Dragon, Karen E.

From: Betty Robey [BETTY.ROBEY@eg.netl.doe.gov]
Sent: Monday, September 08, 2003 11:14 AM
To: Dragon, Karen E.
Cc: BerryAnn, Roland; Stein, Robert; Boord, Leslie F.; Bell, Adrienne
Subject: ISEA Comments Submittal

QA Concepts-ISEA Final Comment...

Karen,

Attached are the ISEA Comments on QA Module Concepts dated August 29, 2003, that we discussed per telephone this morning. These comments were submitted directly to Les Boord instead of being sent directly to the Docket Office as instructed.

Thank you,

Betty

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August 29, 2003

Mr. Les Boord
Deputy Director, NPPTL
National Institute for Occupational Safety and Health
PO Box 18070
Pittsburgh, PA 15236-6544

RE: ISEA Comments on QA Module Concepts

Dear Mr. Boord:

ISEA member manufacturers of respiratory protection appreciate the opportunity to provide comments on NIOSH's QA Module Concept paper, dated July 21, 2003. We believe that the overall draft document is a good start toward meeting NIOSH's goals of promoting improved respirator quality and reliability and addressing administrative issues and fees. ISEA offers the following specific comments:

1.2 Quality Assurance Requirements

Manufacturers would like to know how NIOSH will assess an approval holder that claims to meet ISO 9001:2000 but is not formally registered by an accredited body. Specifically, what procedure or process will be followed by NIOSH for the assessment?

Sections (c) and (d) address the proposed requirement for sending a Quality Manual to NIOSH if one is not already on file or if it has been significantly revised, or not less than every (4) years. If the intent of this requirement is to ensure that the applicant or approval holder does have a functioning quality system so, and the applicant or approval holder is ISO9001:2000 registered, the Quality Manual has been subject to review and approval to a quality system. We recommend an alternative way to document the current quality system is to request a copy of the ISO9001:2000 certification to be sent to NIOSH at the time it is received.

For those bodies not ISO9001:2000 registered, we would recommend submission of an acceptable Quality Manual at the time of initial application. After initial acceptance by NIOSH, the quality manual should only be resubmitted if significant revisions have been made.

Also, in section (d) "significant revision" is used and we believe "significant" needs further clarification. A decision tree showing what is and is not a "significant revision" by NIOSH definitions would be helpful for industry. Clear definitions would minimize, if not prevent, the time spent by NIOSH reviewing incomplete manuals or manual with minor changes (the default mode may be to send every change to NIOSH) and by the company in preparing, submitting, and mailing the document. This may also save storage space at NIOSH, which may increase the efficiency of operations.

Section (g) refers to "Retain servicing records for a minimum of 7 yrs." It is unclear as to what "servicing" refers to and needs to be elaborated.

1.3 Quality Control Requirements

The proposed change in acceptance methods (sampling plan requirements) will put an excessive cost and resource burden on the manufacturer, particularly the small business manufacturer, on an ongoing basis if their process does not meet the CpK requirements or initially to provide the documentation necessary to have an alternate plan approved. Many manufacturers are ISO 9001:2000 registered company and have hundreds of documents that reference MIL-STD-105, which is still a recognized document in the industry and should continue to be accepted for use by NIOSH indefinitely. To have to go back and update documents to MIL-STD-1916 and implement new training for the use of this document is both time-consuming and costly. Also, changing from MIL-STD-105 to MIL-STD-1916 will increase sample sizes for Major A by approximately 4 times which will be costly without any demonstrated improvement.

Current language indicates that alternate sampling plans, shown to be statistically equivalent to the zero defects or Cpk based plans, may be used with approval by the Institute. We believe more detail needs to be provided to indicate what NIOSH will think is equivalent and how the sampling plans will be evaluated. Additionally, we request that NIOSH provide information on how it intends to evaluate and determine when a destructive inspection or test that uses a reduced sampling plan is acceptable

ISEA members also note that the 3-year timeframe for when updated quality plans must be submitted may not be adequate enough for manufacturers to develop process based plans. It is recommended that NIOSH consider a 5-year time frame.

1.4 Audit Programs

Manufacturers who are ISO 9001:2000 certified should be subjected only to quality system and product audits, as the other proposed audits are too numerous and costly without providing additional benefit to the approval process. For example, any manufacturer that is an approval holder is currently performing the functions noted under the Quality Control and NIOSH Specific Requirements Audit. This would seem redundant of NIOSH to perform this activity.

Relative to the criteria for quality management system audits [(c) (1)], NIOSH indicates that that a monitoring report may be submitted in lieu of an onsite quality system audit. Manufacturers request more information as to the timing of the request (is it done prior to scheduling the audit?) and would like details on the process for submitting ISO audit reports to satisfy this NIOSH audit requirement. Respiratory device manufacturers also would like NIOSH to detail the qualifications of a "NIOSH authorized representative."

1.5 Revocation

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.

1.6 Use of External Resources

ISEA agrees with NIOSH's desire to utilize private auditors and laboratories to perform certain functions required of the approval process and we would like to learn of NIOSH's experiences to date of the trial and evaluation programs conducted by NIOSH.

To avoid any bias in auditing, ISEA recommends that the use of external auditors should be limited to third party certified auditors that are in no way connected to the respiratory device industry. Quality system auditing is purely an administrative quality assurance function. Use of industry participants however obtuse, presents a conflict of interest.

