3M Occupational Health and
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NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

Subject: NIOSH Request for Comments on Further Revision to Standard 42 CFR 84 (Fed. Reg. 5/16/96)

Dear Sir or Madam:

Minnesota Mining and Manufacturing Company (3M) submits the following comments to NIOSH for the docket record concerning NIOSH request for comments, in accordance with rulemaking procedures.

We have attempted to arrange our comments in the order of the NIOSH request. We cannot, however, provide the detailed answers to every question in the NIOSH request.

We appreciate the opportunity to offer comments and commend NIOSH for gathering public input prior to initiating further rulemaking.

Respectively submitted,

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3M Comments to NIOSH on further revision to standard
42 CFR 84 (Fed. Reg. 5/16/96)

A. Priority of Technical Modules

Issue 1 Criteria for establishing priorities

(1) What criteria should be used to rank the priority of each module?

There are a number of issues that NIOSH should address in setting the priority for revising modules. The first criteria certainly needs to be one of need for worker protection. If, in their analysis, NIOSH finds that worker protection and health is being compromised by artifacts in a specific module, that module should be given priority for revision. It is doubtful that this is the case. Respirators certified by NIOSH over the past twenty plus years are, in fact, protective.

The second criteria should be need for flexibility of design and the allowance for new, innovative approaches to respirator design and use. Many of the current modules are so design restrictive, or the performance requirements so far exceeding what is practically needed for protection in industry, that innovation and new concepts are stifled, keeping potentially better products out of the hands of users. Examples, such as lightweight Gas and Vapor respirators, will be discussed later.

The third criteria might be considered a combination of cost, efficiency and expediency. This priority forms the basis for our recommendation that the Administrative/Quality Assurance Module should be next for revision. By streamlining the approval process, new innovative and more protective products could be brought to market sooner and at less cost. This will benefit NIOSH, the manufacturer, and the ultimate user.

Issue 2 Priorities for Rulemaking

(1) In general terms, what changes to current respirator certification requirements are needed in the modules identified in this notice?

This is an extremely far reaching question that would require writing a complete proposed rule to answer thoroughly. However, we can offer a brief synopsis of the needs for the proposed modules:

Assigned Protection Factors - There are several problems in this area. The NIOSH Respirator Decision Logic (RDL) of 1987 is badly out of date. Even at that time, it was not based to any extent on actual workplace performance of the respirators. Rather, it was based to a large degree on old laboratory data and lore using many respirators not on the market today.

OSHA, whose function is to enforce regulation, has stated that, in the absence of the NIOSH module, they will create their own APF Table. This is somewhat troublesome as, in the past, OSHA has been very inconsistent with APF Tables in their substance-specific tables.

The NIOSH RDL also contains some inconsistencies. For example, the APF for a negative pressure half-mask respirator is 10. When the same facepiece is equipped with an air supply, and used as a continuous flow airline respirator, the APF is increased to 50, a five fold increase. With a full facepiece negative pressure respirator, the APF is 50; when used as a continuous flow SAR, the APF is still 50.

NIOSH should also review their own data and others to recognize the difference in performance between the loose-fitting facepiece device and the helmets and hoods. This difference in performance is recognized in ANSI Z88.2-1992 by assigning appropriate APFs for these devices.

Our recommendation for this area is quite simple. NIOSH should withdraw the RDL as outdated, and rather than spending the time with rulemaking for this module, simply join with OSHA to create a workable APF table. Relating to a later question, there is a national standard, ANSI Z88.2-1992, that should be adopted by both NIOSH and OSHA as an interim policy. The APF Table in this standard is based, to the degree possible, on valid workplace performance tests of current respirators.

Administrative/Quality Assurance Modules - More specific comments will be made in the discussion of this module later in our comments. The main focus for these modules should be streamlining, removing redundancy, and condensing as much as possible to eliminate much that is simply busy work for manufacturers and NIOSH.

Gas and Vapor Requirements - Revision of this module is not an urgent need. However, revision would allow NIOSH to incorporate changes that would improve comfort and allow more innovative products to be manufactured.

