INTERNATIONAL
SAFETY EQUIPMENT
ASSOCIATION
ISEA

October 27, 2000

NIOSH Docket Office
Robert A. Taft Laboratories
4676 Columbia Parkway
M/S C-34
Cincinnati, OH 45226

Re: FR Doc. 00-16849

Dear Sir or Madam:

The International Safety Equipment Association (ISEA) is the leading organization representing manufacturers and suppliers of personal protective equipment and apparel. We offer the following comments to the July 5, 2000 *Federal Register* notice that introduced concepts that NIOSH is considering in the revision of the Quality Assurance and Administrative modules for respirator certification.

Use of private labs to conduct certification tests

ISEA members support NIOSH in the effort to utilize private laboratories to perform certification bench tests (not including fit testing, man tests etc.), as long as tests are well defined and easily repeatable. It is understood that the use of private labs will only be used for the testing portion of the product approval process and that NIOSH will maintain responsibility and control for the certification of respiratory products.

Manufacturers anticipate assurances from NIOSH that the cost of testing conducted at private sector labs would be consistent with the application fees established by NIOSH. ISEA believes that the use of private sector laboratories is a human resource management issue for NIOSH and should be a contract between the lab and NIOSH. Manufacturers should have no financial relationship with the private lab for activities that are part of the NIOSH certification process. However, manufacturers would want to reserve the right to witness testing done at these test labs as part of the NIOSH certification process and may wish to contract separately with the lab for product development testing.

Selection of the private lab for certification tests should be competitively bid and performance-based. Laboratories deemed appropriate to conduct respirator certification tests should conform to a qualification program for labs, such as ISO Guide 25, NVLAP, NRTL or other criteria and should include requirements for confidentiality of test results.

Use of private auditors to perform NIOSH site audits

ISEA agrees with NIOSH's desire to utilize private auditors for quality systems (facility) audits and product audits. Systems audit should be performed annually in either of the following manners:

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If the manufacturer is ISO certified and the system audit is performed by ASQ/RAB registered ISO auditor, a single audit should satisfy both the requirements for NIOSH system audit and the ISO registration for the manufacturer.

If the manufacturer is not ISO certified, an ASQ/RAB auditor shall perform an ISO-equivalent audit.

Single product audits should be conducted once every two years by a NIOSH ASQ/RAB auditor, an ASQ/RAB auditor trained by NIOSH, or an ISO notified bodies auditor trained by NIOSH to perform such product audits. A product audit is defined as the audit of a quality plan of a specific product.

Product Audits

In the July 5, 2000 Federal Register notice, NIOSH indicated that one concept that they are considering is "requiring an approval holder to self-audit their products and present those results to NIOSH". ISEA does not support the requirement of manufacturers submitting self-audit reports to NIOSH. Often times these product self-audits are used for internal evaluation and monitoring purposes. These types of internal corporate evaluation tools are not typically required to be released for outside review. ISEA believes that the facility and product audits that are required by inspection will adequately evaluate the product quality and systems checks that a manufacturer has established.

Appeals Process

ISEA urges NIOSH to establish an appeals process to resolve any discrepancies between NIOSH and manufacturers. This would include, but not be limited to certification testing, product audits, system audits, facility audits or any other discrepancy.

This official process should be in place and documented before any private laboratory acts as a testing resource for NIOSH certification tests. The appeals process should be published in the *Federal Register* as part of the regulation.

Require pre-certification audit for any new site

ISEA agrees that a pre-certification audit should be conducted for any new production site. A new site is defined as a facility in which the quality assurance system is not currently approved by NIOSH or where no previous production of any NIOSH-approved products has occurred.

Reporting of inactive products

Manufacturers' products will be of a specified quality, regardless of when the product was manufactured. This is based on the manufacturer's quality plan, which includes a first article inspection as a requirement. The reporting to NIOSH of products not manufactured in the previous 12 months is not necessary.

Reporting of obsolete products

NIOSH has suggested that it intends to establish an annual maintenance fee for approved products. ISEA believes that this fee will encourage natural discontuation of product lines. Therefore, NIOSH can assume that when a product's maintenance fee is not renewed and it's TC number thereby cancelled, such a product is obsolete.

Notifying NIOSH of product complaints or non-conformance

ISEA understands the need for NIOSH to be informed of any product that will cause serious harm to users. Therefore, to ensure the health and safety of the respirator user, ISEA recommends that manufacturers report to NIOSH within 3 business days, any substantiated product defect, which is likely to result in a death or serious injury, and that is likely to be found in product released for sale.

