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From: robert.weber@mmm.com
Sent: Friday, April 10, 2009 4:19 PM
To: NIOSH Docket Office (CDC)
Subject: RIN:0920-AA04 and 42CFR pt.84
Attachments: 3M Final written comments for NIOSH Quality Proposed Rule April 10 2009 .pdf

Attached you will find 3M comments on the proposed rulemaking for the quality assurance requirements for respirators

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April 10, 2009

NIOSH Docket Officer
NIOSH Docket #109
Robert A. Taft Laboratories MS-C34
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RE: RIN:0920-AA04, 42 CFR pt. 84, Quality Assurance Requirements for Respirators; Notice of Proposed Rulemaking

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. 3M also manufacturers and sells respirators meeting standards worldwide. As such, we manufacture respirators that must meet quality requirements of several organizations. These manufacturing processes are audited by various authorities. As a result, our quality systems have been designed to produce high quality respiratory protection products worldwide. As 3M, a major manufacturer of various high quality products for over 100 years, we have substantial experience in all phases and applications of quality assurance programs. We are pleased to offer the following comments and recommendations regarding the notice of proposed rulemaking on Quality Assurance Requirements for Respirators published in the *Federal Register* December 10, 2008.

3M supports NIOSH in its effort to update the requirements for quality assurance of respirators. 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.

At the NISOH public hearing on March 23, 2009 NIOSH officials requested additional information on the financial impact associated with the Quality Assurance Requirements for Respirators proposed rule (RIN 0920-AA04). 3M is part of an ISEA effort to prepare a financial impact analysis for the members within the ISEA respiratory protection community. This effort will take a significant amount of time and coordination to develop; therefore we are requesting an extension of the comment period to Oct 9th 2009.

Sincerely,

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

Diane E. Handeland
Division Quality Manager
3M Occupational Health & Environmental Safety Division

3M Comments on Quality Assurance Requirements for Respirators
Proposed Rule dated December 10, 2008

Overall Approach to the Rule

3M supports the philosophy of the NIOSH quality management requirements to include an approach that emphasizes an effective process-based quality management system and the increased use of statistical process control methods. However, we have some concerns with several areas of the proposed rule and these concerns are addressed below.

General Comments

There are a number of proposed requirements that are tied to the Standard Application Procedure (SAP). It is essential to review the revised Standard Application Procedures in conjunction with this Proposed Rule in order to assess the complete impact of this proposed rule on manufacturers and product. As a minimum, the preamble must include the details on which the SAP should be based. This would aid in understanding the scope of the new requirements and not present surprises in the SAP. We also recommend that the proposed rule be written to reduce the amount of additional explanation needed in the SAP.

NIOSH needs to provide clarification for the timing for implementation of all aspects of the proposed rule. It is stated in the preamble that there will be a three year grandfather period for implementation of the new quality plan requirements but no reference is made to the timing for any of the other modified requirements of the proposed rule. There are many items in addition to the quality plan requirements that are addressed in this proposal. For example, manufacturers need to know when provisions like the complaint reporting system or product audit system needs to be fully functional. Sufficient time is required for manufacturer's to implement all of these new and modified requirements.

A new revision of the ISO 9001 Quality Management System standard has been published as of November 2008 and the current revision is now ISO 9001:2008. We realize the reasons NIOSH must identify a specific year or version for all standards incorporated into the rule. In the final rule we encourage NIOSH to update the citation from the 2000 edition to the 2008 edition. All ISO certified manufacturers are following this version or will be by the time this final rule is published so we believe that this will not pose an added burden.

Specific Provisions

Our comments address specific provisions of the proposed rule with reference to the *Federal Register* page number, and where possible, the particular sub-heading, section or question.

p. 75053 84.2 Definitions
(w) Manufacturing facility

It was our original interpretation that the part of this definition referring to "…a supplier whose quality system is a component of the applicant's quality system" was referring to the

manufacturer-supplier relationship that NIOSH has previously termed "subcontractor" in a Letter to Manufacturers dated April 7, 2005. Although NIOSH indicated at the public meeting on March 23, 2009 that this was not the intent, the intent remains unclear. We suggest that NIOSH needs to clarify the definition and elaborate on their expectations within the update of this proposed rule. We also strongly recommend that the definitions and requirements of suppliers vs. subcontractors from the April 7, 2005 NIOSH letter to manufacturers should be incorporated into the proposed rule. We suggest that NIOSH further clarify the definitions and elaborate on their expectations of these relationships within the update of this proposed rule.

p. 75053 84.11 Contents of Application

(b) "Drawings or specifications that depict or describe the respirator assembly and all of its (sic) major components, including accessories;"

Based on our reading of this requirement, we believe this means only the top assembly drawing (i.e. exploded view drawing) that shows the components and the assembly matrix need to be provided in the submission. The component drawings that list the specifications of the product would not be required. We support this change as it will reduce providing drawings to NIOSH that have no benefit to the manufacturer.

