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3M

November 7, 2002

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

RE: Comments on the September 16 Concept of the Proposed NIOSH Certification Standard for Chemical Biological Radiological Nuclear Air Purifying Respirator Standard per Proposed NIOSH Certification Standard for APR CBRN Federal Register Notice May 31, 2002 (Vol.67, Number 105, pg. 38127-38128)

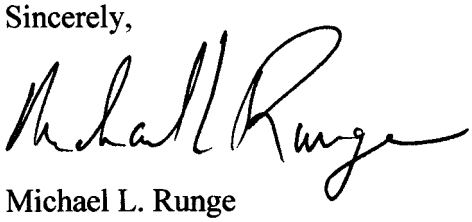
Dear Docket Officer:

3M Company, 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 this 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 provide the National Institute for Occupational Health and Safety with additional comments on proposed Certification Standard for APR CBRN, 67 FR 38127, dated May 31, 2002 as a result of changes made in the September 16 version of the Concept.

We offer the following comments and recommendations regarding Field of View, Common Connector Issues, Thread Design, Gasket Material, and Submission Logistics for full facepiece CBRN APRs.

We appreciate the opportunity to add our comments and knowledge to the rulemaking record and look forward to the promulgation of a fair, protective and useful standard.

Sincerely,



Michael L. Runge
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3M Occupational Health & Environmental Safety Division

MLR:CEC/llb
Enclosures

3M OH&ESD Comments on the September 16 2002 Version of the APR CBRN Concept

Field of View Issue

With respect to field of view (FOV) requirements outlined in the September 16, 2002 CBRN Concept we feel that the standard will not meet the needs and expectations of all users. The FOV requirement as it is written in this version of the CBRN Concept will not allow many proven dual ocular full-face respirators to be approved as CBRN respirators. As the data reflects in Table 1 below, many popular existing and proven military dual ocular full-face respirators will not pass the 70% effective field of view requirement.

Potential users of a CBRN approved respirator will come from a variety of job functions. Potential users include Fire Service, Law Enforcement, Emergency Medical Service, Military Personnel, and Federal Agencies. The operational requirements and expectations of each will be vastly different. For example, certain responders, including the Fire Service and medical personnel, may prefer a full facepiece with a very wide field of vision for activities such as surveys, hazard mitigation, decontamination in a warm zone, evacuation and medical treatment. Other responders, such as law enforcement require a dual ocular full-face that provides better visual acuity for sighting weaponry or that fits with vision-enhancing equipment such as binoculars and night vision equipment for search and rescue and tactical operations. The field of view requirements will be different for each responder group and designing a standard must take into account the diversity of use and the history of field proven designs. Users should be able to select between acuity or wider FOV depending on their needs.

The September 16th, 2002 Concept outlines using EN136 standard procedures for testing FOV. This Concept establishes one performance requirement for both single and dual ocular lens designs. The Concept states that both designs must meet an effective field of view of at least 70 % with an overlap FOV of 20 % or greater. Table 1 outlines FOV results of respirators that have been tested to EN 136. This testing was conducted at both 3M US and European laboratories. The data indicate some variability between tests. This variability may be due to equipment and the EN 136 test method variations.

Taking into account the variability, our findings indicate that these widely used, field-proven, existing dual-lens full-face masks do not pass the September 16th, 2002 proposed FOV requirements. The Avon FM-12 and S-10 are the facepieces of choice for military and civil defense in over 40 countries worldwide. The US Military currently uses the M40. These field proven products should be used as a baseline in establishing minimum performance criteria.

Table 1: Field of View Test Results for Current Dual Lens Full Facepiece Respirators*

Respirator Facepiece	Test Location	Effective FOV (%)	Overlapped FOV (%)
M40 (med)	US	59	32
Avon S-10 (med)	US	57	23
Avon SF 10	US	54	22
M17	US	70	34
Avon FM12	Europe	60	28
Avon FM 12	Europe	61	33
Avon S-10 (med)	Europe	63	22

*Tests performed following EN136 procedures.

Recommendation

We recommend that NIOSH specify different FOV requirements for dual and single lens designs as in earlier versions of the Concept. We recommend that NIOSH adopt the test procedures from EN 136 for measuring Effective FOV and Overlapped FOV. For the single lens full facepieces we recommend that NIOSH adopt the FOV requirements specified in EN 136. We recommend that NIOSH set an effective FOV requirement of 50% with an overlapped FOV of at least 20% for dual ocular full facepieces measured in accordance with EN136 test procedures. Table 2 summarizes 3M's recommendations for FOV requirements for single and dual lens type full facepiece CBRN APRs.

Table 2: Recommended Field of View Requirements for CBRN Full Facepieces.

