

Deleted: .

4.2.8.6.2 The PAPR100 test shall continue until minimum efficiency is achieved or until an aerosol mass of ~~1000 ± 50~~ 200 mg has contacted ~~each filter~~ the system.

Comment: The proposed loading is excessive. The loading concentration for non-powered particulate respirators is excessive, yet this loading is even higher. For a PAPR system with 2 filters, this recommendation would result in a loading of 500 mg

per filter. The loading should be should be set at 200 mg per system. Even this value is excessive, but has been used with other filters. The 1000 mg load could result in so much liquid on the filter that you will measure re-aerosolization of the deposited oil and not filter efficiency degradation.

4.2.9 Breathing gas concentration determinations: O_2 and CO_2 human subject generated

Comment: There should be only one test, see earlier comment regarding using the breathing machine CO_2 test.

4.2.10 Laboratory Respirator Protection Level (LRPL)
4.2.10.1 The measured LRPL shall be determined for each PAPR. Required LRPL values are listed in Table 5.

Comment: Before this standard can be finalized, NIOSH needs to list the test protocol or cite the STP.

Table 5: LRPL Values
Type of PAPR LRPL - Minimum Value ~~(%)~~

Comment: The words in column 1 of Table 5 for tight fitting respiratory inlet coverings are confusing. As written, it appears NIOSH is including the loose fitting helmets and hoods as well in that entry. It also appears that NIOSH thinks there is only one type of loose-fitting respiratory inlet covering, i.e. loose fitting facepiece. This is so wrong. This table currently eliminates loose fitting hoods and helmets from the LRPL test. An alternative to what we recommend below is to list it as "Loose-fitting respiratory inlet coverings." Column 2 of Table 5 shows the LRPL value as a percentage. The LRPL is not a percentage, but rather a dimensionless number. It also uses the NIOSH APF values for setting the pass criteria which are not used by anyone except NIOSH. The OSHA APFs govern respirator selection and are the values NPPTL should use. In fact NIOSH indicated they would update their APFs after the OSHA rulemaking was completed - someday. A pass level of 500 in the negative pressure mode is adequate since this is acceptable for SCBA which are used in more hazardous environments than the PAPRs.

Table 5: LRPL Values

Type of PAPR	LRPL - Minimum Value ~~(%)~~
Half-mask	500
Full Facepiece	10,000
Loose-fitting Facepieces, Hoods and Helmets	250
Loose-fitting Hoods and Helmets	10,000
Tight-fitting Hoods and Helmets	10,000
Tight-fitting Facepieces, Hoods and Helmets with Blower Off (Silent mode)	500

Table 5 Note:
Note: The protection offered by a given respirator is contingent upon (1) the user adhering to complete respirator program requirements (2) use in an approved configuration, and (3) individual fit testing. This data may be used in an applicant's request to OSHA for assignment of an assigned protection factor. *These data cannot be used for assignment of an APF on a half mask, full facepiece, tight fitting hood or helmet or loose fitting facepiece. It could only be used for assignment of an APF for loose fitting hoods and helmets.*

Comment: There are several problems with this note. 1) We suspect the 'protection' intended in the note refers to workplace protection. As such, it does not belong in the LRPL table OR its intention needs to be clearly stated. Items 1-3 have nothing to do with LRPL and should be deleted-or does NIOSH intend that people will be fit tested before being used as LRPL subjects? The last sentence should be deleted. It is OSHA's decision what data they will accept and what they will do as a result of the LRPL test. The sentence also suggests any APF is possible; OSHA says it is either 25 or 1000. NIOSH would better serve its constituency by focusing on areas within jurisdiction and let OSHA set the policy and standards for its jurisdiction.

Recommendation:

~~**Table 5 Note:**~~
~~Note: The protection offered by a given respirator is contingent upon (1) the user adhering to complete respirator program requirements (2) use in an approved configuration, and (3) individual fit testing. This data may be used in an applicant's request to OSHA for assignment of an assigned protection factor.~~

5. Application-Specific Requirements - Performance Requirements Beyond Base

5.1. CBRN Responder Requirements.

5.1.1.1 Required packaging configuration: (minimum packaging configuration): The CBRN ~~tight-fitting~~ PAPR and the required components shall be subjected to the environmental and transportation portions of the durability conditioning in the manufacturer specified minimum packaging configuration. The canisters shall also be subjected to an additional rough handling drop test in its designated minimum packaging configuration.

