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

From: cecolton@mmm.com
Sent: Friday, October 09, 2009 4:58 PM
To: NIOSH Docket Office (CDC)
Subject: RIN: 0920–AA04 42 CFR pt. 84

Attachments: Written comments for QA proposed rule October 9 2009.pdf

Written comments for QA propos...

(See attached file: Written comments for QA proposed rule October 9 2009.pdf)

Craig E. Colton, CIH
Division Scientist
Regulatory Affairs & Technical Service
3M Occupational Health and Environmental Safety Division 3M Center Building 235 - 2E-91 St. Paul, MN 55144-1000
651-733-6297
651-736-7344 Fax
cecolton@mmm.com

3M Occupational Health and Environmental Safety Division

3M Center
St. Paul, MN 55144-1000
651 733 1110

October 9, 2009

NIOSH Docket Officer
NIOSH Docket # 109
Robert A. Taft Laboratories MS-C34
4676 Columbia Parkway
Cincinnati, OH 45226
NIOCINDOCKET@CDC.GOV.

RE: RIN:0920-AA04, 42 CFR pt. 84, Quality Assurance Requirements for Respirators; Notice of Proposed Rulemaking; Reopening of comment Period

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. 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, Reopening of Comment Period published in the *Federal Register* May 21, 2009.

3M supports NIOSH in its effort to update the requirements for quality assurance of respirators. We appreciate the opportunity to add additional comments related to costs 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

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

3M Comments on Quality Assurance Requirements for Respirators
Proposed Rule, Reopening of comment Period dated May 21, 2009

Introduction

In the above mentioned *Federal Register*, NIOSH indicated that the comment period was extended to allow the public to comment on the costs associated with the proposed QA requirements related to inspections, audits, documentation, complaint management, and document control administration because they are significant. To that point we submit the following specific comments.

Specific Comments

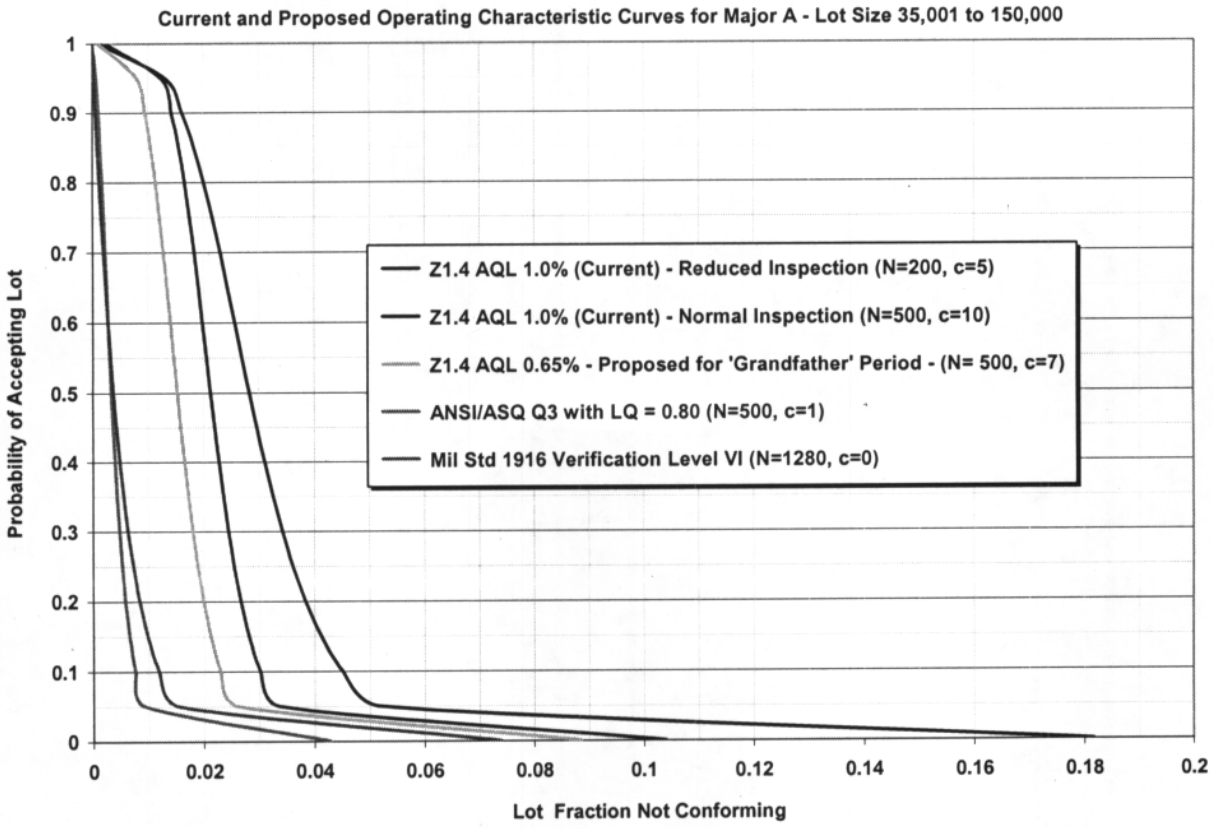
84.42 (a)(5)(i-iv)