Testing or inspection of critical attributes

ISEA supports NIOSH to revise the QA requirements that encourages quality in product design and focus the Institute's attention on corrective action for those manufacturers who have a history of quality problems.

NIOSH should retain the current classification of critical characteristics as cited in Subpart E of 42 CFR 84.41as they remain appropriate.

Most manufacturers have developed statistical sampling plans based upon their process capabilities. The established sampling plans will provide assurance that the product is safe and effective prior to distribution. Quality is not achieved by product inspection. To use a 100% testing or inspection plan is costly and unnecessary. Moreover, it has been established for some time by statisticians and quality experts that even 100% inspection cannot assure 100% defect-free product.

Enhanced sampling procedure

Due to the great differences in types of manufacturing processes, respirator manufacturers should be allowed to choose any sampling plan that offers equal or greater consumer protection as demonstrated by the Operating Characteristics Curves of the specified sampling plans. All in-process sampling will be considered in the final sampling plan.

Charts 2 and 3 shows the increase in consumer protection as compared to the current plan and compares it to the c = 0 plan. Chart 1 compares Major A, Major B, Minor and destructive testing operating curves. ISEA recommends that NIOSH adopt the sampling plans found in ANSI Z1.4 or Z1.9 for the following classification of defects.

Major A AQL = .65%
Major B AQL = 2.5%
Minor AQL = 4.0%

Inspection level 2 for attributes and variables and S-2 for destructive testing shall remain the same.

ISEA believes that this reduction in AQL will offer a substantial increase in consumer protection while still minimizing the manufacturer's risk of making an incorrect decision on the acceptability of a final lot of respirators thus minimizing additional unnecessary cost to the respirator purchasers. ISEA opposes the exclusive use of either c = 0 or Mil Std 1916 because in some cases, it would likely increase consumer cost without proportional amount of increase in consumer protection.

For destructive tests, ISEA recommends that NIOSH adopt the sampling plans found in ANSI Z1.4 or allow a special manufacturers sampling plan that would be based on the following criteria:

1. Existing overall quality plan checks in place by the manufacturer
2. The specific product being made
3. Quality history of the manufacturer

Additionally ISEA believes that NIOSH should adopt that portion of Mil Std 1916 that deals with using process control in lieu of acceptance sampling. ISEA believe this will greatly benefit manufactures of good quality respirators while lowering consumer risk.

