NIOSH Conformity Assessment Interpretation Notice

NIOSH CA 2019-1019
July 2019

Effective Immediately - NIOSH quality control plan requirements

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Subject: Effective immediately, NIOSH Quality Control Requirements

1. SUMMARY

NIOSH guidance for quality control plans is effective immediately. The respirator manufacturer's quality control plans are reviewed and must be determined to be satisfactory, in accordance with 42 C.F.R. Part 84, to achieve and maintain the NIOSH approval (see §§ 84.31(f), 84.33(f), 84.40, 84.41, 84.42, 84.43). The guidance in this notice is published elsewhere and is consolidated here for ease of access; no new requirements or procedures are established in this document.

Prior to this notice, NIOSH required manufacturers to submit a quality manual as part of the approved documentation, which was maintained at NIOSH and intended to include much of the content outlined below. Effective immediately, NIOSH no longer requires each approval holder and associated contractors to submit a comprehensive quality manual. The manufacturer's quality control plan, which can also align with ISO 9001, may take the form of a traditional quality manual. An outline of information needed to satisfy the quality control requirements in Part 84 is provided below.

2. AUTHORITY

42 C.F.R. Part 84, Respiratory Protective Devices

3. BACKGROUND AND SUPPLEMENTAL INFORMATION

The following requirements derived from 42 C.F.R. Part 84 must be completely addressed in each quality control plan. To provide applicants the maximum amount of flexibility, it will be left up to the applicant to decide in which documents general topics are covered (applicable to all quality processes), and in which documents product-specific topics are covered (typically those submitted and referred to as Product Quality Plans (PQPs)). Manufacturers should also reference any applicable standard operating procedures (SOPs) within the quality control plan.

Contract Review Activities

The manufacturer must ensure that only NIOSH-approved configurations are sold under the NIOSH labeling.

Design and Development 42 C.F.R. § 84.41 (a)(2), (b)-(i); 42 C.F.R § 84.61(a)

As part of the design and development process, the manufacturer must address the following:

- Design inputs, including those physical and performance characteristics required in 42 C.F.R Part 84;
- Design outputs, including drawings, classification of defects, and incoming, in-process, and final inspections, typically found in the PQP;
- Appropriate reviews and approvals of the design and development process, including both verification and validation.

The manufacturer must maintain all of the records generated during the design and development process.

Control of Documents and Data 42 C.F.R 84.41 (a)(2)
To achieve document and data control, the manufacturer must:

- Have a process to uniquely identify all documents which constitute quality control plans, drawings, procedures, and forms, including a date of revision or revision level;
- Ensure there is an internal review and approval process for all new and revised drawings and documents;
- Have a procedure in place for the distribution of all controlled documents within the quality system, including a process for the removal of any obsolete documents to prevent unintentional use.

The manufacturer must ensure that any data collection system is controlled to prevent unintentional alteration or deletion.

Control of Purchasing 42 C.F.R 84.41 (a)(4)
The manufacturer must:

- Have a process to identify qualified suppliers;
- Have a process for both the initial approval of suppliers and their periodic evaluations;
- Have a process to communicate material and/or component requirements to suppliers;
- Have a process to receive and review all incoming materials or components.

Product Identification and Traceability 42 C.F.R 84.33 (b), (e)-(g); 42 C.F.R 84.41 (a)(5)
The manufacturer must:

- Have a procedure to identify raw materials used within the production process;
- Properly label all respirators and respirator components;
- Have a process to track, or trace, the essential components of the respirator;
- Have a procedure to properly identify the finished respirator and required major subassemblies with a lot number, serial number, and/or manufacture date.

Control of Production Processes 42 C.F.R 84.41 (a)(5), (7); 42 C.F.R 84.42 (c)

The manufacturer must have adequate documentation to ensure that the manufacturing process is consistently performed and followed, including any procedures for the setup of assembly or testing devices, assembly processes, and inspection procedures.