5.1.1.2 The minimum packaging configuration is the protective packaging configuration in which the end user* shall store or maintain the CBRN ~~tight fitting~~ PAPR and the required components after it has been issued for immediate use. The user's instructions (UI) shall identify the minimum packaging configuration and shall direct the end user

how to store or maintain the CBRN ~~tight-fitting~~ PAPR and the required components inside of the manufacturer specified minimum packaging configuration while in the possession of the end user. The same minimum packaging configuration identified in the UI shall encase the CBRN ~~tight-fitting~~ PAPR and its components when NIOSH performs the durability conditioning. The type of minimum packaging configuration, if any, is left to the discretion of the manufacturer. Examples of common minimum packaging configurations are mask carriers, clamshell containers, draw string plastic bags, hermetically sealed canister bags or nothing at all.

Comment: All CBRN PAPR by definition are tight fitting respiratory inlet coverings, hence it is redundant to repeat here.

5.1.1.2
*** 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.

Comment: End user is a definition and should be listed in the definition section. The asterisk in the text should be removed also.

Suggestion: 2.X . End user: The person who will derive protection from the respirator by wearing it.

5.1.4.1 The PAPR, while the blower is running, and including all components and accessories, shall resist the permeation and penetration of HD and GB chemical agents when tested on an upper-torso manikin connected to a breathing machine operating at an airflow rate of 40 L/min, 36 respirations per minute, 1.1 liters tidal volume. Test requirements for HD are shown in Table 7. Test requirements for GB agent are shown in Table 8.

Comment: The Ct used as a criterion in these tables is defined as the agent concentration integrated over the minimum service life time. It is not clear what 'service life time' means. In addition we believe this requirement only applies to CBRN PAPR and needs rewording.

Recommendation: The CBRN PAPR and LCBRN PAPR, ~~while the blower is running, and~~ including all components and accessories shall be tested while the blower is running and shall resist the permeation and penetration of HD and GB chemical agents when tested on an upper-torso manikin connected to a breathing machine operating at an airflow rate of 40 L/min, 36 cycles ~~respirations~~ per minute, 1.1 liters tidal volume. Test requirements for HD are shown in Table 7.

5.2 LCBRN ~~Receiver~~ requirements. ~~Respirators~~ PAPRs used for lower level CBRN event:

Comment: Receiver should be removed. Receiver has never been defined and while we believe it ended up here because it is the first receivers that most likely use the LCBRN, there may be other people that may select an LCBRN based on their risk assessment. It is clear without the term "receiver" that these requirements apply to the PAPR with cartridges for CBRN and a PAPR's use should not be restricted to a group of people.

6. ~~Additional~~ Optional Enhanced Requirements
6.1 Flammability and Heat Resistance

Comment: NIOSH has not provided any details on this requirement. We recommend the test method in Section 8 of standard, EN 13274-4:2001, Respiratory Protective Devices, Methods of test, Part 4, Flame tests, Single burner moving specimen test: Method 3. The requirement in the two PAPR standards states: "No part of the device shall continue to burn after removal from the flame. The device is not required to meet the other requirements of this standard after being subjected to this test."

6.3 Operational Temperature Range – NIOSH may conduct an additional evaluation to assure the respirator functions within the applicant's specified operational temperature range.

Comment: It is not clear what this requirement means. NIOSH needs to provide more details before we can comment.

6.2.1 ~~Tight-fitting full-facepiece~~ CBRN PAPR ~~respirators~~ shall meet ??? and the CBRN air-purifying respirator (APR) to be granted approval for use in silent (non-powered) as well as normal (powered) mode.

Comment: It is our understanding that tight fitting hoods could be used in the silent mode and that all CBRN PAPRs are tight-fitting and includes tight fitting hoods and helmets. Also, there is apparently a requirement missing after 'meet.'

6.5 Intrinsic Safety

Comment: In 6.5.1 we suggest the following: Units to be identified as intrinsically safe on NIOSH-approved labels must be submitted for certification as intrinsically safe prior to submission to NIOSH. Certification must be through a recognized authority such as Mine Safety and Health Administration (MSHA) or through a "Nationally Recognized Testing Laboratory" (NRTL), as defined by OSHA.