

**National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
Conformity Verification and Standards Development Branch (CV&SDB)**

**STANDARD APPLICATION PROCEDURE
FOR THE
CERTIFICATION OF RESPIRATORS
UNDER 42 CFR 84**

Revision 2.1, August 2015

Introduction

This document revises the NIOSH *Standard Application Procedures for the Certification of Respirators* dated July 2005. This revision was written to clarify the approval process under Title 42, *Code of Federal Regulations* (CFR) Part 84 (also known as 42 CFR 84) and to add the information concerning the modifications to the required fees for applications and yearly maintenance fees that will be assessed. It is recommended that applicants review the entire document before submitting a respirator for approval.

This revision is the second phase of a three phase update of the Standard Application Procedures. The first phase was issued primarily to incorporate the revised fee information published in the Federal Register on January 26, 2015 as well as incorporating several other minor changes. This second phase is issued primarily to incorporate closed-circuit escape respirator (CCER) and Chemical, Biological, Radiological, and Nuclear (CBRN) Respirator application information. The third revision will incorporate more comprehensive changes, stakeholder recommendations and is targeted for publication in December of 2015.

A review and update of this Standard Application Procedure is currently planned for every 5 years. The next planned update after the Phase three publication would be December 2020.

Compliance with all instructions is essential for quick and efficient processing of an application. Failure to follow these instructions completely may result in the rejection and return of your application.

Any time the approval holder makes a change to a critical or major characteristic affecting performance and/or design (including quality assurance provisions), the change must be submitted to NIOSH for approval. Changes to minor characteristics not affecting performance and/or design, and which are not documented in the NIOSH approval records, will not have to be submitted to NIOSH. However, approval holders remain responsible for keeping all changes to minor characteristics on file and available for NIOSH review.

Additional guidance and requirements are published by NIOSH as *Letters to All Manufacturers* and *User Notices*. To obtain a copy of NIOSH *Letters to All Manufacturers* and *User Notices* from 10/99 to the present, please contact the Conformity Verification and Standards Development Branch at (412) 386-4000 or RecordsRoom@cdc.gov.

Revision History		
Document: Standard Application Procedure for the Certification of Respirators Under 42 CFR 84		
Date	Revision	Summary of changes
January 2001	-	Original issue
July 2005	1	Completely rewritten to clarify application procedure and to document NPPTL's move from Morgantown WV to Pittsburgh PA
May 2015	2.0	<ul style="list-style-type: none"> -Updated to add new fee structure and payment instructions -Removed the Private Label Notification form -Replaced form, fit and function terminology with performance and design throughout document -Included definition for performance and design -Updated Cautions and Limitations list -Updated approval schedule listing to include 13G approvals -Included NIOSH Application Checklist for reference/use -Updated mailing address
August 2015	2.1	<ul style="list-style-type: none"> -Updated Branch Name -Updated to add Filtering Facepiece, CBRN and CCER tests to Respirator Test Selection Guide -Added all CBRN Cautions and Limitations -Added NIOSH Standard Cautions and Limitations by Basic Respirator Type -Added Private Label Checklists -Added Filtering Facepiece Sample Assembly Matrix and Drawing -Added Appendix of Selected Letters to All Manufacturers

HOW TO CONTACT THE NPPTL CONFORMITY VERIFICATION AND STANDARDS DEVELOPMENT BRANCH (CV&SDB)

Telephone: 412.386.4000

Fax: 412.386.4051

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Pittsburgh mailing address
for sending mail

NIOSH / NPPTL / Conformity Verification and Standards Development Branch-
Records Room, Building 20
626 Cochran Mill Road
Pittsburgh, PA 15236

Pittsburgh shipping address
for sending hardware

NIOSH / NPPTL / Conformity Verification and Standards Development Branch
Evaluation and Testing Section, Building 37
626 Cochran Mill Road
Pittsburgh, PA 15236

Check the status of your applications at

<http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/AP.pdf> or

<http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/AS.pdf>

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SECTION A - DEFINITIONS and ACRONYMS

A.1 DEFINITIONS

The following definitions are provided for clarification of terms used in these procedures:

Accessory - An item provided with a respirator that does not affect its ability to meet the requirements of 42 CFR 84. The approval remains in effect whether or not the accessory is used.

Amended Application - A correction to an open application, sent only at the request of NIOSH, for the correction of inconsistencies detected during the NIOSH evaluation (see Section B.2.6).

Applicant - The entity that designs, manufactures, or assembles a respirator, and who seeks to obtain a certificate of approval for the respirator; the approval holder. See “Manufacturer.”

Applicant Assigned Reference Number - An identifying number which is a unique number of the applicant’s choosing (see Section C.1).

Assembly Matrix – A cross-reference of major sub-assemblies and accessories that apply to approvals in a respirator family. Components are identified by category, description, drawing number and revision, part number, and applicability to the listed approvals (see Section C.18).

Canister - A gas or vapor removing component which meets the requirements of 42 CFR 84, subpart I, Tables 5, 6, and 7. Canisters may incorporate particulate filters.

Cartridge - A gas or vapor removing component which meets the requirements of 42 CFR 84, subpart L, Table 11. Cartridges may incorporate particulate filters.

Common Matrix - An assembly matrix that contains all of the information for a series of applications. See “Series of Applications”

Component - See “Major sub-assemblies”

Correlation Testing - Testing requested to compare an applicant’s test equipment and results to NIOSH’s. Correlation testing requires a New application with the wording “Correlation Testing Only; respirator is not submitted for approval” in the ‘Reason for Application’ section.

Critical Characteristic – A feature that, if not manufactured properly, could have a direct adverse impact on the safety or health of the user, and for which 100% testing or inspection is required prior to shipment to ensure conformance with all technical requirements of the approval.

Design – The overall specification for the respirator that includes materials, physical envelope and shape, manufacturing processes and quality assurance requirements.

Disposable Respirator – Sometimes called a single-use respirator, is an air-purifying respirator for particulates, and/or chemical gases and vapors that has no user-replaceable parts. The respirator is discarded when it is unsuitable for further use as defined by the applicant.

Exploded View Drawing – A drawing of the complete respirator assembly showing all major sub-assemblies and accessories and their proximity to one another (see Sections C.19 and G).

Family of Products – A group of respirators sharing a common major sub-assembly, such as a facepiece or regulator. The applicant determines the basis for their respirator families.

Features - Descriptors that relate to the makeup, shape, proportions, outward appearance, prominent characteristics, or qualities of the part, but are not separate components or devices. Features should *not* be listed on the approval label (e.g., "super-soft face seal").

Filter - A particulate removing component of a respirator which meets the requirements of 42 CFR 84, subparts K and/or KK.

Field-replaceable - Any component, major sub-assembly, or accessory (e.g., cartridges, hoses, regulators) that can normally be replaced by the user following the manufacturer's User Instructions without any special knowledge, skills, abilities, or equipment.

Filtering facepiece - An N, R, or P-series particulate respirator where the entire facepiece is composed of the filtering media. The unit may have an exhalation valve, and has no replaceable parts. See also "Disposable Respirator"

Intrinsically safe – Not capable of releasing enough electrical or thermal energy under normal or abnormal conditions to cause ignition of a flammable mixture of methane or natural gas and air of the most easily ignitable composition.

Major sub-assemblies - Those components or sub-assemblies (1) that are essential to the respirator's function and effective performance; (2) that affect the respirator's performance or design; and (3) which are normally field-replaceable items. Examples for each respirator type can be found in Section B.2, *Information Common to All Applications*.

Manufacturer - OEM - The individual or organization that controls and is responsible for the production of the complete and final respirator in the form as offered to the user. See "Applicant."

Manufacturer's Code - A unique three-letter code assigned to each manufacturer or applicant by NIOSH.

Model Numbers - A model number is not required to identify each unique configuration. *If a model number is used as the part number for individual components, it must be listed in the Part Number Row of the assembly matrix and approval label.* A full facepiece with model number "RX100" molded into the mask will have "RX100" as the part number. If a component has both a part number and a model number, they must appear in separate rows on the assembly matrix.

New design - An entirely new respirator, component, or arrangement of components (some of which may have been used on other previously approved respirators) which NIOSH has not evaluated in this configuration.

Nuisance level contaminants - Contaminants for which the concentration in the atmosphere is below the established PEL (OSHA permissible exposure limit) or REL (NIOSH recommended exposure limit). Nuisance level protection capability is not evaluated by NIOSH.

Part Numbers - The identifying number located on the component must also be the part number shown on all labels (abbreviated and full) and on the assembly matrix. The location of the part number on the component hardware must be shown on the drawings. A part number is the unique number referenced by users to identify respirator parts. It may not necessarily be what the applicant calls the part number since the applicant may use terms like catalog number, manufacturer number, production component number or other terms.

Pre-filter - An accessory item situated in front of the approved filter that removes coarse particles but does not meet 42 CFR 84 criteria for particulate filters. A pre-filter is a filter often used upstream of an N, R, or P series filter or cartridge. Pre-filters are not classified as N, R, or P filters. When pre-filters are used, the complete assembly must meet the resistance requirements of 42 CFR 84. Pre-filters may be listed on the approval labels. If shown on the approval label, they must be listed as an accessory and designated as a pre-filter.

Performance – The actual operational performance of the respirator with respect to the applicable regulations and design parameters. The respirator must meet or exceed the requirements of the NIOSH regulations under 42 CFR part 84 when evaluated against NIOSH standard test procedures (STPs) as appropriate to the type of respirator.

Private Label - Labeled as belonging to or concerning a company or interest that is not the approval holder. Private-labeled respirators will carry the same TC number that was issued to the approval holder. Only the approval holder may apply for a private label (see Section C.20).

Private Packaging - A respirator that is repackaged and sold by a company that is not the approval holder of the respirator. All part numbers, model numbers and approval labels must be the same as those approved by NIOSH. However, the packaging may reference the packaging company instead of the approval holder (see Section C.20). The approval holder is responsible for ensuring that private packaging arrangements do not mislead the end user.

Product Quality Control Plan (PQP) - Summarizes the manufacturing, inspection, test operations, and applicable documents used in regular production of a specific respirator family.

Product Trade Name - Because of the way that approval holders market and users reference certified respirators, a product trade name that uniquely identifies the respirator or respirator family *is required*. The product trade name may not imply use (see Section C.14).

Protection - A *different type of protection* is defined as protection against a different atmospheric contaminant (e.g., particulates, chlorine gas, ammonia gas, mercury vapor, etc.). A *different level of protection* is defined by a change in the type of facepiece (half mask, full

facepiece) or mouthpiece, filtering efficiency (such as N95 as opposed to N100) and/or the air supply capability (e.g., pressure, duration, demand flow, continuous flow, etc.).

Prototype - Defined as a respirator or component that (a) involves a new design produced using temporary molds, non-production tooling, or regular production tooling in a new fashion, and (b) has demonstrated by applicant's pre-testing to meet 42 CFR 84 minimum design and performance requirements. Respirators may be submitted for approval while in this defined prototype stage (limited production tooling and processes) using a NEW application form. NIOSH may request samples made on regular production tooling and production quality control (Ref. 84.30 (c)). For *non-approval prototype testing* use a NEW application form and state "prototype testing only - respirator is not submitted for approval" in the 'Reason for Application'.

Quality Assurance - A planned and systemic pattern of all activities necessary to provide confidence that all respirators will perform satisfactorily in actual operation.

Quality Assurance Manual - Documents the corporate or company quality systems including the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management and policy (see Section C.16). Hard copies with original approval signatures must be submitted and will be retained in the NIOSH files.

Regular Production Unit (RPU) - A respirator or component made on regular production tooling, or that is identical to units made on regular production tooling and is not made with any operations that will not be included in regular production.

Representative - The entity authorized by an approval holder to act on their behalf. Also, the contact person submitting the application for the approval holder.

Respirator - Any device designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.

Resubmission of an application - An application for approval where the application has previously been *denied*. Resubmitted applications will receive a new task number (TN) and be placed at the end of the application processing queue. All documentation must be updated to the current dates and revision levels as if the respirator had never been submitted before.

Series of Applications - A sequence of applications submitted at the same time (in the same bundle or package). A common assembly matrix that contains all of the information for the submitted series is located in the last application of the series. Assembly matrices may not contain information regarding future submissions (see Section B.2).

Simplified Drawings - They are composed of the exploded view drawing and the major sub-assembly drawings. Any additional drawings the applicant deems necessary for further clarification of a major sub-assembly or part may also be included in the application.

Standard Application Form - The form for submitting respirator approval requests to NIOSH.

A.2 Acronym List

AAR# - Applicant Assigned Reference number

AP - Air-Purifying

AQL - Acceptable Quality Level

AS - Air-Supplied

CBRN - Chemical, Biological, Radiological, Nuclear

CCER - Closed Circuit Escape Respirator

CEL - Certified Equipment List

CFR - Code of Federal Regulations

CGA - Compressed Gas Association

DHHS - Department of Health and Human Services

EBSS - Emergency Breathing Safety System

ESLI - End of Service Life Indicator

IDLH - Immediately Dangerous to Life or Health

MSHA - Mine Safety and Health Administration (Department of Labor)

NFPA - National Fire Protection Association

OSHA - Occupational Safety and Health Administration (Department of Labor)

PAPR - Powered Air-Purifying Respirator

PQP - Product Quality Plan

QA - Quality Assurance

SAF - Standard Application Form

SAP - Standard Application Procedure

SAR - Supplied-Air Respirator

SCBA - Self-Contained Breathing Apparatus

SCSR - Self-Contained Self-Rescuer

TC number – Testing and Certification number; the NIOSH approval number designation

TN - task number; a unique number assigned by NIOSH to each application.

SECTION B - GENERAL INFORMATION

B.1 HOW TO APPLY

NIOSH accepts electronic applications made with the NIOSH Standard Application Form software. This is a Windows application and is furnished to each applicant free of charge. Copies of the software on CD-ROM may be obtained by calling NIOSH at (412) 386-4000. If you would like to review the application prior to requesting the CD-ROM, the application program and form are available at <http://www.cdc.gov/niosh/npptl/resources/certpgmspt/standardapp.html>.

The application software consists of (1) Application Forms located in file SAF_V7 or SAF_V8 and (2) Application Data located in file saf_data.mdb. Version 8 is the latest version, and applications that use the earlier version 7 will be accepted. Version 8 applications are saved as XML files, and have the extension “.xml.” Incomplete applications can be saved and reopened for completion. Completed applications may be viewed and printed by creating the “Application Browser Helper” using the menu item under “File” in the toolbar. The NIOSH created file, “SAFtoHTML.xml,” allows modern web browsers to directly open saved applications for viewing and printing. Make sure the “SAFtoHTML.xml” file is in the same directory as the completed application. The “open” menu item under the “file” toolbar option of most modern web browsers can then be used to open the application for printing.

Save the data file using the file naming convention XXXnnnnnn.mdb or.xml where XXX is your three-letter manufacturer code and the n’s are a unique identifier of your choice. The manufacturer code is assigned by NIOSH and supplied with your copy of the application software on CD-ROM or by E-mail.

The application data file and supporting documents may be submitted on the following electronic media: CD-R only. Applications submitted on re-writable CDs will not be accepted. Revision levels must be included in every controlled document’s file name, and the naming conventions on the next page must be followed. Submit only one application per CD. Applications processed on computer systems using Windows '98 may not process correctly at NIOSH.

Applicants who submit applications via e-mail run the risk of losing data if mail routers strip off large files.

If you wish to have your CD returned after the application is processed, you must submit a pre-paid, return shipping label with the CD. Your CD will be held by the Conformity Verification and Standards Development Branch for as long as the project is open. If a pre-paid, return shipping label is not received with the CD, the CD will be destroyed after the project is closed.

In addition to the application file, the applicant must submit related project documents. These documents must be in English and saved with the following file-naming conventions. Any files created in a language other than English will be returned unprocessed. The only documents that will be accepted in paper form are the Quality Assurance Manual and the fee check.

Replace XXX with your three-letter manufacturer code; ‘n(s)’ in the file name are the unique set of identifying characters for the documentation with the trailing “a” for the revision level. The revision level must be included in the file name for every controlled document file. Spaces must not be used in file names.		
Required Documents	Acceptable Software Packages	File-naming Conventions
Application form	Microsoft Access, Java	XXXnnnnnnnn.MDB or .xml
Pre-submission test data	Adobe Acrobat, Excel, Microsoft Word	nnnnnnnPD. PDF, XLS, XLSX, DOC, DOCX
Drawings	Scanned file, AutoCAD, Adobe Acrobat	nnnnnnnRa.TIF, DWG, PDF, GIF, JPG, BMP
Assembly Matrix	Excel	nnnnnnnAMa.XLS, XLSX
Draft approval labels	Excel	nnnnnnnDLa.XLS, XLSX
QA manual	Adobe Acrobat, scanned file, Excel, Microsoft Word,	nnnnnnnQMa. PDF, TIF, XLS, XLSX, DOC, DOCX, plus one signed paper copy
Product Quality Control Plan	Adobe Acrobat, scanned file, AutoCAD, Excel, Microsoft Word	nnnnnnnPQP. PDF, TIF, DWG, XLS, XLSX, DOC, DOCX
Fees	Paper or PAY.GOV only	Paper or PAY.GOV only
Service Life Plan	Adobe Acrobat, scanned file, Excel, Microsoft Word	nnnnnnnSLP. PDF, TIF, XLS, XLSX, DOC, DOCX
User’s Instructions	Adobe Acrobat, scanned file, Microsoft Word	nnnnnnnnUIa. PDF, TIF, DOC, DOCX
Hardware	Not Applicable	Identified with Applicant-Assigned Reference # for all applicable projects

All information requested in the application form must be addressed. Incomplete applications will be returned to the applicant unprocessed.

B.1.1 WHO MAY APPLY

Only the manufacturer of the respirator may apply for approval. The manufacturer can prepare the application and documentation themselves or use an independent consultant. An independent consultant cannot serve in the capacity of a Primary Contact. A manufacturer does not include re-branders, re-packagers, wholesalers, retailers, distributors, or those who may add accessory items such as welding lenses. Approvals will only be issued to manufacturers, and manufacturers are responsible for insuring that the quality and performance of all approved respirators offered to the market are equal to those originally evaluated and approved by NIOSH.

B.1.2 WHERE TO APPLY

The application paperwork and the test samples must be sent to different addresses. Do not send applications in the same package as the test samples.

Applications must be sent to: NIOSH / NPPTL / Conformity Verification and Standards
Development Branch
Records Room, Building 20
626 Cochran Mill Road
Pittsburgh, PA 15236

Test samples must be sent to: NIOSH / NPPTL / Conformity Verification and Standards
Development Branch
Evaluation and Testing Section, Building 37
626 Cochran Mill Road
Pittsburgh, PA 15236

B.1.3 WEB SITE

Applicants can view project status, search the Certified Equipment List, download the Standard Application Form software, and download the NIOSH and DHHS logos, on the Internet at <http://www.cdc.gov/niosh/npptl/respmanuf.html>.

B.2 INFORMATION COMMON TO ALL APPLICATIONS

NIOSH only approves complete respirators. Applicants may not imply directly or indirectly that components have a separate approval.

Applicants may submit a series of associated applications at the same time. The suggested processing order and an explanation of how the applications build upon each other must be given in the approval history. When the series of applications involves a common assembly matrix, only a single assembly matrix need be submitted with the last application in the series. No application in a series will be approved until all applications in the series are completed.

Hardware submitted for a series of applications must be identified for each project for which it is to be used. For example, a facepiece that is to be used on three projects must have all three Applicant Assigned Reference (AAR) numbers on the packaging. If there are multiple containers, each container must be labeled with all the appropriate information.

Applications are processed in the order received, not necessarily the order tested. There are several testing queues and hardware will be tested at the earliest available time in each queue. If hardware is being sent to NIOSH for the testing of multiple projects, please include this information in the first application where testing will be performed and label the hardware package with each AAR number.

Several screens in the electronic standard application form for New Approval and Extension of Approval identify the data fields that are being entered directly into the NIOSH Certified Equipment List (CEL). This is noted at the bottom of the screen. Required fields are identified by **red text**. Please complete these fields for an accurate reporting of your respirator in the CEL.

If there is any doubt about the appropriate type of application to submit, call NIOSH. See *How to Contact the NIOSH Conformity Verification and Standards Development Branch (CV&SDB)* in the front of this document for contact information.

New Approval and Extension of Approval applications must contain the following items as described in detail in Section C. If any of the items are not submitted, the applicant must state the reason why, i.e., “has not changed since TN-XXXXX.”

