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Testimony on 42CFR Part 84
Quality Assurance Requirements for Respirators

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Notice of Proposed Rulemaking
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Topics:

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    - Classification of CTQC

General comments

- Several proposed requirements are tied to an anticipated update to the Standard Application Procedure (SAP).
  - Recommend that the updates to the SAP be communicated and reviewed in conjunction with the proposed rule in order to better understand the scope of the proposed changes.
  - Recommend that the proposed rule be written to reduce the amount of additional explanation required in the SAP.
  - Example: *Contents of Application p. 75053 84.11* "A table that lists each section and paragraph of this part… that cross-references the…stages of the manufacturing process…during which compliance…is evaluated through quality assurance or control procedures."

General comments (continued)

- Timing for implementation of all aspects of the proposed rule (not just for changes to the quality control plan content) needs to be defined and allow adequate time for manufacturers to implement the added requirements such as product auditing and complaint reporting to NIOSH.

- New revision of ISO 9001 Quality Management System has been published (ISO 9001:2008) and should be incorporated into the final rule.

Definitions Manufacturing facility p. 75053 84.2 (w)

- Definition of manufacturing facility is stated as including suppliers and implies the need for control over the *supplier's* quality system as well as the auditing of *suppliers* by NIOSH.
- It is our interpretation that this requirement is actually referring to what NIOSH has previously termed "subcontractor".
- Recommend that the definitions and requirements for suppliers vs. subcontractors from the NIOSH letter to manufacturers dated April 7, 2005 be incorporated into the proposed rule.

Definitions Manufacturing facility (continued) p. 75053 84.2 (w)

- From the NIOSH letter to manufacturers dated April 7, 2005:
  - "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."
    - Specific requirements for setting up a subcontractor relationship were defined in the NIOSH letter and should be included in the proposed rule.

Contents of Application p. 75053 84.11 (i)

- Proposed rule requires that respirator and component parts submitted for approval are not prototypes and are made using regular production tooling.
  - This requirement could add artificial constraints/delays to the new product development cycle timeline
  - Prototype tools and/or processes may ultimately be used in production
  - Recommend that requirement should be only that the product supplied for approval be identical in all critical aspects (e.g. materials, geometry, functional performance, etc.) as the final product to be manufactured as opposed to a specific constraint on the type of tools used to produce it. This would mean that the requirements on tooling be deleted from the proposed rule.

Changes in device or applicant ownership p. 75054 84.36

- Proposed rule requires that a new owner submit and receive modified certificates of approval from NIOSH prior to any continued manufacture of devices after ownership changes.
  - This would be impossible to accomplish immediately upon change of ownership since the gathering of data needed for preparation of the submission cannot even begin until the actual date of ownership change.
  - Recommend that the new owner be allowed to continue to manufacture and sell devices of the acquired entity under the existing approval (including the approved quality plan) during a grace-period that allows sufficient time for the new owner to assess the product and potential changes to the quality plans, determine any changes needed, prepare the submission and obtain approval from NIOSH.
  - Recommend a minimum of two years be allowed for this transition.
  - Also – where acquired business will be run as a subsidiary, a new submission may not be necessarily required if the existing quality plan and manufacturing system will continue to be followed.

Changes in manufacturing facility or quality system p. 75054 84.37

- Proposed rule requires a written notification to NIOSH within 20 days of a decision to change the location of a manufacturing facility or make substantial change to the quality system

- The submission seeking approval to change the location of the manufacturing facility or to make any substantial change in the quality system associated with an approved devices should be adequate to inform NIOSH.

- It is not clear why an additional notification prior to the submission seeking the approval of the change is necessary.

Quality System, general requirements p. 75054-75055 84.40

- Proposed rule requires compliance with ISO 9001:2000 that is documented either through registration by a qualified registrar or by a self-attesting statement from the applicant.

- Recommend that third party verification by a qualified registrar should be required and that allowing the applicant to self attest to compliance is not adequate.

- Recommend that NIOSH define "qualified registrar" as previously defined by NIOSH in the 2003 QA Module Concepts as a "registrar accredited by the ANSI-RAB National Accreditation Program (or equivalent body for non-US approval holders)".

Respiratory device complaints p. 75056 84.44

- Proposed rule requires applicants to report to NIOSH within 3 days any user complaint that arises from an incident involving safety or health of the user or that indicates a Critical, Major A, or Major B nonconformance.
- Agree that it is incumbent upon the manufacturer to investigate and evaluate complaints related to safety, quality, or performance of a device.
- Recommend that only complaints that impact user safety or health should be required to be reported to NIOSH.
- Three days is insufficient time to adequately investigate, analyze, confirm, plan remedial action, prepare report, and send to NIOSH.

Audit Programs
p. 75056 84.45

- Proposed rule requires applicants to conduct annual audits on respirators or respirator families that are not tested as a complete system during manufacture.

- Agree that it is incumbent upon the manufacturer to ensure the performance of the respirator system.
  - This can be accomplished through many ways that could be more effective than annual audits.
  - Recommend NIOSH consider these in lieu of the annual audit requirement:
    - Design and development planning and validation
    - Robust quality plans for production
    - Validation of process/material changes

Audit Programs (Continued)
p. 75056 84.45

- If audits do become part of the requirements:
  - Recommend that only nonconformances that impact user safety or health should be required to be reported to NIOSH.
  - Three days is insufficient time to adequately investigate, analyze, plan remedial action, prepare report, and send to NIOSH.

