INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION ISEA

Via email: niocindocket@cdc.gov

October 9, 2009

NIOSH Docket Office
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ISEA Comments on 42 CFR Part 84 Notice of Proposed Rulemaking (NPRM)
Quality Assurance Requirements for Respirators RIN 0920-AA04

The International Safety Equipment Association (ISEA) is the leading trade association representing suppliers of safety equipment, including respiratory protective devices certified by NIOSH. ISEA welcomes the opportunity to comment on the December 10, 2008 Notice of Proposed Rulemaking (NPRM) on 42 CFR Part 84 Quality Assurance Requirements and offer the following input on the specific sections of the proposed rule:

§ 84.2 Definitions

(w) The wording of this paragraph is vague and open to future interpretation that could include all suppliers as part of a manufacturing facility. Manufacturers find it troublesome if it is NIOSH's intent 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. This would require valuable resources to be removed from product quality oversight, and instead be spread over numerous, possibly hundreds, of suppliers. Such reallocation of resources has the impact of diminishing rather than improving final product quality. This also places an undue burden on the certification applicant/holder because it will require it to have quality control over the component parts as well as the component supplier's facility even where this facility may be entirely out of the certification applicant/holder's management and control.

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. It should be considered to be an adequate control if the certification applicant/holder finds the parts to be acceptable as the certification applicant/holder takes full responsibility for parts incorporated into the complete respiratory protection devices as submitted for NIOSH approval and sold. As such, NIOSH should deem it sufficient that the certification applicant/holder ensures the quality of the parts supplied to it which are a part of a product submitted for NIOSH approval.

To remove the ambiguity imposed by the language as proposed, ISEA recommends that NIOSH retain the definitions as stated in its April 7, 2005 Letter to Manufacturers, as noted below:

> 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.

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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.

§ 84.10 Application procedures

This clause is too broad as written. Many manufacturers have diverse product lines that are manufactured at unrelated facilities. A noncompliance for one respirator type should not necessarily impede the approval process for a completely different respirator from a different process or system that is not affected by the noncompliance. Having an immediate stop of approval activity for problems with a potentially unrelated product or facility has a direct impact on product availability for the end-user.

A more reasonable approach would be to suspend application processing when the applicant has missed a corrective action deadline or a similar failure that suggests a lack of commitment by the applicant.

§ 84.11 Contents of Application

NIOSH should add a statement that documentation provided as part of previous applications and which remains unchanged, can be referenced in subsequent applications in lieu of re-submitting the same documentation. This will relieve NIOSH of the responsibility of maintaining duplicate copies.

(g) This section is too vague to allow effective evaluation and comment. If the table must list "each section and paragraph" in all of Part 84 with which the respirator complies, compliance with this requirement could become a complex and daunting task. As this is a new requirement, manufacturers need to better understand the details of this concept and degree of specificity being sought by NIOSH. While it is intended to be included in a revision to the Standard Application Procedure, such revision has not yet been made available.

(i) The proposal restricts the submittal of prototypes of respirator and component parts for approval and requires that the respirator or component, as submitted, be made using regular production tooling. There may be times when prototype tools and/or processes become a part of the regular tooling process. It should only be necessary that the certification applicant ensure 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

In situations where there is a change 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 that may be needed, prepare the requisite paperwork for submission and obtain approval from NIOSH. If there is no change in the

manufacturing process or quality system, the new owner should be able to continue manufacturing the device under the existing approval indefinitely.

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

§ 84.37 Changes in manufacturing facility or quality system

(a) When combined with the new definition of a production facility, this paragraph 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.

This section should be rewritten to specify more narrowly the types of changes that must be submitted and approved.

§ 84.40 Quality System

(a) NIOSH must establish a mechanism for reviewing and updating references to standards when a revision to the reference document is published. As an example, a revision of ISO 9001 Quality Management System standard was published in November 2008 and is now designated ISO 9001:2008.

(b) NIOSH proposes to evaluate the applicant's compliance with the ISO Q9001:2000 standard, as is deemed necessary. NIOSH should provide a procedure for resolution in cases where NIOSH has determined a major noncompliance to the standard and with the applicant and its ISO System Registrar.

(c)(1) We support the requirement that applicants shall be certified to ISO Q9001:2000 standard through a recognized accredited registrar (e.g. *ANSI-ASQ National Accreditation Program or equivalent national body for non-US approval holders such as ANAB, RvA, UKAS)* and encourage NIOSH to include a definition of "qualified registrar" in the published, final rule.

