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

From: Jeff.Gutshall@MSANet.com
Sent: Wednesday, April 08, 2009 2:05 PM
To: NIOSH Docket Office (CDC)
Subject: RIN: 0920-AA04 42 CFR pt. 84
Attachments: DocketComments.pdf

Please see the attached comments.

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April 8, 2009

NIOSH Docket Office
Robert A. Taft Laboratories
MS-C34, 4676 Columbia Parkway
Cincinnati, OH 45226

Re: Proposed Rulemaking RIN 0920-AA04, Quality Assurance Requirements, 42 CFR Part 84

MSA is a global leader in the development, manufacture and supply of sophisticated safety products that protect people's health and safety. Our comprehensive line of products is used by workers around the world in the fire service, homeland security, construction and other industries, as well as the military. Principal products include self-contained breathing apparatus, gas masks, gas detection instruments, head protection, respirators and thermal imaging cameras.

The proposed changes to 42 CFR Part 84 are a welcome update to the quality requirements that should provide manufacturers additional quality system flexibility. Apparently we can now realize added benefits from upstream process investments by reducing inspections.

Additionally, some of the discrepancies between NIOSH policies and the regulations that exist today are addressed. However, we have some concerns regarding implementation, and also some comments that, if addressed, could resolve additional discrepancies.

Concerns:

Grandfather Period, Submission Processing Restrictions

> *All active approvals will need to be submitted within 3 years. (3 year proposed grandfather period for existing QA plans, page 75050)* This is arbitrary, and unnecessary. A meaningful implementation system should be considered, such as one where new and revised approvals must be upgraded to the new requirements. This approach would address the products that are the most active, placing limited resources where they are most effective. Older, established products need not be initially changed. New products, and those with problems, would meet the new requirements first.
>
> We have approximately 64 respirator matrices on file. That is a good indication of the number of submissions that would need to be made. Many of these use common components; therefore they cannot be submitted at the same time due to the design of NIOSH's processing system. We have been told in the past that we should only submit one

application at a time, wait for it to be processed, and then submit the next. Historically, we can expect each submission to take at least 60 calendar days for NIOSH to review and approve (this may be longer when inundated with submissions from all approval holders.) If we submit multiple applications at the same time, the overall quantity of submissions can increase due to the re-submissions necessary to accommodate simple clerical processing restrictions that often result in denials.

We have come to expect increased processing times for each application that is not denied if there are interdependencies between applications. Therefore, it is possible for 3800 days (10 years) to get all submitted and approved. Even if we submitted 2 at once and all went well, 5 years would be needed.

Grandfather Period, Compliance Efforts

The quantity of production documents that need to be reviewed and revised for compliance to this rule is overwhelming.

- Our inspection instruction sheets (TSTs) that will be affected by the changes, and that must be revised accordingly number in the thousands. (Murrysville count exceeds 5500 total, majority are NIOSH products) While these MAY not need to be submitted for approval, they need to be reviewed and that review must be documented. At 30 minutes each, 2000 man hours are needed in Murrysville alone. That many can also be assumed for Jacksonville, so we can figure on 4000 man-hours to just update TSTs. 2 man-years of effort for people we do not have.
- TSTs are driven by the requirements on the drawings. Each drawing can affect multiple TSTs, so the number of drawings needing review would be less that the number of TSTs, but each one must be reviewed. Furthermore, the defect classification system used at MSA is common for all products, not just NIOSH related ones. Either all drawings need to be reviewed and updated, or a new NIOSH-only system would need to be proceduralized and implemented for non-NIOSH drawings. We have over 50,000 drawings and specs that would need reviewed, or capital investments made in IT for an alternative system.

We are looking at an investment measured in man-years, and we have not made one application for approval. Manufacturers would be forced to choose between stopping production for unknown periods, or placing their ISO registration at risk.

Requirements for Grandfather Period Will Shut-Down Production.

It is important to realize that all forms, TSTs, and drawings need to be reviewed and revised anyway just to be eligible for the grandfather period due to the AQL change to the new 0.65 requirement from the current 1.00. **This negates the intended benefit of the grandfather period leniency; we will be out of production until the efforts referenced above are complete**. Why spend man-years of effort to comply with system requirements that will be out of date when the effort is complete?

Arbitrary Verification Levels

The codification of verification levels and Limiting Quality (LQ) values are too restrictive and do not permit the manufacturer to react to changing conditions. For example, a Major A characteristic that has never been out of tolerance would have to be inspected nearly the same as one that is new with no history. This adds needless cost to the user.

Supplier Relations & Service Provider Interference

The inclusion of incoming inspection within the same requirements as in-process and final inspection is too restrictive. Manufacturers must be permitted to partner with their suppliers and rate them according to their performance. One score that weighs heavily on supplier selection involves the amount of inspection necessary.

When combined with the new definition of a production facility, paragraph 84.37(a) is vague in the context of a modern production operation. Varying component demands and production equipment issues can be addressed by utilizing external facilities. For a large operation, these decisions are made almost daily. To involve NIOSH in this process would cripple a dynamic operation, drive up costs for the user, and/or restrict product availability. Instead of improving quality, this questionable requirement would negatively impact user safety.

Hardware for Submission

84.11(i) requires that hardware prepared for submission be produced with no operation that will not be incorporated in regular production. This is not entirely possible and we have the opportunity now to correct this misunderstanding about industry. New, and some extended, submissions are made before operational details have been finalized. To assure that all operations are concrete before submission would require operations to commence, then shutdown while we waited for approval. This makes it impossible for a company to be competitive, and costs would be increased needlessly. We believe the objective is to have manufacturers submit hardware produced in accordance with the documents submitted. These documents do not address the details of extra inspection for short periods of time due to training, etc.

Paragraph 84.44 requires notification of certain complaints in 3 days. This is arbitrary, and unnecessary. It is often much longer to substantiate a complaint as valid.

General Comments:

- The rule currently uses the term 'certificate' for an approval goal. Approval holders actually do not get a certificate. People reading this can request copies of certificates, and expect us to have something other than a letter that states our application was approved. Accordingly, 84.31 could be updated.

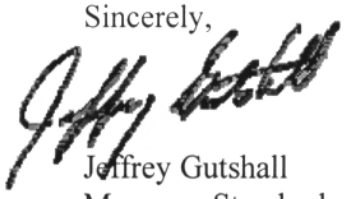
- Why use the term "critical" to describe CTQC in 84.42(4) when critical is a specific classification of defect and the intent of the CTQC is to include non-critical defects also. Just call it NIOSH Controlled Attribute? Better description of what it is.

- We believe it was intended for the Cpk values referenced to be ≥ not >.

- Paragraph 84.42 requires all documents required by this be included in a document control system. We have document control systems for production documents and records that are different than those for engineering documents. We assume that since this meets ISO 9001 requirements, it will meet NIOSH requirements as well.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,



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