

March 23, 2009

**ISEA Oral Comments on 42 CFR Part 84 Notice of Proposed Rule (NPRM) Quality Assurance Requirements  
RIN 0920-AA04**

The International Safety Equipment Association (ISEA) is the leading trade association representing suppliers of safety equipment. ISEA member manufacturers of respiratory protection appreciate the opportunity to comment on the December 10, 2008 Notice of Proposed Rule (NPRM) on 42 CFR Part 84 Quality Assurance Requirements

**84.2 Definitions**

NIOSH proposes to have authority over the manufacturers' suppliers, and to include them as part of the certification applicant/holder's facility from the standpoint of oversight and audits. Yet this facility may be entirely out of the certification applicant/holder's management and control. This places an undue burden on the certification applicant/holder because it will require them to have quality control over the component parts as well as the component supplier's facility.

We believe that it is sufficient for parts supplied to the certification applicant/holder to be inspected by such means as first article inspections, receiving inspections and certificates of compliance. If the certification applicant/holder finds the parts acceptable this will be considered adequate control. The certification applicant/holder takes full responsibility for parts incorporated into the complete respiratory protection devices as submitted for NIOSH approval and sold.

NIOSH should deem it adequate that the certification applicant/holder ensures the quality of the parts supplied to them and as a part of a product submitted to NIOSH for approval.

ISEA recommends that NIOSH retain the definitions as stated in an NIOSH April 7, 2005 Letter to Manufacturers.

*Supplier:* A supplier produces components or subassemblies under their own quality system for delivery to the approval holder. The approval holder confirms the acceptability of incoming goods by accepting a Certificate of Compliance and inspecting incoming goods to ensure compliance with all product design, performance, and quality assurance criteria (drawings and engineering control). The approval holder releases the product for distribution and sale.

*Subcontractor:* The approval holder may authorize a subcontractor to release NIOSH-approved respirators directly from their facility for distribution and sale, or to release components and subassemblies directly to an authorized repair center. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support by maintaining influence

over and active involvement in, the subcontractor's quality system. As such, the subcontractor's facility is considered to be a manufacturing site for the approval holder.

#### 84.11 Contents of Application

NIOSH should add a statement to this section stating that documentation provided to NIOSH on previous applications, which remains unchanged, can be referenced in subsequent applications in lieu of re-submitting the same documentation. This will relieve NIOSH from maintaining duplicate copies of the same documentation.

The proposal requires that respirator and component parts submitted for approval are not prototypes and made using regular production tooling. However, there may be times when "prototype" tools and/or processes actually become a production tool or process. It should only be necessary that the certification applicant ensure that product supplied to NIOSH for approval will be identical in all critical aspects to the final product to be manufactured, rather than a specific constraint with regard to tooling and processes.

#### 84.36 Changes in device or applicant ownership

The new owner needs to be allowed to continue to manufacture and sell devices under the existing approval during a grace-period of at least 2 years. This provides sufficient time for the new owner to assess the product and quality plans, determine any changes needed, prepare the submission and obtain approval from NIOSH.

We suggest that in the case where an acquired business runs as a subsidiary, it should still be allowed to operate under its own approved quality plan and manufacturing systems and continue to manufacture its NIOSH-approved devices.

#### 84.37 Changes in Manufacturing Facility

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.

#### 84.44 Respiratory device complaints

The requirement to notify NIOSH in writing within three work days of any such complaint (Critical, Major A or Major B) is unduly burdensome, and unrealistic to administer. Three work days is not sufficient time to validate and research the complaint, gather information and prepare a report. Situations occur where a Major B complaint is made yet would be of little or no consequence to the user depending upon when the event occurs. An example of this might be a strap breaking when donning a respirator prior to entering the contaminated area. Although a strap breaking when in a contaminated area could be considered a significant event, breakage of the same strap when outside the contaminated area may not be a significant event. NIOSH should consider requiring manufacturers to report only user complaints that are deemed to impact user safety or health as stated in (3)(A)(i).

A time period should be established from the date of the audit to the time the report is sent to the management representative of the applicant.

#### 84.40 Quality System

NIOSH needs to establish a means for updating references to standards when a revision is published. For example, a revision of ISO 9001 Quality Management System standard was published in November 2008 and is now ISO 9001:2008. NIOSH should review standard revisions and if acceptable, establish a means to recognize the revision.

(b) NIOSH proposes to evaluate the applicant with ISO Q9001:2000 standard compliance and should provide a procedure for resolution in cases where NIOSH has determined a major noncompliance to the standard with the applicant and their ISO System Registrar.

#### 84.40 Quality Systems

We support the requirement that applicants shall be certified to ISO Q9001:2008 standard through a recognized Accredited Registrar (e.g. ANSI-ASQ National Accreditation Board (ANAB) or equivalent national body for non-US approval holders such as ANAB, RvA, UKAS). This establishes a consistent set of Quality Management practices that every manufacturer of respiratory devices must maintain.

ISEA does not believe that NIOSH should allow any certification applicant/ holder to self-attest to being ISO 9001:2000 compliant.

#### 84.41 Quality Manual Requirements

NIOSH should only require submission of a new quality manual when it is substantially revised. Manufacturer should not have to provide NIOSH with a quality manual every four years if no changes have been made to the manual.

#### 84.42 Quality control plan content

There is a broad range of valid statistical tools which may be used to assess and assure the performance and consistency of products. It is to the benefit of the end user that the manufacturer has the flexibility to apply the methods that are most appropriate and efficient for their products and processes. While the more commonly used quality assurance tools, and relevant criterion, should be referenced in the regulations, the specific tools to be used should not be limited by the regulations.

Continual improvement toward 100% quality is an inherent goal of ISO certification. Therefore, it is important that the manufacturer have the flexibility to determine the processes they believe are most appropriate to measure and determine the level of confidence that is required for their product and process capabilities to meet NIOSH regulations. Manufacturers must retain the ability to use the statistical methods and analysis to consistently deliver quality products. NIOSH should not mandate the statistical analysis tools for every manufacturer.

In addition, sampling plans and the degree of control required for product inspection and acceptance should be based upon the severity of the hazard where the final product is

intended to be used e.g. Disposable Respirator vs. a SCBA use situation. A broad categorization to cover every family of respirator is not justified.

#### 84.45 Audit programs

(b)(1) This proposal requires an annual audit on each respirator or respirator family for which the respirator or respirator family is not tested as a completed device during the manufacturing process. NIOSH should consider requiring manufacturers to report only audit findings that are deemed to be a health/safety or regulatory compliance issue.

NIOSH also needs to further explain *respirator family* for which the respirator or respirator family is not tested as a completed device during the manufacturing process.

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) (iii).

We think it is important that NIOSH audit all manufacturers equally no matter what their country of incorporation is. We realize that there may be added cost and hardship on the agency in terms of on-site audits, field audits and meeting with manufacturing entities outside of the US, however, NIOSH must be particularly vigilant with respiratory protection devices that are necessary to protect workers and the public health.

ISEA appreciates the opportunity to comments on the proposed quality assurance requirements and will submit more detailed written comments to the NIOSH docket by April 10, 2009.