(c)(2) ISEA reiterates its position stated at the March 23, 2009 public meeting that we do not believe that NIOSH should allow any certification applicant/ holder to self-attest to being ISO 9001:2000 compliant. Permitting an applicant to provide a statement of compliance does not provide the level of verification needed to ensure such compliance. NIOSH must require all applicants/holders to be ISO 9001 compliant which will ensure that all respiratory device manufacturers are maintaining the same, consistent set of quality management practices.

§ 84.41 Quality manual requirements

NIOSH should only require submission of a new quality manual when it is substantially revised. Manufacturers should not have to provide NIOSH with a quality manual every four years if no changes have been made to the manual. This relieves NIOSH of having to store and maintain multiple copies of duplicate documents.

§ 84.42 Quality control plan content

Prior to issuing a final rule, ISEA strongly recommends NIOSH perform a cost/benefit analysis for the proposed sampling plans to the current requirement, taking into account current industrial process capabilities and defect rates. It is critical that such analysis demonstrate that smaller manufacturers are not disproportionately burdened by the cost of complying with the proposed regulation, which may call into question the validity of this rulemaking effort.

(a)(1) through (a)(4)(iii) These sections address the requirements for Drawings, Inspection/Test Procedures and Critical to Quality Characteristics (CTQC) Classifications, respectively. Each section says that the described documents must be made available to NIOSH on request. However, §84.42(a) specifically states that each of these is required content in a control plan while §84.43 specifically states that a control plan must be submitted to NIOSH for approval. The rule should be revised so that it is clear that these items, while part of the control plan, are not subject to the automatic submission and approval requirements.

(a)(5) 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 involving 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 manufacturers 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.

ISEA recommends that NIOSH take an approach comparable to other national and international standards such as the FDA's 21 CFR Part 820, Subpart O, or DIN-EN-137. The Food & Drug Administration's Subpart O simply requires the following for its sampling and statistical techniques:

> (a) Where appropriate, 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.
>
> (b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedure 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."

Similarly, in Europe, the DIN-EN-137 standard for SCBA devices simply requires that the products satisfy the performance requirements set forth in the standard, with no specific quality requirements outlined.

There is a broad range of valid statistical tools which may be used to assess and assure the performance and consistency of released products. It is to the benefit of the end-user that the manufacturer has the flexibility to apply the methods that are the 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 regulation, the specific tools to be used should not be limited by the regulation.

Elimination of AQL based quality plans and transition to one of the sampling plans identified in §84.42 (a) (5) will be a burden on applicants that have to undergo such a process. Such a process may involve a substantial volume of documentation across multiple product lines requiring multiple submittals to bring the quality system documentation into compliance with the new requirement. Such an effort to update documentation, even over a 3-year period, may jeopardize forward progress. ISEA suggests applying this requirement only to documentation in support of future applications rather than all standing approvals to ease the burden of transition.

Limiting Quality (LQ) and Cpk values are dependant upon the manufacturer's process capabilities and may be used to improve process capabilities. However, they are tools that may be utilized by the manufacturer and should not be included in regulation. It is important that the manufacturers have the flexibility to determine the processes they believe are most appropriate to measure and decide the level of confidence that is required for their product and process capabilities to meet NIOSH regulations.

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.

(a)(5)(i-iv) NIOSH should not impose quality level specifications and references to specific verification levels should be removed from the regulation. Manufacturers should be permitted to utilize various levels, as they pertain to performance, history, validation efforts, process controls, and other factors, similar to that allowed in ANSI Z1.4 through special and general levels. Special levels already account for zero defects allowed and promote high probabilities of acceptable quality levels.

Therefore, ISEA maintains that NIOSH does not need to be informed of or to mandate requirements for the quality control plans of Major B or minor characteristics. Such quality specifications should be limited to the performance requirements identified in 42 CFR Part 84. Further, we recommend NIOSH allow manufacturers and suppliers to utilize commercially acceptable and recognized sampling plans and practices, including ANSI Z1.4, ANSI Z1.9, Mil-Std-1916, C=0, and others. Manufacturers and suppliers should be granted flexibility to select levels appropriate for product and process applications, so long as they are statistically equivalent.

NIOSH should allow suppliers of manufacturers to provide certifications, evidence, and other appropriate documentation for verification of in-process inspection and testing, and not rely on non-value-added end-item sampling at the point of the incoming inspection. Trends in supply chain management and manufacturing are to utilize smaller and smaller lot sizes, while maintaining low-to-no stock quantities and more frequent deliveries. End-item sampling is becoming significantly less applicable in the manufacturing community. In-process controls including start-up, in-process, or 100% inspection and testing are executed by suppliers and manufacturers and are utilized to ensure product quality, negating the need for end-item sampling.