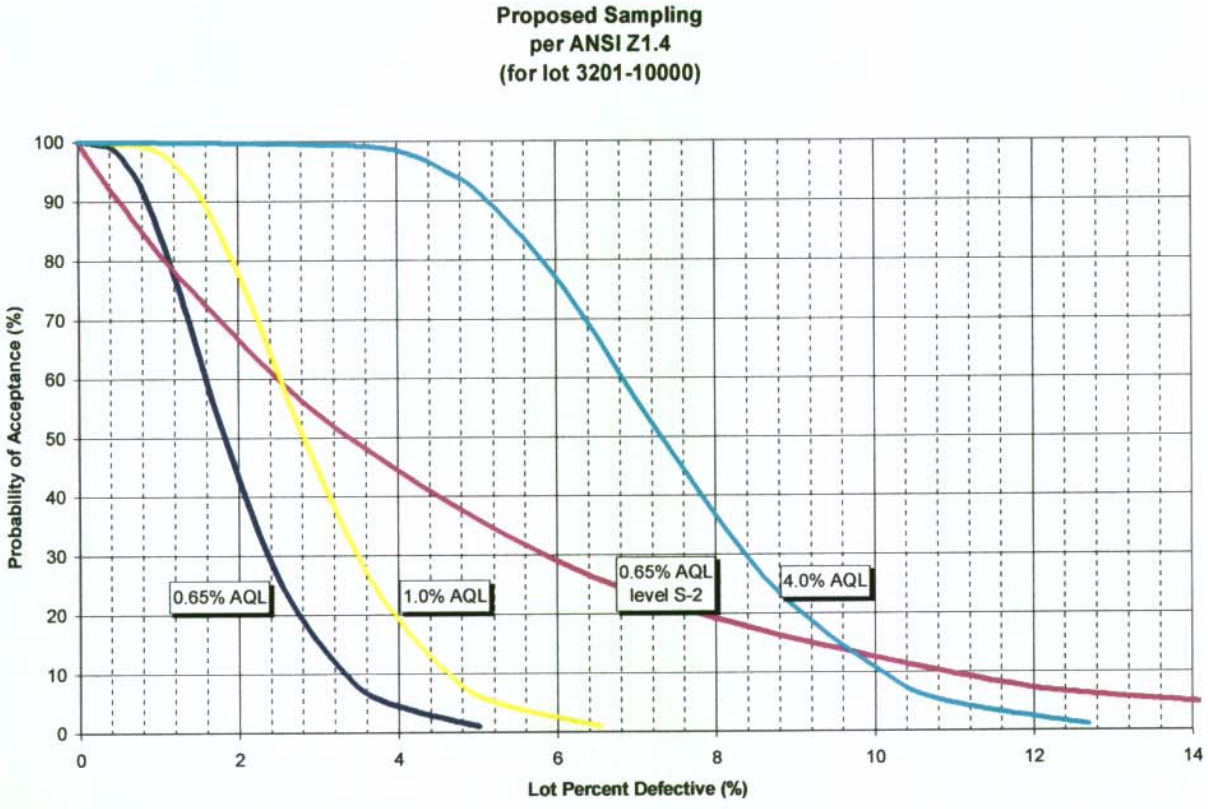

CHART 1

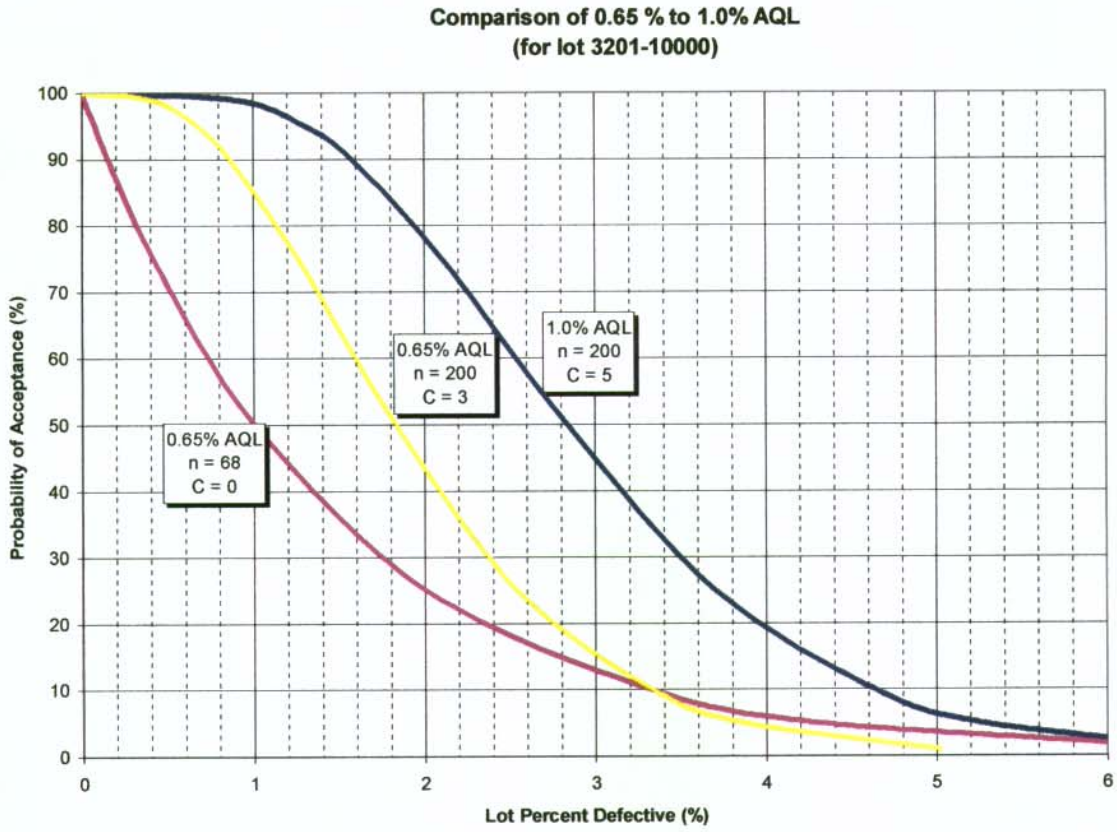
Comparison of 0.65 % to 1.0% AQL
(for lot 3201-10000)
Probability of Acceptance (%)
Lot Percent Defective (%)
0.65% AQL
n = 68
C = 0
0.65% AQL
n = 200
C = 3
1.0% AQL
n = 200
C = 5
100
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6

