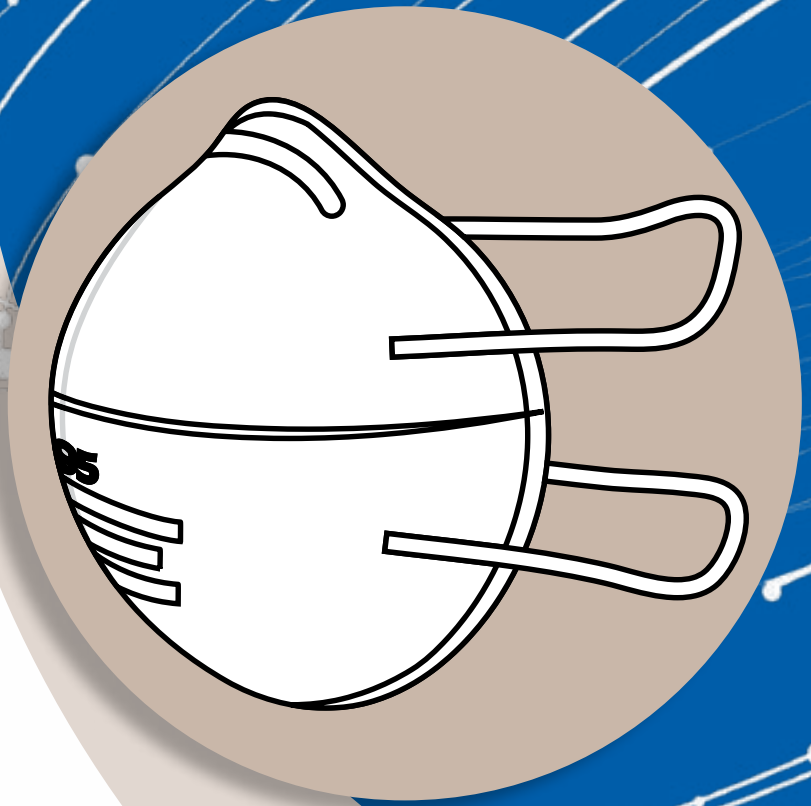
Know Before You Apply:

Summarized Quality Requirements Needed to Achieve NIOSH Approval



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

Disclaimer

Mention of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention.

The *Know Before You Apply: Summarized Quality Requirements Needed to Achieve NIOSH Approval* booklet provides a general overview of the NIOSH approval process. This booklet is for guidance purposes only. All manufacturers must meet the regulatory requirements stated in 42 Code of Federal Regulations Part 84 to become NIOSH approval holders.

Get More Information

Find NIOSH products and get answers to workplace safety and health questions:

1-800-CDC-INFO (1-800-232-4636) | TTY: 1-888-232-6348

CDC/NIOSH INFO: cdc.gov/info | cdc.gov/niosh

Monthly *NIOSH eNews*: cdc.gov/niosh/eNews

Suggested Citation

NIOSH [2023]. Know before you apply: summarized quality requirements needed to achieve NIOSH approval. By Sewchok H, Miller C. Pittsburgh, PA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2023-132.

DHHS (NIOSH) Publication No. 2023-132

DOI: https://doi.org/10.26616/NIOSHPUB2023132

July 2023

Contents

What Makes the NIOSH Approval Different?

The National Institute for Occupational Safety and Health (NIOSH) is the federal agency responsible for testing and approving respirators used in U.S. workplace settings. The National Personal Protective Technology Laboratory (NPPTL) is the division within NIOSH responsible for executing all functions of the NIOSH Respirator Approval Program. NIOSH only approves respirators that pass its strict quality assurance and performance requirements as identified in regulation **42 Code of Federal Regulations Part 84** (42 CFR Part 84).

