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NIOSH Docket Office  
Robert A. Taft Laboratories  
M/S C34, 4676 Columbia Parkway  
Cincinnati, OH 45226

Re: NIOSH Proposed Changes to Quality Module, 42 CFR part 84

MSA is taking this opportunity to provide our comments regarding the draft that NIOSH issued for a new quality module. The draft that we refer to was obtained from the NIOSH website and is dated July 14, 2003, updated July 21, 2003.

The administrative and regulatory changes that NIOSH has issued in the past have resulted in associated process changes within our organization. These process changes have been beneficial over time, and we anticipate that the current proposed changes will be just as beneficial if we provide complete consideration to how these changes may affect all aspects of the industry.

Paragraph 1.2(a) recognizes the benefits of an ISO 9001:2000 compliant quality system. While a registered system does not necessarily mean that a system produces quality products, it does indicate that management has committed the resources to achieve that goal. For this reason alone, registration should be a goal of all manufacturers that intend to make quality products. As Deming proposed as point #3 in his 14 points of improving quality: "Cease dependence on inspection to achieve quality. Eliminate the need for inspection on a mass basis by building quality into the product in the first place."

*Enforcing minimum requirements tends to reduce the level of quality of the entire industry to those minimum requirements. Total cost benefits are lost in the focus of meeting the minimum requirements. We recommend that NIOSH provides an incentive for all NIOSH approval holders to achieve a higher level of quality, rather than simply enforce a set of minimum requirements as codified in a set of regulations. This can be accomplished fairly through the use of a tiered system. One example is shown in Table 1.*

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**Table 1**

Tier	Quality System Characteristics	Regulatory Requirements
I	Self-declared as meeting the intent of ISO 9001:2000	-Additional NIOSH system audits -Annual product self-audits -Frequent product NIOSH audits -High sampling verification levels
II	Registered to ISO 9001:2000	-‘Base-line’ NIOSH system audits -bi-annual product self-audits -Reduced product NIOSH audits -Reduced sampling verification levels or capability based equivalents

*Additional tiers can be added if future requirements are conceived. For example, if approval applicants supply qualification test plans and validation/verification results, or a product has a trouble-free history, a Tier III could further reduce the NIOSH oversight role.*

Paragraph 1.2(f) asks the manufacturer to establish a retention period for quality records that is based upon the “expected life” of the respirator’s major components.

*This requirement asks manufacturer’s to establish a public record regarding expected product life. This may impact how warranty claims and liability exposure is assessed. We ask that NIOSH assigns an arbitrary period for this retention requirement. This approach will isolate the requirement from particular, potentially unrelated, business decisions.*

Paragraph 1.2(g) mentions servicing records.

*Specific guidelines should be established for the scope of ‘servicing.’ Is the intention to cover factory rework/enhancement programs only? Some manufacturers may have differing record-keeping requirements for services that are performed by the user, authorized representatives, factory repairs, etc. A blanket requirement such as proposed here will result in differing approaches to compliance.*

Paragraph 1.3 is confusing and does not reflect the intent of the Standard Application Procedures (SAP). This new module provides an opportunity to codify the best administrative practices that NIOSH and the manufacturers have learned in recent years. In particular:

- As worded, the ability to supply attribute drawings and aggregate quality control flowcharts in lieu of production documents for a submission is not permitted. Because the SAP previously required these now disallowed documents, we invested a considerable amount of time creating an internal system to generate, control, and utilize these. If we must supply production drawings, quality control procedures, inspection procedures, etc., we see no benefit to the attribute drawings and they will only serve as a source for error in the future.

The manufacturer-to-NIOSH documentation traffic will increase dramatically. Assuming a volume of 1200 document changes per year, and recognizing that each drawing revision causes a revision to the associated inspection document, NIOSH will be reviewing over one change every hour from one manufacturer alone.

*We propose that NIOSH continue to use and improve the simplified drawing/respirator matrix system currently required by the SAP. Furthermore, the regulations need to reflect this policy as a requirement.*

- Similarly, it appears that a flowchart AND all supporting documents must be submitted. Inspection procedures and work instructions are not indexed to a product, rather by part number or operation, such as a facepiece, for example. A facepiece or any other component can be used on many products. Furthermore, the production of a component can involve operations in multiple facilities. For example, there is no single place to go to find how a facepiece is produced, let alone a complete SCBA. If we are to provide these as specified in these paragraphs, there is no need for a flowchart. Metrics and capabilities are established by operation, not product. There is no meaningful method of relating this in an application that is based upon a product.