Unlike particulate filters where the NIOSH tests assure a minimum level of efficiency, the requirements for a gas and vapor respirator measure a minimum service life. In many cases, the required service life far exceeds the practical

need in industry. With cleaner workplaces, lower permissible exposure limits, and better work practices, exposures to high concentrations of gasses or vapors are less common where chemical cartridges are used.

The current NIOSH service life requirements dictate the amount of carbon or sorbent the manufacturer must use in a given cartridge or respirator. This becomes design restrictive. In many applications, the service life of an approved cartridge is many times longer than needed for the application. This leads to infrequent filter changes, possible contaminant migration in the sorbent, and less diligent inspection, cleaning and maintenance. The major restriction is that this is an impediment to application based, user friendly design because it dictates the weight of the cartridges or respirator and the breathing resistance of the cartridge. The worker should not be required to carry around two weeks of carbon sorbent capacity on his face. A smaller, lightweight cartridge, changed at more frequent intervals, would add much to comfort and better protection.

Ideally, the manufacturer would specify a service life that NIOSH would confirm. This would allow the manufacturers the ability to have approved a variety of products for the user's needs and the market would dictate the preferred size. Failing that, NIOSH should consider a low capacity category with service life requirements about half of the current standard. This has been done recently in Japan, Korea, Australia, and New Zealand. Europe has had the A1 category in the CEN standards for years, which allows something less than half the capacity of their A2 cartridge.

Since the cartridges are only approved for compounds with good warning properties, with end of service life indicators, or with administrative controls, reducing the service life requirements in no way makes the cartridge less protective.

Supplied Air, Positive Pressure, and SCBA - The major task for NIOSH in updating these modules is to remove design requirements that are restrictive and streamline to a performance standard. The required testing needs to be evaluated and improved so that it is meaningful, consistent and repeatable. An important need is for NIOSH to write and publish test methods that are clear and repeatable. This area is very weak at present.

There needs to be an industry accepted definition of the term "positive pressure" and performance requirements that would allow either approval as a "positive pressure" respirator or assurance that all continuous flow and pressure demand respirators will be accepted by NIOSH and OSHA as "positive pressure". Currently, this is not the case.

For supplied air systems, the current 4 cfm requirement is far too low for positive pressure. Minimum air flow should be based on inhalation flow rates at a

moderate, sustainable work rate. This may be 6 - 7 cfm. NIOSH should also establish air quality requirements that do not reference a 30 year old, out of print Compressed Gas Association standard.

The current performance requirements for SCBA are out of date. The easiest way to update would be for NIOSH to incorporate many of the performance requirements of NFPA 1981 (1992) for open circuit devices. If NIOSH plans to continue approving SCBA systems for firefighting, consistency with NFPA 1981 is essential. There should also be an approval category of SCBA *not for firefighting*. This would allow less severe requirements in certain areas, such as flame resistance. SCBA manufacturers already offer two levels of SCBA.

Powered Air Purifying Respirators (PAPR) - This module needs to be updated to include the new classes of filters created in 42 CFR 84.

NIOSH should also investigate the possibility of adding low flow devices, or breathing assist devices for those applications where the current flow requirements far exceed the need. In many cases, the current required flows are design restrictive for application-specific devices. This would allow for approval of PAPRs as "positive pressure" devices, particularly if minimum air flows were higher than currently required. The low flow devices suggested would clearly be identified as "negative pressure".

Simulated Workplace Protection Factor Test - There is no need for NIOSH to waste time on a module until the extensive research needed to prove some correlation between this test and actual respirator performance in the workplace has been successfully completed and accepted. This has been tried in the past and no correlation has been identified to date.

There also would have to be developed a method for analyzing and interpreting results to obtain an accurate and achievable Assigned Protection Factor.

(2) Are there any subject areas for improving current certification requirements that are not identified in this notice that should be considered in the prioritizing process? If so, please include an explanation of the importance of the subject and describe in general terms the changes needed in current requirements.

The notice is comprehensive and allows commenting in any area. However, NIOSH should consider devising some method of simplifying the approval labels. These are difficult for the manufacturers to understand and practically impossible for the users.