Lens Type	Effective FOV (%)	Overlapped FOV (%)
Single	70	80
Dual	50	20

Common Connector Issue

While the September 16, 2002 version of the APR CBRN Concept does not mention interchangeability, the Concept still specifies a common connector. The following caution and limitation from the Concept suggests that interchanging the parts would violate the approval;

> "Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the applicable regulations."

However, the standard would still allow interchangeability to happen. In fact recently, several NIOSH presentations have indicated these CBRN standards will promote interchangeability.

3M believes specifying the connection and requirements for canisters as listed above does not necessarily ensure proper function even though they physically connect. The only way to ensure proper function is to test the facepiece and canister combination. Without data there can be no assurance that the desired outcome will be achieved with certainty.

In the last 30 years (30 CFR 11 and 42 CFR 84, Subpart D Approval and Disapproval § 84.30) interchangeability has not been allowed. NIOSH has only approved complete respirator systems. We infer from this that NIOSH has maintained that it is necessary to have data on the performance of the system that assures that the desired performance is achieved.

In fact, in 1984 NIOSH issued a User's Notice[1] on this subject stating "Several cases have been reported to NIOSH where unapproved modifications or use of an unapproved subassembly have resulted in respirator failures. Therefore, users of NIOSH/MSHA approved respirators are cautioned against interchanging subassemblies or making unapproved modifications to their respiratory protective devices." The User's Notice also indicated "A user who modifies a certified respirator may not be able to determine whether a change will decrease respiratory protection." This points out all the more reason why these combinations need to be tested first before allowing interchangeability.

Respirators are designed as a system. This includes the combined performance of the individual components, as well as the quality system of the manufacturer. Interchangeability should only be allowed when there is testing to show the combination works. For this reason 3M recommends that the following wording be added to the cautions and limitations section of the approval label:

Caution/Limitation

> This respirator is approved as a system using facemasks and canisters supplied and tested by the same manufacturer. Interchanging facemasks and canisters of different manufacturers is not permitted unless declared permissible by federal regulators during a federally declared terrorist emergency. Interchanging a respiratory protection component voids the NIOSH approval and could compromise the protection afforded to the user resulting in death or serious injury.

An emergency would be a terrorist event where replacement canisters made by the respirator manufacturer are not immediately available. The replacement parts are expected to be available in the near term, so even if the regulator declares an emergency, permission is not granted for the long term.

The surprising issue is that NIOSH would allow interchangeability of parts in such dangerous situations even for emergencies without complete testing of the respirator

assembly. The fact that components will fit together even though they are not intended to go together will enable a whole host of things to emerge as "systems" if there is ever a declaration allowing mix and match. Given the potentially dangerous environments these products may be used in and no data indicating that untested combinations will function properly even if they fit together, NIOSH should also test the permutations of combinations not covered by a single respirator manufacturer's submission, grant an approval for this combination if the assembly passes and NIOSH owns and maintains that approval. When changes are made by the manufacturer to a component of an approved system NIOSH would then be notified as to the approvals they would need to retest. If interchangeability is desired, tests can be designed to ensure that the parts go together and work to together to provide proper performance, but it is a very different test protocol than what industry or NIOSH is currently using.

This would provide some confidence in proper operation when parts are interchanged while still allowing first responders to have interoperability to protect themselves in emergencies when supplies are affected. This approach provides the same level of protection for first responders that is guaranteed for industrial users.

Thread Design

Millions of full-face respirators designed with a DIN style thread have been used for years in military and industrial applications. There are several existing standards with specifications for DIN threads. Simply adapting the EN 148-1 thread requirements as proposed by NIOSH would exclude many respirators, such as the M40, designed for and used by the US Military and first responders. These respirators currently allow interchangeability (but not permitted by NIOSH approval) of canisters and have a long history of successful field and laboratory performance. The comments below are based on a review of the following specifications:

- EN 148-1,
- NATO STANAG 4155, and
- Military Specification PD-EA-M-1801/E5-1-1054/D-1-1076.

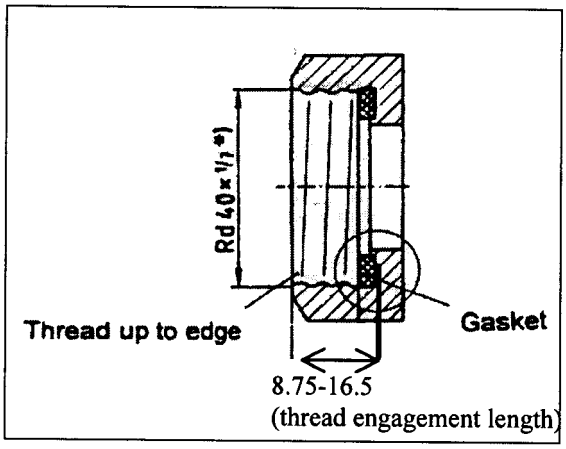
Thread Specification Background

Each document specifies a thread and thread engagement length. Each of these specifications requires the thread to be a rolled thread RD 40 x 3.63 mm. However, the thread engagement length of the canister to respirator specification is different between these documents. The thread engagement length as used in these comments is the distance from the bottom of the gasket to the edge of the internal threads (see Figure 1). The internal threads are the female threads located on the respirator facepiece. The external threads are the (male) threads located on the canister.