The NIOSH approval is more than just passing a one-time test or a recognition that a product meets a standard at the time of application. Achieving NIOSH approval requires active quality assurance that is further described in this booklet. A NIOSH approval holder must continue to meet the conditions of the approval as granted. The result is confidence that when a respirator is approved by NIOSH, it can protect the user. This confidence is critical to the millions of workers who rely on respirators to protect them from **exposures to respiratory hazards in workplace settings**.

Terms and Definitions to Understand Before You Apply

Respirator

A device designed to provide the wearer with respiratory protection against inhalation of hazardous contaminants from the surrounding atmosphere. NIOSH approves respirators for use in occupational settings.

Manufacturer

Applicants and approval holders may be referred to as "manufacturers" throughout this booklet.

Manufacturer Code

NIOSH issues a three-digit code specific to each applicant—known as a manufacturer code—to track applications for each manufacturer. NIOSH issues only one three-digit code to each applicant. Once you receive a code, you never need to apply for another. However, you must have this assigned manufacturer code before you begin the respirator approval application process. This code will only be used for tracking purposes and does not imply NIOSH approval or that NIOSH approval is pending. A manufacturer code will only be issued to the company that controls the design and manufacturing of the respirators put forward for approval. If there are any changes to the information provided to achieve the code, NIOSH must be informed by email to the NIOSH NPPTL Records Room.

Standard Application Form (SAF)

Once you obtain a manufacturer code, NIOSH will send you the Standard Application Form to submit a single approval request for a new respirator. All required documentation must be provided including the quality control plan, test samples, and appropriate fees, as detailed in the six Standard Application Procedures that NIOSH provides (see additional resources on page 12).

Terms and Definitions to Understand Before You Apply

Quality Management System (QMS)

This overall system should include product quality control plans (PQPs), a quality manual or manuals, standard operating procedures, and any other quality documentation. This system must be complete to ensure product quality and meet the specific requirements in 42 CFR Part 84.

Product Quality Control Plan (PQP)

The documentation required as part of an application to demonstrate the quality inspections for a specific respirator or respirator component.

Inspection Procedures

The U.S. Code of Federal Regulations 42 CFR Part 84 requires that all approval holders provide detailed explanations of how they will carry out inspection procedures within their manufacturing sites. Your company must also define its processes to (1) ensure that only acceptable materials or components are used within the production process, (2) discard nonconforming material or products (i.e., return materials to the vendor), and (3) evaluate the impact of nonconforming material on any in-process or distributed product. All procedural records must be maintained for the life of the product.

Respirator Samples

Full-production or limited-production respirators/ respirator parts made and released using the defined quality management system, including inspection records.