(3) How should the modules be ranked, and why?

Suggested Ranking:

1. Administrative/Quality Assurance Modules - Proper extensive revision and streamlining of this module will reduce the submission and approval process burden for both NIOSH and manufacturers. Therefore, as future modules are revised and approvals updated, the lengthy submission and review process could be largely eliminated, avoiding the backlog pressures NIOSH is currently experiencing.

2. Gas and Vapor Requirements - As described above, revision of this module offers opportunities to develop new concepts and more comfortable and user accepted products.

3. Powered Air Purifying Respirators (PAPR) - Update to incorporate new filter classifications, low flow devices, and loose-fitting facepiece category.

4. Supplied Air, Positive Pressure, and SCBA - This module is ranked lower in priority for several reasons. First, products approved to the current requirements are protective. Users are not at risk. Second, the module is large and complex. To revise it will be a lengthy process. Other modules should not wait for the time required to revise this module. Third, many of the difficulties with this area could be improved by NIOSH rewriting and formalizing the test procedures currently used. Many are still in draft form and subject to interpretation.

5. Assigned Protection Factors - Not needed as a module of 42 CFR 84. As discussed above, working with OSHA and industry to adopt an APF Table would be more beneficial. The ANSI Standard would make an excellent starting position. In addition, NIOSH and OSHA should devise a method to update APFs on a regular basis as new information is available. Locking this into a module of 42 CFR 84 makes updating untimely.

6. Simulated Workplace Protection Factor Test - This module is also not needed. Until such testing can be correlated to actual protection provided to the wearer, it cannot be made a part of 42 CFR 84. This would be an expensive waste of time for both NIOSH and manufacturers.

(2) (sic) Are there existing national or international standards that could be adopted by NIOSH to replace current certification requirements pertaining to a given module?

There are standards around the world that NIOSH should review and consider when each module is addressed, such as the European CEN standards, Japanese MOL standards and so forth. NIOSH may not wish to adopt these standards verbatim or in their entirety, but reviewing them would increase the knowledge base from which NIOSH is working. The manufacturers and multinational company users would welcome some uniformity in U.S. standards and international standards.

The ANSI Standard, Z88.2 (1992), has already been proposed as a method to relieve NIOSH of the burden of creating the Assigned Protection Factor module. NFPA 1981 (1992) would make an excellent starting point for revision of open circuit SCBA for firefighting requirements.

The use of International Organization of Standards (ISO) is strongly encouraged and will be addressed in section B.

(3) (sic) How would potential changes to current requirements achieved through a proposed module affect public health?

No one likes to wear a respirator. The less design restrictive and open the approval requirements can be made, the more comfortable and acceptable the manufacturers can make their products. The result will be better acceptance and wear time by the user which will result in better protection. Wear time is the single most important factor in respirator performance. For example, if a respirator is providing a protection factor of 1000 and is not worn for 1 minute in an hour, the maximum protection factor that can be achieved is 56.

Questions 4 though 7.

No comments are offered for these questions.

Issue 3 Informing Respirator Community of Changing Priorities

(1) How should NIOSH notify respirator purchasers and users of revised priorities?

Most users don't know that NIOSH ever established such priorities. Notification could be in the form of a Federal Register notice, a press release to the various trade journals, etc. We also encourage NIOSH to communicate with the major user groups such as AIHA, CMA, NAM, AISI and others. NIOSH should also make better use of their Internet Web page. This is a most effective way to communicate timely information.

B. Administrative / Quality Assurance Module

Issue 1 Use of Independent Laboratories

(1) Are private sector testing laboratories capable of conducting the respirator testing currently performed by NIOSH?

There are laboratories who are capable, or could become capable of conducting the certification testing. Most would have to acquire facilities, equipment and supplies. The fact that it is possible is obvious, as respirator manufacturers have developed the testing capability, so it follows that an independent laboratory could. The needed key element would be for NIOSH to develop clear and concise test protocols for the laboratories to follow.