(a)(5)(i) ISEA strongly encourages NIOSH to assess the adverse effects on current manufacturing capabilities and economic impact that may be imposed by implementing the requirements of the proposed new sampling plans.

We disagree with the NIOSH view in the summary of this proposed rule 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 cited 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 nor does it address the economic impact on manufacturers. The charts accompanying these comments highlight the changes in sampling requirements between current plans and the proposed plans (Attachment I). As evidenced by the charts, implementation of NIOSH's proposal will increase the amount of sampling and inspection cost for most 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 testing equipment, software packages, product samples or other fixed expenses that will be incurred. In addition, manufacturers report an ongoing cost of more than $21,000,000 to maintain compliance with the proposed sampling plan. Data compiled by ISEA manufacturers is attached to these comments. (Attachment II) 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.

ISEA contends that there is no demonstrated "disappointing outcome" in respirator use, failure rates or user safety that shows the need for this *de facto* requirement that all processes improve. Sudden increases in batch rejections could dramatically reduce the number of available devices as manufacturers go through screening process on more batches than usual, and in the case of destructive inspection these batches become permanently unshippable. 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.

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, ISEA 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.

(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 ample 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. As such, it is recommended that these sections be deleted.

(a)(7) We are concerned with the ambiguity in this section as to NIOSH's overall intent in granting approval to alternate sampling approaches for destructive testing. If NIOSH intends to approve plans that are submitted based on current sampling approaches and plans, then there is no effect. If NIOSH intends to restrict approval to those plans that have also switched to a consumer-protection approach, manufacturers cannot accurately predict or comment on any increased cost of test scrap. NIOSH should either clarify its intent or delete this section.

§ 84.44 Respiratory device complaints

(a)(3)(A)(ii) The requirement for notification of Major B complaints should be eliminated so that the system can focus on more critical issues. Major B characteristics are detectable by the user. This type of complaint would inherently get adequate attention based on the reduction in respiratory protection. However, the fact that the user can detect the condition and avoid harm should take these types of failures out of a system that could focus intense attention on more serious incidents. 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 an IDLH contaminated area could be considered a significant event, breakage of the same strap when outside the contaminated area may not be a significant event.

(a)(3)(B) The requirement to notify NIOSH in writing within three work days of any such complaint related to Critical, Major A or Major B nonconformance 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. The timing of any notification requirement should be driven by the date that a manufacturer verifies the complaint, not when it is received.

§ 84.45 Audit programs

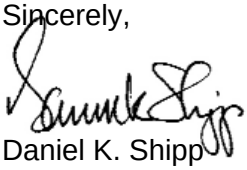
(a) (3) A defined period should be specified from the date of the NIOSH audit to the time the final report is sent to the management representative of the applicant. ISEA recommends that 60 days is a sufficient turn-around time.

(b)(1) The 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 issue or regulatory compliance issue. By requiring manufacturers to be ISO 9001 compliant, NIOSH should be confident that manufacturers are addressing these issues, and they can audit the reports during facility audits. The requirement as written is onerous both to NIOSH and manufacturers by requiring non-value-added work in that manufacturers will need to report non-critical information, and NIOSH will need to review it.

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). A more reasonable amount of time would be one month.

We thank you for your consideration of these comments.

Sincerely,



Daniel K. Shipp
President

Attachments

Attachment I

AQL 0.65% (Major A)
Normal
Sample Size Analysis

Lot Size	ANSI Z1.4 Level II (current)		C=0		Mil-Std-1916 Level VI		% Change from current
	Sample size	Acceptance no.	Sample size	Acceptance no.	Sample size	Acceptance no.	
15	15	0	15	0	15	0	0%
25	20	0	20	0	25	0	25%
100	20	0	20	0	100	0	400%
250	20	0	20	0	250	0	1150%
1000	80	1	47	0	512	0	540%
10000	200	3	68	0	1024	0	412%

AQL 0.65% (Major A)
Reduced
Sample Size Analysis

Lot Size	ANSI Z1.4 S-4 Reduced (current)		C=0 (n/a - no reduction)		Mil-Std-1916 Level V		% Change from current
	Sample size	Acceptance no.	Sample size	Acceptance no.	Sample size	Acceptance no.	
15	8	0	15	0	15	0	88%
25	8	0	20	0	25	0	213%
100	8	0	20	0	100	0	1150%
250	8	0	20	0	192	0	2300%
1000	8	0	47	0	192	0	2300%
10000	8	0	68	0	512	0	6300%