(g) "A table that lists each section and paragraph of this Part....that cross-references the stages of the manufacturing process....evaluated through quality assurance or control procedures."

This is a new requirement and the details of this concept and degree of specificity being sought by NIOSH is not explained. While the details are intended to be included in a revision to the Standard Application Procedure, that revision has not yet been made available. To assess the impact of this requirement, NIOSH must supply this information before publishing a final rule.

(i) "A statement that the respirator and component parts submitted for approval are not prototypes and were made using regular production tooling..."

This requirement could add artificial constraints or delays to the new product development cycle timeline since applications for approval could not take place until the investment (time and money) in production tooling is made in order to create the samples necessary for submission. Currently production tooling may be developed and built in parallel with the device approval cycle. We recommend that the requirement for submission samples should be only that the product supplied for approval be identical in all critical aspects (e.g. materials, geometry, functional performance, etc.) as the final product to be manufactured as opposed to a specific constraint on the type of tools used to produce it. This would mean that the requirements on tooling should be deleted from the proposed rule.

p. 75054 84.36 Changes in device or applicant ownership

(a) "...The new owner making or having made such an acquisition shall complete the application submissions and must receive a modified certificate of approval from NIOSH for each device prior to any continued manufacture of the device after ownership of the device or applicant is changed."

This proposed requirement indicates that on the date an acquisition closes, the new owner would not be allowed to continue to manufacture the acquired devices because modified certificates of approval would be needed before the product could be sold. Due to confidentiality reasons, it would be impossible for the new owner to even be allowed to assess requirements and potential changes and prepare plans for a submission until after the acquisition is complete. Therefore it would not be possible for the new owner to receive modified certificates of approval before the acquisition date. There will also be some time period from the date of sale before changes to the existing manufacturing processes could be considered or implemented. 3M has experience in acquiring other manufacturers and our experience in these cases is manufacturing operations generally remain status quo for a period of time, typically at least two years. Stopping the sale of newly acquired products as of the closing date would create a burden to users in that product supply would be disrupted during this period. These users would have to switch manufacturers as soon as their supplies were exhausted resulting in costs to the users to select and buy new equipment, revise the written respirator program, conduct new fit testing and training, and re-evaluate change schedules for chemical cartridges. If the supply of products were not available before the inventory is exhausted, it could result in misuses of a new respirator, or worse, not having respiratory protection when it was required.

We suggest that the new owner be allowed to continue to manufacture and sell devices of the acquired entity under the existing approval during a grace-period that allows sufficient time for the new owner to assess the product and potential changes to the quality plans, determine any changes needed, prepare the submission and obtain approval from NIOSH. We suggest that a minimum of two years be allowed for this grace-period.

In addition new ownership through acquisition should not necessarily result in an "Application for Modification of a Certificate of Approval" or cause revocation of existing approvals. Where an acquired business is run as a subsidiary, we recommend that it should be allowed to operate under its existing approved quality plan and manufacturing systems and be allowed to continue to manufacture NIOSH-approved devices. If the subsidiary decides to change its quality plan or some other aspect of the product, it would need to make submissions for these changes.

p. 75054 84.37 Changes in manufacturing facility or quality system
(a) "The applicant shall notify NIOSH in writing, within 20 work days, of a final decision to change the location of a manufacturing facility...."

The reason for informing NIOSH of a business decision ahead of the submission in these cases is not clear. A submission seeking approval to change the location of the manufacturing facility or to make any substantive change in the quality system associated with one or more approved devices should be sufficient to inform NIOSH. This includes changing location of a manufacturing facility. Once approval is received, it is understood that these changes may be implemented.

p. 75054-75055 84.40 Quality System, general requirements
(a) *"...the applicant shall establish and maintain a quality system that is compliant with the ISO Q9001:2000 standard..."*

(c)(1) "For applicants who are registered by a qualified registrar...."
(c)(2) "For all other applicants, a statement self attesting to being in compliance with the ISO 9001:2000 standard."