1. NIOSH Standard Application Form
2. Pre-Test Data
3. Simplified drawings
4. Assembly Matrix
5. Draft Approval Label(s)
6. Quality Assurance Manual
7. Product Quality Control Plan
 - a. Classification of Defects document
 - b. Sampling Plan
8. Fees
9. Service Life Plan (for units that are sealed and cannot be opened prior to use e.g. CCERs and CBRN APERs)
10. User Instructions manual
11. Test samples and hardware

Major sub-assemblies which must be listed on the approval labels and assembly matrix include, but are not limited to:

Air-Purifying Respirators (filtering facepiece)

1. Respirator by part number
2. Accessories (optional on approval label, required on assembly matrix)

Air-Purifying Respirators (negative pressure)

1. Facepiece (hood, helmet)
2. Cartridge (includes filter/cartridges when permanently bonded together)
3. Canisters
4. Filters
5. Unclassified pre-filters (optional on approval labels, required on assembly matrix)
6. Hoses
7. Adapters
8. Accessories (optional on approval label, required on assembly matrix)
9. User Instruction (required on assembly matrix)

Powered Air-Purifying Respirators (PAPR)

1. Facepiece (hood, helmet)
2. Cartridge (including filter/cartridges when permanently bonded together)
3. Canisters
4. Filters
5. Unclassified pre-filter (optional on approval label, required on assembly matrix)
6. Hoses
7. Adapters
8. Blower assembly
9. Battery assembly
10. Waist belt assembly/harness
11. Accessories (optional on approval label, required on assembly matrix)
12. User Instruction (required on assembly matrix)

Supplied-Air Respirators

1. Facepiece (including hood, helmet, etc.)
2. Breathing tube
3. Regulator assembly or flow control valve or orifice
4. Waist belt assembly/harness
5. Air line hose
6. Quick disconnects
7. Accessories (optional on approval label, required on assembly matrix)
8. User Instruction (required on assembly matrix)

Self-Contained Breathing Apparatus

1. Facepiece (including hood, helmet, etc.)
2. Breathing tube
3. Regulator assembly
4. Pneumatic assembly
5. Harness and backpack assembly
6. Cylinder and valve assembly
7. Accessories (optional on approval label, required on assembly matrix)
8. Service life plan (CCER only) and User Instructions (required on assembly matrix)

Combination Respirators

All in each applicable category above.

B.2.1 APPROVAL SCHEDULES

The following list of NIOSH approval schedules is provided to assist the applicant in creating the assembly matrix and labels. This list is provided as a tool only and is not all inclusive. Unique respirators submitted for approval which may fall across or outside these guidelines, or for which a current NIOSH policy does not exist, will be subject to NIOSH review. Schedules will be assigned by NIOSH upon completion of the submission:

- *13F - Self-Contained Breathing Apparatus (SCBA) for entry or escape, demand or pressure-demand, open-circuit or closed-circuit, Self-Contained Self-Rescuers (SCSR), and combination escape only Self-Contained Breathing Apparatus/Supplied-Air Respirator (ESCBA/SAR)
- *13F-CBRN - Self-Contained Breathing Apparatus (SCBA) for entry or escape, pressure-demand, open-circuit, with Chemical, Biological, Radiological and Nuclear (CBRN) approval for use in firefighting and in conjunction with Safety Equipment Institute (SEI) and National Fire Protection Association (NFPA).
- *13G – Closed Circuit Escape Respirators for use in escaping from immediately dangerous to life or health (IDLH) and non-IDLH atmospheres
- *14G- Filter Self-Rescuers (FSR), gas mask respirators with or without N, R, or P rated filters, and tight-fitting Powered Air-Purifying Respirators (PAPR) with or without High Efficiency (HE) filters that meet gas mask canister requirements. Air-Purifying CBRN respirators, Air-purifying CBRN Escape respirators (APER), tight-fitting CBRN Powered Air-Purifying Respirators
- * 19C- Supplied-Air Respirators (SAR), Type C and CE, including demand, pressure-demand, or continuous flow classes
- * 21C- Powered Air-Purifying Respirators (PAPR) with High Efficiency (HE) filters
- * 23C- Chemical cartridge only respirators and Powered Air-Purifying Respirators (PAPR) with chemical cartridges or combination chemical cartridges with High Efficiency (HE) filters and combination chemical cartridge/supplied-air respirator systems. Loose-fitting CBRN Powered Air-Purifying Respirators
- * 84A- Particulate filtering respirators and combination chemical cartridge/filter respirators with N, R, or P rated filters and combination N, R, or P rated filters/supplied-air respirator systems

B.2.2 NEW APPROVALS

An applicant must provide all the requested information on the NEW application form when a respirator is a new design, or where a different type or different level of protection is sought for

an existing respirator. NIOSH assigns a new testing and certification (TC) number for each new respirator system design that is approved.

An application may be submitted for only **one** basic new respirator design per application. If an application contains more than one design, the application will be denied. If an applicant submits a new respirator with two new facepieces, for example, a half-mask and full-facepiece that use the same new filter, NIOSH requires two separate applications resulting in two new approvals because each facepiece represents a separate design and level of protection.

B.2.3 EXTENSIONS OF APPROVAL

Any time the approval holder makes a change to a critical or major characteristic affecting performance and/or design (including quality assurance provisions), the change must be submitted to NIOSH for approval. Changes to minor characteristics not affecting performance and/or design which are not documented in the NIOSH approval records do not have to be submitted to NIOSH. However, approval holders remain responsible for keeping all changes to minor characteristics on file and available for review at NIOSH's request.

An approval holder must use an Extension of Approval application form for one change or addition to one or more previously approved device configurations or several changes or additions to one previously approved device configuration, i.e. an extension of approval may be submitted for one new accessory on several previously approved facepieces, but not for several new accessories on several different facepieces. Changes to approval labels, assembly matrices, User Instructions, service life plans, and drawings are also considered Extensions of Approval. Alternate new items such as two new alternate filter media require separate applications since each requires testing. The approval holder must list the TC numbers of all affected approvals in the "Reason for Application." If all of the TC numbers on a given assembly matrix apply to the extension, the assembly matrix may be referenced instead of listing the individual TC numbers.

For SCBAs only, an extension is acceptable for multiple changes affecting a single SCBA even if it affects several major sub-assemblies.

For SCBA's with Part 84 and CBRN approvals, any Part 84 Extensions of Approval cannot contain changes to the CBRN approval. The only documents that may be submitted are those that are part of the Part 84 extension.

NIOSH *will not* assign new approval (TC) numbers for extensions of approval if the type or level of protection changes. For example, a filtering facepiece without an exhalation valve may be submitted and approved. The subsequent submission of the same mask with an exhalation valve would be considered to be a new 'Type' and would be issued a different TC number than the original version and an application for a New approval is to be submitted. Additions of a new respirator arrangement to a respirator family, model or series such as a new cartridge on an existing half mask model, require a New TC number and an application for a new approval is required.

Describe exactly and completely the change or additions to the approved respirator and how they will affect the previously approved respirator (s). Provide descriptive information on the previously approved respirator (s). For example, "An extension of approval to allow our 'xyz' alternate filter to be used as an alternate to our 'abc' filter on our non-powered half mask particulate respirators, models 123, 456, and 789. No other components are affected. This request is for use of an alternate filter only." The Extension of Approval request must clearly indicate:

1. The affected respirators by name, TC number, and part number
2. Complete details of the change
3. Related documentation that has changed since the last approval (assembly matrix, inspection procedures, drawings, etc.)

When adding an accessory to an already approved assembly, the applicant must include the accessory in the exploded view drawing, the assembly matrix, and the major sub-assembly drawings. If accessories are listed on the approval labels, the labels must be updated.

When changes are made that affect the User Instructions or service life plan, highlight or clearly note the changes in the document.

Extensions of Approval to add alternate components to existing NIOSH-approved respirators apply to respirators that will be shipped from the manufacturer's plant in the various configurations. These Extensions of Approval are not meant to apply to configuration changes that will be done in the field either by the end-user or by manufacturer representatives. If the alternate components are to be field-replaceable, the approval holder must submit an Extension of Approval for an "upgrade (or retrofit) kit." The applicant must submit one application for each upgrade kit that is being issued. The "upgrade kit" can be in the form of a parts list or a drawing, and it must be listed on the assembly matrix with its own controlled document number and revision level. If the kit is submitted as a picture drawing, the drawing must contain a parts list. The manufacturer's User Instructions to the field/technician conducting the upgrade must also be submitted as a controlled document and listed on the matrix. The first time these items are listed on the matrix they will have a matrix code of "N." Subsequent submittals will be designated with a "R."

B.2.4 QUALITY ASSURANCE APPROVALS

A Quality Assurance Approval is a submission requesting approval of a quality system or a change to some aspect of the previously approved quality assurance manual. Quality manual changes must include a revision history sheet showing the date and reason for revision.

In the *Reason for Application* completely state the details of the changes to the QA manual. Also indicate the respirators and manufacturing facilities affected. Quality assurance approval submissions must not affect the performance and/or design of the respirators and must not result in a different type or level of protection. If the changes impact any of these aspects of the covered respirators, then you must submit an Extension of Approval application to address these changes.

B.2.5 RESUBMITTAL APPLICATIONS

If your application is for hardware or documentation that has been previously submitted to NIOSH and denied, select request type ‘Resubmittal of New’ or ‘Resubmittal of Extension’ as appropriate. The *Reason for Application* must include the changes made to address the respirator or documentation deficiencies, an explanation why the respirator or documentation now meets NIOSH requirements, and the task number (TN) of the previously denied application. Failure to provide this information will result in your application being returned, unprocessed.

B.2.6 AMENDED APPLICATIONS

An amended application is submitted only at NIOSH’s request, and is used on open applications that have an inaccuracy somewhere in the application. Approval holders should submit only the portion of the application requested by NIOSH. The application will retain the same Applicant-Assigned Reference Number and NIOSH-assigned Task Number. NIOSH will advise the applicant as to any additional documents required to be submitted for an amended application.

B.2.7 APPROVAL LABEL PROTECTIONS and CAUTIONS & LIMITATIONS

PROTECTIONS

N100-Particulate Filter (99.97% filter efficiency level) effective against particulate aerosols free of oils; time use restrictions may apply	R100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	P100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols
N99-Particulate Filter (99% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply	R99-Particulate Filter (99% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	P99-Particulate Filter (99% filter efficiency level) effective against all particulate aerosols
N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply	R95-Particulate Filter (95% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	P95-Particulate Filter (95% filter efficiency level) effective against all particulate aerosols
HE-High Efficiency Particulate Air filter for powered, air-purifying respirators		
CBRN – Chemical, Biological, Radiological and Nuclear		

AG - Acid Gas (gas mask only)

CD - Chlorine Dioxide

CN - Chloroacetophenone

DE - Demand

FM - Formaldehyde

HN - Hydrogen Cyanide

MV - Mercury Vapor

PD - Pressure-Demand

SB - Supplied-Air Abrasive Blast

TDI - Toluene-2, 4-diisocyanate

AM - Ammonia

CF - Continuous Flow

CO - Carbon Monoxide

EO - Ethylene Oxide

HC - Hydrogen Chloride

HS - Hydrogen Sulfide

ND - Nitrogen Dioxide

PH - Phosphine

SC - Self-Contained

VC - Vinyl Chloride

CL - Chlorine

CS - Chlorobenzylidene Malononitrile

ESC - Escape

HF - Hydrogen Fluoride

MA - Methylamine

OV - Organic Vapor

SA - Supplied-Air

SD - Sulfur Dioxide

EOSTI-25 - End of Service Time Indicator 25%

EOSTI-33 – End of Service Time Indicator 33%

[NOTE: HS (esc) - Hydrogen Sulfide (escape only) has been replaced with HS and ESC for new approvals]

CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- D - Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G - 7.1 Grade D or higher quality.
- E - Use only the pressure ranges and hose lengths specified in the User's Instructions.
- F - Do not use powered air-purifying respirators if airflow is less than four cfm (115 lpm) for tight fitting facepieces or six cfm (170 lpm) for hoods and/or helmets.
- G - If airflow is cut off, switch to filter and/or cartridge or canister and immediately exit to clean air.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- I - Contains electrical parts that may cause an ignition in flammable or explosive atmospheres.
- J - Failure to properly use and maintain this product could result in injury or death.
- K - The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- L - Follow the manufacturer's User Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.
- AA - This respirator is to be used for escape only and will protect against the inhalation of certain respiratory hazards.
- BB - Not for use for entry into atmospheres immediately dangerous to life or health.
- CC - For entry, do not exceed maximum use concentrations established by regulatory standards.
- LL - This respirator contains filter or cartridge components that are not approved for all protections in all configurations. Check the specific row on the NIOSH approval label to ensure proper use.

CBRN- Specific CAUTIONS AND LIMITATIONS

- Q- Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard.
- R- Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.
- T- Direct contact with CBRN agents requires proper handling of the respirator after each use and between multiple entries during the same use. Decontamination and disposal procedures must be followed. If contaminated with liquid chemical warfare agents, dispose of the respirator after decontamination.

- U- The respirator should not be used beyond 6 hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation.
- V- Not for use in atmospheres immediately dangerous to life or health or where hazards have not been fully characterized.
- W- Use replacement parts in the configuration as specified by the applicable regulations and guidance.
- X- Consult manufacturer's User Instructions for information on the use, storage, and maintenance of these respirators at various temperatures.
- Y- The respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.
- Z- If during use, an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air
- DD- This respirator provides respiratory protection against inhalation of certain gas and vapor chemical agents, biological particulates, and radiological and nuclear dust particles. This respirator provides limited dermal (skin) protection to the head area and eyes.
- EE- Eye irritation may be experienced based upon the CBRN agent and exposure (concentration and duration).
- JJ- CBRN Agents, depending on how they are used, may provide disabling effect as a result of skin exposure.
- GG- Direct contact with CBRN agents requires proper handling of the respirator after use. Correct disposal procedures must be followed.
- HH- When used at defined occupational exposure limits, the rated service time cannot be exceeded. Follow established canister change out schedules or observe End of Service Life Indicators to ensure that canisters are replaced before breakthrough occurs.
- II- This respirator provides protection from certain inhalation hazards associated with fire.
- NN- This respirator is a one-time-use device with no replaceable parts. Discard after use regardless of contaminant exposure.
- QQ- Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained.
- UU- The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours.
- VV- PAPRS with TC-23C approvals may NOT be used for escape from IDLH atmospheres.

B.3 INFORMATION SPECIFIC TO 42 CFR 84 PARTICULATE FILTERS

The Part 84 requirements for particulate filters allow for the possibility of a limited number of multiple approvals of one filter. That is, one filter can be approved as an N, R, and P as well as for multiple efficiency levels. However, the protections listed on the approval label for the filter may identify only the series and efficiency levels at which the filter is tested. The available multiple series efficiency levels are:

R100/P99	N100/R99	N99/R95	N100/R95
R100/P95	N100/P99	N99/P95	N100/R99/P95
R99/P95	N100/P95	HE/P100	

No other combinations are permitted. The same filter can also be used on a respirator as either a single filter or in a multiple filter configuration. However, the possibility exists that the filter may meet one series rating (N, R, and P) or efficiency (100, 99, and 95) when tested as a single filter and a different series rating when tested in a multiple configuration. If a filter is identified using a single part number, the least protective series rating(s), tested in either configuration, will appear on the label. If an applicant wants to show different series ratings based upon different configurations, different part numbers must be used for each configuration. Filters that are approved for use on powered and non-powered respirators as an HE/P100 will carry a dual label.

SECTION C - SPECIFIC INSTRUCTIONS FOR PREPARING AN APPLICATION

The paragraphs in this section are numbered to correspond to the different sections on the Standard Application Form (SAF).

C.1 PROJECT REFERENCE NUMBERS

Applicant Assigned Reference Number: The applicant assigns a unique reference number of their choice to each application. The first 3 characters of this number must be their 3-character manufacturing code as assigned by NIOSH. This number must also appear on each hardware sample package and on the payment check. *Never re-use applicant-assigned reference numbers except on amended applications (which can only be requested by NIOSH).*

Task Number: NIOSH assigns a unique Task Number (TN) to each project received, and will notify the applicant of their TN by email. All inquiries must refer to the TN or applicant-assigned reference number.

C.2 TYPE OF APPLICATION

Select the correct type of application (NEW, EXTENSION or QUALITY ASSURANCE APPROVAL). Refer to Section B for specific information on each application type.

C.3 MANUFACTURER

Enter the complete manufacturer name, address, phone number, FAX number, and e-mail address.

C.4 MANUFACTURING SITE(S)

Enter the address of the manufacturing site for which approval is sought, if different from C.3.

C.5 APPLICATION REPRESENTATIVE

List one or two people who can assist us if we have questions regarding the application. Please do not list every contact person you have for NIOSH. If your company policy dictates that you must list all of your NIOSH contacts, list the primary contact in section C.5 and the remainder of the contacts in section C.9, *Reason For Application*. When the applicant is located outside of the United States, or a manufacturer hires a consultant to handle the application submission, the applicant may have, and should list, an authorized application representative located in the United States. Approval and Denial letters will be issued to the manufacturer with a copy

addressed to the authorized representative. All hardware will be returned to the authorized U.S. representative. NIOSH reserves the right to obtain documentation directly from the applicant if necessary. NOTE: A formal letter designating one official / primary contact must be on file at NIOSH. Any time this official contact changes, NIOSH must be notified in writing.

C.6 DATE OF APPLICATION

State the date of the application in a MM/DD/YY format. Processing of the application will not begin until NIOSH has received the application, check, and any test samples. All items must be received within 2 weeks of receipt of the first item or they will be returned.

C.7 TYPE OF PRODUCT

Select whether this application is for an air-purifying, atmosphere-supplying, or combination air-purifying atmosphere-supplying respirator.

C.8 SPECIFIC QUESTIONS PERTAINING TO SUBMISSION

For an amended application, check “yes” and refer to section B.2.6 of this document for specific instructions.

Check “yes” if this application is submitted as a result of any type of field problem or non-conforming site or product audit. Also enter the task number of the related site or product audit.

When the respirator is intended for mine use, the “yes” box must be marked (new applications only). More information is provided in section C.12 of this document.

When the application is dependent upon the approval of an application in process, the “yes” box must be checked and the reference number(s) or task number(s) must be indicated. For example, if a new facepiece was submitted for approval and then a second application is submitted with the same facepiece being added to a different product line, the second application cannot be approved until the first application is approved. Also, if there are two or more applications that use the same assembly matrix, check the “yes” box and identify all subsequent applications in C.10, *Approval History*. The second and subsequent applications using the same assembly matrix cannot be processed until the first application is approved. If this section does not apply, check the “no” box.

If the application is the result of a product recall or retrofit program, the “yes” box must be checked and a copy of the recall/retrofit notice must be submitted with the application. If this section does not apply, check the “no” box.

C.9 REASON FOR APPLICATION

Provide a complete, concise, descriptive reason for your application. Do not provide information relating to respirator use or future respirator development. List the TC numbers of all approvals affected by this application. If all of the TC numbers on the assembly matrix apply to the

extension, the assembly matrix may be referenced instead of the individual TC numbers. If an application for Extension of Approval is the result of a field problem, site audit, or product audit, state that fact and list any associated task numbers here.

Quality Assurance approval applications must completely state the details of the change and the respirators and manufacturing facilities affected. Quality Assurance approvals must not affect performance and/or design, and must not result in a different type or different level of protection.

Correlation applications must state what NIOSH Standard Test Procedure is to be used and how many trials are requested. Special correlation tests that are not constant with a NIOSH Standard Test Procedure will not be honored unless otherwise agreed upon by NIOSH.

Resubmittals must state the modification that was made to address the original rejection / denial, and demonstrate that the respirator or documentation now meets all requirements.

Example #1 of a Well-Written Reason for Application:

This application is for an extension of approval of our model XXX N95 filtering facepiece, [TC-84A-9999] to allow use of filter material manufactured by ABC, part number 12345, to be used as an alternate to the filter material we currently use which is manufactured by DEF, part number 67890. This request is for use of an alternate filter media only. No other components or processes are affected. Both filter media are made of electrostatically charged melt blown polypropylene and both pass the testing required to meet the criteria for N95 protection. Our current filter design with the DEF filter requires two separate filters layers from two separate roll-stocks to be assembled into our mask. The new filter material from ABC also uses two filter layers, but the two filter layers are bonded together on the sides so that both filters are on the same roll-stock.

Example #2 of a Well-Written Reason for Application:

This application is for an extension of approval to our EZLine Supplied-Air Respirator family to allow an alternate breathing hose. This breathing hose, p/n 12345, will be an alternate breathing hose for all approvals listed on the EZLine assembly matrix (EZLineAMrC.xls) which is included in our list of documents. The 12345 breathing hose utilizes an 85 degree elbow which allows greater mobility to the user than the original 67890 hose. The internal dimensions and the connectors are the same in both hoses. Test data is included to prove that the respirator performs the same regardless of which breathing hose is used.

Example #3 of a Well-Written Reason for Application:

This request is for a modification of approvals TC-13F-AAA, TC-13F-BBB, TC-13F-CCC, and TC-13F-DDD issued for the Eagle Open-Circuit, Pressure-Demand, Entry and Escape, Self-Contained Breathing Apparatus or Combination, Open-Circuit, Pressure-Demand, Entry and Escape, Self-Contained Breathing Apparatus and Type C, Supplied-Air Respirator to make the following changes as indicated on assembly matrix Eagle_AM26.XLS:

- To add four new airline/manifold pneumatic accessories, part numbers 1000001, 1000002, 1000003, and 1000004.
- To add a new supplement to User Instruction Manuals part number A000009 for the airline attachments.
- To add Hose/Handwheel Assy's 1005 and 1006 to Backframes 1007 and 1008 and remove Hose/Handwheel Assy's 1000 and 1001.

