QA Module Concepts

October 16 Public Meeting

Section 1 – Update QA/QC

❖1.1 General Requirements

- Establish a Quality System which contains both Quality Assurance and Quality Control activities.

Section 1 – Update QA/QC

❖1.2 – Quality Assurance Requirements

- Establish an ISO 9001:2000 type QS.
- Maintain a good organizational structure
- Submit an acceptable Quality Manual
- Submit a Quality Manual ≤ 4 years
- Keep Q records for lifetime of respirator
- Retain servicing records for 7 years

Section 1 – Update QA/QC

❖1.3 – Quality Control Records

- Quality Control plan flow chart
- Design, production, engineering drawings
- Assembly, inspection & testing procedures
- Classification of defects
- Sampling plan requirements

Section 1 – Update QA/QC

❖1.3 – Sampling Plans

- 3 year extension of 105 for existing manufacturers
- Zero defect plan MS1916 for inspection
- Process capabilities and statistical control

Section 1 – Update QA/QC

❖1.4 – Audit Programs

- Pre-approval audits
- Manufacturing site audits
  - ➢Quality Management System audit
  - ➢Quality Control/NIOSH requirements
- Product audits
- CPIP audits and investigations

Section 1 – Update QA/QC

- 1.5 - Revocation of Approval for lack of maintenance of Quality System

Section 1 – Update QA/QC

❖1.6 – External Resources

- External Auditors
- External Laboratories

Section 1 – Update QA/QC

❖1.7 – Reporting Requirements

- Good production practices
- Changes to approved respirators
- First piece inspection
- Respirator audit program
- Complaint reporting

Section 1 - Questions & Replies

❖ General Observation on Questions

- Strategic – General principles and guidelines.
- Tactical – Specific requirements for implementation.

Section 1 - Questions & Replies

❖1.1 General Requirements

- No comments received on this section

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- How will NIOSH assess approval holders that claim ISO 9001:2000 status but are not formally registered?

- The way that we do now, through QM review and site audits. Having a single standard should make this easier.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Can an ISO certificate be sent in lieu of submitting a Quality Manual every 4 years?

- NIOSH will consider this. It is an unusual quality system that has no changes in 4 years, however.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Can "significant" and "significant revision" be defined more specifically?

- Clarification will be made through policy documents if necessary, but two examples would be a change in management structure or change in ownership.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- What exactly are “servicing records” which need to be retained for 7 years?

- Servicing Records are records that apply to any respirator brought back to the manufacturing point or a factory authorized service representative.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Can the importance of product and process design controls be stressed?

- Yes. This entire module is a step in that direction.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- NIOSH is encouraged to embrace "state of the art" practices from the Quality Engineering field.

- It is the intent of the Institute to accommodate "state of the art" practices without overly constraining the range of acceptable approaches.

Section 1 - Questions & Replies

❖ 1.2 Quality Assurance Requirements

- NIOSH could outline the requirements of ISO9001:2000 in the CFR. Any approved ISO9001:2000 registered company would meet these requirements.

- NIOSH considered that approach. Incorporating ISO9001:2000 by reference has many advantages.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Add the definitions of Design Verification, Validation, Design Validation, Process Validation.

- These are important concepts but the phrases are not specifically used in the Module.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Can language be added to stress the independence and authority of the organizational structure?

- Organizational structure requirements should be adequately addressed by the ISO9001:2000 requirements.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Why does NIOSH need to have a Quality Manual resubmitted on a <4 year cycle?

- The Quality Manuals of MANY manufacturers are not submitted on a timely basis when updated. This is an attempt to improve this performance.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- "Acceptable" Quality Manual should be defined.

- If "acceptable" needs to be defined, this will be handled as a policy issue.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- "Significant Revision" should be clarified. A decision tree would be helpful for the industry.

- If "significant revision" needs to be defined, this will be handled as a policy issue. Refer to previous examples.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- "Servicing Records" is unclear and needs to be elaborated.

- Servicing Records are records that apply to any respirator brought back to the manufacturing point or a factory authorized service representative.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Can "or equivalent national body for non-US approval holders" be added to the ISO 9001:2000 statement?

➢NIOSH has no objection to this addition.

Section 1 - Questions & Replies

❖1.2 Quality Assurance Requirements

- Can a letter be used in place of a quality manual submission at 4 years if no changes have been made?

- NIOSH will consider this. It is an unusual quality system that has no changes in 4 years, however.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Comment – Transition from Mil Std 105D to 1916 will be costly and is unnecessary.

- Neither comment should be true if implemented well and thoughtfully.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- How will alternative sample plans be evaluated to determine equivalence?

- Statistically

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- When is a destructive sampling plan or reduced sampling plan appropriate?

- Requirements for reduced sampling plans are outlined within the plans.

➢ Destructive sampling may need to be addressed outside the proposed plans.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Will NIOSH expand the time frame from 3 to 5 years for sample plan transition?

- The Institute believes that 3 years is an ample time to accomplish the transition.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- For what reasons is the same information contained in the quality system requested for each individual SAP? How can redundancy be reduced?