(2) What qualification requirements (e.g., certification by National Voluntary Lab Accreditation Program (NVLAP), American National Standards Institute (ANSI), NRTL, etc.) should NIOSH require of private laboratories who perform certification and product audit testing under NIOSH guidance?

As a minimum, NIOSH should require the laboratories to be ISO certified. Other accreditation could be considered. The AIHA Technical Affairs Department has expressed interest in performing this accreditation function.

(3) Should NIOSH assign the testing of a manufacturer's respirators to laboratories approved by NIOSH or should the manufacturer be permitted to use the laboratory of choice among approved laboratories?

Either method would be acceptable as long as turnaround times in the assigned laboratories were reasonable. However, allowing manufacturers the choice would allow for competition in providing quality service in areas of turnaround time and cost. This would allow new and better products to be brought to market sooner.

(4) What type of monitoring should NIOSH perform to assure that private sector laboratories continue to provide quality service?

NIOSH should conduct regular audits to confirm adherence to test protocols and verification of accurate test results. NIOSH should be available to manufacturers to mediate differences in results, should they occur. Certification by ISO and the required ISO audits would serve NIOSH as assurance the laboratory is following required procedures.

Issue 2 Quality Auditors

(1) What qualification requirements (e.g., certification by ANSI Registrar Accreditation Board, United Kingdom Accreditation Service, International Auditor and Training Certification Association, etc.) should NIOSH require for the acceptance of independent quality auditors to perform manufacturing site audits under NIOSH guidance?

This question is somewhat unclear but suggests that NIOSH may use independent quality auditors to perform audits specifically for NIOSH. This would be an acceptable approach for those manufacturers not ISO certified. However, most of the respirator manufacturers are currently ISO certified. In this case, NIOSH should take advantage of this certification and its required audits to eliminate the need for NIOSH to conduct its own site audits.

NIOSH should develop the criteria for the information needed in a quality plan and audit. The manufacturers would then incorporate these criteria in their ISO quality procedures. The required ISO audits would assure that the plan is being followed and the criteria met.

ISO requires audits be conducted by certified auditors, such as Underwriters Laboratory (UL). The summary of the audit and the renewal of the ISO certification would be forwarded to NIOSH for the manufacturers file.

This method could also eliminate a great deal of paperwork required for the submission of a new or revised product to NIOSH for approval. Once the manufacturer's certified plan was on file at NIOSH, future submissions should require only reference to that plan and the one or two page final release specifications for that particular product.

We also encourage NIOSH to become an ISO certified laboratory. The major benefit would be that test equipment would be calibrated and certified to the same standard as manufacturers and should reduce, if not eliminate, the need for equipment correlation. The second benefit would be that NIOSH test methods and procedures would be formalized, fully documented and followed. Many test procedures are still in draft form after a number of years. A comprehensive, complete set of standards which would be used consistently by NIOSH and manufacturers would improve the efficiency of the approval process.

(2) What measures should NIOSH use to ensure the integrity of the program using private quality auditors?

If NIOSH were to follow the suggested use of ISO audits they need not be concerned with this issue, as ISO requires certified auditors.

(3) What frequency of audits would be considered a minimum to provide assurance that only quality products are distributed?

Semiannual audits are a requirement of ISO certification. That should be acceptable to NIOSH.

(4) Should manufacturing sites be audited prior to the issuance of a NIOSH certification?

For manufacturers who are ISO certified, this should not be an issue. For a new manufacturer, or one not ISO certified, an audit prior to issuance of an approval would be appropriate.

Issue 3 Fee Structure

(1) How should certification fees be structured and calculated to recoup the cost of the certification process?

We have no specific information regarding setting of fees. Fees should be structured to be fair and equitable to NIOSH and all manufacturers. The fee structure for NIOSH would be affected by any NIOSH decision to use third party laboratories. Excessive fees could be a deterrent to improving products for better user protection. NIOSH should use this opportunity to streamline the approval system to reduce the cost of the approval process, rather than raising fees to a prohibitive level.

(2) Should manufacturers be required to pay for manufacturing site and product audits?