Internal Thread

While the specified thread in all three documents is RD 40 x 3.63 mm, the internal thread depth on the facepiece specified in the M40 Military Specification PD-EA-M-1801/E5-1-1054/D-1-1076 (Mil Spec) is shorter than what is required by EN 148-1 and NATO STANAG 4155. This was done to provide a lower profile full-face and faster canister attachment. It is important to note that this shorter internal thread is still compatible with the longer external thread of the EN 148-1. The internal thread height specification of EN 148-1 requires a thread engagement length (distance from bottom of gasket to edge) to be 15-16.5 mm, while the Mil Spec requires 8.75-9.25 mm. Because the M40 is compatible with the C2A1 and EN 148-1 canisters we suggest adapting the high end number (15-16.5 mm) for the internal thread from the EN 148-1 standard, and the low end of the Mil Spec (8.75-9.25 mm) to make an internal thread length recommendation of 8.75-16.5 mm. Opening up the internal thread depth specification to accommodate both internal thread designs will allow existing US Military and First Responder respirator designs to be part of CBRN. This is shown in Figure 1.

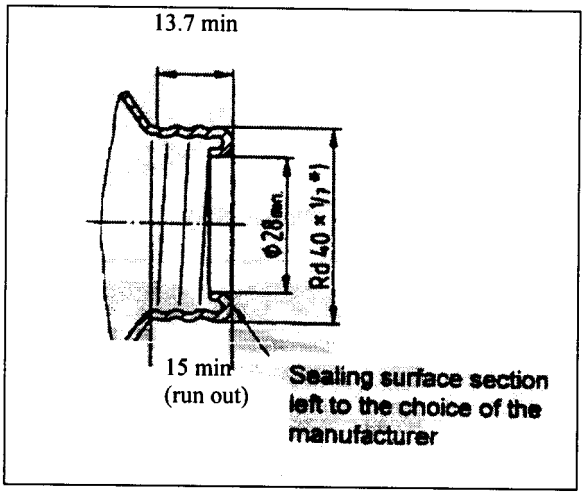
Figure 1: Internal Thread



External Thread

The NATO STANAG 4155 and EN 148.1 have a minimum external (male) thread run out of 16 mm, while the US Military Standard for the C2A1 minimum external male length is 15 mm. These minimum run out requirements are required to ensure the canister will seal with the gasket. Since the C2A1 canister is compatible with the EN 148-1 internal threads, we recommend establishing the C2A1 minimum run out of 15 mm as the standard minimum run out for the APR CBRN standard. This is shown in Figure 2.

Figure 2: External Thread



Gasket

In order to ensure a seal between the canister and full-face, a minimum/maximum gasket thickness is also required. To ensure that the C2A1 canister will be compatible with the EN 148-1 external threads, a gasket with a minimum thickness of 1.5 mm is required. This is calculated by subtracting the minimum run out on the canister (15 mm) from the maximum internal thread height engagement (16.5 mm). The maximum thickness also needs to be established to ensure enough thread engagement. The recommended maximum gasket thickness is 2.5 mm. This is currently the maximum thickness according to EN 148.1.

Recommendation

We recommend a rolled thread RD 40 x 3.63 mm. Table 3 summarizes other parameter recommendations regarding thread design.

Table 3: Summary of Recommended Thread Parameters

Parameter	Requirement (mm)
Internal Thread – Thread Engagement Length	8.75 – 16.5 mm
External Thread – Run Out Length	15 mm
Gasket Thickness (minimum / maximum)	1.5 mm / 2.5 mm

This not only allows a common connector in the NIOSH APR CBRN standard, but makes it possible for existing military and first responder masks to be tested to the new standard.

Gasket Material

Under section 4.3.2 of the September 16, 2002 Concept paper it states, "the gasket material shall be ethylene propylene diene monomer, EPDM, with a hardness of 65 ± 10 shore A durometer at room temperature." Specifying the gasket material precludes the use of other materials cited in the literature and documented by the military to make an acceptable gasket for CBRN-type applications, e.g. butyl rubber. These materials should not be excluded as potential gasket materials. Further the specification as written is incomplete as "EPDM" is not a specific material but rather a broad class of rubber compounds. Without a specific formulation and its processing conditions specified, there is a risk that any given EPDM compound will not meet the needs of a CBRN full facepiece in areas such as agent permeation resistance. A statement specifying only the dimensions and the Shore A durometer is an excellent performance specification that will ensure reliable and compatible sealing geometry while allowing manufacturers to utilize materials that are known to them to meet all the performance needs of this component. The respirator must still pass the "live agent" permeation resistance test. We recommend that the standard remove the reference to EPDM or any other material and only specify the gasket dimensions and Shore A hardness as currently stated in the Concept.