- Once the Quality Module is adopted, the requirements of the SAP can be addressed to reduce redundancy.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- The proposed Quality Plan Flowchart requests much more information than currently.

- Yes it does. The requirements have been expanded based on audit results and field experience.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- "The procedures in this paragraph are required…but do not have to be submitted to the Institute." How likely is this work to be performed?

- Very. The procedures will be verified during site audits.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Can "classification of defects" be changed to "critical to quality characteristics"?

➢ The Institute will consider this suggestion. It more correctly reflects current usage and practice.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Why is Classification of Defects required in a balanced quality system?

- It is part of the balance. It is required as part of the initial review process as well as ongoing testing and inspection programs.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Cpk indices require variable data. They cannot be calculated for attribute data.

- True, but the data must reflect the ability of the process. Variable process data should be available and properly chosen for evaluation.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Can control chart information be used in place of zero defects sampling for attribute data?

- Yes, if properly used and applied.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Why does NIOSH specify requirements for minor characteristics that do not affect "form, fit or function"?

➢ A very good question. NIOSH will consider dropping requirements for minor characteristics.

Section 1 - Questions & Replies

❖1.3 Quality Control Requirements

- Mil Std 1916 requires ~4 times as many samples for Major A characteristics as 105D. This will be costly.

- This is understood, and is part of the incentive to work towards the use of process controls wherever possible.

Section 1 - Questions & Replies

❖1.4 Audit Programs

- Certified ISO9001:2000 manufacturers should be subject only to quality system and product audits. Others are redundant.

- For certified manufacturers the amount of redundancy is minimal. With care the NIOSH requirements can be incorporated into ISO audits.

Section 1 - Questions & Replies

❖1.4 Audit Programs

- Can NIOSH provide additional information on submitting a monitoring report in lieu of an onsite audit?

- Specific details will be developed once the Quality Module is adopted.

Section 1 - Questions & Replies

❖1.4 Audit Programs

- What are the details of the qualifications of "NIOSH authorized representative"?

- The representative is selected through Federal contract procedures. Minimum requirements include RAB certification and familiarity with the respirator industry.

Section 1 - Questions & Replies

❖1.4 Audit Programs

- What mechanism is proposed for submitting ISO audits to satisfy NIOSH requirements?

- Currently written notice is given prior to site audits. It is anticipated that an ISO audit report could be sent in response. Details will be worked out once the Quality Module is adopted.

Section 1 - Questions & Replies

❖1.5 Revocation of Approval

- No questions were received for this section.

Section 1 - Questions & Replies

❖1.6 External Resources

- An appeals process to resolve any discrepancies between NIOSH and manufacturers. The process should be in place before any private laboratory testing is used.

- NIOSH will consider this comment, and anticipates this will be in place.

Section 1 - Questions & Replies

❖1.6 External Resources

- The use of auditors associated in any way with the respirator industry presents a conflict of interest.

- The potential of conflict of interest always exists. Initial experience does not seem to justify undue concern.

Section 1 - Questions & Replies

❖1.6 External Resources

- Can NIOSH clearly define when a NIOSH vs. a third party auditor would be used?

- Those details will be developed by policy. Typically third party auditors would be used for routine situations. Special requests by manufacturers for NIOSH auditors would typically be honored.

Section 1 - Questions & Replies

❖1.6 External Resources

- External laboratories should be certified to ISO9000:2000.

- The testing laboratory standard is ISO17025 and that is the standard which is anticipated to be used. It includes most ISO9000 requirements.

Section 1 - Questions & Replies

❖1.6 External Resources

- What accreditation do the NIOSH laboratories currently maintain?

- None at this point. Very early steps towards ISO17025 registration have begun.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- Several of the requirements outlined are costly without adding benefit.

- NIOSH believes that all of the requirements add benefit.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- Can NIOSH provide additional guidance in defining “form, fit and function”?

- This is standard existing language. The existing letters and notices will continue to apply.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- First piece inspection is redundant and a non-value added activity.

➢NIOSH is currently considering the cost/benefit value of requiring first piece inspection.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- Manufacturers should only report complaints of death, serious injury or serious hazard.

- NIOSH feels it is part of the agency's responsibility to collect information on any injury or hazard.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- NIOSH should define “major” classification of defects as used in this section.

- The current definitions of critical and major characteristics apply. (See 42 CFR 84.41)

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- A decision tree to aid in determining significant changes would be useful.

- Any aids developed to determine significance will be generated after the Quality Module is adopted.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- A 3-day audit failure time frame is to short.

➢NIOSH is considering a slightly longer reporting time frame.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- Is the audit of each product line strictly a performance audit?

- It is anticipated that the answer to this question is yes.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- Complaints need to be reported in 3 days. Can this be lengthened to 10 days?

➢NIOSH is considering a slightly longer reporting time frame.

Section 1 - Questions & Replies

❖1.7 Reporting Requirements

- First piece inspection is redundant and a non-value added activity.
- First piece inspections are common practice and the requirement should be removed.