Sampling Plan

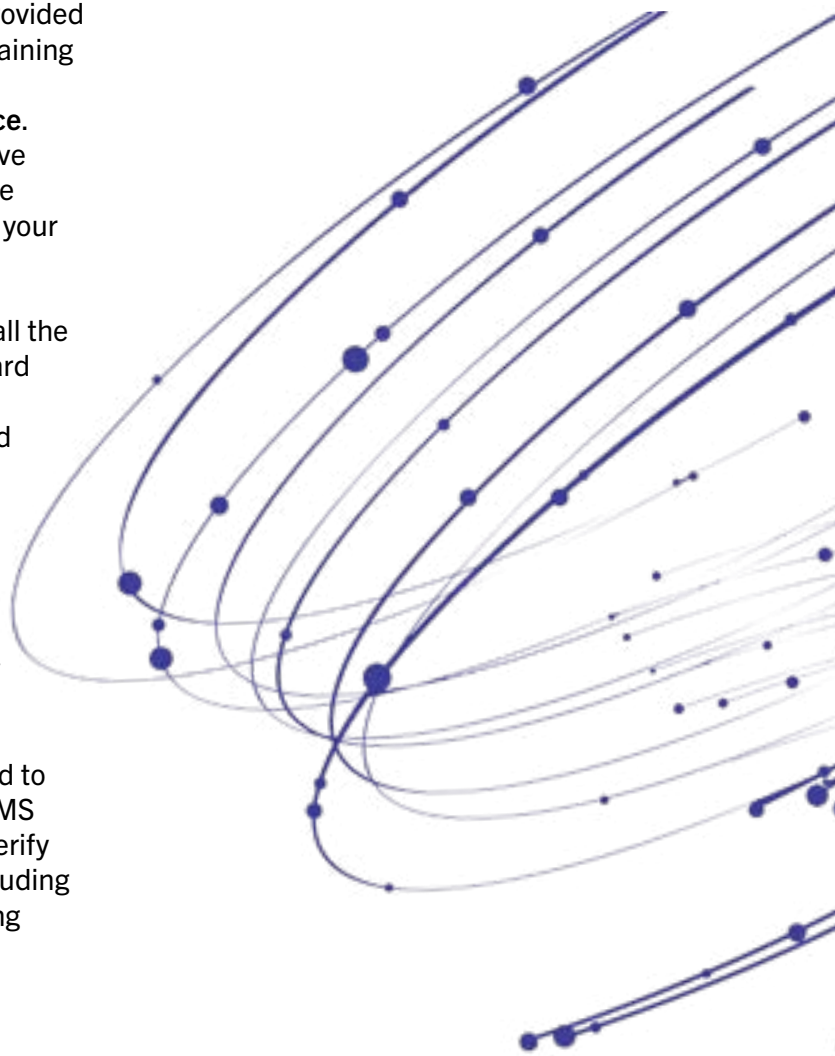
A statistical method to determine how many samples should be be evaluated and tested for a given lot, along with the number of allowable defects considered acceptable for the lot. Methods that are typically accepted by NIOSH are published standard procedures such as MIL-STD-105D.

The NIOSH Approval Process at a Glance

As a manufacturer seeking NIOSH approval, you must take several steps before submitting your product for NIOSH approval as described in this booklet. These steps include answering a defined set of questions provided by NIOSH to assess your readiness to apply for NIOSH approval, obtaining a NIOSH manufacturer code, and ensuring that you understand and **have completely prepared all the required documentation in advance**. NIOSH expects that, prior to submitting your application, you will have all the required elements of the production process in place using the same quality management system that you are submitting as part of your application package.

After NIOSH issues you a manufacturer code, you may then submit all the required elements of your application package, including the Standard Application Form, application fee payment or proof of payment, respirator samples for NIOSH evaluation, and any additional required documentation as listed on page 6 within this booklet. If NIOSH accepts the submission of your application, NIOSH will assign it a task number. NIOSH will then review your application and test your product in accordance with Standard Testing Procedures.

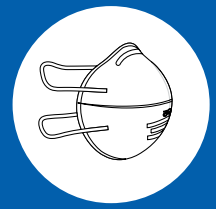
While there are many parts of the overall NIOSH review process, **the quality assurance review may present the biggest challenge for new applicants**. NIOSH will evaluate your quality management system (QMS) to ensure you have the processes in place to maintain the quality of your respirators. This review will include a site visit, referred to as a site qualification, to any location in which manufacturing and QMS activities are specified. As part of the site qualification, NIOSH will verify that specific quality documents, such as inspection procedures, including classification of defects (see 42 CFR Part 84 Subpart E), the sampling plan, and sampling levels have been fully and correctly used.



NOTE

*NIOSH approval is **not** guaranteed. Any respirators produced prior to receiving your NIOSH approval **should not** be assumed to be acceptable. Therefore, production quantities should be carefully considered until the approval is finalized.*

The NIOSH Approval Process for First-Time Applicants at a Glance



Before you apply:

1. Establish a QMS
2. Implement the QMS
3. Complete production run using the QMS
4. Obtain a manufacturer code
5. Prepare your application package

Submit a complete application

NIOSH initial review of application package

NIOSH reviews quality management system

NIOSH performs testing

Site qualification assessment

Not acceptable (denied)

Provisionally Acceptable: Submit responses to Corrective Action Request (CAR) issued to you by NIOSH

NIOSH reviews CAR

CAR accepted

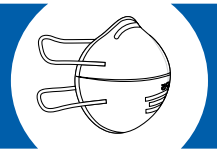
Acceptable for Final Review

Approval

NOTES

It is important to read the regulation and the resources referenced in this booklet prior to applying. An application can be denied at any point in this process if it is determined to not meet the requirements.