*We propose that NIOSH accept flowcharts that reflect the operations involved in the actual production of **components** that make-up a respirator from a high level. This approach allows NIOSH to review the appropriate, critical information while allowing the manufacturer to reflect the reality of the production environment through their detailed production documents. These production documents and records would be made available for inspection by auditors, rather than controlled at NIOSH. In this way, NIOSH would be apprised of significant changes in production while not having to review and authorize day-to-day changes in organization and work-flow changes.*

- NIOSH refers to ‘a complete functional device’ as the objective of the quality control plan flowchart. Often, contractual requirements prevent shipment of a complete device. Industry practices involve the shipping of facepieces and cartridges separately, for example. Also, SCBAs are most frequently ordered less cylinders, or with facepieces separate for individual issue. Flowcharts are not capable of describing this reality.

*The component flowchart approach mentioned above could allow the description of the steps involved in a ‘virtual’ respirator production without necessitating a NIOSH review and authorization of day-to-day changes in distribution and various contractual details.*

- Paragraph 1.3(2)(b) is not clear.

*We recommend that the identifying number not be referred to as a part number. Depending on the document control scheme used by the manufacturer, part numbers*

*may be called assembly, or model numbers depending upon the context. The term 'identifying designation' would even allow the use of words to identify the component, and still meet the intent of this paragraph.*

- Paragraph 1.3(a)(5)(a) mentions an 'assessment plan' but does not define its requirements or role in the approvals process.
- Paragraph 1.3(a)(5)(a) appears to specify sampling plan requirements for all phases of production.

*We suggest that the regulations be worded to allow manufacturers to specify where in production specific attributes are inspected. If, for example, an attribute is inspected at final assembly, additional 'upstream' sampling directed at exposing problems early in production should be at the manufacturer's discretion. Such sampling systems can be quite dynamic and should be permitted to change without regulatory oversight.*

- Paragraph 1.3(a)(5)(c) can be modified to accommodate limited-use applications. For example, an instruction manual submitted to NIOSH for review may include instructions for a wide number of configurations available to general industry. However, a consumer version may be only one specific configuration.

*As currently permitted for approval labels, allowance can be made to use abbreviated versions of the instructions for specific-application packaging.*

- Paragraph 1.3(a)(5)(d) should be used to specify new requirements for approval labels.

*It is MSA's experience that the approval label should include the approval numbers that apply to that product. However, the inclusion of the product configuration information, such as is shown in the matrix, or the older text/paragraph descriptions of the approved configurations is confusing and potentially misleading to the user. The user's instructions are reviewed by NIOSH and can serve as approved configuration information. The use of a matrix may be the best solution for some products, so the manufacturer should be allowed to provide a matrix if desired. Either way, the label should not be relied upon for this information.*

Paragraph 1.7(b) refers to 'form, fit, or function'. This is not a definitive term in any industry; other than reference to any characteristic of a part. Therefore, its use negates the ability to use the SAP for submission requirements, as its use means that any change to the product must be submitted, not just those characteristics on file at NIOSH.

*We suggest that this wording be changed to 'changes directly related to achieving the performance requirements of the standard, or as defined by the documentation on file at NIOSH, or as defined by consultation with NIOSH personnel.'*

In paragraph 2.2, reference is made to 84.33(f) of 42 CFR part 84.

*We suggest that this paragraph be modified to allow the simplified system required by the SAP. A manufacturer exposes themselves to clear liability if they are to meet codified requirements for complete drawings as specified in 1.3 of the proposed module, while supplying the required simplified drawings as spelled out in the SAP.*

Sections 2.5 and 2.6 define a new fee structure for approvals, administration, and maintenance. The effects of these must be considered by the manufacturers well in advance of their implementation. The standard should allow a period for implementation, before fees are assessed.

*The details of these new fees must be made available before budget planning is conducted for the manufacturer's fiscal year that is impacted by the change. This means that these details must be published at least three quarters prior to the year that NIOSH intends to implement them. It would be helpful if NIOSH would provide an example of how a 'typical' approval holder will be affected by the fees associated with one year's participation independent of any approval application activity. For example, a breakdown of the fees that a manufacturer would see for a facility's audits and fees anticipated to maintain approvals for a group of approvals could be provided independent from the regulations.*

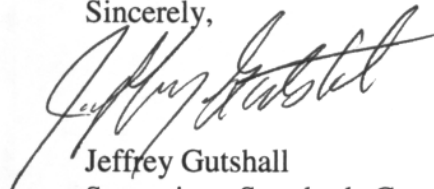
To minimize the financial impact of the maintenance fees defined in section 2.6, manufacturers will be reducing the number of active approvals.

*MSA wants to see NIOSH issue guidelines regarding product retirement.*

- *Are there options for, or different categories of, inactivation?*
- *What does an inactive approval really mean? Can it still be used?*
- *To what extent can a user maintain an inactive approval? If components for an inactive approval are also used on an active approval, how is the user informed of the impact of using that 'active approval component' on the inactive approval as a replacement/maintenance item?*

Thank you for considering these comments.

Sincerely,



Jeffrey Gutshall  
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Safety Products Division