C.10 APPROVAL HISTORY

This section provides additional information on approval history and other pertinent information applicable to this application. Do not list additional requests in the Approval History.

If the application is one of a series being submitted, review Section B, *General Information*, and be sure to clearly list the applicant-assigned reference numbers of all applications in the series and include a suggested processing order. When using a common assembly matrix for the entire series of applications, place the assembly matrix in the last application of the series and reference the application in which it is located in all applications in the series.

List the application task number where this respirator was last tested by NIOSH.

An Example of a Well-Written Approval History:

The new filter media is documented on revised specification sheet ZM-FL-A02 Rev A.

The change is documented in the mask's Bill of Materials (Item 2) on page 3 of drawing 103-01 Revision M.

This modification does not affect facepiece fit, but does affect breathing resistance. Happy Breathing Company has tested the facepiece covering this extension and finds that it still meets the requirements of 42 CFR 84 for breathing resistance. Happy Breathing has not changed any of the chemical, filters, or construction for the canisters since they were granted NIOSH approval in TN-xxxxx. Happy Breathing is relying on the breathing resistance data accompanying this submission, AAR#ph24, to obtain this approval.

This change will be applicable to the XXX mask and private labels YYY & ZZZ.

C.11 DESCRIPTION OF RESPIRATOR

New approval and extension of approval information is entered in the electronic application form by selecting options from list boxes. The respirator description fields vary based on the type of respirator selected. Both new and extensions of approval require a detailed narrative description.

C.12 INTENDED PROTECTION AND SAFE DESIGN

Air-Purifying respirators only: State all contaminants for which approval is sought. Chemical cartridges (23C or 84A) must identify the specific contaminants for which approval is sought (e.g., chlorine, chlorine dioxide, etc.). Gas masks (14G) can list specific contaminants for which approval is sought, or may use “Acid Gas” as a protection if the protection applies. **NOTE:** NIOSH does not permit the use of any form of chromium-impregnated sorbent material due to the suspected carcinogenic effects. In the case of CBRN respirators (APR and PAPR), identify the capacity level requested as CAP 1, 2, 3 or other. For CBRN air purifying escape respirators (APER), identify the rated duration as CBRN Escape 15, 30 or other.

Atmosphere-Supplying respirators only: Confirm that any materials used in the construction of the respirator which may be exposed to oxygen pressures above atmospheric pressure are safe and compatible for their intended use (e.g., exposure to elevated concentrations of oxygen). Identify CBRN when applicable.

Combination Air-Purifying Atmosphere-Supplying respirators: Follow the requirements of both Air-Purifying and Atmosphere-Supplying respirators above.

The term “Intended for Mine Use” identifies respirators to be used for emergency use in mines. We require this information to determine if the application must be evaluated and approved by both NIOSH and the Mine Safety and Health Administration (MSHA). Respirators to be used for mine rescue and other emergency use in mines must be approved by MSHA under 30 CFR Part 75.1714. If you have questions regarding the need for co-approval, please call NIOSH. See *How to Contact the NIOSH Conformity Verification and Standards Development Branch (CV&SDB)* in the front of this document for the phone number.

C.13 PRE-SUBMISSION TEST DATA AND STATEMENTS

Respirator performance test data must accompany each application and must:

- Specify components used for test configuration by part number
- Show units of measure for all test data (units of measure must match 42 CFR 84 criteria)
- Submit copies of actual test data with all results and conclusions

A “Respirator Test Selection Guide” is provided for reference in Section E. NIOSH expects that the applicant will have performed each NIOSH test and any additional tests they deem appropriate during the process of validating that the device meets NIOSH approval and certification requirements.

NOTE for resistance testing: Applicant data must include resistance values for all combinations of related air-purifying respirators (including combination units). This data must be representative of each complete assembly (including facepiece) for which approval is being sought. For resistance testing, NIOSH will test and verify the highest and lowest resistance combinations reported by the applicant.

When an end of service life indicator (ESLI) is required on an air-purifying respirator due to poor warning properties of a gas or vapor, include information:

- demonstrating that the ESLI is a reliable indicator of sorbent depletion,
- on the effects of any industrial chemical interference with the indicator,
- on the shelf life of the indicator,
- affirming that the ESLI is visible to the user when worn, and
- affirming that the ESLI will withstand normal handling without damage

Any respirators that have an ESLI should list caution S on the approval label. Also, the User Instructions must contain a special section that is labeled “S-Special or Critical User Instructions” where the ESLI information is contained. See *Approval Labels* in Section G for an example.

C.14 MODEL NUMBERS AND PRODUCT TRADE NAMES

A product trade name that uniquely identifies the respirator or family is required. This name will be listed in the Certified Equipment List for public reference. In the electronic application for a new approval, the model number field can be blank but the product trade name field must be completed before proceeding to the next data screen. A product trade name may indicate a protection but it may not imply use. Model numbers previously used for particulate filtering devices approved under 30 CFR 11 standards may not be reused or carried over to devices or configurations to be approved under 42 CFR 84 standards, except for powered air-purifying respirators (PAPRs).

C.15 TEST SAMPLES AND HARDWARE

Regular production units submitted for approval must be the result of actual manufacturing processes, or representative thereof [42 CFR 84.11(e)]. Applications have been denied because the hardware provided for testing did not go through the manufacturer’s normal assembly, inspection, and test processes and subsequently failed approval testing. Applications are denied even if the component which failed is not related to the reason for application.

Use the "Respirator Test Selection Guide" in Section E to determine the minimum number of samples required for testing. Submit a sufficient number of samples for testing at the time of application, and under separate cover from the application. In the application and on the packing slip with the samples, list the item by part number and description and quantity submitted for testing. Also include a copy of the User Instructions in the box with the test samples.

The outside of each shipping container and packing slip should clearly indicate "Test Samples" along with the name of the applicant, applicant-assigned reference number(s), part number(s), and quantities. The sample hardware and any additional test samples requested by NIOSH must clearly show the part number on each item, regardless of how it is packaged. When additional samples are requested by NIOSH, please mark the shipment to the attention of the NIOSH person requesting the samples. Also mark the applicant-assigned reference number, task number and state “additional samples.” No cross-reference lists will be accepted.

For any material the applicant wants returned upon completion of testing, the applicant must submit pre-paid return shipping labels or provide other return means with the samples. Indicate, "Please return samples" on the packing slip. If NIOSH denies an application based upon documentation issues, the application and in most cases, all sample hardware will be returned.

NIOSH does not retain samples for any completed projects, approved or denied. If prepaid return shipping instructions are not provided, the samples will be promptly destroyed. NIOSH is not responsible for customs charges. The applicant is responsible for all shipping costs. The applicant is responsible for making all arrangements to clear the hardware through customs when shipping hardware to or from NIOSH.

The sample hardware submitted with the application will be tested. No substitutions, additions, or deletions are permitted by the applicant after receipt of the application at NIOSH. If NIOSH evaluators determine a need for additional testing, additional samples may be requested.

C.16 QUALITY ASSURANCE DOCUMENTATION

Understanding the requirements of 42 CFR 84 and specific quality system characteristics as noted below are necessary to adequately design and maintain quality assurance and quality control programs acceptable to NIOSH. Prior to obtaining any approvals under 42 CFR 84, all approval holders are required to have an approved Quality Assurance Manual on file at NIOSH. Any submittals for existing approvals under Part 11 must be made under 42 CFR 84 guidelines.

If you have previously had a Quality Assurance Manual approved and there is no change, complete the applicable blocks on the SAF. If a previously-approved Quality Assurance Manual is being revised, it is not necessary to submit the entire manual. Submit only the sections that have been revised and an updated revision history sheet.

PART 1. Quality Assurance Manual

Submit a Quality Assurance (QA) Manual that will document, as a minimum, the system characteristics of the following elements:

- A. Statement of Quality Assurance
 - Upper management approval of the manual (usually a signature)
 - A revision history sheet showing date and reason for revision
 - A Table of Contents
 - Management assurance that the QA system meets NIOSH requirements
- B. Description of Management Responsibilities as they relate to:
 - the company Quality policy
 - Organization of personnel
 - Verification of quality (internal auditing)
 - Quality system review
 - ISO Certifications (if applicable)

- C. Structure of Quality System
 - Identify how quality procedures and instructions are prepared and implemented
- D. Contract Review Activities
- E. Design Control for aspects of safety, performance, and dependability of the product reliability programs
- F. Control of all documents and data
- G. Quality in Purchasing
- H. Control of Customer-Supplied Product
- I. Product Identification and Traceability
- J. Control of Production Processes
- K. All areas of Inspection and Testing: Receiving, In-process, and Final Inspection
- L. Control of Inspection, Measuring and Test Equipment
- M. Inspection and Test Status
- N. Control of Nonconforming Product
- O. Corrective and Preventive Actions
- P. Inventory and Handling Controls
- Q. Control of Quality Records
- R. Internal Quality Audits
- S. Training
- T. Servicing

PART 2. Product Quality Control Plan and Documentation

Quality documentation is required to be submitted as part of an application to demonstrate to NIOSH the manufacturer's process characteristics involved in controlling and monitoring the quality of the respirator being manufactured. NIOSH reserves the right to request additional information such as procedures and sub-assembly drawings to determine if an effective quality plan has been designed and is being implemented.

One Product Quality Control Plan (PQP) must be submitted for each particular respirator or product line. Graphical flow charts are the best representation of an applicant's production process; however, text form is acceptable. The PQP must be submitted with the initial application for a respirator or product line, and whenever there are changes to the manufacturing process or inspection/test documents.

Inspection procedures are required to meet the requirements outlined in 42 CFR 84, Subpart E, *Quality Control*. Test procedures are required to demonstrate compliance with the applicable test requirements in 42 CFR 84 for the respiratory protection provided by the respirator. The applicant must define critical and major characteristics for each respirator and its components. Minor characteristics must be on record with the manufacturer. Items that must be submitted are the:

- A. PQP flowcharts showing all inspection and test operations and identifying each procedure by applicant-assigned document number. Inspection or test procedures must be clearly identified on the flow chart.

- B. Sampling plan and classification of defects document as described in Title 42 CFR 84.41 (c), (d), (e), (f), (g), and (h)
- C. In-process inspection and test procedures for those items listed on the assembly matrix
- D. Final inspection and test procedures for the completed respirator and for those items listed on the assembly matrix
- E. Drawings
- F. Assembly matrix

If inspection or test procedures were previously accepted on another project, they need not be submitted again unless they have been changed.

Whether or not an approval holder needs to notify NIOSH of component material changes depends on the definition of that characteristic as a critical, major, or minor characteristic. Minor characteristic changes that do not affect performance and/or design do not have to be submitted to NIOSH for approval if the approval records maintained by NIOSH are not affected. An example would be a color change. The approval holder is still obligated to maintain records of these minor changes which are subject to audit and shall be made available for NIOSH review upon request.

Paragraph 84.33(g) states “Each respirator, respirator component, and respirator container shall, as required by NIOSH to assure quality control and proper use of the respirator, be labeled distinctly to show the name of the applicant, and the name and letters or numbers by which the respirator or respirator component is designated for trade purposes, and the lot number, serial number, or approximate date of manufacture.” The approval holder is responsible for identifying on respirator drawings the location of this required information on their respirator.

See also the Letter to All Manufacturers of September 24, 2012 in the Appendix on “Sampling Procedures” for a more extensive discussion.

C.17 FEES

When submitting an approval request for any reason, an application fee of \$200 is required at the time of submission. If submitting a check, the check must contain the AAR number. Processing will not begin until all items (application, check, and test samples) are received. Checks are to be made payable to NIOSH. Checks must be freshly issued and should not be dated more than 14 days prior to the submittal date. If a domestic applicant utilizing Pay.Gov, please follow the instructions provided below and ensure that you reference the AAR# in the pay.gov form so that it can be linked to your approval request.

Applicants will be provided an estimate of the cost that will be incurred during the evaluation as part of the Initial Review Process. Authorization to proceed, based on the estimate, is required to proceed with the evaluation. If estimated costs will be exceeded, a new estimate will be

provided and permission to continue will be required from the applicant. During Final Review an invoice for all fees incurred in the processing of an application will be generated and provided to the approval holder for payment. Invoices will contain specific payment instructions and identify authorized methods of payment. Respirator Approval Application Based fees are as follows:

Administrative Fees:

Fee type	Legal citation	Amount	Due date
Application	42 C.F.R. §84.20(b)(1)	\$200 per application submitted	Upon receipt of any application request
Approval	42 C.F.R. §84.20(b)(1)	\$100 per each certificate of approval issued	Upon receipt of the invoice. The final letter (approval or denial) will not be issued until the invoice has been paid. Once the invoice has been paid, the final letter will be issued to the applicant.
Approval Modification	42 C.F.R. §84.20(b)(1)	\$50 per each certificate of approval modified	Upon receipt of the invoice. The final letter (approval or denial) will not be issued until the invoice has been paid. Once the invoice has been paid, the final letter will be issued to the applicant.
Site Qualification	42 C.F.R. §84.20(b)(3)	<ul style="list-style-type: none"> • Existing approval holder, paper review: \$400 per each request to inspect new production facility • Non-approval holders: <ul style="list-style-type: none"> ▫ Domestic site visit - \$2,500 ▫ International site visit - \$7,500 	Upon agreement on the date of the site qualification examination

Testing fees will be charged in accordance with the following fee tables and will be due upon receipt of the invoice. The final letter (approval or denial) will not be issued until the invoice has been paid. Once the invoice has been paid, the final letter will be issued to the applicant.

Respirator Test Fees

Air Purifying Respirator Fees:

0001 Determination of particulate filter penetration (PAPR)	\$150.00
0003 Exhalation Resistance	\$150.00
0004 Exhalation Valve Leakage	\$300.00
0005 IAA Fit Test	\$1,800.00
0005* Qualitative Fit Testing	\$1,300.00
0005A IAA Fit Test for Full Facepieces	\$1,800.00
0006 IAA Fit Test for Half Masks	\$1,800.00
0007 Inhalation Resistance	\$150.00

0012 Air Flow Determination PAPR	\$150.00
0014 Leakage of Drink Tubes and Accessories	\$300.00
0025 Silica Dust Loading for PAPRs	\$1,200.00
0030 Noise Level in PAPRs with Hoods or Helmets	\$450.00
0033A Ammonia Service Life Testing for Cartridges	\$750.00
0033B Ammonia Service Life Testing for Canisters	\$750.00
0033C Ammonia Service Life Testing PAPR Cartridges	\$750.00
0033D Ammonia Service Life Testing PAPR Canisters	\$750.00
0034 Carbon Monoxide Service Time	\$750.00
0035 Chlorine Service Time Testing	\$750.00
0036 Chlorine Dioxide Service Time Testing	\$750.00
0037 CN Service Time Testing	\$2,400.00
0038 Ethylene Oxide Service Time Testing	\$450.00
0039A Formaldehyde Service Time Testing for Cartridges	\$750.00
0039B Formaldehyde Service Time Testing for Canisters	\$750.00
0039C Formaldehyde Service Time PAPR Cartridges	\$750.00
0040 Hydrogen Chloride Service Time Testing	\$500.00
0041 Hydrogen Cyanide	\$1,800.00
0042 Hydrogen Fluoride Service Time Test	\$750.00
0043A Hydrogen Sulfide Service Time Testing for Cartridges	\$750.00
0043B Hydrogen Sulfide Service Time Testing for Canisters	\$750.00
0043C Hydrogen Sulfide Service Time Testing PAPR Cartridges	\$750.00
0044 Mercury Vapor Service Time Testing	\$2,400.00
0045A Methylamine Service Time Testing for Cartridges	\$450.00
0045B Methylamine Service Time Testing for Canisters	\$450.00
0045C Methylamine Service Time Testing PAPR Cartridges	\$450.00
0045D Methylamine Service Time Testing PAPR Canisters	\$450.00
0046A Organic Vapor (CCL4) Service Time Cartridges	\$450.00
0046B Organic Vapor (CCL4) Service Time Canisters	\$450.00
0046C Organic Vapor (CCL4) Service Time PAPR Cartridges	\$450.00
0046D Organic Vapor (CCL4) Service Time PAPR Canisters	\$450.00
0047 Phosphine Service Time Testing	\$750.00
0048A Sulfur Dioxide Service Time Testing Cartridges	\$450.00
0048B Sulfur Dioxide Service Time Testing Canisters	\$450.00
0048C Sulfur Dioxide Service Time Testing PAPR Cartridges	\$450.00
0048D Sulfur Dioxide Service Time Testing PAPR Canisters	\$450.00
0050 CS Service Time Testing	\$2,400.00
0051 Dioctyl Phthalate(DOP) P100	\$1,200.00
0052 Dioctyl Phthalate(DOP) P99	\$1,200.00
0053 Dioctyl Phthalate(DOP) P95	\$1,200.00
0054 Dioctyl Phthalate(DOP) R100	\$1,200.00

0055 Dioctyl Phthalate(DOP) R99	\$1,200.00
0056 Dioctyl Phthalate(DOP) R95	\$1,200.00
0057 NaCl (Salt) Particulate Testing N100	\$1,200.00
0058 NaCl (Salt) Particulate Testing N99	\$1,200.00
0059 NaCl (Salt) Particulate Testing N95	\$1,200.00
0060 Determination of End of Service Life Indicator Drop	\$300.00
0061 Determination of End of Service Life Indicator Visibility	\$300.00
0062 Nitrogen Dioxide Service Time Testing	\$750.00
0063 CO2 Volume Tight Fitting PAPR Running	\$300.00
0064 CO2 Volume Tight Fitting PAPR Unit Off	\$300.00
0065 Breath Response PAPR Air Flow Resistance	\$300.00
0066 Determination of End of Service Life Indicator	\$300.00
0067 Qualitative Fit Test, Bitrex or Saccharine	\$1,800.00

New Site Qualification Fee, existing manufacturer	\$400.00
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* Quantitative fit testing, using corn oil, may be performed in place of the qualitative fit testing performed with IAA, at the request of the applicant.

Supplied Air Testing Fees:

0100 Strength of Hose and Coupling, C and CE SAR	\$150.00
0101 Tightness of Hose and Couplings, C and CE, SAR	\$150.00
0102 Non-Kinkability of Hose, C and CE, SAR	\$150.00
0103 Gasoline Permeability of Hose/Couplings, C and CE	\$450.00
0104 Regulator 100,000 Cycle Test, Demand/PD, C/CE	\$3,000.00
0105 Air Flow Determination, CF, C and CE SAR	\$300.00
0105A Air Flow Determination, Demand/PD, C and CE SAR	\$300.00
0106 Inhalation Air Flow Resistance, PD, C and CE SAR	\$150.00
0107 Exhalation Air Flow Resistance, PD, C and CE SAR	\$150.00
0108 Inhalation Air Flow Resistance, Demand, C/CE SAR	\$150.00
0109 Exhalation Air Flow Resistance, Demand, C/CE SAR	\$150.00
0110 Gas Tightness Test, IAA, C and CE SAR	\$450.00
0111 Sound Level in Hood or Helmet, C and CE SAR	\$450.00
0112 Protection Level, Abrasive Blast, CE, NaCL or Corn Oil	\$450.00
0113 Air Flow Resistance, CF, C and CE SAR	\$150.00
0114 Sound Level Hood/Helmet Escape SCBA	\$450.00
0115 Rated Service Time, CF, Escape SCBA	\$150.00
0116 Air Flow Resistance, CF, Escape SCBA with Hood	\$150.00
0117 Positive Pressure, PD, CCSCBA,	\$150.00
0118 Low Temperature Operation SCBA	\$1,200.00
0119 Low Temp Operation, Combo SCBA and C/CE SAR	\$1,200.00
0120 Positive Pressure, SCBA	\$75.00
0121 Rated Service Time, SCBA, Demand and PD	\$75.00

0121A Rated Service Time, CCSCBA, Demand and PD	\$75.00
0122 Exhalation Resistance, SCBA, Demand and PD	\$150.00
0123 Gas Flow Measurement, SCBA, Demand and PD	\$150.00
0124 Remaining Service Life Indicator, SCBA, Demand/PD	\$150.00
0124A Alarm Pressure, CCSCBA, Demand and PD	\$150.00
0125 Gas Tightness, IAA, SCBA, Facepiece and Mouthpiece	\$750.00
0125A Gas Tightness, IAA, SCBA, Hoods or Helmets	\$750.00
0126 By-Pass Valve Flow, SCBA, Demand and PD	\$150.00
0127 By-Pass Valve Flow, CCSCBA, Demand and PD	\$150.00
0128 Accuracy of Gauge, SCBA	\$150.00
0132 Inhalation Breathing Resistance, Demand SCBA	\$150.00
0133 Exhalation Breathing Resistance, PD SCBA	\$150.00
0134 Gasoline Permeation of Breathing Bag, CCSCBA	\$750.00
0135 Inhalation and Exhalation Resistance, CCSCBA, D/PD	\$150.00
0136 Demand Gas Flow, CCSCBA, Demand and PD	\$150.00
0137 Continuous Gas Flow, CCSCBA, CF and Demand Flow	\$450.00
0138 Safety Relief Valve Operation, CCSCBA, Demand/PD	\$150.00
0139 CO2 Facepiece Level Determination, SCBA	\$450.00
0140 Man Tests, SCBA	\$3,000.00
0141 Man Test 5, CCSCBA	\$150.00
0142 Vibration (Ro-Tap), Man Test 1, CCSCBA, Demand Esc	\$750.00
0143 Low Temperature Operation, CCSCBA	\$1,200.00
0144 Gas Flow, Constant Flow CCSCBA	\$300.00
0145 Sound Level End of Service Life Indicator, SCBA	\$750.00
0146 Diaphragm Overpressurization, Belt Mounted SCBA	\$300.00
0147 Mode Transfer Test, SCBA/SAR	\$150.00
0148 Remote Gauge Leak Flow, SCBA, Demand and PD	\$150.00
0148A Remote Gauge Leak Flow, CCSCBA, Demand and PD	\$150.00
0155 Man Test 6, SCBA Liquefied Gas	\$2,400.00