Regarding the sampling plan requirements in 84.42(a)(5)(i), current manufacturing capabilities and cost should have been assessed to determine the potential adverse effects to meeting such requirements as proposed by the new sampling 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.

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%. While this level is more stringent than what is required by the current standard, these approved levels may not achieve the levels necessary to routinely pass the proposed sampling plans. Sudden increases in lot rejections could dramatically reduce the number of respirators available.

While having 4 to 6 sigma capabilities is a worthwhile goal, it may not be achievable for all CTQC as listed in the 4 categories without significant capital expenditures and product development efforts. 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.



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." While NIOSH indicates these changes to be moderate, we feel 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.

As a member of the International Safety Equipment Association (ISEA), we participated in an effort to supply cost estimates to NIOSH that are submitted with the ISEA comments. The charts accompanying those comments highlight the changes in sampling requirements between current plans and the proposed plans. As evidenced by the charts, implementation of NIOSH's proposal will increase the amount of sampling and inspection cost for most manufacturers (ISEA does not represent all respirator manufacturers) without a demonstrated benefit to the end-user for the increase inspection. This runs contrary the statement on pp. 75046 - 75047 Section C of the Federal Register notice that reads *"The proposed rule would enable manufacturers…(to) save inspection resources and cost…"*

The respiratory protection device manufacturers of ISEA account for more than 97% of all NIOSH respirator certifications. A survey of these manufacturers indicates that the economic cost for additional human resources in transitioning to NIOSH's proposed sampling plan is estimated at a one-time cost of more than $4,000,000. This estimate does not include any costs

associated with the procurement of any testing equipment, software packages, product samples, or other fixed expenses that would be incurred. In addition, manufacturers report an ongoing cost of more than $21,000,000 to maintain compliance with the proposed sampling plan. Given that these increases are significant, are applied across all product lines and will be experienced by all manufacturers, manufacturers may seek to make economically practical decisions which could result in the end-users having limited product choices.

3M contends that there has been no demonstrated "disappointing outcome" in respirator use, failure rates, or user safety that shows the need for this de facto requirement to prompt this change. Sudden increases in lot rejections could dramatically reduce the number of available devices as manufacturers go through screening process on more lots than usual, and in the case of destructive inspection these lots become waste. Reduced shipments could lead to shortages that require users to continue to use devices after they should be replaced and could also cause product shortages for the next pandemic or other public health crisis for which respiratory protective devices are critical.

We contend 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.

With respect to the sampling plan requirements, 3M recommends that § 84.42 (a)(5) be rewritten as follows:

> (5) Each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.
>
> Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur, the sampling plans are reviewed. These activities shall be documented.

By imposing specific quality requirements, NIOSH is creating a specification standard which does not allow flexibility for manufacturers to implement new and better quality tools and techniques. We recommend NIOSH create performance based criteria rather than specification based criteria. For example, manufacturers can control final product quality by understanding, validating, and controlling input variables so that extensive final product testing may not be required.

References:

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