Quality control plan content p. 75055 84.42

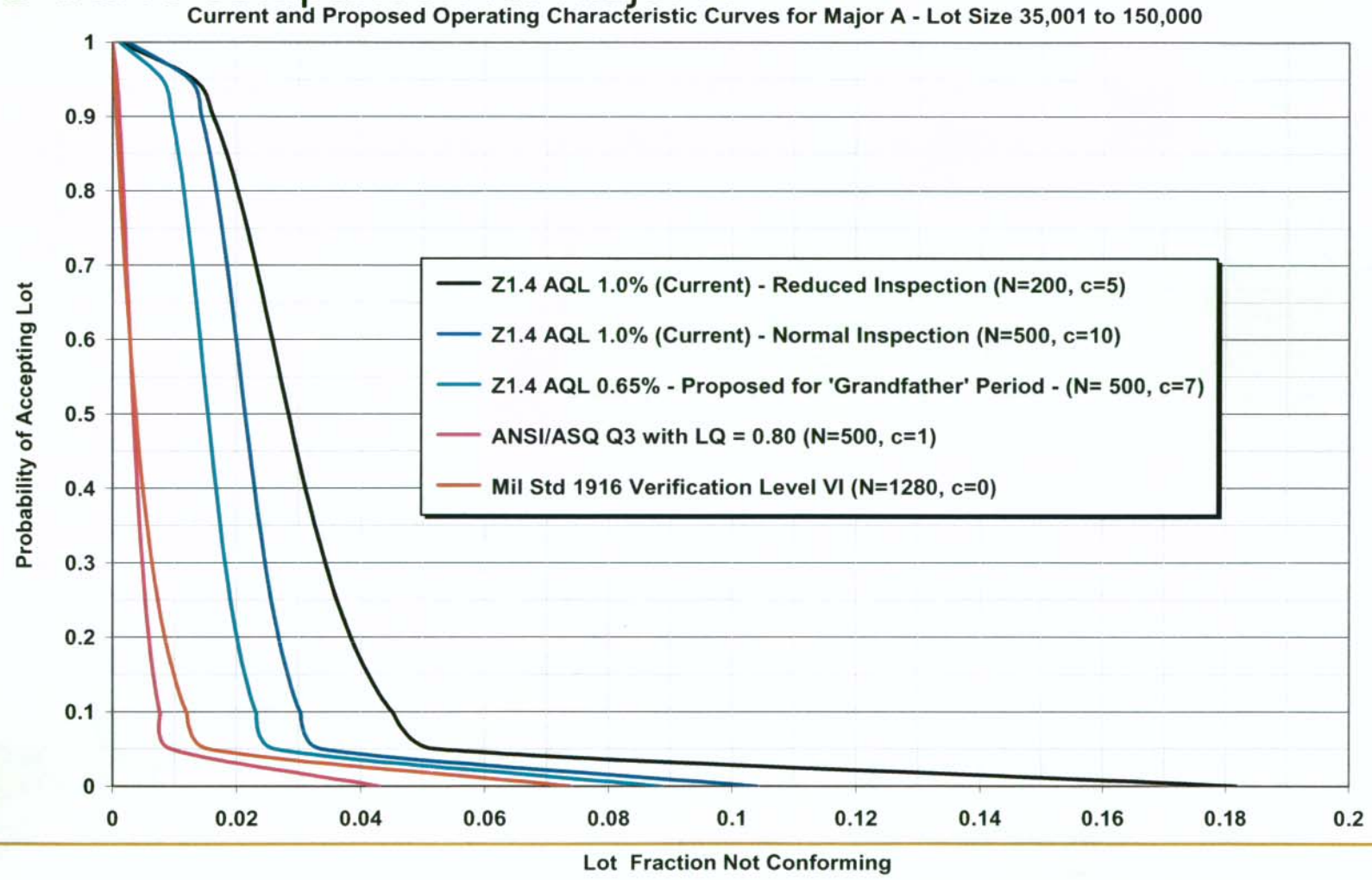
Proposed Quality Assessment Sampling Plans

- While NIOSH indicates these changes to be moderate, we believe them to be severe.
  - Comparison of sampling plans (technical analysis… by H&H Servicco Corp) does not address statistical differences between the current plans and the proposed plans.
  - An analysis of Operating Characteristic (OC) curves between the sampling plans shows that the proposed plans will actually increase the amount of sampling and the inspection cost.

Quality control plan content p. 75055 84.42

Proposed Quality Assessment Sampling Plans (continued)

OC Curve comparison for Major A



Quality control plan content p. 75055 84.42

Proposed Quality Assessment Sampling Plans (continued)

OC Curve comparison for Major A

- From the previous slide: for a characteristic currently classified as Major A CTQC with an actual AQL=0.8% and actual RQL=2.36% (per ANSI Z1.4, AQL 1% Lot size 35001 – 150000 level II):
  - This would have to improve to an actual AQL=0.004% and actual RQL=0.234% under the Mil-Std-1916.
  - This would require at least a 30 times improvement in the nonconformance rate to provide an equivalent pass rate.
  - For given manufacturing process capabilities, this proposal will actually increase sampling by at least a factor of 4.
  - It can also be concluded from the previous slide, that a manufacturer meeting the current requirements will have a 95% probability of accepting lots with a nonconformance level of 1% while that probability decreases to 15% under the Q3 plan and 5% under the Mil-Std 1916 plan.

Quality control plan content p. 75055 84.42

Classification of CTQC (Critical to Quality Characteristics)

- Recommend that NIOSH should only impose quality level specifications for the product requirements as stated in 42CFR84 and allow manufacturers the flexibility to assess and control other CTQC.
  - This will help ensure that the critical performance factors of the device that protect the user safety and health are adequately controlled.

- Improved enforcement of the current quality plan requirements may go farther to help ensure quality of the product to the user vs further tightening of the quality inspection requirements.

- *Thank you!*