Air Purifying CBRN Respirators:

0301 Cyclohexane (Set of 9 Canisters)	\$1,000.00
0302 Cyanogen Chloride (Set of 9 Canisters)	\$2,400.00
0303 Hydrogen Cyanide (Set of 9 Canisters)	\$2,400.00
0304 Phosgene (Set of 9 Canisters)	\$1,400.00
0305 Hydrogen Sulfide (Set of 9 Canisters)	\$800.00
0306 Sulfur Dioxide (Set of 9 Canisters)	\$800.00
0307 Ammonia (Set of 9 Canisters)	\$1,000.00
0308 Nitrogen Dioxide (Set of 9 Canisters)	\$1,200.00
0309 Phosphine (Set of 9 Canisters)	\$1,000.00
0310 Formaldehyde (Set of 9 Canisters)	\$1,000.00

0311 NPPTL Environmental Conditioning	\$16,000.00
0311 NPPTL Modified Environ. Cond.-Minus 125 Canisters	\$8,000.00
0312 Field of View	\$1,000.00
0313 Communications	\$5,000.00
0314 Fogging	\$3,000.00
0316 Haze, Luminous Transmittance & Abrasion	\$2,000.00
0350 GB (SMARTMAN) Qualifier LAT(QLAT) Only ¹	\$9,142.00
0351 HD (SMARTMAN) QLAT Only ¹	\$9,142.00
0350 GB (SMARTMAN) Remainder LAT (RLAT) ¹	\$9,142.00
0351 HD (SMARTMAN) RLAT Only ¹	\$9,142.00
0350/0351 Aerosol process TDA-99M (SMARTMAN) Only ¹	\$600.00
0352 Laboratory Respirator Protection Level (LRPL)	\$20,000.00
0352 Partial LRPL	\$16,000.00
0353 Weight & Diameter	\$200.00
0353 Canister Thread Analysis	\$1,065.00

Note: 1 Testing Performed at RDECOM

Air Purifying Escape CBRN Respirators and CBRN Self Contained Escape Respirators:

0401 Cyclohexane (Set of 9) (APER only)	\$1,000.00
0402 Cyanogen Chloride (Set of 9) (APER only)	\$2,400.00
0403 Hydrogen Cyanide (Set of 9) (APER only)	\$2,400.00
0404 Phosgene (Set of 9) (APER only)	\$1,400.00
0405 Hydrogen Sulfide (Set of 9) (APER only)	\$800.00
0406 Sulfur Dioxide (Set of 9) (APER only)	\$800.00
0407 Ammonia (Set of 9) (APER only)	\$1,000.00
0408 Nitrogen Dioxide (Set of 9) (APER only)	\$1,200.00
0409 Phosphine (Set of 9) (APER only)	\$1,000.00
0410 Formaldehyde (Set of 9) (APER only)	\$1,000.00
0411 NPPTL Environmental Conditioning	\$20,000.00
0312 Field of View	\$1,000.00
0414 Fogging	\$4,000.00
0450 GB (SMARTMAN) Qualifier LAT(QLAT) Only ¹	\$9,142.00
0451 HD (SMARTMAN) QLAT Only ¹	\$9,142.00
0450 GB (SMARTMAN) Remainder LAT (RLAT) Only ¹	\$9,142.00
0451 HD (SMARTMAN) RLAT Only ¹	\$9,142.00
0450/0451 Aerosol Process TDA-99M (SMARTMAN) ¹	\$600.00
0452 Laboratory Respirator Protection Level (LRPL)	\$20,000.00
0452 Partial LRPL	\$16,000.00
0454 Human Subject Breathing Gas Test	\$3,500.00
0417 Flammability, Heat Resistance, CO protection only	\$14,000.00

Note: 1 Testing Performed at RDECOM

Powered Air Purifying CBRN Respirators:

0501 Cyclohexane (Set of 9 Canisters), Tight Fitting	\$1,000.00
0502 Cyanogen Chloride (Set of 9 Canisters) Tight Fitting	\$2,400.00
0503 Hydrogen Cyanide (Set of 9 Canisters) Tight Fitting	\$2,400.00
0504 Phosgene (Set of 9 Canisters) Tight Fitting	\$1,400.00
0505 Hydrogen Sulfide (Set of 9 Canisters)Tight Fitting	\$800.00
0506 Sulfur Dioxide (Set of 9 Canisters) Tight Fitting	\$800.00
0507 Ammonia (Set of 9 Canisters) Tight Fitting	\$1,000.00
0508 Nitrogen Dioxide (Set of 9 Canisters) Tight Fitting	\$1,200.00
0509 Phosphine (Set of 9 Canisters) Tight Fitting	\$1,000.00
0510 Formaldehyde (Set of 9 Canisters) Tight Fitting	\$1,000.00
0511 Cyclohexane (Set of 9 Canisters) Loose Fitting	\$1,000.00
0512 Cyanogen Chloride (Set of 9 Canisters) Loose Fitting	\$2,400.00
0513 Hydrogen Cyanide (Set of 9 Canisters) Loose Fitting	\$2,400.00
0514 Phosgene (Set of 9 Canisters) Loose Fitting	\$1,400.00
0515 Hydrogen Sulfide (Set of 9 Canisters) Loose Fitting	\$800.00
0516 Sulfur Dioxide (Set of 9 Canisters) Loose Fitting	\$800.00
0517 Ammonia (Set of 9 Canisters) Loose Fitting	\$1,000.00
0518 Nitrogen Dioxide (Set of 9 Canisters) Loose Fitting	\$1,200.00
0519 Phosphine (Set of 9 Canisters) Loose Fitting	\$1,000.00
0520 Formaldehyde (Set of 9 Canisters) Loose Fitting	\$1,000.00
0550 GB (SMARTMAN) Qualifier LAT(QLAT) Only1	\$9,142.00
0551 HD (SMARTMAN) QLAT Only1	\$9,142.00
0550 GB (SMARTMAN) Remainder LAT (RLAT)1	\$9,142.00
0551 HD (SMARTMAN) RLAT Only1	\$9,142.00
0550/0551 Aerosol process TDA-99M (SMARTMAN) Only1	\$600.00
0552 Laboratory Respirator Protection Level (LRPL) Tight	\$20,000.00
0552 Partial LRPL Tight Fitting	\$16,000.00
0553 Laboratory Respirator Protection Level (LRPL). Loose	\$20,000.00
0553 Partial LRPL Loose Fitting	\$16,000.00

Note: 1 Testing Performed at RDECOM

Self-Contained Breathing Apparatus and Retrofit, CBRN:

0200 GB LAT 1	\$9,142.00
0201 HD LAT 1	\$9,142.00
0202 LRPL	\$20,000.00
0202 Partial LRPL	\$16,000.00
0200/0201 Aerosol Process TDA-99M (SMARTMAN) Only	\$600.00

Note: 1 Testing Performed at RDECOM

Test Fees to be charged for New and Unspecified Tests:

All Closed-Circuit Escape Respirator (CCER) testing	\$500/ day for testing plus actual costs for test subjects and required medical coverage
All Wildland Firefighting Respirator testing	\$500/day for testing plus actual costs for test subjects and required medical coverage
Emergency Breathing Safety System (EBSS) testing for SCBA	\$500/day for this test plus actual costs for test subjects and required medical coverage

Annual approval maintenance fees are also charged for approval holders who hold active and/or obsolete certificates of approval. These fees will be invoiced by NIOSH annually. Invoices will be provided in September with payment due by October 30 of the applicable year. Invoices will itemize the number of manufacturing sites and approvals and apply the fees per the following table:

Maintenance Fees:

Fee type	Legal citation	Amount	Due date
Maintenance of Product Performance (product audit)	42 C.F.R. §84.20(b)(5)	<ul style="list-style-type: none"> • Annual fee: \$761 per each approval holder • Variable fee: as billed by NIOSH based on the respirators chosen to be tested each year 	October 30 of applicable year
Records Maintenance	42 C.F.R. §84.20(b)(1)	\$50 per every listed ¹ approval on file with NIOSH on July 1 st of each year	October 30 of applicable year
Quality Assurance Maintenance (site audit)	42 C.F.R. §84.20(b)(4)	<ul style="list-style-type: none"> • Annual fee: \$3,000 per every manufacturing site registered with NIOSH • Variable fee:² <ul style="list-style-type: none"> ▫ 1 day domestic audit - \$2,500 per site ▫ 2 day domestic audit - \$5,000 per site ▫ 1 day international audit - \$7,500 per site ▫ 2 day international audit - \$10,000 per site 	October 30 of applicable year
Maintenance of Testing and Approval Facilities	42 C.F.R. §84.20(b)(2)	\$34 per every listed ¹ approval on file with NIOSH on July 1 st of each applicable year	October 30 of applicable year
Maintenance of Test Equipment	42 C.F.R. §84.20(b)(2)	\$36 per every active ³ approval on file with NIOSH on July 1 st of each applicable year	October 30 of applicable year

1. "Listed" approvals include all active and obsolete approvals. The Certified Equipment List (CEL) reflects the current listed approvals maintained by NIOSH. See <http://www.cdc.gov/niosh/npptl/topics/respirators/CEL/default.html>.

2. Applies to design as well as manufacturing sites.

3. Does not include obsolete approvals

Checks are to be made payable to NIOSH. Checks must be freshly issued, not dated more than 14 days prior to the submittal date, and must reference the AAR# or NIOSH invoice number.

PAY.GOV Instructions:

Domestic applicants may use the electronic fees transfer program known as PAY.GOV.

Step 1 – Prior to making any payment of respirator approval fees, applicants must establish an account with PAY.GOV.

- A. Follow the web link provided below:
 - a. PAY.GOV homepage: <https://pay.gov/paygov/homepage>
- B. On the center of the web page click on the link “Click here to register” to start the process or go to the web page address provided below:
 - a. Registration: [Pay.gov - Register for a Pay.gov Account](#).
 - b. Read the User Responsibility Statement fill in the box and select accept.
 - c. Select the “Continue with Self Enrollment” tab.
 - d. Complete the required field in the On-Line Self Enrollment form and then select “submit.”
 - e. With your Pay.Gov user name and password, log into the Pay.Gov system from the home page.
 - f. Access the forms necessary to submit payments on-line using this process.
- C. Fee Payment User Instructions
 - a. Open the Pay.Gov home page.
 - b. Locate the “User Fee Form”.
 - i. Go to the Fine Public Forms section below the log in.
 - ii. You can search for forms by three options:
 1. Form Name
 2. Agency Name
 3. Search Public Forms
 - iii. Use one of three links listed of the six forms in the system for the Centers for Disease Control and Prevention (CDC)
 1. Form Name: CDC Royalty BMLA and User fee Form.
 - a. Select CDC User Fee Form.
 2. Agency Name: CDC Royalty BMLA and User Fee Form.
 - a. Select CDC User Fee Form.
 3. Search Forms: CDC Royalty BMLA and User Fee Form.
 - a. Select CDC User Fee Form.
 4. Click on the form name to open the On-line fillable form.
 - iv. Complete the On-line CDC User Fee Form.
 1. Complete all mandatory blocks marked with asterisks.
 2. Under CDC Invoice No., enter your three digit Applicant Assigned Reference number (AAR#).
 - a. If payment is for an existing Task Number, (TN), enter the associated TN number.
 3. For “Payment Options,” select the “NIOSH User Fee” from the three choices.

4. Enter a short description in the comments block regarding the payment. Add any specific identifying information regarding the submission that may help in processing the payment.
- c. When you submit the form you will be prompted to enter your Automated Clearing House (ACH) debit information.
- D. Currently Pay.Gov accepts payment directly by the Automated Clearing House (ACH) feature or through credit or debit cards as follows:
 - a. Credit Cards: Visa, MasterCard, American Express and Discover.
 - b. Debit Cards: Visa, MasterCard processed only.

(Note: more in depth instructions and information can be found on [Pay.Gov homepage](#).)

C.18 ASSEMBLY MATRIX

An assembly matrix must be submitted electronically in Microsoft Excel 97 or above formats. An assembly matrix is a table of major sub-assemblies and accessories and must be formatted as shown in the example in Section G. The assembly matrix cannot be part of the exploded view drawing.

An “X” placed in the wrong box on a label or assembly matrix may be a simple error from an approval holders’ perspective but this simple error can cause NIOSH hours of needless research to verify whether or not the component is approved.

When a series of applications involving a common assembly matrix are submitted, only one assembly matrix need be submitted. This assembly matrix must be submitted with the last application in the series. The applicant-assigned reference number for the application that contains the assembly matrix must be identified in the *Approval History* section of each application in the series.

When a new TC number is being requested, identify the rows for your new TC number using the numbering convention of “schedule #, AAR#, alpha character” in the TC Number column. For example, if your Schedule# is 84A, and your AAR# is MOR699, the TC Number cell for the first row of the new approval would be 84A-MOR699a. The second row would be numbered 84A-MOR699b; the third row would be numbered 84A-MOR699c, etc. “TC-“ can only appear in the column heading; do not use “TC-“ in the assembly matrix row.

Features that describe the respirator cannot be listed on the assembly matrix as a separate column. Features associated with specific model numbers may be coupled together in the description column heading (e.g., Model 1201-Low Flow, Model 1202-Easy Flow, etc.).

In addition to listing the required respirator components, there must be a column that lists the part number and revision level of the most current User Instructions. Schedule 13F approvals for SCSR’s must also include the part number and revision level of the service life plan. Please note, that the listing of user’s instructions on filtering facepiece assembly matrices is not required.

More than one assembly matrix may be submitted with an application if relevant.

Columns with information shall not be shaded. Assembly matrices may not contain future submittals or show unapproved assemblies. Ensure that blank cells are entirely blank and do not contain any unnecessary information, spaces, embedded characters, hidden rows or columns, etc.

The complete respirator and/or the respirator components listed on the assembly matrix must match exactly to those illustrated on the exploded view drawing. If the facepiece is numbered 1a, 1b and 1c on the assembly matrix, it is also numbered 1a, 1b, and 1c on the exploded view drawing.

When more than one of the same major sub-assembly is listed on the assembly matrix row, they must be identified as alternate components by stating "Alternate" in the column heading.

Some components may be an accessory on one approval and a required component on another. The Reason for Application must explain if a component is an accessory, otherwise NIOSH will assume the component is required. The assembly matrix must list all major sub-assemblies and accessories, and indicate the NIOSH evaluation status for each component or sub-assembly as follows:

- X** = an existing component that has been previously tested and approved by NIOSH in this configuration.
- N** = a new component. If a new TC number has been requested, "N" must appear in every column across the entire row. If an Extension of Approval is requested, "N" should only appear in columns for components new to the approval.
- P** = Pending. A component submitted in an earlier application that is currently being evaluated by NIOSH.
- R** = a re-design or revision of an existing component where the part number has not changed. In addition, R is to be used indicating a change to any associated document with that component.
- = a component designated by the approval holder as obsolete. No "double dash" marks are allowed. An obsoleted item must be shown on the matrix as obsolete for the TC number/Part number combination at least once. Once you have submitted an assembly matrix with obsoleted items, you may drop these items from the matrix in future submissions. If obsoleting an approval then dash marks must be in every block that a component for that approval was marked.
- A** = **Accessory** item. An item that does not affect the ability of a respirator to meet the requirements of 42 CFR 84. The approval remains in effect whether the accessory is used or not.

For easier review and evaluation, it is recommended that you color or **bold** the rows and columns containing new or redesigned (N or R) components. If no cells are marked N or R, the applicant should reconsider whether an application for approval is required. If in doubt, call NIOSH. Refer to *How to Contact the NIOSH Conformity Verification & Standards Development Branch (CV&SDB)* for the phone number.

C.19 DRAWINGS

All drawings must be in English. All engineering and CAD drawings must be saved and submitted in full view mode and in black and white. There should be only two levels of drawings submitted for an application, the exploded view drawing and major sub-assemblies. The signature blocks on each submitted drawing must contain the initials or signature of the preparer and approver along with the approval date for the drawing revision.

EXPLODED VIEW DRAWING

Applicants must submit an exploded view drawing (see Section G) showing all major sub-assemblies of the respirator assembly. The only exception is that the User Instructions and Service Life Plans do not need to be illustrated on the exploded view drawing. The exploded view drawing must not contain dimensions, future submittals or unapproved assemblies.

To reference major sub-assemblies from the assembly matrix to the exploded view drawing, an identifying numbering system of the major sub-assemblies on the exploded view drawing must match exactly with an identifying numbering system on the assembly matrix. If a facepiece is shown as item 1 on the assembly matrix, it will also be item 1 on the exploded view drawing. The applicant may use dotted lines around sub-assemblies on an exploded view drawing to group the smaller parts together into one major sub-assembly. If the profile of a component changes, i.e., from a facepiece to a facepiece with side window, the components must be shown separately as 1a, 1b, etc.

Special note for filtering facepieces and disposable respirators only: For filtering facepieces, mouthpiece respirators and disposable respirators, the exploded view drawing is the major sub-assembly drawing, and will show the complete respirator with critical or major dimensions, materials, and characteristics as listed on the checklists.

MAJOR SUB-ASSEMBLY DRAWINGS

Applicants must submit major sub-assembly drawings for each major sub-assembly shown on the exploded view drawing. If a major sub-assembly is unchanged from a previous submittal and the drawing is already on file at NIOSH, the drawing does not have to be re-submitted.

The major sub-assembly drawings may not contain future submissions or show unapproved assemblies.

All major sub-assembly drawings must meet the requirements defined in the “Major Sub-Assembly Drawing Checklists” found in Section F.

All drawings must be under the approval holder’s control and in compliance with their document control system.

Major sub-assembly drawing numbers and revision levels must match exactly with those found on the assembly matrix.

Major sub-assemblies must have permanent identifying part numbers marked on them. This part number must appear in the part number row of the assembly matrix. The part number location must be clearly shown on the major sub-assembly drawings.

MATERIAL SPECIFICATIONS ON DRAWINGS

For material specifications, use the criteria of affecting performance and/or design. For example, if an accessory would not affect the performance and/or design, materials could be identified as plastic, metal, rubber, etc. But if the items did affect performance and/or design, they would be identified as stainless steel 480, butyl rubber, etc.

Couplings must be specified by both type and manufacturer, even if the type is a manufacturer name. For example, we would interpret Foster-Schrader to be a Schrader style/compatible coupler manufactured by Foster. In addition, the specific model or part number must be identified. Do not use the phrase “or equivalent.”

COMPONENT VENDORS

Component vendors need not be specified if the applicant controls all specifications for the component. If the applicant does not determine all specifications of the component, then the applicant must provide the name of the vendor. Per 42 CFR 84.42(c) and 84.43(c), the approval holder is obligated to manufacture to the documentation in effect at the time the approval is issued.

Also see the April 7, 2005 Letter to All Manufacturers in the Appendix on “Clarification of Supplier and Subcontractor Relationships” for a more in-depth discussion.

C.20 APPROVAL LABELS AND PRIVATE LABELS

Approval labels used in final User Instructions, on packaging, or on devices must be legible. Labeling requirements will vary based on the type and intended use of the respirator. See Section G for example label formats for different respirators. The list of protections must be in the same order and identical in every way to the matrix. Submit draft versions of the appropriate labels. If you're not able to submit draft labels, you must obtain pre-authorization from NIOSH for each application.

Labels must be submitted for all New Approvals and for Extensions of Approval where the components change. Labels must be done in Excel and follow the format of the examples in Section G. All major sub-assemblies in the approved respirator configuration must be on the approval label. Accessories may be listed on the approval label, but are not required. Due to the large size of the files when the NIOSH and DHHS logos are imbedded, NIOSH will accept draft labels with the location of the logos noted. The applicant is responsible for inserting the logos during label production. Approval Labels may not contain future submittals or show unapproved assemblies.