We generally agree with the proposed requirement that applicants establish and maintain a quality management system that is compliant with ISO 9001. We believe that this establishes a consistent set of Quality Management practices that every manufacturer of respiratory devices must maintain, which will benefit the end user of these devices. However, we do not believe that applicants can simply "self attest" to being in compliance with the ISO 9001 standard. The applicant may not be expert in the requirements of the ISO 9001 standard and their statement would be only an opinion that they comply. Third party verification by a qualified registrar is required to ensure compliance to the ISO 9001 standard. NIOSH needs to define "qualified registrar," as previously defined by NIOSH in the 2003 QA Module Concepts, where it defined a qualified registrar as "a registrar accredited by the ANSI-RAB National Accreditation Program (or equivalent national body for non-US approval holders)."

p. 75055 84.41 Quality manual requirements
(b) "The applicant shall also submit to NIOSH a current copy of the quality manual: (1) Whenever it is substantially revised or, at a minimum, once every four years; and (2) Upon request from NIOSH"

We agree with this requirement, and submit it is much more reasonable than the current practice of submitting an updated manual every year. In practice, we have found that the various Quality Manuals do not often change significantly, and are typically requested by NIOSH prior to a manufacturing facility audit.

p. 75055 84.42 Quality control plan content
(a) "The applicant shall develop a quality control plan that documents all Manufacturing, assembly, inspection, testing, and servicing processes applicable to the respiratory device for which certification is sought and maintained. The quality control plan shall contain the following elements:"
(a)(1) "Quality control plan flowchart. The flowchart must depict all processes used in the production of the approved device, including processes comprising manufacturing, assembly, inspection, testing, and servicing of the device and its components. All inspection and testing activities conducted throughout the entire production process must be included. The quality control plan must be submitted with each application for approval..."
(a)(2) "Design, Production, and/or Engineering Drawings and Specifications. Drawings and specifications must be accurate and sufficiently detailed to fulfill their use in procurement, manufacturing, assembly, inspection, and testing activities. Upon request by NIOSH, the applicant shall provide copies of these drawings or specifications to NIOSH or an authorized NIOSH representative for inspection and review."
(a)(3) "Assembly, Inspection, and Testing Procedures. The applicant shall design, document, and validate procedures for all assembly, inspection, and testing activities, whether procured or performed by the applicant, to ensure that sufficient process description is available to successfully perform all necessary production activities. Acceptance and rejection workmanship criteria must be incorporated into relevant procedures to assure that the approved device meets

all design, performance, and regulatory requirements. Upon request by NIOSH, the applicant shall provide copies of these procedures to NIOSH or an authorized NIOSH representative."
(a)(4) Critical to Quality Characteristics (CTQC)
(i) "The applicant shall generate, maintain, and update as necessary, CTQC documents for each stage in the production process for an approved respiratory device. A CTQC document shall list all Critical, Major A, Major B, and Minor Characteristics for which inspection or testing shall be performed. Upon request by NIOSH, the applicant shall provide copies of CTQC documents to NIOSH or an authorized NIOSH representative."
(ii) "The applicant shall incorporate the criteria listed in a CTQC document into inspection procedures established pursuant to paragraph (a) (3) of this section at the appropriate stages of assembly. The appropriate stage of assembly for a criterion is a stage at which the criterion can be fully evaluated by the assembler without the evaluation being obstructed or otherwise limited as a result of the addition to the assembly of other hardware, components, or performance elements."
(iii) "The applicant shall classify each of the CTQC of the device according to the importance of the potential effect of a nonconformance, into the following classes:"

NIOSH needs to provide greater detail regarding their requirements for submitted documentation supporting the manufacturer's Quality Plan. It is currently unclear what level of documentation needs to be submitted as well as how an overall quality system approach (for instance, the use of statistical process control and validation activities) may impact the level of specific release documentation within the Quality Plan that would be required as a part of the submission package.

By requiring manufacturers to be compliant with ISO 9001, NIOSH is helping to ensure that the requirements for design assurance (a framework for ensuring design work involves appropriate planning, controls, inputs, outputs, review processes, and validation of results) are being followed. To build upon this concept, we recommend NIOSH allow flexibility for the manufacturer to describe their quality plans. Based upon the level of statistical process control and validation activities, the manufacturer is in the best position to identify how to consistently deliver quality product to the user. Alternate methods and criteria for ensuring quality may become available and should not be disallowed simply because the requirements stated in the rule are too specific and limiting.

(a)(5)(i-iv) "Incoming...Inspection Sampling Plan."