CHART 2

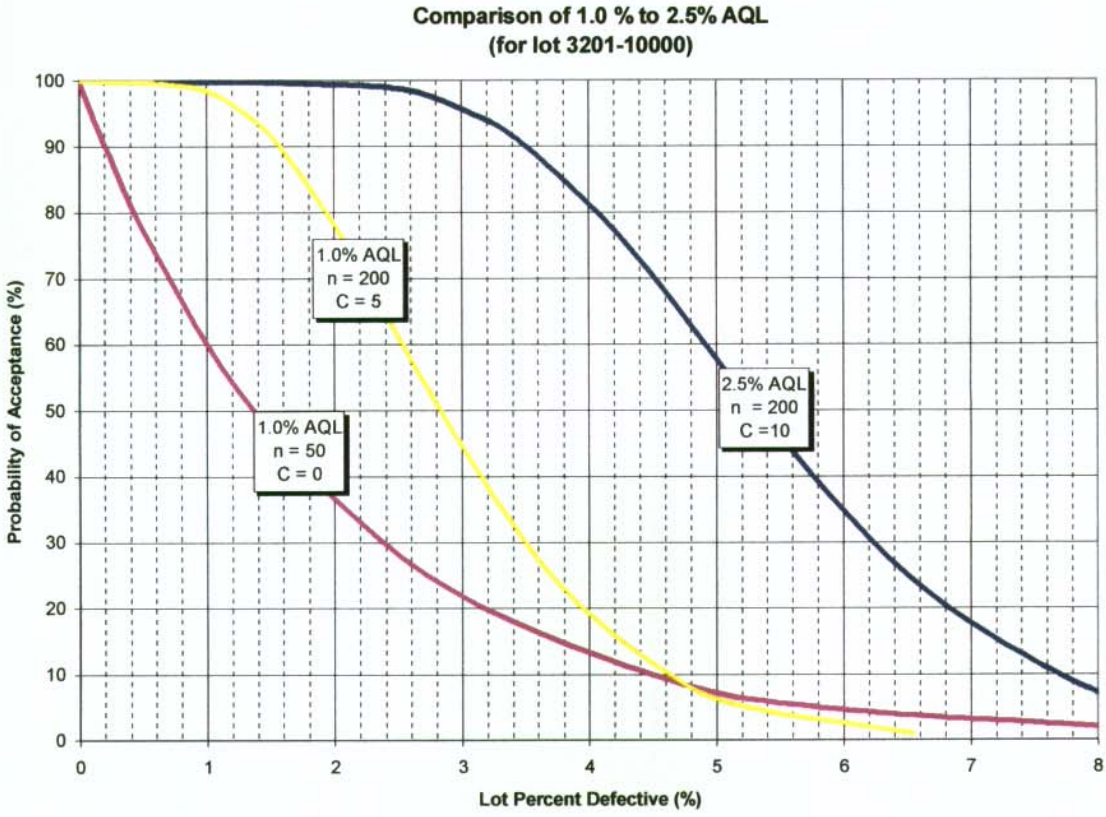

CHART 3

Providing product to NIOSH

ISEA understands the need for NIOSH to have product available for audits. NIOSH should add the cost of purchasing the product to the audit fee. Product audits should not exceed one per year for each respirator classification.

Record retention policy

ISEA maintains that a records retention policy is the responsibility of each manufacture and will be established to control the scope of any product recall if ever deemed necessary. Many manufacturers have developed records retention policies as an ISO 9000 requirement.

Proposed fee schedule

ISEA manufacturers support a new fee structure only if it can be ensured that the fees generated are returned to NIOSH to directly support improvements in the respirator certification program, rather than the agency's general fund or general treasury. In supporting a fee increase, manufacturers would want assurances that the income generated from increased fees would be

resources in addition to what NIOSH is appropriated from CDC and that NIOSH would continue to receive appropriations at least at the FY2001 level. It is our hope that the income generated from the increased fees would support improvements in the program, such as reducing the approval time for a certified respiratory device from 90 days to 60 days, with day one beginning when the submittal package arrives at the Morgantown facility.

A notification of any changes to the fee structure should be made 12 months prior to the effective date. Any increase shall not exceed the consumer price index for the previous year. This proposal permits manufacturers and NIOSH to make appropriate budget adjustments and will provide manufacturers an opportunity to comment on such changes.

In reviewing the proposed fee structure, we observed that a field product audit fee was not included. ISEA recommends that such fee not exceed 10% of the original new approval fee for that particular respiratory device.

The ISEA questions the basis for some fees that are proposed to increase more than 2800%. Such dramatic increases appear to be arbitrary. We ask that the assessment be explained in greater detail.

We look forward to working with NIOSH on these concepts as they become refined into a proposed rule. Thank you for your consideration.

Sincerely,

Janice C Bradley

Janice C. Bradley, CSP
Technical Director