Before You Apply



Manufacturer Code

Contact the NIOSH NPPTL Records Room at RecordsRoom@cdc.gov to request a manufacturer code. The first step in this process will require you to supply answers to a set of defined questions. This will help you, and NIOSH, to assess if the NIOSH approval process is right for your product and your company. If your answers demonstrate you are ready to apply for NIOSH approval, NIOSH will follow up with you and seek additional information. If NIOSH determines you are not ready, you will be informed by email.

NIOSH asks all manufacturers to provide photos of the production line and quality assurance area as well as photos of the facility with a visible logo or company name on the building. Manufacturers should not send digitally altered images. NIOSH will assign a three-letter manufacturer code after the information provided is reviewed and accepted by NIOSH. A manufacturer must have an assigned manufacturer code before beginning the respirator approval application process. Manufacturers should use this identification code for every approval application, regardless if they complete the process for one respirator or many.

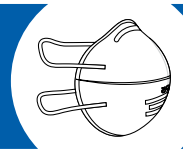
Elements Required in Your Application Package

Manufacturers must submit the following according to the Standard Application Procedure with their application:

- ❑ Standard Application Form
- ❑ Assembly matrix
- ❑ Draft approval label
- ❑ Drawing(s)
- ❑ Any overarching QMS documents (see page 8)
- ❑ Pre-submission test data
- ❑ Additional information required by the type of respirator submitted for approval
- ❑ Product Quality Control Plan
  - ❍ Inspection procedures
  - ❍ Sampling plans
  - ❍ Classification of defects
- ❑ User instructions
- ❑ Respirator samples
- ❑ **$200 fee**

These documents and respirator samples should all be submitted within a two-week time period and include the $200 (U.S. dollar) application fee.

In-progress Applications for First-Time Applicants



Once you receive your manufacturer code, the next step is to fill out the Standard Application Form and submit your package, which should include all the information on the checklist on page 6 within this booklet. NIOSH will assign a task number (TN) specific to your application package and inform the primary contact by email. The application package will go through respirator sample testing and review including a quality assurance review (see pages 8 through 11).

While NIOSH reviews the application, NIOSH reviewers may correspond with the applicant's primary contact to clarify or correct identified issues as the project moves through the review process. NIOSH reviewers will email the primary contact and communicate the expected timelines for response. If everything is determined to be sufficient and meets the requirements, a manufacturing site qualification visit or visits will be scheduled (for first-time applicants only).

At any time during the review process, NIOSH can deny the application and will formally inform the manufacturer.

Site Qualification Visit

NIOSH will visit a first-time applicant's facility, or facilities, to determine if the quality management system presented, including the production process, inspection, etc., are consistent with the supplied documentation and meet NIOSH requirements. NIOSH will verify that records are available and show that the QMS was followed as described in the application when manufacturing the samples sent to NIOSH. The findings from this assessment will be scored and will fall into one of three categories: (1) acceptable, (2) provisionally acceptable, or (3) not acceptable.

A NIOSH approval will ONLY be granted if the site qualification is acceptable.

If the site qualification is determined to be provisionally acceptable, corrective actions will be required before the site qualification will be considered acceptable and an approval is issued. If the site qualification is not acceptable, the project will be denied. NIOSH will provide site qualification letters to summarize the findings and separate approval or denial letters.

NOTE

To stay informed of all NIOSH announcements and application process requirements, applicants are encouraged to frequently check the NIOSH NPPTL conformity assessment notice webpage. Approval holders will automatically be added to the NIOSH NPPTL manufacturer listserv to receive notice when there are new conformity assessment notices. Private label assignees should sign up for the NIOSH NPPTL general listserv in order to receive important NIOSH respirator approval program updates.