COMPLETE LIST OF NIOSH STANDARD CAUTIONS AND LIMITATIONS BY BASIC RESPIRATOR TYPE

Filtering Facepiece: A, B, C, J, M, N, O, P

Chemical Cartridge (no filter): A, B, C, H, I*, J, K*, L, M, N, O, S*AA*, FF

Chemical Cartridge (with filter): A, B, C, H, I*, J, K*, L, M, N, O, P, S*AA*,FF

Gas Mask: A, H, I*, J, L, M, N, O, P, S*, AA*, BB, CC, FF

PAPR (HEPA only): A, B, C, F, I*, J, L, M, N, O, P, S*, AA*, FF*

PAPR (G/V cartridge only): A, B, C, F, H, I*, J, K*, L, M, N, O, S*, FF*

PAPR (G/V cartridge & HEPA): A, B, C, F, H, I*, J, K*, L, M, N, O, P, S*, FF*

PAPR Gas Mask: A, F, H, I*, J, L, M, N, O, P, S*, BB, CC, FF*

SAR (Air Line): A*, B, C, D, E, I*, J, K*, M, N, O, S*

SAR combination (with cart. and/or filter) A*, B, C, D, E, G, H, I*, J, K*, L*, M, N, O, P, S*, AA, FF*

SCBA: I*, J, M, N, O, S

CBRN APR: A, I*, J, L, M, O, R, S*, T, V, W, X, Y, Z, CC, HH, QQ, UU

CBRN APER: A, I*, J, L, M, O, R, S*, X, AA, DD, EE, GG, II, JJ, NN

CBRN PAPR (loose fit 23C) A, B, C, F, H, I*, J, L, M, N, O, R, S*, Y, GG, QQ, UU, VV

CBRN PAPR (tight fit 14G) A, F, H, I*, J, L, M, N, O, R, S*, Y, Z, BB, CC, GG, UU, VV

CBRN SCER: I*, J, M, N, O, S*, R, X, AA, BB, DD, EE, JJ, GG, II, NN

CBRN SCBA: I*, J, M, N, O, S, Q, R, T, U

* Notes:

A- For a SAR, this is not needed if the unit is equipped with an escape bottle

- I- Applies if the respirator contains electrical components and the intrinsic safety has not been evaluated and approved by MSHA or a recognized independent laboratory.
- K- When used with half mask, gas proof goggles are required.
- S- With unique or unusual design or critical operation requirements or a private label version.
- AA- Depending on use or design such as a mouthbit
- II- Applies only with CO protection
- FF- If face-mounted cartridge or canister only
- LL- If protection varies depending on assembled configuration

Closed Circuit SCBA: An S will be assigned to all units referring users to the Special section in the User Instructions. The User Instructions are to call out the following wording as listed in Federal Register Notice Volume 50. No. 222 published 11/18/85:

Limitations:

- Do not use this apparatus where there is direct exposure to flames or in high radiant heat (this limitations applies to 100 percent oxygen apparatus only)
- Provide proper care, training and maintenance of the apparatus as specifically described in the manufacturer's instructions and maintenance manuals.
- After each use of this apparatus, a fully charged breathing gas container and a recharge of carbon dioxide scrubber shall be installed.
- Thorough cleaning and disinfecting of facepiece, breathing tube and breathing bag must be done in accordance with manufacturer's instructions

Cautions:

- Keep exposed hair to a minimum when using apparatus near open flames or in radiant heat
- A good facepiece seal is important since facepiece leakage will seriously reduce service time
- Use of pure oxygen or oxygen enriched air increases flammability and lowers the ignition temperature of most materials.

Cautions and limitations may vary or additional ones may apply depending on design and performance.

Combination units usually require all cautions and limitations from either type.

Cautions and limitations for Closed Circuit Escape Respirators (CCER), Self-Contained Self Rescuers (SCSRS) and Filter Self Rescuers (FSR) will be determined based on design and use.

If the respirator contains electrical components and the applicant wishes to list the respirator on the NIOSH approval label as intrinsically safe, first obtain intrinsic safety approval from the MSHA under Title 30 CFR Part 18 or other recognized independent laboratory and submit verification of such approval in the application.

Private Labeling vs. Private Packaging

Under Private Labeling, Approval Holder A may enter into an agreement to allow Company B to sell Approval Holders A's respirator as being manufactured by Company B. In doing so, all packaging, labeling, markings, User Instructions and other marketing literature should reflect Company B. Such an approach appears to the user that the approval holder of the respirator is Company B. The only reference to the approval holder is in a Special Instructions S section. The respirator name, model numbers and part numbers may or may not be the same as that used by Approval Holder A. However, the NIOSH TC number will not be changed. Approval Holder A remains liable for the respirator quality and all packaging, labeling, markings and other marketing literature which pertains to the NIOSH approval. Approval Holder A must ensure that the private labeler does not misrepresent the NIOSH approval. Private labeling is always submitted to NIOSH for approval.

Application to Private Label is accomplished by completing an Extension of Approval. An Extension of Approval is necessary for all private label requests. If a part number or model number changes, the Extension of Approval must be submitted showing this change in the assembly matrix and all labeling.

A Special Cautions and Limitation "S" is to be added to the private label approval label. A "S-Special Instructions Section" is to be added to the private label User Instructions as follows:

The model/part number "respirator type" has been manufactured by approval holder Company A for private label Company B under TC-XXY-nnnn

Under Private Packaging, Approval Holder A may enter into an agreement to have its respirators sold by Company B whereby Company B puts the assembled respirator in a different or additional package. In doing so, the respirator name, model number, part number, respirator labeling, markings, user instructions and other marketing literature must show Approval Holder A as being the approval holder. The packaging may represent Company B and its catalog or other reference number. However, this packaging must be done in a manner which does not purposely mislead the user into thinking that Company B is the approval holder. It is recommended that clarifiers be included on the packaging, for example, "Sold by Company B and Manufactured by Approval Holder A" or "Made by Manufacturer A for Company B." The NIOSH approval label will not be changed. Approval Holder A remains liable for respirator quality and all packaging, labeling, markings and other publicity that pertains to the NIOSH approval. Approval Holder A must ensure that the private packager does not misrepresent the NIOSH approval. The Institute need not be notified of Private Packaging arrangements.

PLEASE NOTE: Private Packaging does not result in any changes to any NIOSH documentation on file for the approved respirator configuration. User Instructions and NIOSH approval labels that are printed on the respirator carton and the carton artwork are part of the NIOSH documentation and must not be changed to remain a Private Packaging arrangement.

C.21 USER'S INSTRUCTIONS

User Instructions must be submitted to NIOSH for all respirator types, and must be listed in a column on the assembly matrix as a controlled document with a part number and revision level. User instructions are not required to be listed on the assembly matrix for filtering facepiece respirators. Changes to the User Instructions require an Extension of Approval. All User Instructions and associated procedures such as maintenance requirements, inspection procedures, donning and doffing instructions, etc. that pertain to the respirator for which approval is sought must be submitted as a complete document. NIOSH will not accept only the amended pages. The file description for the *User Instructions* must clearly and specifically identify the model or product line and revision level (refer to the table of file-naming conventions in Section B.1). To facilitate the NIOSH review process, please bold, underline or otherwise clearly note all changes in the User Instructions from the prior revision level.

NOTE: User Instructions will not be allowed to compensate for design issues.

User Instructions/instruction sheets for retrofit or conversion kits approved for use on NIOSH-approved respirators must reference the specific NIOSH approval numbers to which they apply.

For Caution and Limitation S, Special or Critical User Instructions, noted on the approval label and listed in the User Instructions:

Approval Holders have discretion in what they would identify as special cautions or limitations. However, to be “special” it must go beyond the standard Cautions and Limitations and be unique or unusual for the class of respirator.

If the approval holder states “special or critical user’s instructions and/or specific use limitations apply,” they must be readily identified within a separate section of the User Instructions with the heading, “*S - Special or Critical User’s Instructions.*” Examples of special or critical instructions would be SCBA cold temperature use limitations, special donning procedures, service life limitations, hose lengths, number of connections, pressure ranges, and end of service life indicators.

For private label respirators the S- Special or Critical User Instructions section in the private label holders’ user instructions will state:

The model/part number “respirator type” has been manufactured by approval holder Company A for private label Company B under TC-XXY-nnnn

If special or critical user instructions and/or specific use limitations are stated, these items will be reviewed to ensure they are correct and appropriate.

For all tight fitting respirators that must be fit tested prior to use, the following OSHA reference must be included in the user instructions:

Before occupational use of this respirator a written respiratory protection program must be implemented meeting all the local government requirements. In the United States employers must comply with OSHA 29 CFR 1910.134 which includes medical evaluation, training, and fit testing.

For all air purifying respirators that include a nuisance level odor removal layer in the filter or other design, the following must be included in the user instructions:

This respirator offers nuisance level relief from (type of odor (such as organic vapors)) that are below the Permissible Exposure Limit (PEL). Nuisance level refers to concentrations not exceeding the OSHA PEL or other government occupational exposure limits, whichever is lower.

Requirements Specific to Air-Supplied Respirators

The approval labels must be included in the User Instructions for all Air-Supplied Respirators, including combination air-purifying/supplied-air respirators and combination gas mask/supplied-air respirators. The approval label may be an insert in the User Instructions.

Requirements Specific to Air-Purifying Respirators

The approval label may be placed on the container or inserted in the box or User Instructions.

For filtering facepieces, location of the approval label and User Instructions within the final packaging arrangement, are to be stated either on the respirator drawing or as an attachment to these documents. Packaging artwork is not required but will be accepted as fulfillment of this requirement.

For all respirators equipped with passive End of Service Life Indicators, wording that emphasizes visibility without manipulation to the respirator, cartridges, filters, or facepiece may be used. For example:

S - Special or Critical User Instructions: This respirator is equipped with a passive End of Service Life Indicator (ESLI). The ESLI must be readily visible to the wearer of this respirator without manipulation of the respirator, cartridges, facepiece or indicator. If you cannot readily see the indicator, do not wear the respirator.

In addition, information necessary to explain the color change or any other operational mechanism of the ESLI should be included.

C.22 SERVICE LIFE PLAN - LIMITED TO ALL CLOSED-CIRCUIT EMERGENCY ESCAPE RESPIRATORS AND CBRN AIR PURIFYING ESCAPE RESPIRATORS

Include a service life plan which contains information on reliability engineering methodology and appropriate service life dates that the user may rely upon for determining safe and reliable performance of the respirator under intended use conditions. The service life plan is a separate document from the User Instructions. Technical details for consideration must include:

- storage life of the various components based on intended use and environment
- component deterioration with time, both chemically and physically
- the useful life of elastomers including o-rings, breathing tubes, and seals
- packaging design specs to eliminate deformation and enhance timely deployment
- carrying characteristics which include expected daily shock and vibration assault
- life expectancies of compressed gas cylinders, chemical scrubbers, and oxygen generators with expected moisture effects and degeneration over time
- inspection procedures which address daily and periodic validation of condition to assure acceptability for emergency use
- specific shelf, deployment, or carrying life as applicable and interdependency
- intrinsic safety characteristics
- acceptable end-user maintenance vs. return to approval holder for service
- allowable conditions of use including applicable regulations governing use
- other characteristics to the specific SCSR design required to determine the weakest links and expected acceptable performance over the approved service life of the unit
- description of how units will be date marked to clearly identify when the unit is to be removed from service. The date used can be the manufacturing date, deployment date, or terminal end-of-service life date.

The service life plan must be based upon, and include, solid reliability engineering data that clearly show component parts are good for the requested service life. This data can be manufacturer data, accelerated aging test data, literature review data, or data derived from actual field experience with similar components of the same material. An example would be a breathing tube of similar design and the same material used on another respirator under similar expected conditions.

Service life plans may be a composite of text document, spreadsheet, database file with drawings inserted or attached. Where composite documents are produced, NIOSH prefers that all parts be merged into a single document in a NIOSH-compatible format of the approval holder's choice.

When the service life plan changes, clearly delineate what has changed in the document by either bolding or underlining text changes when the updated draft is submitted for approval.

The service life plan is to be listed on the assembly matrix drawing in a separate column as a controlled document showing the part number and the revision level.

NOTE: The service life plan is not to be confused with the air-purifying cartridge service life which indicates the length of time required for an air-purifying element to reach a specific effluent concentration or the time for which adequate breathing gas is supplied.

C.23 PACKAGING, ART WORK AND CARTON DESIGN

Under 42 CFR 84.33 the applicant must submit with their application full-scale reproduction approval labels with a sketch or description of the method of application and position on the containers (cartons, boxes, etc.).

The following guidelines should be used in preparing the packaging and advertising of NIOSH-approved particulate respirators advertised and marketed as “Surgical Masks” and used in the health care industry:

Package advertising using phrases such as “NIOSH-approved surgical mask,” or “NIOSH-approved, fluid resistant and less costly,” or “NIOSH-approved high efficiency N95 respirators” is misleading and misrepresents the NIOSH approval status. While these individual phrases themselves may be accurate approval holders may not imply that a respirator is NIOSH-approved for any characteristic for which it has not been tested or evaluated by NIOSH. NIOSH cautions approval holders to carefully review all packaging, advertising and sales literature and correct any materials which imply that NIOSH has evaluated or approved respirator characteristics that are outside the requirements of 42 CFR 84. NIOSH does not recognize N95 respirators as “high efficiency,” therefore this advertising is misleading and not permissible.

Approval holders may not imply “use” for approved respirators. For example, packaging may not say “NIOSH-approved Paint Spray Respirator.” It may say “NIOSH approved OV/P100 respirator; approval holder recommended for lacquer paints.” Additionally, the trade name may not imply use, such as “Paintspray Plus.”

The following guidelines are presented for use in preparing packaging, advertising and sales literature:

1. A standard caution on the NIOSH approval label for respirators certified to use particulate filters is “P - NIOSH does not evaluate respirators for use as surgical masks”. Therefore the terms “NIOSH approved” and “surgical mask” should not be used in the same sentence or appear on the same or subsequent line in advertising or on packaging.
2. Since FDA requires the words “surgical mask” to appear on two of the four side panels making up a container, the NIOSH approval label should not appear on these two panels. It is suggested that all information related to the NIOSH approval, including the approval label, applicable cautions, limitations, and warnings, and instructions for use be listed on a different panel from the two containing the words “surgical mask.” FDA clearance documentation must be included with the respirator application.
3. Bullet items such as “fluid resistant,” “less costly,” “comfortable fit,” etc. that are not specific criteria found in 42 CFR 84 should not be used with the terms “NIOSH approval” or “NIOSH-approved”.

NIOSH does not directly approve advertising and sales literature. Approval holders that follow the suggested guidelines listed above do not have to submit packaging changes to NIOSH.

Approval holders may refer to their respirators as surgical masks or any other associated medical name *only* if they have been cleared by the U. S. Food and Drug Administration (FDA) as a surgical mask. In addition, do not imply that the respirators have been approved by NIOSH as surgical masks.

All packaging, whether by private label or private packager, must conform to the above guidelines.

C.24 SUMMARY OF RELATED DOCUMENTS

Provide a complete and accurate listing of all new and/or revised files that pertain to the current application. Give a specific file name to each controlled document submitted with the application. The summary of related documents must precisely match the electronic files submitted. Applications may be returned without being processed if the summary is incorrect. The following information must be included:

File Name: The file name with extension must be listed. Specific file-naming conventions can be found in Section B.1. Spaces must not be used in file names. File names are derived from the controlled document number, not the applicant-assigned reference number. For example, your file name for drawing 10222 revision A should be 10222Ra.dwg. For future submissions of the same document, the only change to the file name will be to the revision level; the next submission of the drawing above would be 10222Rb.dwg. Files submitted using the applicant-assigned reference number as file names will be returned.

Document Type: Pre-test data, drawing, assembly matrix, draft approval label, QA manual, process quality control plan, service life plan, User Instructions, etc.

Description: Detailed description giving specific information identifying model name/number, revision level, drawing number, and title.

Program: The software program (including version) used to create the file.

<u>File Name</u>	<u>Document Type</u>	<u>Description</u>	<u>Program</u>
nnnnPD.xls	Pre-submission Test Data	Test Name	Excel 7.0
nnnnUIa.pdf	User Instructions	Title of manual	Adobe Acrobat
nnnnSLP.doc	Service Life Plan	Model Name/Number Rev. Number	Word
nnnnra.dwg	Drawing	Title, Dwg No. Rev. No., Model, etc.	AutoCAD 14
nnnnAMa.xls	Assembly Matrix	Model Name/Number Rev. Number	Excel 7.0

nnnnDLa.xls
nnnnQMa.doc

Draft Approval Label
Q/A Manual

Model Name/Number
Date (mm/dd/yy)

Excel 7.0
Word

If “zipped” files are submitted, provide the individual file name, description, and program for each working file contained in the zipped file.

If there is more than one User Instruction or assembly matrix, call them out by their individual titles/names.

If NIOSH has requested replacement files, give the replacement files the same name as the original files. This will prevent instances where an incorrect document and a corrected document both end up in the project documents. Send replacement files only at the request of NIOSH, and send them directly to the requestor. The requestor is responsible for having the corrected files posted to your project.

Please note that NIOSH will accept only those replacement or new files that have been requested specifically by NIOSH. Do not request that NIOSH replace a document that may have errors or incorrect information that you have found but not requested by NIOSH. These files will not be accepted.

NOTE: If FDA surgical mask clearance has been received then the clearance documentation (such as the 510(K) form) must be included with the respirator application.

SECTION D - APPROVALS and DENIALS

D.1 APPROVAL AND FAILURE DOCUMENTATION

If the respirator meets or exceeds all of the requirements outlined in these procedures and 42 CFR 84, NIOSH will grant an approval and assign a TC number. All submitted documentation and supporting test data will become part of the approval record. NIOSH will send a letter to the applicant stating the nature of the approval and will return final approval label files, if applicable, with the appropriate approval documentation. For applicants using consultants or authorized representatives, the final letter of approval and enclosed documentation will be sent directly to the applicant with a copy of the approval letter to the consultant or authorized representative.

When application approval labels and assembly matrices contain rows of information on additional approvals other than the ones evaluated in the individual application under review, approval letters will indicate that only the approvals sought under the individual application are granted.

If the respirator fails to meet the requirements of 42 CFR 84, the application will be denied and all documentation, diskettes and sample hardware will be returned or destroyed. NIOSH will not maintain documentation or sample hardware for any respirators that have failed to meet all of the requirements. If NIOSH denies an application based upon documentation issues, the application, diskettes and all sample hardware will be returned to the applicant’s U.S. or Canadian address or

authorized representative. Foreign applicants are recommended to have and use their U.S. representative's address on return shipping labels.

NOTE: If any failure occurs in a series of applications, all related applications will also be denied. Assume an applicant submits facepiece ABC in one application and a new cartridge in a second application that will utilize facepiece ABC along with other previously approved facepieces. If facepiece ABC fails, both applications will be denied. NIOSH will not permit the second application to be amended. In such a case, the second application may be resubmitted after removing the ABC facepiece.

Subsequent requests for approval of previously failed units must be submitted with all associated documentation and the reason for failure must be addressed.

D.2 CRITERIA FOR THE DENIAL OF APPLICATIONS

D.2.1 DENIAL PRIOR TO ASSIGNMENT OF A TASK NUMBER:

Reasons why applications will not be accepted and will be denied prior to issuance of a TN:

- An application is received displaying an applicant-assigned reference number that has been previously used by the applicant.
- A major section of the application such as the assembly matrix, QC plan, approval labels, pre-test data, User Instruction or drawing package is missing, in an unacceptable file format, or uses an unacceptable file-naming convention.
- Sample hardware, application package and check are not received within two weeks of one another.
- Shipping boxes contain sample hardware associated with different applications without any separate packaging to indicate what sample hardware goes with each application, or packages of sample hardware received within the same box are not clearly labeled.
- An assembly matrix is not associated with every application (except QA applications).
- Failure to provide a complete file list in the related documents section of the application.

D.2.2 DENIAL OF A PROJECT UNDERGOING NIOSH EVALUATION:

Reasons why applications may be denied:

- Assembly matrix, exploded view drawing, approval labels, or major sub-assembly drawings are incorrect (content or format) or show unapproved assemblies.

- Pre-submittal test data is not complete. For example, it does not include total resistance on the complete assembly or all assemblies involved in the submittal(s).
- Sample hardware submitted does not match sub-assembly drawings, part numbers, or the assembly matrix drawing.
- Drawings are not in accordance with the documentation control procedures stated in the applicant's quality assurance manual.
- Additional information requested by NIOSH is not received within two weeks of the date requested.
- The application is for a new or unique respirator which cannot be approved under current regulations for which there is no existing NIOSH policy (e.g., smoke hoods, SAR with pneumatic tools, etc.).
- Applicant's pre-submittal test data indicates that their respirator would fail the NIOSH regulatory test requirements or the appropriate pre-test data is not submitted with the application.
- The official submittal either (1) requested approval of two respirators of different basic designs (includes submitting a filter media and alternate in the same application) or (2) requested a new approval and an extension of approval in the same application.
- The electronic Standard Application Form (SAF) has errors, deficiencies or is incorrect.
- Items on the assembly matrix do not correspond exactly to the Reason for Application, drawing revision levels are wrong, components on the exploded view drawing are miss-numbered, or documents are otherwise incorrect.
- Protection or intended use claims that have not been requested or approval received from other governing agencies (such as FDA for surgical masks or medical claims).
- Quality Assurance documentation does not have sufficient inspections identified, missing required inspection steps or inspections identified are not sufficient to meet the NIOSH requirements.