ISO certified manufacturers are already paying for the required ISO audits. If NIOSH would accept the results of these audits, no additional expense would be incurred by NIOSH or the manufacturer for specific NIOSH audits. For those manufacturers not ISO certified, a fee for the NIOSH audit would be reasonable.

(3) Should fees be collected by NIOSH for respirator complaint investigations?

Many of these complaints are minor, or even frivolous in nature. It would be unfair to charge for this investigation. In situations where it is conclusively shown that the manufacturer was in violation of the NIOSH approval requirements, a fee may be appropriate.

Issue 4 Interchangeability of Parts

(1) Should NIOSH allow replacement parts for respirators by manufacturers other than the original manufacturer of the respirator?

Absolutely not! The quality, function, fit, and other parameters of a replacement part cannot be assured by anyone other than the original manufacturer. For example, an exhalation valve is used on many different respirators. To the average user, many of these appear to be simple rubber or elastomeric discs. In actual fact, each has very specific properties to assure proper operation and sealing. No one, other than the original manufacturer, knows which parameters are critical to proper function. Allowing replacement parts from other than the original manufacturer could seriously jeopardize the health of the user.

The one possible exception would be for the air supply hose for supplied air respirators. As long as the end user is using a hose that is the proper diameter and with the correct fittings, the need for approval is questionable.

(2) How should the effectiveness of replacement parts be assured?

By requiring that they come from the original manufacturer made to the same certified specifications and quality plan as the approved respirator. Any other system would be ineffective.

(3) Would NIOSH need to adopt or develop component-specific certification requirements to allow alternate suppliers for replacement parts?

They would and it would be a horrendous task. Consider the number of individual parts in a typical supplied-air or an SCBA system. This effort does not seem productive for NIOSH and certainly of no particular benefit to the user.

(4) Should NIOSH consider certifying respirator components in addition to, or instead of, complete respirator?

Yes, but only for use on respirators by the same manufacturer. For example, NIOSH could approve a filter for a given manufacturer. That filter could then be used on any <u>approved</u> facepiece by the <u>same</u> manufacturer. Doing this could be one method of simplifying the submission and approval process. It would also help to simplify the NIOSH approval labels which are difficult for the users to understand. Since NIOSH presently approves only systems, and many manufacturers do not sell by system, a whole series of system numbers are created and documented that have no use other than the NIOSH approval submission and label. This is certainly not productive as it only creates additional paperwork for NIOSH to review with each submission. In addition, putting all systems on one approval label is a nightmare for the users.

(5) Do other certifying agencies or standards organizations allow suppliers other than the original manufacturer to provide replacement parts for certified units?

Only one, and in a very limited sense. European CEN standards allow for the interchangeability of filters, cartridges, or canisters. Interchanging other parts such as valves, lenses, straps, hoses, etc. is not permitted. Our experience in Europe, however, indicates that customers rarely use this option. The far more common practice is to continue to buy these components from the original supplier. The reason seems to be one of confidence and accountability of the supplier. Therefore, this option has no economic value to the user.

It is also interesting to note that other countries, such as Japan, Korea, and Australia, whose standards are loosely based on the European CEN standards, have chosen not to incorporate the interchangeability of components.

(6) If suppliers other than the original manufacturer were permitted to provide replacement parts, how should NIOSH monitor these alternate suppliers?

NIOSH would have to provide the same monitoring and control that they presently provide for original manufacturers. This could require a tremendous amount of resources at NIOSH.

(7) If suppliers other than the original manufacturer were permitted to provide replacement parts, how should NIOSH monitor those parts?

Same response as #6.

(8) Would NIOSH need to adopt design specifications to ensure that interchangeability of parts is safe?

Probably, but adopting design specifications would severely limit development of new products by the original manufacturers. This is another weakness of using unlimited interchangeability.

Issue 6 NIOSH Product Procurement for Audit

(1) What would be the maximum number of respirators per year, aside from problem investigations, that NIOSH should request from a manufacturer, at no charge to NIOSH?