AQL 0.65% (Major B)
Reduced
Sample Size Analysis

Lot Size	ANSI Z1.4 S-4 Reduced (current)		C=0 (n/a - no reduction)		Mil-Std-1916 Level II		% Change from current
	Sample size	Acceptance no.	Sample size	Acceptance no.	Sample size	Acceptance no.	
15	2	0	5	0	12	0	500%
25	2	0	5	0	12	0	500%
100	2	0	11	0	12	0	500%
250	8	0	13	0	12	0	50%
1000	8	0	19	0	24	0	200%
10000	13	1	29	0	32	0	146%

Estimated Additional Hours and Cost for Compliance

Attachment II

	Filtering Facepiece Respirators			Facepiece Respirators - Facepiece			Facepiece Respirators - Filter Cartridge		
Initial Compliance	Technician	Engineer	Total	Technician	Engineer	Total	Technician	Engineer	Total
1a	918	5849		1388	4068		9300	16036	
2a	256	102		70	670		68	1370	
3a	200	506		160	255		1760	1869	
Total hours	1374	6457		1618	4993		11128	19275	
Estimated cost	$ 34,350	$ 484,275	$ 518,625	$ 40,450	$ 374,475	$ 414,925	$ 278,200	$ 1,445,625	$ 1,723,825
Ongoing Compliance									
1b	113005.5	1350		7120	500		44010	5908	
2b	1604	2810		3024	3430		21280	28645	
3b	4768	1410		1950	565		15315	4181	
Total hours	119377.5	5570		12094	4495		80605	38734	
Estimated cost	$ 2,984,438	$ 417,750	$ 3,402,188	$ 302,350	$ 337,125	$ 639,475	$ 2,015,125	$ 2,905,050	$ 4,920,175

	Supplied Air Respirators			PAPRs			SCBA		
Initial Compliance	Technician	Engineer	Total	Technician	Engineer	Total	Technician	Engineer	Total
1a	3750	5617		925	2870		7350	12600	
2a	68	170		68	370		0	0	
3a	800	834		160	299		125	160	
Total hours	4618	6621		1153	3539		7475	12760	
Estimated cost	$ 115,450	$ 496,575	$ 612,025	$ 28,825	$ 265,425	$ 294,250	$ 186,875	$ 957,000	$ 1,143,875
Ongoing Compliance									
1b	1750	2500		2486	500		86875	5250	
2b	9166	13588		7266	7796		1575	3150	
3b	6856	1814		3212	482		1680	5376	
Total hours	$ 17,772	$ 17,902		$ 12,964	$ 8,778		90130	13776	
Estimated cost	$ 444,300	$ 1,342,650	$ 1,786,950	$ 324,100	$ 658,350	$ 982,450	$ 2,253,250	$ 1,033,200	$ 3,286,450

KEY

1a. Quality Plans: Plan Updates and Documentation Changes, includes updates to drawings, product standards, work instructions, PQPs, etc.
2a. Annual Respirator System Product Quality Audit Testing: Setting up the system
3a. Complaint Handling and Reporting to NIOSH: Setting up the system
1b. Quality Plans: Inspection Testing for Production each year
2b. Annual Respirator System Product Quality Audit Testing: Carrying out the requirements each year
3b. Complaint Handling and Reporting to NIOSH: Carrying out the requirements each year

Estimates $25/hour for a techician and $75/hour for an engineer

Estimated Additional House and Costs for Compliance
Summary of All Categories

Additonal one-time compliance cost	Technician Hours	Engineer Hours	Total
1a. Quality Plans: Plan Updates and Documentation Changes, includes updates to drawings, product standards, work instructions, PQPs, etc.	23,631	47,040	70,671
2a. Annual Respirator System Product Quality Audit Testing: Setting up the system	530	2,682	3,212
3a. Complaint Handling and Reporting to NIOSH: Setting up the system	3,205	3,923	7,128
Total hours	**27,366**	**53,645**	**81,011**
Estimated cost	**$684,150**	**$4,023,375**	**$4,707,525**

Additonal ongoing compliance cost	Technician Hours	Engineer Hours	Total
1b. Quality Plans: Inspection Testing for Production each year	255,246.5	16,008	271,254.5
2b. Annual Respirator System Product Quality Audit Testing: Carrying out the requirements each year	43,915	59,419	103,334
3b. Complaint Handling and Reporting to NIOSH: Carrying out the requirements each year	33,781	13,828	47,609
Total hours	**332,942.5**	**89,255**	**422,197.5**
Estimated cost	**$16,647,125**	**$4,462,750**	**$21,109,875**

Notes:
1. Salary for technician ($25/hr) and engineer ($75/hr) is based upon National Salary Trend for area and includes overhead.
2. Resource requirements will be adjusted yearly and may increase or decrease depending upon the business opportunities.