SECTION E - RESPIRATOR TEST SELECTION GUIDE

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
1	Chemical Cartridge, Subpart L, Non-powered Note: Adequate O2 necessary and concentration limitations	3/7 4 5/5A/6 33-48, 50 or 62 60 61 66 Note: ESLI tested where used	Exhalation/Inhalation resistance Exhalation valve leakage Facepiece fit (IAA) Gas or vapor (as applicable) ESLI visibility ESLI damage resistance ESLI indicator	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 3 sets OV cartridges 10 sets of cartridges for each gas or vapor Note: All combinations with an ESLI must be submitted to verify ESLI visibility and damage resistance.
2	Chemical Cartridge with Particulate filter Non-powered	3/7 4 5/5A/6 33- 48, 50 or 62 51-56 57-59 60 61 66 Note: ESLI tested where used	Exhalation/Inhalation resistance Exhalation valve leakage Facepiece fit (IAA) Gas or vapor (as applies) DOP for Particulates NACL for Particulates ESLI visibility ESLI damage resistance ESLI indicator	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 3 sets OV cartridges 26 cartridges with filters for each particulate class of filter + 10 sets of cartridges with filters for each gas or vapor Note: All combinations with an ESLI must be submitted to verify ESLI visibility and damage resistance.
3	Gas Masks, Subpart I Non-powered Note: Entry into non-IDLH with sufficient O2 & escape. May need ESLI for entry	3/7 4 5/5A/6 14 33-48, 50 or 62 60 61 66 Note: ESLI tested where used	Exhalation/Inhalation resistance Exhalation valve leakage Facepiece fit (IAA) Leakage of Drinking Tube and Accessories Gas or vapor (as applies) ESLI visibility ESLI damage resistance ESLI indicator	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 3 set OV canisters 10 sets of canisters for each gas or vapor Note: All combinations with an ESLI must be submitted to verify ESLI visibility and damage resistance.
4	Gas Masks with Particulate filters Non-powered Note: Entry into non-IDLH with sufficient O2 & escape.	3/7 4 5/5A/6 14 33-48, 50 or 62 51-56 57-59 60 61 66 Note: ESLI tested where used	Exhalation/Inhalation resistance Exhalation valve leakage Facepiece fit (IAA) Leakage of Drinking Tube and Accessories Gas or vapor (as applies) DOP for particulates NACL for particulates ESLI visibility ESLI damage resistance ESLI indicator	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 3 set OV cartridges 26 canisters with filters for each filter + 10 sets of canisters with filters for each additional gas or vapor Note: All combinations with an ESLI must be submitted to verify ESLI visibility and damage-resistance.
5	Particulate testing- 42 CFR 84 Negative pressure.	3 4 7 51-56 57-59	Exhalation resistance Exhalation valve leakage Inhalation Resistance DOP for particulates NaCl for particulates	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 26 filters for each type

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
5a	Filtering Facepieces - 42 CFR 84 Particulate Negative Pressure	3 4 7 51-56 57-59	Exhalation resistance Exhalation valve leakage (if present) Inhalation Resistance DOP for particulates NaCl for particulates	3 Exhalation valve assemblies (if present) 26 Filtering Facepieces for each type
6	PAPR with particulate and/or chemical cartridge or canister Powered air-purifying	1 3 4 5/5A/6 7 12 14 25 30 33-48, 50 or 62 60 61 63 64 65 66	DOP (dioctyl phthalate)- PAPR only Exhalation resistance Exhalation valve leakage Facepiece fit (IAA) Inhalation Resistance PAPR air flow Leakage of Drinking Tube and Accessories PAPR Silica dust (for res) Sound level Gas or vapor (as applies) ESLI visibility ESLI damage resistance CO ₂ and O ₂ for tight fitting PAPR w/ blower on CO ₂ and O ₂ for tight fitting PAPR w/ blower off Airflow resistance of breath responsive PAPR's ESLI indicator Note: ESLI tested where used	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 3 sets OV cartridges 10 filters or filter/cartridge combinations + 10 sets of cartridges or canisters with filters for each gas or vapor Note: All combinations with an ESLI must be submitted to verify ESLI visibility and damage-resistance.
7	SCBA - open-circuit, entry, Demand Subpart H	4 118 121 122 123 124 125 126 128 140 132 139 145 148 155 146	Exhalation valve leakage Low Temperature Test Rated Service Time Test Exhalation Resistance Test Gas Flow Test Remaining Service Life Indicator Test (IAA), Gas Tightness Test Bypass Flow, Test - Adj. Bypass Valve Gas Pressure Gauge Test (Accuracy of gauge) Man Tests and Weight Determination Test Inhalation Resistance Test Maximum CO ₂ Inspired Gas Test (CO ₂ Dead Space) Alarm Sound Level Test Gauge Leakage of Gas Test Man Test 6 for Respirators Using Liquefied Gas Regulator Over Pressurization Test (is only done on all belt mounted regulators)	2 complete units plus one each of all accessories 3 cylinder gauges, 3 remote gauges as required

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
8	SCBA - open-circuit, entry, Pressure-Demand	118 120 121 122 123 124 125 126 128 139 140 145 148 155 146	Low Temperature Test Positive Pressure Test Rated Service Time Test Exhalation Resistance Test Gas Flow Test Remaining Service Life Indicator Test (IAA), Gas Tightness Test Bypass Flow, Test - Adj. Bypass Valve Gas Pressure Gauge Test (Accuracy of gauge) Maximum CO ₂ Inspired Gas Test (CO ₂ Dead Space) Man Tests and Weight Determination Test Alarm Sound Level Test Gauge Leakage of Gas Test Man Test 6 for Respirators Using Liquefied Gas Regulator Over Pressurization Test (is only done on all belt mounted regulators)	2 complete units plus one each of all accessories 3 cylinder gauges, 3 remote gauges as required
9	SCBA - closed-circuit, entry	117 121.1 124.1 125 127 128 134 135 136 or 137 138 139 140 141 142 143 144 145 148.1 155 NOTE: Rated Service Time is tested during Man Test 4, assuming that all previous Man Tests have been satisfactorily completed.	Positive Pressure Test Rated Service Time Test Alarm Pressure (IAA) Gas Tightness Test Bypass Flow Test-Adj. Bypass Valve Gas Pressure Gauge Test (Accuracy of gauge) Breathing Bag Test Breathing Resistance Test Gas Flow Test (Demand only) or Gas Flow Test, (Constant flow with Demand) Safety Relief Valve Operation Test Maximum CO ₂ Inspired Gas Test (CO ₂ Dead Space) Man Tests and Weight Determination Test Man Test 5 for Inspired Gas Test Vibration Test for Escape, Demand Low Temperature Operation Test Gas Flow Test on Constant Flow Alarm Sound Level Test Gauge Leakage of Gas Test Man Test 6 for Liquefied Gas	2 complete units, plus one each of all accessories 21 scrubbers or O ₂ generating canisters or 21 fully charged O ₂ cylinders plus 1 breathing bag 1 relief valve override tool (if needed) 3 cylinder gauges 3 remote gauges (if needed)

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
10	Self-Contained Self-Rescuers	125 134 135 138 139 140 141 142 143	(IAA) Gas Tightness Test Breathing Bag Test Breathing Resistance Test Safety Relief Valve Operation Test Max. CO ₂ Inspired Gas Test (CO ₂ Dead Space) Man Tests and Weight Determination Test Man Test 5 for Inspired Gas Test Vibration Test Low Temperature Operation Test	26 complete units plus one each of all accessories plus 1 breathing bag 1 relief valve override tool (if needed) 3 cylinder gauges 3 remote gauges (if needed)
			NOTE: Rated Service Time is tested during Man Test #4. Apparatus with O ₂ cylinders will be tested according to 128, Gas Pressure Gauge Test (Accuracy of gauge), as appropriate Gas flow will be tested as appropriate according to: 136-Gas Flow Test (Demand only) or 137-Gas Flow Test (Constant flow with Demand)	
11	SCBA - open-circuit escape Demand	118 121 122 123 125 128 132 139 140	Low Temperature Test Rated Service Time Test Exhalation Resistance Test Gas Flow Test (IAA), Gas Tightness Test Gas Pressure Gauge Test (Accuracy of gauge) Inhalation Resistance Test Maximum CO ₂ Inspired Gas Test (CO ₂ Dead Space) Man Tests and Weight Determination Test	2 complete units plus one each of all accessories 3 cylinder gauges
12	SCBA - open-circuit escape Pressure-Demand	118 120 121 123 125 128 139 140	Low Temperature Test Positive Pressure Test Rated Service Time Test Gas Flow Test (IAA), Gas Tightness Test Gas Pressure Gauge Test (Accuracy of gauge) Maximum CO ₂ Inspired Gas Test (CO ₂ Dead Space) Man Tests and Weight Determination Test	2 complete units plus one each of all accessories 3 cylinder gauges
13	SCBA - open-circuit escape Constant Flow	114 115 116 118 125.1 128 132 139 140	Sound Level Special Test, (Hoods & Helmets) Flow Rate Service Time Test Airflow Resistance Test (Constant Flow Hoods) Low Temperature Test (IAA), Gas Tightness Test Gas Pressure Gauge Test (Accuracy of gauge) Inhalation Resistance Test Maximum CO ₂ Inspired Gas Test (CO ₂ Dead Space) Man Tests and Weight Determination Test	3 complete units

Item	RESPIRATOR TYPE	*NIOSH TITLE Test #	TOTAL MATERIALS NEEDED
14	Supplied-Air Type C-CE Demand Subpart J	4 Exhalation valve leakage 100 Strength of Hose and Coupling Test 101 Tightness Test 102 Non-kinkability Test 103 Gasoline Permeation Test 104 Air Regulating Valve Test (100,000 Cycles) 105.1 Airflow Test, Demand Class 108 Inhalation Resistance Test 109 Exhalation Resistance Test 110 (IAA), Gas Tightness Test NOTE: For Abrasive Blast, Type CE, Supplied-Air Respirators, perform all above tests <u>plus</u> 112-Abrasive Blast, Quantitative Fit	2 complete units plus one each of all accessories All combinations of the maximum length of hose made up from the minimum hose lengths plus All necessary quick-disconnects 2 additional 25-foot lengths of airline hose
15	Supplied-Air Type C-CE Pressure-Demand	4 Exhalation valve leakage 100 Strength of Hose and Coupling Test 101 Tightness Test 102 Non-kinkability Test 103 Gasoline Permeation Test 104 Air Regulating Valve Test (100,000 Cycles) 105.1 Airflow Test, Pressure-Demand Class 106 Inhalation Resistance Test, 107 Exhalation Resistance Test 110 (IAA), Gas Tightness Test NOTE: For Abrasive Blast, Type CE, Supplied-Air Respirators, perform all above tests <u>plus</u> 112-Abrasive Blast, Quantitative Fit	2 complete units plus one each of all accessories All combinations of the maximum length of hose made up from the minimum hose lengths plus All necessary quick-disconnects 2 additional 25-foot lengths of airline hose
16	Supplied-Air Type C-CE Constant Flow	4 Exhalation valve leakage 100 Strength of Hose and Coupling Test 101 Tightness Test 102 Non-kinkability Test 103 Gasoline Permeation Test 105 Airflow, Continuous Flow Class 110 (IAA), Gas Tightness Test 111 Sound Level Test 113 Airflow Resistance Test NOTE: For Abrasive Blast, Type CE, Supplied-Air Respirators, perform all above tests <u>plus</u> 112-Abrasive Blast, Quantitative Fit	2 complete units plus one each of all accessories All combinations of the maximum length of hose made up from the minimum hose lengths plus All necessary quick-disconnects 2 additional 25-foot lengths of airline hose
17	Vinyl Chloride Special Use, Subpart N	Tests as listed for item # 2, above	Materials as listed for item # 2, above
18	Combinations of any respirators in this guide	All Tests for each category as appropriate plus For Combination SCBA/SAR: 119 Low Temperature Test, SAR Mode 147 Mode Transfer Time Test For Combination SAR/AP 14 Supplied Air Check Valve Leakage Test	All samples for each category as appropriate

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
19	Filter Self Rescuer	3 4 5 7 33-48, 62 51-56 57-59 60 61 NOTE: ESLI tested where used	Exhalation resistance Exhalation valve leakage Facepiece fit (IAA)(as applicable) Inhalation Resistance Gas or vapor (as applicable) DOP for particulates (as applicable) NACL for particulates (as applicable) ESLI visibility (as applicable) ESLI damage resistance (as applicable)	20 complete respirator assemblies 3 exhalation valve assemblies Note: All combinations with an ESLI must be submitted to verify ESLI visibility and damage resistance

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
20	CBRN Air Purifying Respirators (CBRN APR)	3	Exhalation Resistance	4 Complete Respirators for Live Agent Testing, Qualifying
		4	Exhalation Valve Leakage	
		7	Inhalation Resistance	6 Complete Respirators for Live Agent Testing, Remaining, after Environmental Conditioning.
		14	Leakage of Drink Tubes and Accessories	125 Canisters, minimum
		51	Diethyl Phthalate(DOP) P100 & 6 P100 w/Test 0301	48 Complete Respirators for bench testing, minimum
		64	CO2 Volume	
		301	Cyclohexane (Set of 9 Canisters)	
		302	Cyanogen Chloride (Set of 9 Canisters)	
		303	Hydrogen Cyanide (Set of 9 Canisters)	
		304	Phosgene (Set of 9 Canisters)	
		305	Hydrogen Sulfide (Set of 9 Canisters)	
		306	Sulfur Dioxide (Set of 9 Canisters)	
		307	Ammonia (Set of 9 Canisters)	
		308	Nitrogen Dioxide (Set of 9 Canisters)	
		309	Phosphine (Set of 9 Canisters)	
		310	Formaldehyde (Set of 9 Canisters)	
		311	NPPTL Environmental Conditioning	
		312	Field of View	
		313	Communications	
		314	Fogging	
		316	Haze, Luminous Transmittance & Abrasion	
		350	GB (SMARTMAN) Qualifier LAT (QLAT)	
		351	Only1 +	
		351	HD (SMARTMAN) QLAT Only1 +	
		350	GB (SMARTMAN) Remainder LAT (RLAT) 2 trials +	
		351	HD (SMARTMAN) RLAT, 2 trials +	
		352	Laboratory Respirator Protection Level (LRPL)	
		353	Weight & Diameter / Canister Thread Analysis	
			+Tests Performed at RDECOM	

21	CBRN Powered Air Purifying Respirators (CBRN PAPR)	<p>1 Initial DOP</p> <p>3 Exhalation Resistance</p> <p>4 Exhalation Valve Leakage</p> <p>5 IAA Fit Test</p> <p>5A IAA Fit Test for Full Facepieces</p> <p>6 IAA Fit Test for Half Masks</p> <p>7 Inhalation Resistance</p> <p>12 PAPR Air Flow Test</p> <p>14 Leakage of Drink Tubes and Accessories</p> <p>25 Silica Dust Testing</p> <p>51 Dioctyl Phthalate(DOP) P100 & 6 P100 w/Test 0301</p> <p>64 CO2 Volume</p> <p>501 Cyclohexane (Set of 9 Canisters), Tight Fitting</p> <p>502 Cyanogen Chloride (Set of 9 Canisters) Tight Fitting</p> <p>503 Hydrogen Cyanide (Set of 9 Canisters) Tight Fitting</p> <p>504 Phosgene (Set of 9 Canisters) Tight Fitting</p> <p>505 Hydrogen Sulfide (Set of 9 Canisters)Tight Fitting</p> <p>506 Sulfur Dioxide (Set of 9 Canisters) Tight Fitting</p> <p>507 Ammonia (Set of 9 Canisters) Tight Fitting</p> <p>508 Nitrogen Dioxide (Set of 9 Canisters) Tight Fitting</p> <p>509 Phosphine (Set of 9 Canisters) Tight Fitting</p> <p>510 Formaldehyde (Set of 9 Canisters) Tight Fitting</p> <p>511 Cyclohexane (Set of 9 Canisters) Loose Fitting</p> <p>512 Cyanogen Chloride (Set of 9 Canisters) Loose Fitting</p> <p>513 Hydrogen Cyanide (Set of 9 Canisters) Loose Fitting</p> <p>514 Phosgene (Set of 9 Canisters) Loose Fitting</p> <p>515 Hydrogen Sulfide (Set of 9 Canisters) Loose Fitting</p> <p>516 Sulfur Dioxide (Set of 9 Canisters) Loose Fitting</p> <p>517 Ammonia (Set of 9 Canisters) Loose Fitting</p> <p>518 Nitrogen Dioxide (Set of 9 Canisters) Loose Fitting</p> <p>519 Phosphine (Set of 9 Canisters) Loose Fitting</p> <p>520 Formaldehyde (Set of 9 Canisters) Loose Fitting</p>	<p>4 Complete respirators for Live Agent Testing, Qualifying</p> <p>6 Complete respirators for Live Agent Testing, Remaining, after Environmental Conditioning.</p> <p>102 Canisters (tight fitting) or Cartridges (loose fitting)</p> <p>49 Complete respirators for bench testing, Loose Fitting</p> <p>43 Complete respirators for bench testing, Tight Fitting</p>
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Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
		311	NPPTL Environmental Conditioning Procedure	
		312	Field of View	
		313	Communications	
		314	Fogging	
		550	GB (SMARTMAN) Qualifier LAT(QLAT) Only 1 +	
		551	HD (SMARTMAN) QLAT Only1 +	
		550	GB (SMARTMAN) Remainder LAT (RLAT) 2 trials +	
		551	HD (SMARTMAN) RLAT Only 2 trials +	
		552	Laboratory Respirator Protection Level (LRPL) Tight	
		553	Laboratory Respirator Protection Level (LRPL). Loose	
		+Tests Performed at RDECOM		

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
22	CBRN Air Purifying Escape Respirators (CBRN APER)	3 4 7 51 64 401 402 403 404 405 406 407 408 409 410 411 312 414 450 Only 1 + 451 450 451 452 454 417 +Tests Performed at RDECOM	Exhalation Resistance Exhalation Valve Leakage Inhalation Resistance Diocetyl Phthalate(DOP) P100 CO2 Volume Machine Cyclohexane (Set of 9) Cyanogen Chloride (Set of 9) Hydrogen Cyanide (Set of 9) Phosgene (Set of 9) Hydrogen Sulfide (Set of 9) Sulfur Dioxide (Set of 9) Ammonia (Set of 9) Nitrogen Dioxide (Set of 9) Phosphine (Set of 9) Formaldehyde (Set of 9) NPPTL Environmental Conditioning Field of View Fogging GB (SMARTMAN) Qualifier LAT (QLAT) HD (SMARTMAN) QLAT Only1 + GB (SMARTMAN) Remainder LAT (RLAT) 2 Trials + HD (SMARTMAN) RLAT 2 trials + Laboratory Respirator Protection Level (LRPL) Human Subject Breathing Gas Test Flammability, Heat Resistance, CO protection (only for APERs with CO protection)	4 Complete respirator assemblies for Live Agent Testing, Qualifying 6 Complete respirator assemblies for Live Agent Testing, Remaining, after Environmental Conditioning. 234 Complete Respirator assemblies for bench testing, minimum
23	CBRN Self Contained Breathing Apparatus, Open Circuit (CBRN SCBA) (Must be in conjunction with Part 84 testing and NFPA/SEI 1981 submittal)	200 201 202 219/220 +Tests Performed at RDECOM	GB LAT + HD LAT + Laboratory Respirator Protection Level (LRPL) Emergency Breathing Safety System (EBSS)	2 SCBA units, low pressure without cylinder, Live Agent Testing 4 SCBA units, high pressure, without cylinder, Live Agent Testing 2 Spare SCBA unit for Live Agent Testing, without cylinder 48 Facepieces with P100 filters, Configured in the Air Purifying Mode for LRPL 2 SCBA units, per pressure for EBSS testing

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
24	CBRN Self Contained Escape Respirators (CBRN SCER)	0003 0004 0007 0064 0411 0312 0414 0450 0451 0450 0451 0452 0455 0417	Exhalation Resistance Exhalation Valve Leakage Inhalation Resistance CO2 Volume Machine NPPTL Environmental Conditioning Field of View Fogging GB (SMARTMAN) Qualifier LAT(QLAT) Only 1 + HD (SMARTMAN) QLAT Only 1 + GB (SMARTMAN) Remainder LAT (RLAT) 2 trials + HD (SMARTMAN) RLAT 2 trials + Laboratory Respirator Protection Level (LRPL) Human Subject Breathing Gas Test Flammability, Heat Resistance	4 Complete respirators, without cylinders for Live Agent Testing, Qualifying 6 Complete respirators, without cylinders for Live Agent Testing, after Environmental Conditioning 115 Complete respirators for bench testing, minimum
+Tests Performed at RDECOM				

Item	RESPIRATOR TYPE	*NIOASH Test #	TITLE	TOTAL MATERIALS NEEDED
25	Closed Circuit Escape Respirators, (CCER), 42 CFR part 84, sub part O	600 601 602 603 604 605 610 611 612 613 614 0615 616	Determination of Gasoline Permeation Test on Breathing Bags Standard Operating Procedure (SOP) For Environmental Treatments Determination of Capacity of As-Received and Environmentally-Treated Determination of Performance of As-Received And Environmentally Treated Determination of Capacity Test of Closed-Circuit Escape Respirators (CCERs) at applicant's Recommended Minimum Temperature Determination of Breathing Circuit Integrity (Breathing Gas Supply, Inward Leakage And Continuity) Throughout The Docking Process for Dockable Closed-Circuit Determination of Wearability Evaluation Of Donning Determination of Capacity with Human Subjects on Treadmill Determination of Performance with Human Subjects on Treadmill Assessment of Stressors With Human Subject testing: Capacity, Performance and Wearability Standard Testing Procedure (STP) To Conduct Man-Test 4, CCER to be Used in Underground Coal Mines Standard Operating Procedure (SOP) for Human-Subject Work Rate (VO2) Determination for Performance and Capacity Testing	CAP 1 Versions – 32 with mining use - 34 CAP 2 Versions – 17 with mining use – 19 CAP 3 Versions – 17 with mining use – 19 Spare units should be available and can be included with the required units listed.
26	Wildland Fire Fighter Respirator	Contact NIOSH on testing required and number of samples.		