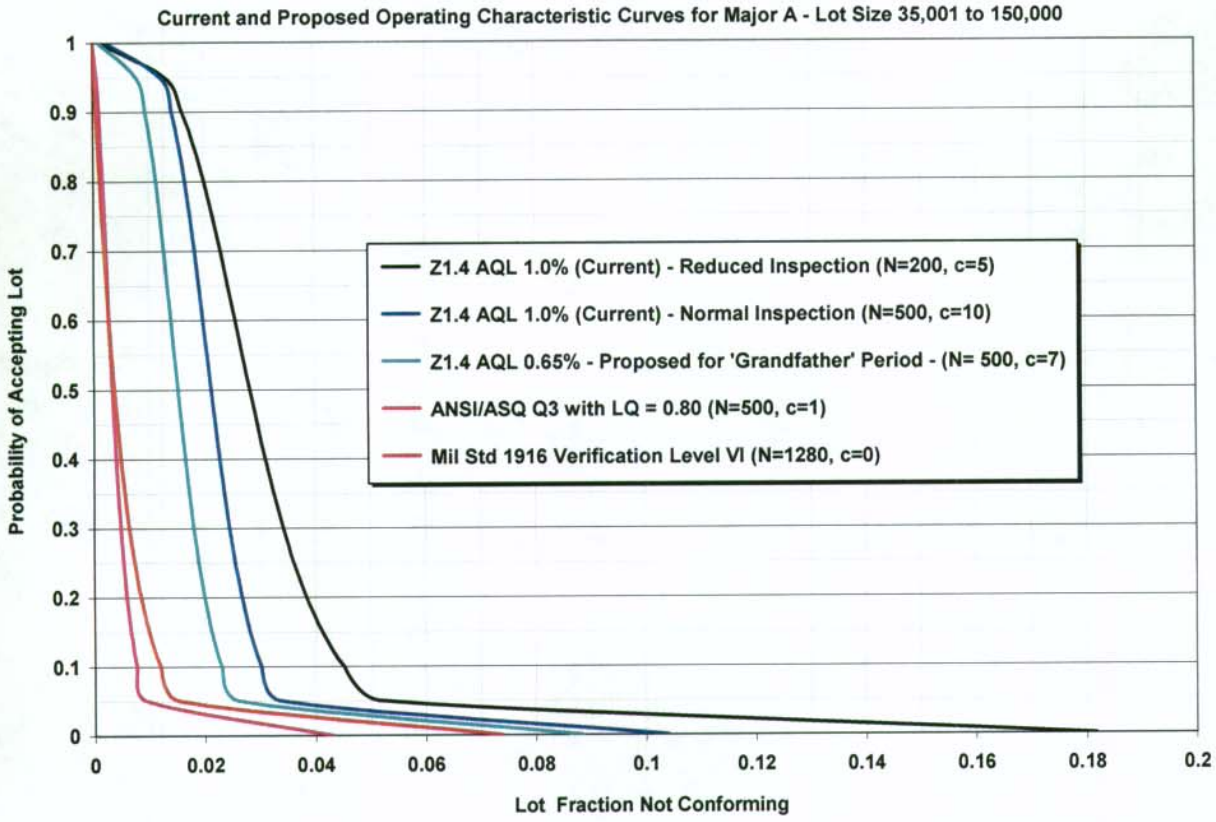
NIOSH should not impose quality level specifications for Major B or Minor CTQC. Some product properties have no direct bearing on product usability or efficacy but rather attempt to evoke a particular level of brand image. These usually fall into the area of *"minor characteristics – a nonconformance that is not likely to materially reduce the usability of the respirator for its intended purpose, or a nonconformance that is a departure from established standards and has little bearing on the effective use or operation of the respirator" (84.42 (a)(4)(iii)(D)*. For example, a manufacturer may choose to sell products with higher or lower levels of surface imperfections (scratches, mottling, etc) on castings. These typically have no effect on the safety or reliability of the product but may affect brand image.

Therefore, we recommend that NIOSH does not need to be informed of or to mandate requirements for the quality control plans of major B or minor characteristics and should limit such specified quality specifications only to the performance requirements identified in 42 CFR Part 84.

Regarding the sampling plan requirements in 84.42(5)(i), current manufacturing capabilities and economic impact should be assessed to determine the potential adverse effects of meeting such requirements as proposed by the new sampling plans. We disagree with the NIOSH view in the summary of this proposed rule (p. 75049 84.42) that "the three samplings plans are … moderately more stringent than the current requirements of this section." We submit that they are drastically more stringent. The technical analysis noted in the summary (p. 75050; technical analysis … by H&H Servico Corp) does not address the statistical differences between the current plans and the proposed plans. In comparing the Operating Characteristic (OC) curves of the proposed plans to the current plans (see fig. 1); the proposed change may require drastic improvements in nonconformance levels that do not significantly improve the product performance. This will most likely increase the amount of sampling and inspection cost for most manufacturers. This is counter to the statement on pp. 75046 - 75047 section C; *"The proposed rule would enable manufacturers...(to) save inspection resources and cost..."*