Quality Assurance Requirements

Labeling 42 CFR 84.33 (d)

The manufacturer must ensure that only NIOSH Approved® configurations are labeled as NIOSH approved.

Design and Development 42 CFR 84.41 (a)(2), (b)–(i); 42 CFR 84.61(a)

The manufacturer must address design inputs (physical and performance characteristics), design outputs (drawings, classification of defects, and incoming, in-process, and final inspections), and appropriate reviews and approvals of the design and development process, including both verification and validation.

Control of Documents and Data 42 CFR 84.41 (a)(2)

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. The manufacturer must ensure there is an internal review and approval process for all new and revised drawings and documents and 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 all data collection is controlled to prevent unintentional alterations.

Control of Purchasing 42 CFR 84.41 (a)(4)

The manufacturer must have a process in place that can achieve the following:

1. Identify qualified suppliers and be able to evaluate both the initial quality of suppliers and the sustained quality through periodic evaluations,
2. Communicate material and/or component requirements to suppliers, and
3. Receive and review all incoming materials or components.

Product Identification and Traceability 42 CFR 84.33 (b), (e)–(g); 42 CFR 84.41 (a)(5)

The manufacturer must be able to achieve the following:

1. Implement a procedure to identify raw materials used within the production process;
2. Properly label all respirators and respirator components;
3. Track, or trace, the essential components of the respirator; and
4. Implement a procedure to properly identify the finished respirator and required major subassemblies.

Control of Production Processes 42 CFR 84.41 (a)(5), (7); 42 CFR 84.42 (c)

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

Control of Equipment 42 CFR 84.41 (a)(3)

The manufacturer must have a process to select appropriate measuring and test equipment and maintain a calibration schedule. The manufacturer will be required to review the calibration records and identify the testing equipment's calibration status. As part of this process, the manufacturer must maintain all calibration records and evaluate the impact of out-of-tolerance equipment against any in-process or distributed product.

Corrective Actions 42 CFR 84.41 (a)(7)

When the manufacturer identifies an issue with a respirator or its production, through a legitimate source, such as an internal or external audit, the manufacturer must be able to correct the part of the system that is not conforming to the approved production procedure, thereby causing the issue. The manufacturer must also be able to mitigate the negative outcomes of this nonconformity.

Inventory and Handling Controls 42 CFR 84.41 (a)(5)

The manufacturer must identify a process to prevent the damage of all raw materials, in-process components, and finished NIOSH products.

Quality Records 42 CFR 84.43 (a)

Records of all the requirements listed here and otherwise noted in the NIOSH approval application process must be retained and accessible.

Internal Audits 42 CFR 84.41 (a)(7)

The manufacturer must establish a schedule for internal audits and maintain those audit records. As part of this, 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 product quality control plan.

Training 42 CFR 84.41 (a)(7)

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. A procedure must be in place to ensure applicable personnel are notified of production process modifications.

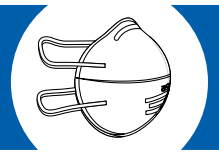
Organizational Structure 42 CFR 84.41 (a)(7)

The manufacturer must establish an organizational structure to identify those positions responsible for fulfilling the requirements of the product quality control plan.

NOTE

This guidance is provided in this document to help you better prepare for the rigorous NIOSH approval process. This is a summary of Conformity Assessment Notice: NIOSH quality control plan requirements, NIOSH CA 2019-1019 and the guidance is not all-inclusive. For the exact requirements of the NIOSH approval process, see the Standard Application Procedure for the respirator type you wish to produce.

Quality Assurance Review Requirements



1. Clearly define **incoming** inspection procedures and verify that the materials received conform to the ordered specifications.
2. Clearly define **in-process** inspection procedures used to verify material or design quality, **when applicable**.
3. Clearly define **final** inspection procedures and verify that the fully assembled respirator conforms to the specifications on the drawing and the required performance specifications. (Refer to drawing checklist to the right.)