* Actual tests selected may vary depending on design and intended use.

SECTION F - CHECKLISTS

The following checklists will be used by NIOSH to review submitted documents for compliance to this procedure and 42 CFR Part 84. It is highly recommended that the approval holder review their documents using these checklists prior to submitting them to NIOSH. These checklists may not be all-inclusive. Additional requirements may exist.

ASSEMBLY MATRIX

1. _____ Matrix must be titled and show the date or revision level.
2. _____ Matrix lists the applicant's name and address.
3. _____ Drawing revision level reflects the current revision level on file at NIOSH or a new drawing has been submitted with the application. If the drawing is within another application at NIOSH, this information must be identified in the reason for application.
4. _____ Numbering system used for major sub-assemblies shown on the matrix and exploded view drawing must match.
5. _____ Part numbers (model numbers optional). The number marked on the component is the number that must appear in the part number row.
6. _____ Description of respirator. Features that describe the respirator cannot be listed on the matrix as a separate column. Features associated with specific model numbers may be coupled together in the description (e.g., Model 1201-Low Flow).
7. _____ Top row must be a general category, i.e., facepiece, adapter, etc. Accessories must be included. "Alternate" will be in the column heading if there are more than one of the same sub-assemblies.
8. _____ Bottom row is for the NIOSH task number where component was last tested. If New, indicate N.
9. _____ First column from left is the Applicant Assigned Reference number (AAR#).
10. _____ Second column from left is TC number column. Is a new TC number in the proper format: schedule # and AAR# followed by an alpha character? Is "TC-" only listed in the category heading?
11. _____ Third column from left is the list of protections. Verify that the list matches the protections listed in the SAF. See complete list of protections and Cautions and Limitations in Section C.20. For SCBAs, the End of Service Time Indicator (EOSTI) is to be identified as EOSTI-25 or EOSTI-33 (CBRN/NFPA 2013 units).
12. _____ Airline hoses must be listed under components instead of accessories.
13. _____ Key Box uses only the characters X, N, P, R, -, or A.
14. _____ Cylinders are only approved for one duration (30, 45, 60 or 75 minutes).
15. _____ TN/AAR# of the previously approved/pending matrix is in the top right-hand corner.
16. _____ Current exploded view drawing number and revision is located in the top right corner.
17. _____ All approvals have a column for the part number/rev level of the User's Instructions, except for filtering facepiece respirators (FFR).

18. ____ SCSR's or CCER's contain the Service Life Plan part number and revision level.
19. ____ Flow Indicator is listed for PAPR.

SELF-CONTAINED BREATHING APPARATUS

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1. _____ Confirm that any materials used in the construction of the respirator which may be exposed to oxygen pressures above atmospheric pressure are safe and compatible for their intended use (e.g., exposure to elevated concentrations of oxygen).

Cylinder & Valve

1. _____ Burst disc pressure is given on the drawing, or there is a note that states that it meets CGA S-1.1 6.3. Requirement is 90-100% of 5/3 service pressure
cylinder fill pressure $\times 5 \div 3 =$ upper limit
highest pressure $\times .90 =$ lower limit
2. _____ Torque requirement for connection of cylinder valve to cylinder.
3. _____ Cylinder construction (material(s) of construction, fiber reinforced, type of fiber).
4. _____ Full cylinder volume at operating pressure - Compressed Air Volume.
5. _____ Markings on cylinder: compressed breathing air, compressed breathing oxygen, liquefied breathing air, or liquefied breathing oxygen, DOT marking requirements.
6. _____ Pressure-gauge range has a scale reliable to within + or - 5% of full scale (minimum of five graduations empty, 1/4, 1/2, 3/4, full).
7. _____ Where pressurized oxygen is used, the gauge must have the words "Oxygen" and "Use No Oil." Also, if it is a closed circuit unit with oxygen, all materials must be compatible for use with oxygen.
8. _____ Procedure to assure proper gas mixture for refill purposes (percent oxygen). Applies to specialty gases only; does not apply to Grade D air.
9. _____ Specification and dimensions of outlet threads are identified.

Respiratory Inlet Covering (Facepiece or Hood)

1. _____ If a pressure demand valve, shows it is spring loaded.
2. _____ Lens meets impact resistance GGG-M-125d Oct. 11, 1965 (amended July 30, 1969).
3. _____ Lens has statement if anti-fog is needed or not.

4. _____ Statement to indicate if and when nose cup assembly is needed.

SELF-CONTAINED BREATHING APPARATUS

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Backpack Harness Assembly

1. _____ Inspection procedures or classification of defects include a visual inspection of the buckles.
2. _____ Location of NIOSH harness label.

Pneumatic Assembly

1. _____ For all compressed gas SCBA, a statement that it has an in-line filter downstream of the air source that will effectively remove particles from the gas stream (42 CFR 84.87).
2. _____ Type of connections on SAR hose (for an SCBA/SAR combination).
3. _____ Pressure-gauge range has a scale reliable to within + or - 5% of full scale (minimum of five graduations: empty, 1/4, 1/2, 3/4, full).
4. _____ When pressurized oxygen is used, gauge has the words "Oxygen" and "Use No Oil".
5. _____ Statement showing all SCBA components critical to the performance of the respirator will function at the minimum temperature, including seals and O-rings (42 CFR 84.98).
6. _____ Statement as to how the remote pressure gauge is attached, i.e., loctite or torque.
7. _____ Parts list showing all parts and materials of the pneumatic assembly.

1st Stage Regulator

1. _____ Intermediate Pressure Range

Second Stage Regulator Assembly

2. _____ Parts list showing all parts and materials of the regulator.
3. _____ If a belt mounted regulator assembly, a pressure relief valve is required along with a statement of diaphragm over-pressurization requirement.

SUPPLIED-AIR RESPIRATOR

Respiratory Inlet Covering (Facepiece/Hood/Helmet)

1. _____ Lens has statement on impact resistance GGG-M-125d, Oct. 11, 1965 (amended July 30, 1969). Does not apply to types B, BE, C, and CE.

Air Supply Valve/Orifice/Demand or Pressure-Demand Regulator

1. _____ Parts list required showing all parts that make up the air supply valve/orifice/regulator.

Hose/Couplings

1. _____ Couplings must be specified by both type and manufacturer, even if the type is a manufacturer name (example: Foster-Schrader which we would interpret to be a Schrader style/compatible coupler manufacturer by Foster). The specific model or part number must be identified; it cannot say “or equivalent”.
2. _____ Maximum pressure rating of hose

Breathing Tube

1. _____ Inspection procedures or classification of defects include a method for checking the clamps on the breathing tube.

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FILTERING FACEPIECE

The filtering facepiece drawing may serve as both the exploded view and major sub-assembly drawing.

1. _____ Reference dimensions for facepiece, liner, valve, straps, and nosepiece.
2. _____ Material specification for filter media, valve, nosepiece, straps, liner.
3. _____ Vendor and part number for the components are identified if no material specifications are listed
4. _____ Location of nosepiece, liner, straps and valve.
5. _____ Identify part number and location
6. _____ Lot number location, on mask or packaging, and code or date of manufacture.
7. _____ Expiration date (if applicable)
8. _____ Filter efficiency (N95, N99, N100, etc.) including nuisance protections.
9. _____ Filters containing carbon layers include a statement that carbon is chromium free.
10. _____ Final filter media form is identified/shown (pleated, flat, etc.).

11. _____ Filtering mechanism is identified (electrostatic, mechanical or other).
12. _____ Vendor for filter material is identified if the filter specification is not determined by the respirator manufacturer.
13. _____ Elasticity and length of the straps and method of attachment. Elasticity is listed as a percentage or maximum length (a known force should be identified as well)
14. _____ If staples or sonic welds are used to fasten straps, the drawing must clearly indicate whether or not the attachment points are within the breathing zone. Reference the November 15, 2000 Letter to All Manufacturers in the Appendix f or related inspection procedures.
15. _____ Page two of the drawing details the abbreviated and as applicable, private label abbreviated labels.
16. _____ P100 filtering facepieces are either purple or magenta in any part of the body; the location of the color needs to be identified on the drawing.
17. _____ The drawing must contain the inspection procedures or the relevant document number (s).

FILTERING FACEPIECE PRIVATE LABELING CHECK LIST

1. _____ Included assembly matrix showing private label version under current approval (TC) number.
2. _____ If private label is a different model/part number than primary number, part number and description are to be in a new separate column on the matrix.
3. _____ If the private label is the same model/part number as the primary number, then the approval holder name and private label company name are to be in the description column of the primary filtering facepiece part/model number.
4. _____ Add private label abbreviated label to page 2 of drawing.
 - A. _____ Abbreviated label must include the following items:
 - a. Private label company name
 - b. NIOSH
 - c. Appropriate approval (TC) number
 - d. Protection (N95, R95, P95, etc.)
 - e. Model or part number
 - f. Lot or date code (optional)

5. _____ Include a draft of the full private label approval label. Must include Cautions and Limitations Special “S”.
6. _____ Include private label user instructions with application.
7. _____ “S” Special user instructions section required with statement:
Model nnnn filtering facepiece respirator has been manufactured by approval holder xxx for private label company yyyy under TC-84A-nnnn.
8. _____ Specific contact information and a contact person must be included for the private label company. Information may be added by separate contact sheet or in the reason for application section.

ALL OTHER PRIVATE LABELING RESPIRTORS CHECK LIST

1. _____ Included assembly matrix showing private label version(s) under current approval (TC) number.
2. _____ If the private label has a different model/part number(s) than the primary number(s), the part number(s) and description(s) are to be in new separate column(s) on the matrix.
3. _____ If the private label component(s) are the same model/part number(s) as the primary number(s), then the approval holder name and private label company name are to be placed in the description column of the primary component part/model number(s) on the assembly matrix.
4. _____ Include a draft(s) of the full private label approval label(s). Must include Cautions and Limitations Special “S”.
5. _____ Abbreviated cartridge, canister or harness labels must include the following items:
 - a. Private label company name
 - b. NIOSH
 - c. Appropriate approval (TC) number (canister and harness labels only)
 - d. Protection (N95, R95, P95, etc.)
 - e. Model or part number
 - f. Cautions and Limitations (canister and harness labels only)
 - g. Lot or date code (optional)
6. _____ Include private label user instructions with application.
7. _____ “S” Special user instructions section required with statement:
Model nnnn (type respirator) respirator has been manufactured by approval holder xxx for private label company yyyy under TC-nnX-nnnn.

8. _____ Specific contact information and a contact person must be included for the private label company. Information may be added by separate contact sheet or in the reason for application section.

**SELF-CONTAINED SELF-RESCUER/CLOSED CIRCUIT ESCAPE RESPIRATOR
(CCER)
(page 1 of 1)**

1. _____ Firing mechanism, as applicable.
2. _____ Case seal information (assembly procedures), and a statement that it can be opened within 15 seconds.

Regulator

1. _____ Parts list showing all parts and materials of the regulator.

If the unit has a cylinder:

1. _____ Burst disc pressure or states that it meets the CGA S-1.1 6.3. Requirement is 90 – 100% of 5/3 service pressure.
cylinder fill pressure x 5 ÷ 3 = upper limit
highest pressure x .90 = lower limit
2. _____ Torque requirement for connection of cylinder valve to cylinder.
3. _____ Cylinder construction (material(s) of construction, fiber reinforced, type of fiber).
4. _____ Full cylinder volume at operating pressure.
5. _____ Markings on cylinder: compressed breathing air, compressed breathing oxygen, liquefied breathing air, or liquefied breathing oxygen, DOT markings.
6. _____ Pressure-gauge range has a scale reliable to within + or - 5% of full scale (minimum of five graduations empty, 1/4, 1/2, 3/4, full).
7. _____ Where pressurized oxygen is used, the gauge must have the words “Oxygen” and “Use No Oil”. If respirator is a closed circuit unit with oxygen, all materials must be compatible for use with oxygen (42 CFR 84.86).
8. _____ Procedure to assure proper gas mixture for refill purposes (percent oxygen).
9. _____ Specification and dimensions of outlet threads are identified.

10. _____ For compressed oxygen units, drawing specifies that cylinder is to be charged with oxygen meeting requirements of the US Pharmacopeia for pure oxygen [84.79(b)].

NEGATIVE PRESSURE AIR-PURIFYING RESPIRATOR EXCEPT FILTERING FACEPIECE (page 1 of 1)

Respiratory Inlet Covering - except filtering facepiece (mouth bit, half mask, full facepiece, hood, helmet)

1. _____ Elasticity or tensile strength as appropriate, length and method of attachment of straps.

Filter - except filtering facepiece

1. _____ Material specifications.
2. _____ Filtering mechanism for filter media.
3. _____ Lot number location and code, or date of manufacture.
4. _____ Filter efficiency (N95, N99, N100, etc.) include nuisance protections.
5. _____ Final filter media form (pleated, flat, etc.).
6. _____ Vendor for filter material is identified if the filter material specification is not determined by the respirator manufacturer.
7. _____ Filters containing carbon layers include a statement that carbon is chromium free.

Cartridge or Canister

1. _____ Material specifications including each carbon, with fill volume and mesh.
2. _____ Statement that the carbon is chromium free.
3. _____ Lot number location and code, or date of manufacture.
4. _____ Vendor for carbon material is identified if the carbon specification is not determined by the respirator manufacturer.
5. _____ Location and material of End of Service Life Indicator (ESLI) -- ESLI's are required for MV, HS, CO, and EO.
6. _____ Color and markings conform to either ANSI K13.1-1973 or ANSI Z88.7-2001, and the applicable specification is identified.
7. _____ Protections are listed and match those found in the SAF.

POWERED AIR-PURIFYING RESPIRATOR

(page 1 of 1)

Respiratory Inlet Covering (half mask, full facepiece, hood, helmet)

1. _____ Elasticity and length of the straps, method of attachment.

Filter

1. _____ Material specifications for filter media.
2. _____ Lot number location and code, or date of manufacture.
3. _____ Filter efficiency, including applicable nuisance protections.
4. _____ Final filter media form is identifiable (pleated, flat, etc.).
5. _____ Filtering mechanism is identified (electrostatic, mechanical or other).
6. _____ Filters containing carbon layers include statement that carbon is chromium free.
7. _____ Vendor for filter material is identified (only if the filter material specification is not determined by the respirator manufacturer).

Cartridge or Canister

1. _____ Material specifications including each carbon, with fill volume and mesh.
2. _____ Protections listed.
3. _____ Lot number location and code, or date of manufacture.
4. _____ Vendor for carbon material is identified (only if the carbon specification is not determined by respirator manufacturer).
5. _____ Filters containing carbon layers include a statement that carbon is chromium free.
6. _____ Location and material of End of Service Life Indicator, if used.
7. _____ Color and markings conform to either ANSI K13.1-1973 or ANSI Z88.7-2001, and the applicable specification is identified.

Blower

1. _____ Lot number location and code, or date of manufacture.
2. _____ Intrinsic safety certification (if intended for mine use).

Battery

1. _____ Battery type is specified, i.e., cadmium, lithium, etc.

NIOSH APPLICATION CHECK LIST

All Applications:

1. Is the AAR (applicant assigned reference) Number unique to the approval request/application?
2. Have all the applicable sections of the Standard Application Form (SAF) been completed?
3. If hardware is included, are the individual hardware items for evaluation identified with the AAR number and part numbers referenced on the assembly matrix?
4. If hardware is included, is the shipping container marked with the associated AAR number and/or TN number?
5. If hardware is included, does the hardware shipped include a packing slip accurately identifying what was actually shipped?
6. Is the application fee check or electronic funds transfer for \$200 included? Is the application fee check dated recently, less than 2 weeks before the application is to be submitted? Does the fee check include your EIN number if you are a US company or a US subsidiary? Does the check include your AAR number?
7. Does the assembly matrix match what was requested in the Reason for Application section of the SAF? Does the Assembly Matrix and SAF represent the actual configuration of the new or modified approval?
8. Does the reason for application accurately reflect what is being sought in the way of new approvals or modifications to existing approvals?
9. Have you identified under what NIOSH task number where this (these) respirator(s) were last tested?
10. Are all the files included with the application listed in the SAF?
11. Are all the files supplied in the acceptable file formats?
12. Are all the files properly identified/listed in the SAF?
13. Are new or revised drawings required and have these drawings been included in the application documents?
14. Do the revision levels on all drawings match those listed on the assembly matrix?
15. Do the item numbers on the exploded view drawing match the item numbers on the assembly matrix?
16. Do all the part numbers on the approval labels match the part numbers listed in the assembly matrix?
17. Is all the required information present on the sub-component drawings or for filtering facepieces, respirator drawings as indicated on the appropriate checklists?
18. Are all applicable draft approval labels included with the application, (respirator, cartridges, filters, along with other labels as required)?
19. Do the assemblies identified on the label match those identified on the matrix (or matrices) with the possible exception of accessories and user instructions?
20. Are all of the appropriate Caution and Limitation (C&L) statements identified on the individual approvals?

21. ____ Are all of the C&L statements referred to on the approvals spelled out on the label(s)?
22. ____ Do the user instructions include all the required information, (OSHA 1910.134 statement on fit testing, donning instructions, assembly instructions, additional warnings and cautions, private label statement (as required), name and contact information of the appropriate company and other items)?
23. ____ Have all the included documents been verified for the correct revision numbers and do these document revision levels match what is listed in the SAF?
24. ____ Is the pre-submittal testing indicating that all performance requirements specified in 42 CFR 84 complete and provided in the application?

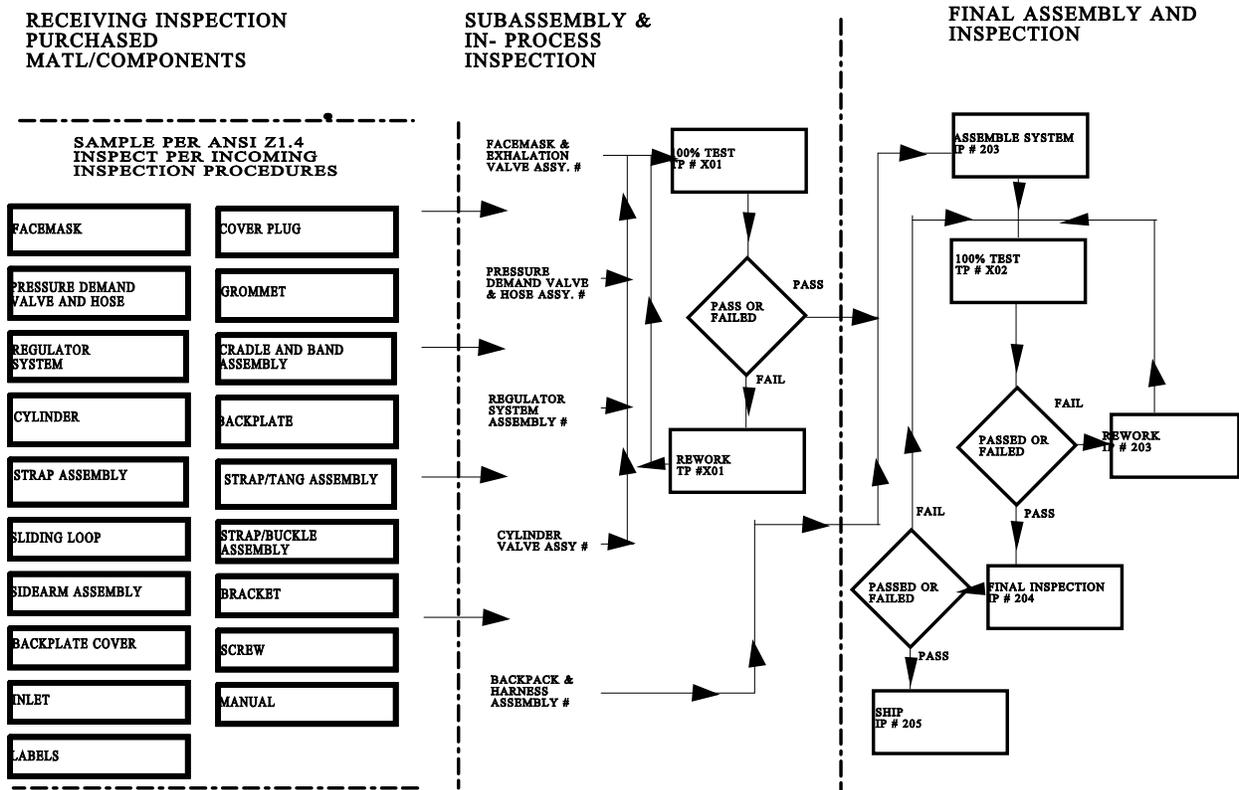
Specific Instructions:

25. ____ For filtering facepieces, are the abbreviated labels, primary company and private label company, listed and shown on page 2 of the drawing?
26. ____ For all other respirators, are the abbreviated labels, for the primary company and private label company, listed and shown on page 2 of the applicable subassembly, harness or abbreviated label drawings?