This is kind of an open end question that will vary with the respirator system and the manufacturer. For example, few manufacturers would object to supplying 50 or 100 half-mask disposable respirators. Conversely, supplying 10 or 20 SCBA

systems could be cost prohibitive. We believe NIOSH can determine a reasonable quantity to request.

(2) How should NIOSH acquire products for audit (i.e., by voucher, reimbursement, random selection by NIOSH at the manufacturer or distributor)?

Acquiring the products in any fashion other than buying from an authorized distributor tends to lose the desired objective of auditing product representative of what the user is receiving. This system then makes charging the manufacturer unwieldy. There have been cases in the past where NIOSH has procured the audit product but not done the testing and reporting until six months or more later. It would be much simpler to estimate this cost and include it in the original submission fee. The manufacturers would prefer fewer invoices and billings.

(3) Should manufacturer be charged for these product audits, since they are a condition of certification?

Again, to avoid additional invoices and billings, it would be simpler to build this cost into the submission fees.

Issue 6 Limitations of NIOSH Approvals

(1) Should the NIOSH certification be valid for a limited time?

We see no value to placing a time limitation on NIOSH approvals. As long as the manufacturer is producing the approved product to the certified plan, and resubmitting modifications for approval, as is done now, a time limit is unneeded. Having to resubmit a product for approval simply due to a time limit seems overly burdensome to the manufacturer and NIOSH resources.

(2) What conditions should be met for a time-limited NIOSH certification to be renewable?

Per (1), we do not believe that time-limited certifications are of any value.

(3) What time limits should be used for a NIOSH certification and renewal?

Same as (2).

(4) Should certification holders be required to notify NIOSH of changes in production status and the number of produced units when production is halted?

The production status and the number of produced units should be of no value to NIOSH nor the user. Manufacturers will not supply it.

However, NIOSH does need to incorporate a system where an approved product is obsoleted and the approval deleted when the product is no longer manufactured. The ideal vehicle for this would be the NIOSH Certified Equipment List and the Internet. The Certified Equipment List should be expanded to include the detail it did a few years ago. It should be available to users via the Internet. The most pressing need is to keep it correct and update on, at least, a monthly basis. Manufacturers would be pleased to notify NIOSH of errors in a useful List, if they knew corrections would be made by the next month. Users would have available a List that would show all currently approved products including new ones. When a manufacturer discontinued an approved product, they would be required to notify NIOSH who would mark the product as obsolete. After some period of time, the obsolete approval could be dropped from the list.

Far a respirator user, the current Certified Equipment list has little value. It is complicated, hard to use and contains little useful information. The users generally contact the manufacturer, or check the label, to see if a product is approved. NIOSH should ask manufacturers, distributors, users and OSHA what they need to see in a Certified Equipment List.

(5) How would purchasers and users be affected if the certification of their respirator expires?

The time limit and expiration of approval would cause nothing but confusion to the users. It would cause difficult problems for distribution and the end user to assure they don't get caught with obsolete or noncompliant products in inventory and risk OSHA citation. In the case of an obsoleted or discontinued product by the manufacturer, the user would need to seek another product as the obsolete unit would no longer be available. The users would most likely contact the manufacturer in this case.

(6) Would an expired certification benefit purchasers and users by informing them that their respirator is no longer produced?

No, the fact that a given respirator or system is no longer produced does not mean it no longer functions. The next purchase will inform the user of the obsolescence. In the case of a discontinued product, the ability to go to an up-to-date Certified Equipment List via the Internet would inform the user of the discontinuance and allow planning of transition to a current product.

(7) Could information on the number of respirators produced under a certification be used to benefit purchasers and users?

As a manufacturer, we see no value to the user for this information. For example, in selecting tires for an auto, the buyer is not concerned with the number of tires the manufacturer produces. This is true of any product purchased.

While gross sales figures of manufacturers are available in the public domain, individual product volumes and sales are very sensitive, closely-held information. It is, in fact, illegal for manufacturers to share this information with each other. Making it available to purchasers would certainly make it available to competition. Even making this information available to NIOSH would be questionable as it could be garnered under a FOIA request. We believe all manufacturers would vigorously object to such a request or requirement by NIOSH.