➢NIOSH is re-evaluating the need for first piece inspection to be specified as a requirement.

Section 2 – Admin. & Fees

❖2.1 – Application Procedures

- Applications will be to NIOSH
- Examinations will be conducted by NIOSH
- Applicants may consult with NIOSH
- Mergers/Changes will be reported to NIOSH

Section 2 – Admin. & Fees

❖2.2 Application Contents

- Applications will be in a standard format
- A complete description of the respirator
- Plans for Quality Control & Quality Assurance
- Pretest data, exams, inspections & tests
- Note that standard production was used
- Complete respirators for testing

Section 2 – Admin. & Fees

❖2.3 Language and Section Changes

- Specific obsolete language and references will be removed from Subparts K, L, N & KK

Section 2 – Admin. & Fees

❖2.4 Voluntary Withdrawal of Approval

- Notification includes NIOSH, agents and distributors

Section 2 – Admin. & Fees

❖2.5 Fees for Approvals

- Fees for examination, inspection, testing and approval will be at flat rates
- Fees will be refunded if no work is done
- Novel products will be charged per hour
- Fees for site audits may be charged
- Problem investigations may be charged
- Fees for product audits may be charged
- Travel costs may be billed at actual costs

Section 2 – Admin. & Fees

❖2.5 Fees for Approval

- New Approvals

Most	$2,800 - $5,000
Gas Masks	3,400 + 1,600 per gas

- Extensions

Most	$2,200 - $3,500
Fit Test	5,000

Section 2 – Admin. & Fees

❖2.6 Maintenance Fees

- Annual, based on # of active approvals

Section 2 – Admin. & Fees

❖2.7 Administration of Fees

- Approvals – payment with application
- Travel – billed by NIOSH
- Maintenance fees – submitted annually

Section 2 - Questions & Replies

❖2.1 Application Procedures

- Electronic transfer of funds was included in the July 14 draft. Can this be retained?

- NPPTL has discovered that it does not have a mechanism to accept electronic transfer of funds, but will continue to seek one.

Section 2 - Questions & Replies

❖2.2 Application Contents

- A separate statement requiring pre-testing is redundant.

- This is in a list of requirements and is the only place that it is given.

Section 2 - Questions & Replies

❖2.2 Application Contents

- Specifying prototype or regular production tooling is restrictive and unnecessary.

- This is existing language. NIOSH will consider if it is too vague.

Section 2 - Questions & Replies

❖2.2 Application Contents

- Would products have to be delivered in cases where NIOSH uses an external testing lab?

- Yes. The details of where the products need to be delivered will generated after the Quality Module is adopted.

Section 2 - Questions & Replies

❖2.3 Language and Section Changes

- No comments were received on this section.

Section 2 - Questions & Replies

❖2.4 Voluntary Withdrawal of Approval

- Notification of agents/distributors serves no purpose or is redundant of activities performed during voluntary withdrawal.

- The comment ignores the possibility of a manufacturer leaving the respirator business.

Section 2 - Questions & Replies

❖2.4 Voluntary Withdrawal of Approval

- Why would NIOSH be interested in this other than to know that the product is no longer being offered?

- Among other reasons, to stop billing the manufacturer for an annual maintenance fee.

Section 2 - Questions & Replies

❖2.5 Fees for Approvals

- Manufacturers should not have to support indirect costs with fees. This is a "cost of doing business" for NIOSH.

- Recent guidance directs the agency to recover the full cost of any goods or services that it provides.

Section 2 - Questions & Replies

❖2.5 Fees for Approvals

- How are direct costs calculated and controlled?

- Direct costs are determined and controlled through existing accounting systems with initial fees based on historical data.

Section 2 - Questions & Replies

❖2.5 Fees for Approvals

- Can the new fee schedule be phased in over time?

- While it would not be possible to "phase in" the new fee structure, it would be possible to delay its implementation for a specified time from the other parts of the standard.

Section 2 - Questions & Replies

❖2.5 Fees for Approvals

- How will manufacturers be notified for request of payment for non-certification fees?

- The details of billing will be developed once the Quality Module is adopted.

Section 2 - Questions & Replies

❖2.6 Maintenance Fees

- NIOSH should describe the functions performed for which fees are assessed.

- Most of those functions have been fairly well described.

Section 2 - Questions & Replies

❖2.6 Maintenance Fees

- Can ample notification of pending implementation of maintenance fees be given to allow manufacturers to voluntarily withdraw approvals?

- NIOSH will attempt to honor this request.

Section 2 - Questions & Replies

❖2.7 Administration of Fees

- No comments were received on this section.

Section 3 – Approval Labels

❖3.0 Approval Labels

- Comments are being sought on information required on labels

Section 3 - Questions & Replies

❖3.0 Approval Labels

- NIOSH should look for ways to eliminate the matrix from the label.

- OK

Additional Questions & Replies

- NIOSH, as a test facility, should seek certification by an ISO9001:2000 registrar.

- NIOSH is in the early stages of pursuing certification to ISO17025 as a test facility.

Additional Questions & Replies

- Thank you for your time and attention.