For example, on Major A CTQC with an actual AQL=0.8% and actual RQL=2.36% (per ANSI Z1.4, AQL 1% Lot size 35001 – 150000 level II), this would have to improve to an actual AQL=0.004% and actual RQL=0.234% under the Mil-Std-1916. This would require at least a 30 times improvement in the nonconformance rate to maintain an equivalent lot pass rate. For given manufacturing process capabilities, this proposal will actually increase sampling by at least a factor of 4. It can also be concluded from the graph (fig. 1) that a manufacturer meeting the current requirements will have a 95% probability of accepting lots with a nonconformance level of 1% while that probability decreases to 15% under the Q3 plan and 5% under the Mil-Std 1916 plan. Most manufacturers usually operate at nonconformance levels much lower than 1% but may not achieve levels necessary to routinely pass the proposed sampling plans. The proposed sampling plans may force manufacturers towards 100% inspection plans which have been proven to be only 85% efficient in segregating nonconforming product (Juran, Gryna p. 377 sec. 15-10).

Fig 1.



The three Quality Assessment Sampling Plans in the proposed rule all mandate 4 to 6 sigma capabilities. While having 4 to 6 sigma capabilities is a worthwhile goal, it may not be achievable for all CTQC as listed in the 4 classes without significant capital expenditures and product development efforts and may be of limited benefit to the end-user.

A program of continuous improvement or improved enforcement of the current NIOSH quality requirements may be more effective in increasing product quality levels to the end-users than dictating tighter acceptance sampling plans for all manufacturers.

p. 75056 84.42 (a)(6)(i-ii)
The grandfather provision requires new AQL levels (0.65% vs current 1% for Major A) which would require changes to quality plans and will require time to review and update these plans. We recommend that NIOSH not require changes to the AQL levels for currently approved quality plans during the grandfather period.

(a)(8) "If attribute… actual value."
We disagree with the requirement to record the actual value of an attribute failed characteristic in all cases. The recording of such values should be assessed based on the utility it provides in each case.

p. 75056 84.44 Respiratory device complaints

(3)(A) " The applicant shall immediately evaluate and investigate any complaint that:
(ii) Indicates a Critical, Major A, or Major B nonconformance..."
(3)(B) "The applicant shall notify NIOSH in writing within 3 work days of any such complaint....."

We disagree with the requirement for reporting to NIOSH complaints that fall under category (3)(A)(ii) indicating Critical, Major A, or Major B nonconformances. There could be a variety of complaints from users that do not impact user safety or health. As an alternate to the above proposed requirement, NIOSH should require manufacturers to report only user complaints that are deemed to impact user safety or health as stated in (3)(A)(i). The above proposed requirement is unduly burdensome and unrealistic to administer both for NIOSH and the manufacturers. Manufacturers will need to report non-critical information, and NIOSH will need to review it. By requiring manufacturers to be ISO 9001 certified, NIOSH could be confident that manufacturers are addressing these issues, and can audit customer complaints during facility audits. In addition, a period of three work days is insufficient time to research and validate the complaint, gather information and prepare a report. We recommend that this time be extended to 10 working days after validation of the complaint.

p. 75056 84.45 Audit programs

(b)(1) "*Applicants shall conduct an annual audit on each respirator or respirator family...*"
....during such audit, the applicant shall notify NIOSH within three working days of finding any nonconformance of a critical or major characteristic...."

We agree that it is incumbent upon the manufacturer to ensure the performance of the respirator system. This can be accomplished through many ways that could be much more effective and a more efficient use of resources than annual audits. We recommend that NIOSH, in lieu of the annual audit requirement, allow: design and development planning and validation; robust quality plans for production; and validation of process/material changes.

We also recommend that NIOSH require manufacturers to report only audit findings that are deemed to impact user safety or health. There could be characteristics that do not impact user safety or health even if they are found to be outside of the current manufacturer acceptance requirements. Often manufacturer's specifications may include a safety factor that makes them more stringent than those required by NIOSH.

In addition, three work days is insufficient time to research, gather information and prepare a report and notify NIOSH of any nonconformance of a critical or major characteristic, as classified by the applicant under 84.42(a) (4) (iii). We recommend that this time be extended to 10 working days after validation of the audit result.

References:

Juran, Joseph M and Gryna Frank M. : Quality Planning and Analysis, 2nd edition. *McGraw-Hill, Inc.* p. 377 (1980)