The manufacturer is expected to verify the accuracy of all measurements and information included on a drawing. Incoming, in-process, and final inspections must be assigned a classification of defects according to the definitions in 42 CFR Part 84 Subpart E.

NOTE

The checklist on this page is abbreviated and specifically for FFRs. See the full version of this checklist, and the engineering drawing checklists for other respirator types, in the appropriate Standard Application Procedure.

Engineering Drawing Checklist for Filtering Facepiece Respirators (FFRs)

Below is an FFR-specific **example** of a checklist that can be found in the SAP. It shows what you must include on the drawing. Manufacturers should prepare this information before starting the application process.

- Proper title, signature/initials, number, date, and revision level
- Applicable product quality control plan document number(s)
- Location of the full NIOSH approval label
- Dimensions for facepiece, liner, valve, straps, and nosepiece
- Material specifications, including color, for filter media, valve, nosepiece, straps, and liner
- Dimensional location of nosepiece, liner, straps, and valve
- Part number and its location on the respirator
- Lot number and lot number key
- Location of the lot number (on the respirator or on the packaging) is noted
- Abbreviated approval label
- Filtration efficiency (N95, N99, N100, etc.) including nuisance protections
- Filters containing carbon layers include a statement that carbon is chromium free
- Final filter media form (cup, flat fold, duckbill, etc.)
- Filtering mechanism (electrostatic, mechanical, or other)
- Strap attachment method
- Strap elasticity definition (listed as a percentage or maximum length at a known force)
- Staples or sonic welds, if used to fasten straps, are identified as whether or not the attachment points are within the breathing zone
- Private label version and abbreviated label, if applicable
- Expiration date, if applicable
- Documentation of the purple or magenta label color requirement for P100 filters, only when applicable

Product Quality Control Plan

NIOSH must have confidence that approved respirators in use provide the expected (same) level of protection as the lot sample that was originally tested by NIOSH. Implementation and use of a quality control plan using a sampling standard ensures the quality of the product. Before you apply, familiarize yourself with how to implement an effective sampling standard, such as those in the table below. If you do not understand how to effectively use one of these sampling standards or an equivalent standard, you are not yet ready to apply for a NIOSH respirator approval.

The sampling standard for each inspection must be clearly stated in this part of your application. **You must clearly define a lot size.**

Examples of standards and minimum inspection levels acceptable to NIOSH

Procedure	Minimum Inspection Level	
	Normal	Destructive[1]
MIL-STD-414	IV	I
ANSI/ASQ Z1.9-2003	II	S-3
MIL-STD-105D	II	S-2
MIL-STD-105E	II	S-2
ANSI/ASQ Z1.4-2003	II	S-2
ISO 2859[2]	II	S-2

For more information about how to select and use a sampling procedure, see the NIOSH Conformity Assessment Notice (CA 2021-1034R1).

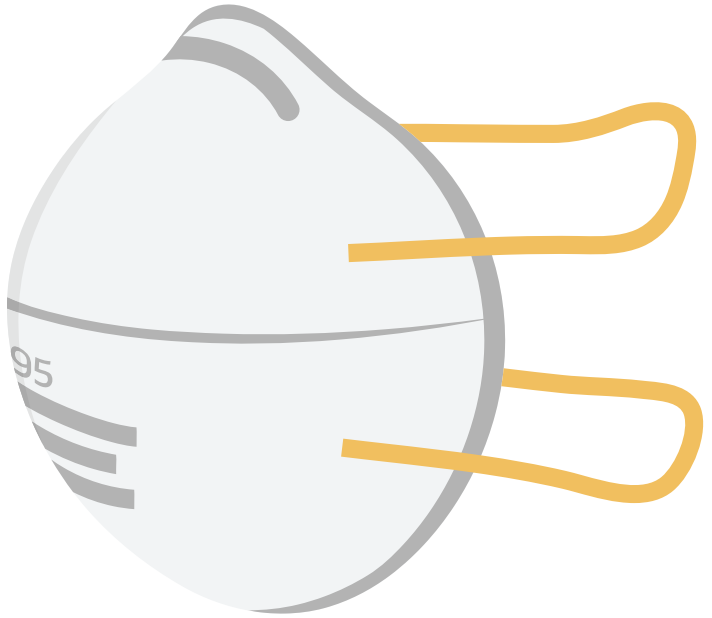
[1]Destructive inspections are considered those that, once performed, render the respirator or respirator component unable to be used.