ISEA also encourages the Institute to clearly define the circumstances under which a NIOSH or non-NIOSH auditor would be selected.

External laboratories should also be certified to ISO 9001:2000 which will cover the quality system requirements part of the qualification process. Manufacturers would want to reserve the right to witness testing done at these test labs as part of the NIOSH certification process.

1.7 Approval Holder Audit, Inspection and Reporting Requirements
Manufacturers contend that several of the requirements outlined in this section are time-consuming and costly to both manufacturers and NIOSH, without providing added benefit. For example, manufacturers question the purpose of having records and maintaining them for use in determining if an extension of approval is required. It should be the approval holders responsibility to determine whether or not an extension is required based upon the guidelines provided by NIOSH. A record should not be required for this process. Further, manufacturers would like additional guidance from NIOSH in defining "form, fit and function."

ISEA members also believe that the proposed first piece inspection presents a non-value added requirement, as it adds expense but does not provide any additional safeguards. Whether the product is "new" or a "restart" has no bearing on the requirements that the product has to meet. There are adequate controls in place for all products and how often they are made does not affect those controls. The product will always go through a normal inspection and test process prior to release so a first piece inspection is redundant. To require a 2 piece inspection for a 12 month period will not provide any extra assurance that the product meets the requirements.

The approval holder respirator audit program is also viewed as an unnecessary requirement and expense. Assuming that the intent is to require the approval holder to report internal non-conformances or failures for critical or major characteristics, this seems unwarranted since products already go through an inspection and test process prior to release. Manufacturers audit daily at final inspection and do not ship non-conforming product. A separate tracking system would need to be established to obtain sample products for such an audit. To provide NIOSH with a report of this audit activity is unnecessary and costly.

Manufacturers should report only those complaints pertaining to death, serious injury or serious hazard. NIOSH should also define "major" classification of defects and give examples as it pertains to this section.

2.2 Application Contents

ISEA members believe that the requirement of a separate statement indicating pre-testing (and supplying all related data) is redundant since the standard application form itself requires applicant to list all the tests performed on the product for the purpose of the submittal. Manufacturers find that there is no difference in whether a respirator and/or components were made from prototype tooling or regular production tooling when the final product is still be required to meet all specifications, drawings and test requirements prior to release. To include such a statement in the application is restrictive and unnecessary

ISEA members would like NIOSH to clarify whether delivery of products also pertains in the case where NIOSH elects to use a "NIOSH Authorized Representative" for testing.

2.4 Voluntary Withdrawal of Approval

The voluntary withdrawal of a NIOSH-approved product or configuration would only likely occur in one of three instances: 1) if the device was never introduced to the marketplace, 2) if the device was discontinued or 3) if it was discovered that the approval of the device in question should not have been granted in the first place.

In instance #1, notification to the agents and/or distributors of the approval holder that NIOSH approval has been withdrawn serves no purpose, since the configuration and/or the components necessary to create the configuration were never available for sale.

In instance #2, an approval holder would not be producing and shipping a product after voluntary withdrawal of an approval. Therefore, the agents and distributors of the approval would already have been notified by the approval holder that the product is no longer available. Since the product in distribution was NIOSH approved at the time of sale, it again serves no purpose to subsequently notify agents and/or distributors that the approval has been withdrawn. Because of the concern that agents and/or distributors may want to return product inventory for which approval has been withdrawn, approval holders will be discouraged altogether from withdrawing approvals. At the very least, approval holders will significantly delay withdrawal of the approval, in which case, notification to agents and/or distributors is of no value.

Although instance #3 is rare, it has occurred, and it is agreed that a user's notice and notification to agents and/or distributors would be required.

2.5 Fees for Approval

ISEA realizes that it is the hope of the certification program to become self-sustaining, by using all fees collected to maintain the program. However, manufacturers believe that since NIOSH is a federally funded entity, they should not have to absorb all the costs associated with the approval process. In particular, manufacturers question why they should bear the burden of all the indirect costs as listed. Rather NIOSH should consider them as a part of their "cost of doing business." Manufacturers would also like additional information on how direct costs are calculated and controlled.

Finally, while we recognize that NIOSH has not increased its fees for several years, manufacturers ask NIOSH to consider that the new fee schedule be phased in, rather than be assessed all at one time. The impact on manufacturers of 3 to 4 times the present cost seems rather excessive and manufacturers will need to plan accordingly, as many budgets and R&D activities are developed several years in advance.

2.6 Maintenance Fees
NIOSH should specifically outline the fee structure and describe the functions performed for which fees are assessed. Again, manufacturers believe that some of the costs associated with the program are inherent to NIOSH's existence and should be borne by the Institute itself.

3.0 Approval Labels
While NIOSH has not indicated its plan regarding approval labels in this concept, we encourage NIOSH to look for ways to make the label more useful to the user by eliminating the matrix from the label, thereby simplifying it. The matrix can be placed in other locations (e.g., instruction manual) and in other ways (e.g., contact the manufacturer, websites).

Finally, ISEA respirator manufacturers recommend that NIOSH, as a test facility itself seek certification by a registrar to ISO 9001:2000. It should be noted that this simply ensures that the Institutes procedures are monitored and audited and ISEA members believe that this serves as a good check and balance.

We hope that you will give our comments careful consideration and we look forward to NIOSH's continued progress on this important endeavor.

Sincerely,

Janice C. Bradley, CSP
Technical Director