Inspection and Test 42 C.F.R 84.41 (a)(4)-(6)

The manufacturer must**:**

- Have a process to identify, review, and approve any incoming, in-process, and/or final inspections;
- Ensure that inspection records provide sufficient detail to facilitate the identification of the lot and sample size, inspections performed, data collected, and the acceptance criteria;
- Have a process for the release of materials throughout the manufacturing process and ensure that only products meeting all production requirements are released for distribution;
- Document the locations where performance inspections take place, when multiple inspection sites are used; and
- Properly maintain inspection records for time periods deemed appropriate to product life.

Control of Equipment 42 C.F.R 84.41 (a)(3)

The manufacturer must:

- Have a process to select appropriate measuring and test equipment;
- Maintain a calibration schedule;
- Have a process to review the calibration records;
- Have a process to identify the testing equipment's calibration status;
- Maintain all calibration records; and
- Have a process to evaluate the impact of out-of-tolerance equipment against any in-process or distributed product.

The manufacturer must maintain these records.

Inspection and Test Status and the Control of Nonconforming Product 42 C.F.R 84.41 (a)(4), (5)

The manufacturer must:

- Have a process to identify the product's acceptance status;
- Have a process in place to ensure only acceptable materials or components are used within the production process and segregate any unacceptable products, materials, or components;
- Have a process for the final disposition of a nonconforming product, such as the return of materials to the vendor, the evaluation of material, rework of product, or the scrapping of material;
- Have a process to evaluate the impact of nonconforming material on any in-process or distributed product. These records must be maintained for a time period deemed appropriate to the useful life of the material or finished good.

Corrective Actions 42 C.F.R 84.41 (a)(7)
The manufacturer must have processes to:

- Identify how the corrective action process is initiated, such as internal or external audits, customer complaints, or other acceptable input;
- Identify the correction of the nonconformity;
- Mitigate the negative outcomes of the nonconformity;
- Prevent the reoccurrence of the nonconformity;
- Verify that corrective actions have been sufficiently implemented.

The manufacturer must maintain all corrective action records.

Inventory and Handling Controls 42 C.F.R 84.41 (a)(5)
The manufacturer must have a process to prevent the damage of all raw materials, in-process components, and finished NIOSH products.

Quality Records 42 C.F.R 84.43 (a)
The manufacturer must establish the retention time for all records, as appropriate.
Note: NIOSH recommends that some records be maintained according to the lifetime of the product.
Records must be readily retrievable, legible, and protected against alteration.

Internal Audits 42 C.F.R 84.41 (a)(7)

- The manufacturer must establish a schedule for internal audits;
- The manufacturer must maintain the records for internal audits;
- The manufacturer must establish a procedure to determine how internal auditors are qualified;
- The internal audit program must cover the entire quality system, including the approved quality plan.

Training 42 C.F.R 84.41 (a)(7)

- The manufacturer must maintain all training records;
- The manufacturer must have a procedure to train and monitor personnel, which includes ensuring only authorized personnel assemble, test, and inspect a NIOSH-approved product;
- The manufacturer must have a procedure to ensure applicable personnel are notified of production process modifications.

Quality Management 42 C.F.R 84.40; 42 C.F.R 84.41 (a)(7); 42 C.F.R 84.42

- The manufacturer must have a process to review the quality system;
- The manufacturer must ensure that management reviews the internal audit records.

Organizational Structure 42 C.F.R 84.41 (a)(7)
The manufacturer must establish an organizational structure to identify those positions responsible for fulfilling the requirements of the quality control plan.

4. REFERENCES

42 C.F.R. Part 84, Respiratory Protective Devices

Standard Application Procedure for the Approval of Air-Purifying Filtering Facepiece Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Closed-Circuit Escape Respirators Under 42 CFR Part 84, revised October 16, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Supplied-Air Respirators, Industrial Self-Contained Breathing Apparatus, and Combination Supplied-Air Respirators/Industrial Self-Contained Breathing Apparatus Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Powered Air-purifying Respirators and Chemical, Biological, Radiological and Nuclear Powered Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Air-purifying Respirators and Chemical, Biological, Radiological and Nuclear Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Self-Contained Breathing Apparatus, and Chemical, Biological, Radiological and Nuclear Self-Contained Breathing Apparatus Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2