[2]Reduced sampling is not permitted with this plan.

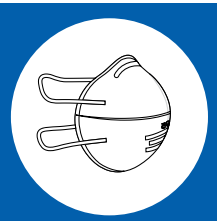
Acceptable Quality Level (AQL)

A classification of defects document must be submitted with each application. 42 CFR Part 84.41(c) through 84.41(e) requires you to identify each characteristic. The NIOSH classification of defects is specific to respirators and their definitions must be carefully considered.

Defect Classification	Major A	Major B	Minor
AQL+	1.0	2.5	4.0



Familiarize Yourself with These Resources Before You Apply



42 CFR Part 84 — The Code of Federal Regulations (CFR) are the rules and regulations published in the Federal Register by the executive departments and agencies of the federal government of the United States. Part 84 addresses NIOSH approval requirements for respiratory protective devices.

Standard Application Procedure (SAP) — This document should be used as a companion to the Standard Application Form, offering detailed explanations for each part of the approval process. A separate version of the document has been created for each class of respirator. NIOSH recommends that applicants review the entire document to determine the appropriate respirator class before submitting a respirator for approval.

Standard Testing Procedures (STPs) — Explanation of how NIOSH tests the submitted respirator against the performance requirements set in 42 CFR Part 84.

Conformity Assessment Notices and Letters to Manufacturers — Documents developed to provide information about policy, procedure, or testing changes.