Logistics

The current proposal involves 110 respirators and 116 additional canisters tests, testing could take as long as 54 days. 3M is concerned with the costs and timeliness of approvals. Under the current process of accepting approval applications, there could be several months between approvals for applications received on the same day. To prevent unfairness due to "the order the mail is opened", 3M recommends that the release of approvals be held and released at the same time for all applications submitted within the same initial time period, e.g., the first 30 days after NIOSH begins accepting APR CBRN applications for approval. To further prevent delays, we recommend that NIOSH implementation of the DEIMS (unproven submission software) be delayed until after the CBRN standards are resolved.

Cautions/Limitations

NIOSH needs to review the current statements provided in the Concept. The following caution:

> This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles only. Procedures for monitoring radiation exposure and radiation body protection must be followed.

indicates that the particulate filter is only acceptable for radiological and nuclear dust particles. This implies the filter cannot be used against bioaerosols and other dusts such as silica and asbestos that may be present as well. We believe this to be an

oversight by NIOSH as data indicate that the P100 particulate filter would be effective against these materials as well.

NIOSH should consider the following revision to the caution:

> When using this respirator to reduce inhalation exposure to radiological and nuclear dust particles, procedures for monitoring radiation exposure and radiation body protection must be followed.

As a protection statement, perhaps this better addresses NIOSH's concern:

> P100 – Particulate filter (99.97% filter efficiency level) effective against all particulate aerosols, **including radiological and nuclear dust particles and biological aerosols. (3M added)**

Given the likelihood that some of the CBRN agents will be skin absorbable, we recommend that the following caution be strengthened, to read:

> Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. **Failure to do so may result in death or sickness even when the respirator is properly fitted, used and maintained. (3M added)**

Summary

Our recommendations for the September 16, 2002 version of the APR CBRN Concept are listed here:

1. Recommended Field of View Requirements of 70% effective FOV and 80% overlapped FOV for single lens type full facepieces and 50% effective FOV and overlapped FOV of 20% for dual lens type CBRN full facepieces. In both cases the recommended Effective and Overlapped FOV should be measured in accordance with EN 136 procedures.

2. Common connector: 3M recommends that,

- the following wording be added to the cautions and limitations section of the approval label:

  Caution/Limitation

  This respirator is approved as a system using facemasks and canisters supplied and tested by the same manufacturer. Interchanging facemasks and canisters of different manufacturers is not permitted unless declared permissible by federal regulators during a federally declared terrorist emergency.

Interchanging a respiratory protection component voids the NIOSH approval and could compromise the protection afforded to the user resulting in death or serious injury.

- A definition for emergency should be provided to convey that it is a very short term, temporary situaion.

- NIOSH should also test the permutations of combinations not covered by a single respirator manufacturer's submission, grant an approval for this combination if the assembly passes and NIOSH owns and maintains that approval.

3. Common thread: we recommend a rolled thread RD 40 x 3.63 mm with an:

- Internal Thread – Thread Engagement Length of 8.75 – 16.5 mm
- External Thread – Run Out Length 15 mm
- Gasket Thickness (minimum / maximum) 1.5 mm / 2.5 mm

4. Gasket material: We recommend that the standard remove the reference to EPDM or any other material and only specify the gasket dimensions and Shore A hardness as currently stated in the Concept.

5. 3M recommends that the release of successful submissions be held and released at the same time for all applications submitted within the same initial time period, e.g., the first 30 days after NIOSH begins accepting APR CBRN applications for approval. To further prevent delays, we recommend that NIOSH implementation of the DEIMS be delayed until after the CBRN standards are resolved.

6. Caution/Limitation statements: the following caution should read:

> This respirator provides respiratory protection against inhalation of radiological and nuclear dust particles only. Procedures for monitoring radiation exposure and radiation body protection must be followed.

NIOSH may want to modify the protection statement for the filter to read:

> P100 – Particulate filter (99.97% filter efficiency level) effective against all particulate aerosols, **including radiological and nuclear dust particles and biological aerosols. (3M added)**

Given the likelihood that some of the CBRN agents will be skin absorbable, we recommend that the following caution be strengthened, to read:

> Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. **Failure to do so may result in death or sickness even when the respirator is properly fitted, used and maintained. (3M added)**

Reference

National Institute for Occupational Safety and Health: "Respirator User's Notice: Use of Unapproved Subassemblies." Morgantown, WV, November 6, 1984.