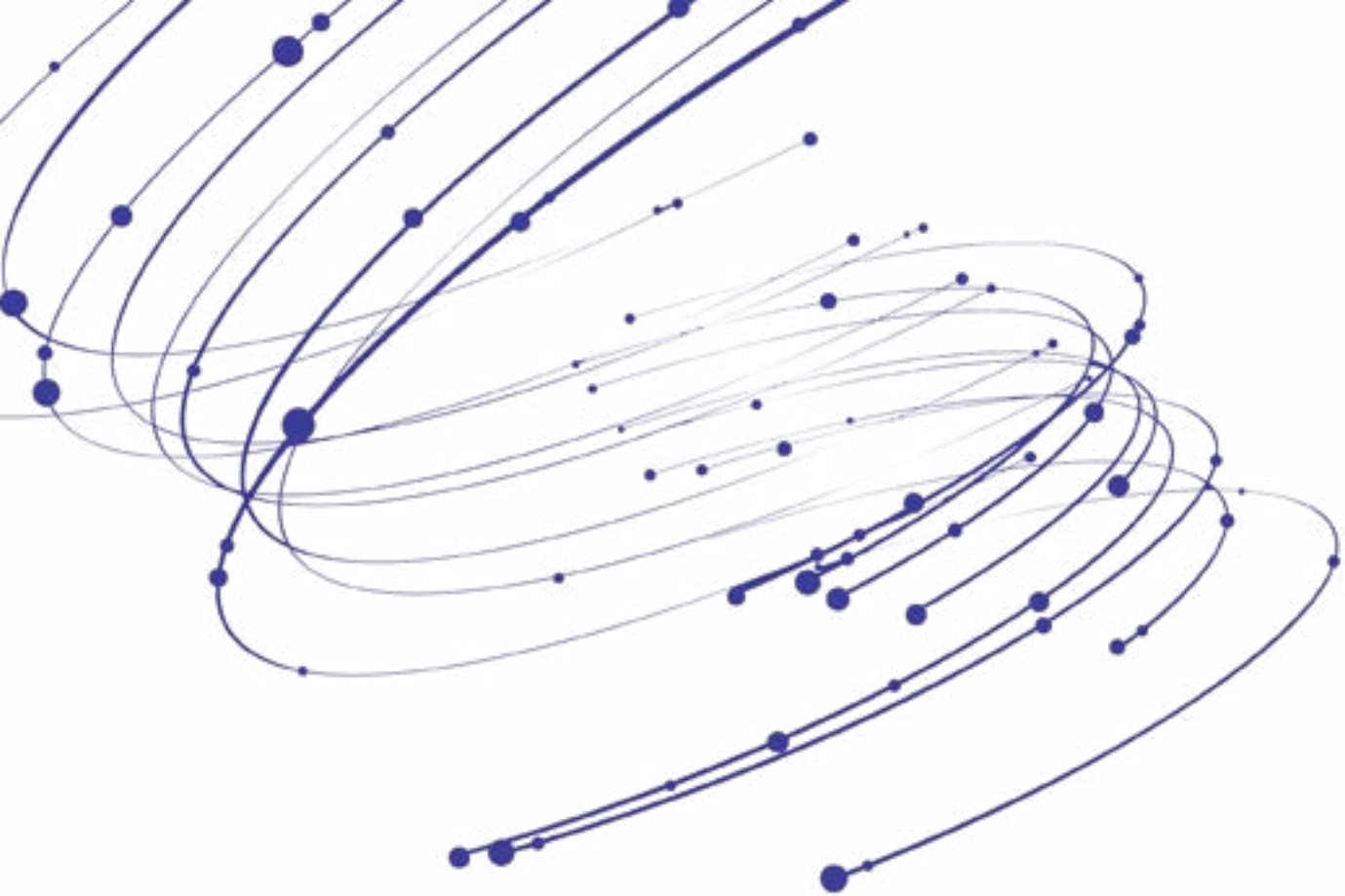
Noteworthy Conformity Assessment Notices and Letters to Manufacturers

- Conformity Assessment Notice, NIOSH Respirator Approval Contents and Meaning, NIOSH CAN 2019-1012
- Summarized Information about NIOSH Respirator Approval Program (i) Basic Application Procedures, (ii) Quality Assurance Requirements, and (iii) Supplier or Subcontractor Agreements, NIOSH CA 2021-1034-R1
- Conformity Assessment Notice: NIOSH quality control plan requirements, NIOSH CA 2019-1019
- Conformity Assessment Letter: Interim guidance regarding applications for NIOSH Approval of Filtering Facepiece Respirators in accordance with the Food and Drug Administration (FDA) Final Order, NIOSH CA 2018-1010R1.0

Are You Ready to Apply?

- ✔ Have you thoroughly reviewed the information provided in this booklet as well as the information at each of the links on page 12?
- ✔ Have you designed, developed, and produced a respirator using your documented quality assurance processes and procedures?
- ✔ Have you implemented a quality control system that includes the requirements in 42 CFR Part 84 Subpart E and the information provided in NIOSH CA 2020-1019?
- ✔ Has your current/final respirator design been evaluated against the NIOSH Standard Testing Procedures (STPs) to verify performance of the design?
- ✔ Have you established an inspection and sampling procedure based on variables or attributes to ensure that critical respirator performance requirements are met, per NIOSH requirements?
- ✔ Are you prepared to send photos to NIOSH of the production line and quality assurance area as well as of the facility with a visible logo or company name on the building?

NIOSH expects that the samples tested for pre-submission test data and sent to NIOSH for evaluation were made using the fully executed quality management system described to NIOSH. This would include everything from design and development through all inspections described in the PQP.



National Institute for Occupational Safety and Health

NIOSH®

Promoting productive workplaces through safety and health research

DHHS (NIOSH) Publication No. 2023-132

DOI: https://doi.org/10.26616/NIOSHPUB2023132