SECTION G - DOCUMENT EXAMPLES

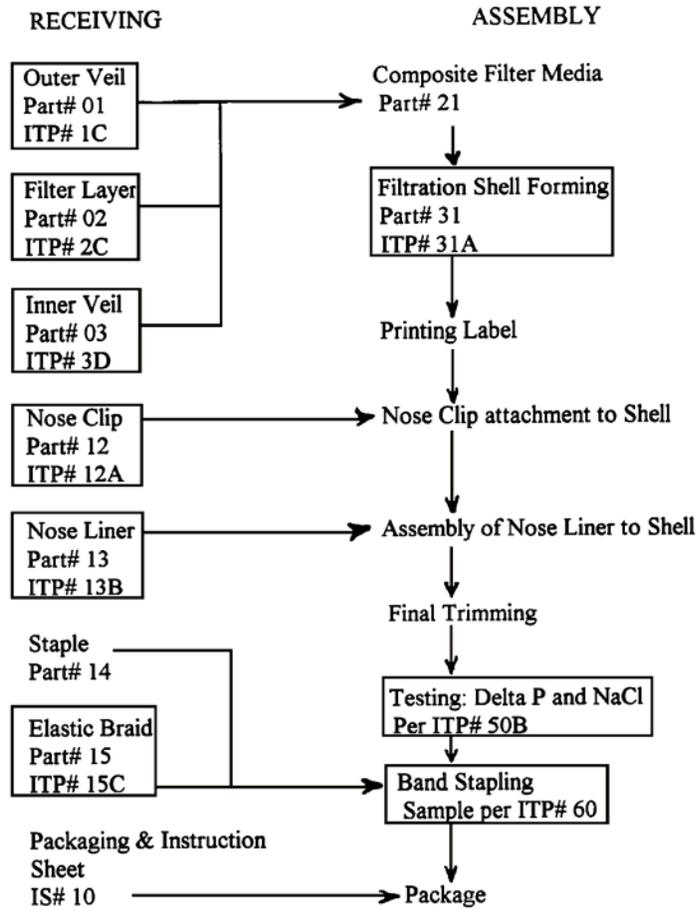
PQP Flowcharts

PRODUCT QUALITY PLAN FLOWCHART FF100 SCBA



PRODUCT QUALITY PLAN FLOWCHART

Model XY01 Filtering Facepiece



XYZ Respirator Co.

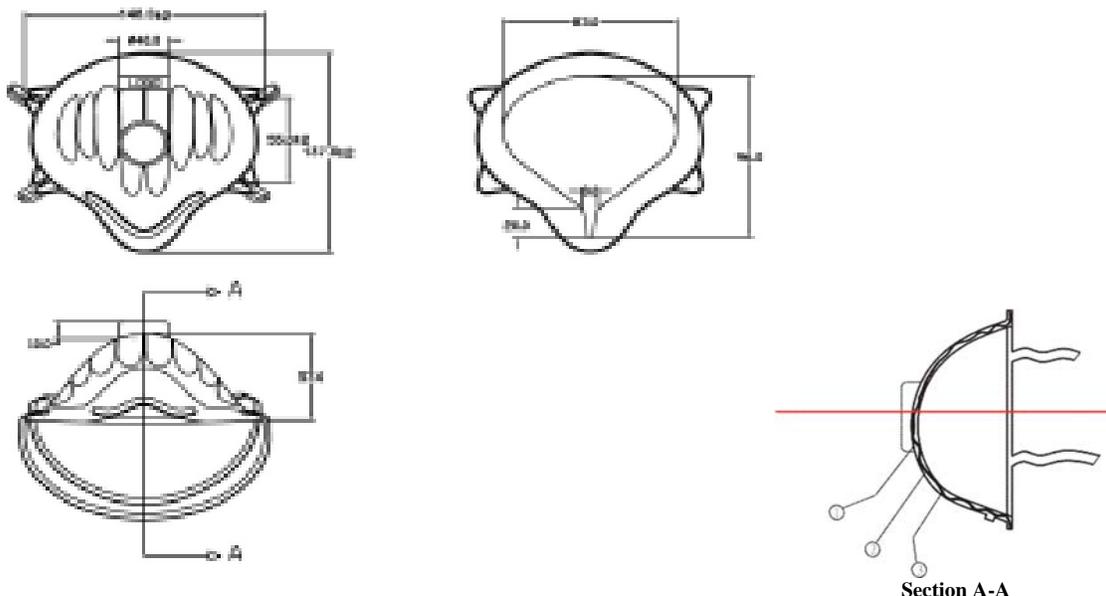
Approvals: Production Engr QA Mgr General Mgr

ARK *MKS* *MST*

Title: PQP for Model XY01 Filtering Face Piece
Product Plan Document # XY01P

Revision: B

Sample FILTERING FACEPIECE “exploded view” drawing



Notes:

Single drawing covering both exploded view and sub assembly

See product quality control plan (file name LW1000PQP) for material type, test specifications, classification of defects, test methods and process flow charts.

Final filter media shape will be cup type

a. Outer layer can be either 10 gm/m² polyester or 30 gm/m² PP

Filtering Mechanism: Electrostatic

a. Media type: Electrostatic

b. Melt blown filter media, Polypropylene

c. Basis weight of filter media, 30 gm/m², 2 layers

d. Carbon material: The carbon layer, item 2, is chromium free

Length and elasticity of head straps

a. Upper strap: 11 1/2 +/- 1/4"

b. Lower strap: 10 1/2 +/- 1/4 "

c. Elasticity: 2.5 kgs at full extended length

Alternate methods of attaching head straps by welding or stapling

a. Attachment point not in the breathing zone

Logo marking indicates location of part number and abbreviated NIOSH label

Lot number is located on the bottom of the final packaging box.

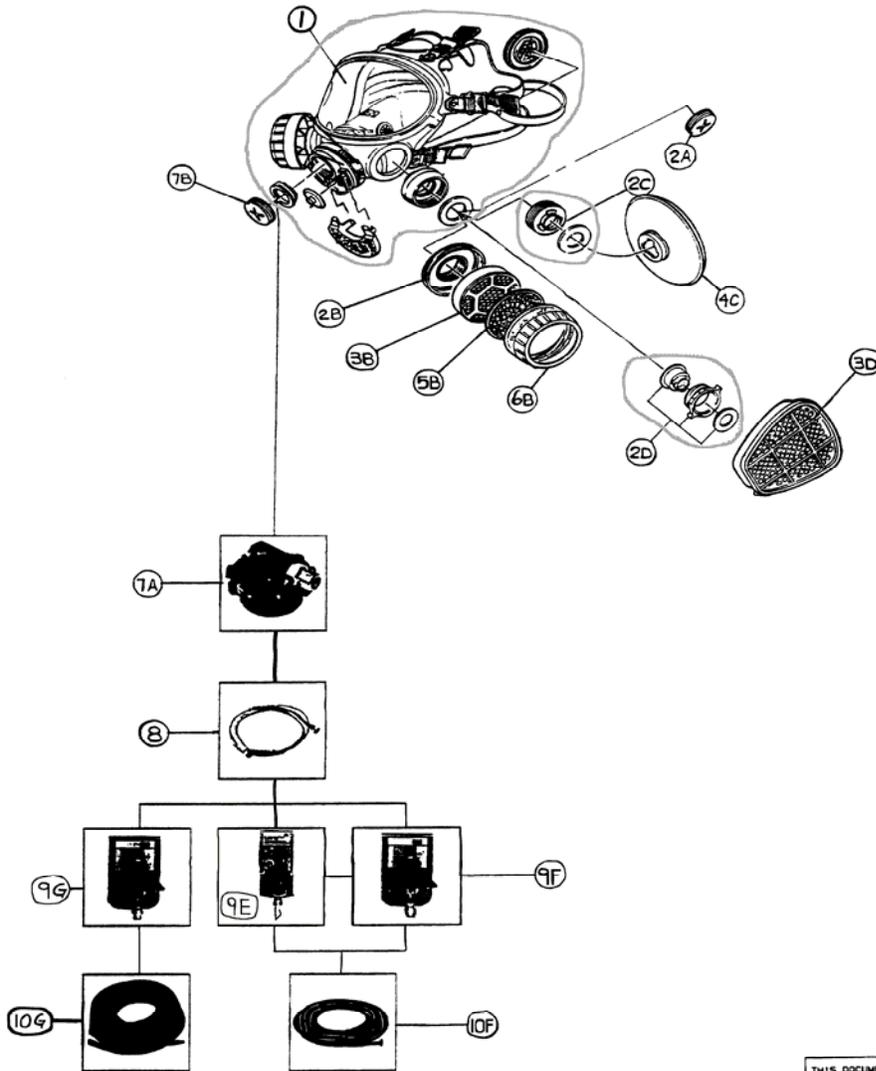
Nosepiece: 100 mm long X 5 mm wide X 1 mm thick

a. Material: Aluminum

Reference Standard Operating Procedure LW1000LN for lot numbering system.

Approved	Lucky Wing Manufacturing, Pittsburgh, PA		
Dwg: LWW 7/25/2015	Part Number: 123456	Title: Filtering Facepiece LW1000 N95	
Release: LLW 7/26/2015	Scale: NTS	Rev: 0	DRAWING No. LWM001

Sample exploded view drawing Full Facepiece Combination Supplied Air and Air Purifying Respirator



BORDER FORM: D131
PLOT SCALE = 1.0000

THIS DOCUMENT CONTAINS INFORMATION WHICH IS PROPRIETARY NO REPRODUCTION OR PUBLICATION OF THIS DOCUMENT IN WHOLE OR IN PART SHALL BE MADE WITHOUT WRITTEN AUTHORIZATION		DIVISION OH	MODEL
DWM		DIVISION CODE	OHS
TITLE NIOSH COMPOSITE DRAWING PROTOTYPE			
FIGM NO.	SIZE	DRAWING NO.	REV
	D	SK-10453	1
DO NOT SCALE DRAWING		DET. LIST: <input type="checkbox"/> YES <input type="checkbox"/> NO	SHT. 1 OF 1

1/8" (INCH)	1 DFTG	DATE	52-22-84
25.4MM (1 INCH)	CHKD	DATE	
TOLERANCES EXCEPT AS NOTED		DATE	
.0	.00	DATE	
.00	.0001	DATE	
ANGLES	INDICES	DATE	
MATCHING	INTERPRET PER 78-6070-CSS1-G	DATE	
FINISH	THIRD ANGLE PROJECTION	DATE	

Example Assembly Matrix for FILTERING FACEPIECES

KEY:

X = CURRENTLY APPROVED IN THIS CONFIGURATION

N = NEW COMPONENT OR CONFIGURATION

"-" = OBSOLETE

R = REDESIGN

P = PENDING

A = ACCESSORY

Lucky Wing Manufacturing
Pittsburgh, Pennsylvania, USA

Phone : 412-555-1212

TN or AAR# of previously approved or pending matrix : n/a

n/a; See simplified Drawing of each face piece

Exploded view drawing number :

Date : August 1, 2015

Rev: 1

RESPIRATOR LW1000 APPROVAL MATRIX		
	Respirator	
DESCRIPTION	LW1000 N95	LW1000V N95V
REV.	0	0
DRAWING NO.	LWM001	LWM002
MODEL/ PART No.	123456	123457
	X	
		R
	TN-16000	TN-16001

Appl.Assgn. Ref.#	NIOSH APPROVAL NUMBER, TC-	PROTECTION
LWM101	84A-1234	N95
LWN102	84A-1235	N95
NIOSH TASK NUMBER WHERE COMPONENT WAS LAST TESTED (IF NEW, INDICATED AS "N")		

Example Approval Label for FILTERING FACEPIECE



Double Wing Manufacturing Company
Almost Heaven, West Virginia USA
1-800- 123-4567

THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATION:

TC-	Protection ¹	Respirator	Cautions and Limitations ²
		Whisper	
84A-AARa	N95	X	ABCJMNOP

1. Protection

N95 - Particulate Filter (95% filter efficiency level)
Effective against particulate aerosols free of oil;
time use restrictions may apply

2. Cautions and Limitations

- A - Not for use in atmospheres containing less than 19.5% oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- J - Failure to properly use and maintain this product could result in injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.



Example Approval Label for HALF-MASK RESPIRATOR

DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567



THIS RESPIRATOR IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

TC-	Protection ¹	Facepiece	Alternate Filter				Alternate Cartridge					Alternate Filter Retainer			Cautions & Limitations ²
			H A L O	A R C H	W I N G	C R O W N	1 0 0 0 1	1 0 0 0 2	1 0 0 0 3	1 0 0 0 4	1 0 0 0 5	9 4 3 5	9 4 3 5	9 4 3 5	
84A-AArA	N95/CL/MV	X	X						X			X	X		ABCHJLMNOPS
84A-AARb	R95/AM/MA	X		X			X					X	X		ABCHJLMNOP
84A-AARc	R95/OV	X		X		X						X	X		ABCHJLMNOP
84A-AARd	P99/OV	X			X	X								X	ABCHJLMNOP
84A-AARe	R100/OV	X				X	X							X	ABCHJLMNOP
23C-AARf	FM	X								X					ABCHJKLMNO
23C-AARg	CL/HC/SD/HS(esc)	X						X							ABCHJLMNO

1. PROTECTION

N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; Time use restrictions may apply	R100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	P99-Particulate Filter (99% filter efficiency level) effective against all particulate aerosols	R95-Particulate Filter (95% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply
--	--	---	--

AM – Ammonia MA – Methylamine FM – Formaldehyde CL – Chlorine OV - Organic Vapor
MV – Mercury Vapor HC – Hydrogen Chloride SD – Sulfur Dioxide HS(esc) – Hydrogen Sulfide (escape only)

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- J - Failure to properly use and maintain this product could result in injury or death.
- K - The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- L - Follow the manufacturer User Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.



Example Approval Label for FILTER

DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567



CROWN FILTER

THIS FILTER IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

PROTECTION	FILTER	RESPIRATOR COMPONENTS															CAUTIONS AND LIMITATIONS	
		ALTERNATE FACEPIECE					ALTERNATE CARTRIDGE					ALTERNATE HOSES		ALTERNATE REGULATOR				
	CROWN	1000	2000	3000	4000	5000	1001	1002	1003	1004	1005	943-25	943-50	943-100	3021	3022	3025	
P100	X	X																ABCJLMNOP
P100	X		X															ABCJLMNOP
P100/OV	X	X	X				X											ABCJHLMNOP
P100/AM/MA/SA/CF	X			X	X	X			X			X	X	X	X			ABCDEGHJLMNOPS
P100/FM/SA/CF	X			X	X	X		X				X	X	X			X	ABCDEGHJKLMNOP
P100/CL/HC/SD	X			X	X	X			X									ABCHJLMNOP
P100/CL/HC/SD/HS(esc)/SA/PD	X					X					X		X			X		ABCDEGHJLMNOPS

1. PROTECTION

P100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols

- | | | |
|------------------------|-----------------------|---------------------|
| AM - Ammonia | CF - Continuous Flow | FM - Formaldehyde |
| HC - Hydrogen Chloride | HS - Hydrogen Sulfide | MA - Methylamine |
| PD - Pressure-Demand | SA - Supplied-Air | SD - Sulfur Dioxide |
| OV Organic Vapor | ESC - Escape-only | CL - Chlorine |

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- D - Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G-7. Grade D or high quality.
- E - Use only the pressure ranges and hose lengths specified in the User's Instructions.
- G - If airflow is cut off, switch to filter and/or cartridge or canister and immediately exit to clean air.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- J - Failure to properly use and maintain this product could result in injury or death.
- K - The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- L - Follow the manufacturer's User Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.



Example Approval Label for CHEMICAL CARTRIDGE



DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567
1001 CARTRIDGE

THIS CARTRIDGE IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																			
TC-	Protection	Cartridge	Alternate Facepiece					Alternate Filter					Alternate Hoses/Lengths			Alternate Regulator			Cautions & Limitations
			1	2	3	4	5	H	W	G	G	C	9	9	9	3	3	3	
		1001	0	0	0	0	0	A	I	A	L	O	4	4	4	0	0	0	
23C-AARa	OV	X	X																ABCHJLMNO
84A-AARb	OV/N95	X		X				X											ABCHJMNOP
84A-AARc	OV/N100	X	X	X					X										ABCHJLMNOP
84A-AARd	OV/R99/SA/CF	X			X	X	X			X			X	X		X	X		ABCDEGHJLMNOPS
84A-AARe	OV/P95/SA/DE	X			X	X	X				X				X			X	ABCDEGHJLMNOPS
84-AARf	OV/P100	X			X	X	X					X							ABCHJLMNOP

1. PROTECTION

N100-Particulate Filter (99.97% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply	R99-Particulate Filter (99% filter efficiency level) effective against all particulate aerosols; time use restrictions may apply	P100-Particulate Filter (99.97% filter efficiency level) effective against all particulate aerosols
N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply	P95-Particulate Filter (95% filter efficiency level) effective against all particulate aerosols	OV – Organic Vapor DE - Demand CF – Continuous Flow SA – Supplied Air

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- D - Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G-7.1 Grade D or higher quality.
- E - Use only the pressure ranges and hose lengths specified in the User's Instructions.
- G - If airflow is cut off, switch to filter and/or cartridge or canister and immediately exit to clean air.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- J - Failure to properly use and maintain this product could result in injury or death.
- L - Follow the manufacturer User's Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.



Example Approval Label for SUPPLIED-AIR RESPIRATOR with EGRESS CARTRIDGES AND FILTERS

DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567
T500 SAR

TYPE C AND CE CONTINUOUS FLOW SUPPLIED-AIR RESPIRATOR

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																			
TC-	Protection	Filter	Alternate Facepiece					Alternate Cartridge					Alternate Hoses/Length			Alternate Regulator			Cautions & Limitations
		C	1	2	3	4	5	1	1	1	1	1	9	9	9	3	3	3	
		R	0	0	0	0	0	0	0	0	0	0	4	4	4	0	0	0	
		O	0	0	0	0	0	0	0	0	0	0	3	3	3	2	2	2	
		W	0	0	0	0	0	1	2	3	4	5	-	-	1	1	2	5	
		N											2	5	0				
													5	0	0				
84A-AARa	P100	X	X																ABDJLMNOP
84A-AARb	P100	X		X															ABCJLMNOP
84A-AARc	P100/OV	X	X	X				X											ABCJHLMNOP
84A-AARd	P100/AM/MA/SA/CF	X			X	X	X				X		X	X	X	X			ABCDEGHLMNOPS
84A-AARe	P100/FM/SA/CF	X			X	X	X	X					X	X	X			X	ABCDEGHJKLMNOPS
84A-AARf	P100/CD/HC/SD	X			X	X	X			X									ABCHJLMNOP
84A-AARg	P100/HC/SD/HS (esc)/SA/PD	X					X					X		X			X		ABCDEGHLMNOPS

1. PROTECTION

P100-Particulate Filter
(99.7% filter efficiency level) effective against all particulate aerosols

- | | | | |
|------------------------|-----------------------|---------------------|--------------------|
| AM - Ammonia | CF - Continuous Flow | CL - Chlorine | FM - Formaldehyde |
| HC - Hydrogen Chloride | HS - Hydrogen Sulfide | MA - Methylamine | OV - Organic Vapor |
| PD - Pressure-Demand | SA - Supplied-Air | SD - Sulfur Dioxide | ESC - Escape-only |

2. CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- D - Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G-7. Grade D or high quality.
- E - Use only the pressure ranges and hose lengths specified in the User's Instructions.
- G - If airflow is cut off, switch to filter and/or cartridge or canister and immediately exit to clean air.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- J - Failure to properly use and maintain this product could result in injury or death.
- K - The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- L - Follow the manufacturer's User Instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning



Example Approval Label for SUPPLIED-AIR RESPIRATOR



DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567
T500 SAR

TYPE C AND CE CONTINUOUS FLOW SUPPLIED-AIR RESPIRATOR

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

Respirator Components														
TC-	Protection	M O D E L	Facepiece	Hood or Helmet	Flow Regulator & Belt	Cape	Quick Disconnect	Hose 25'	Hose 50'	Breathing Tube	Visor	Inner Lenses	Outer Lenses	Cautions & Limitations
			T200	T100	T28061	T26-1	T28-0	T20-25	T20-50	T16-4	T18-1	T24-0	T24-4	
19C-AARa	SA/CF	T5000 SA		X	X	X	X	X	X	X	X	X	X	BCDEJMNOS
19C-AARb	SA/CF	T5000 SB	X		X		X	X	X	X				BCDEJMNOS

1. PROTECTION

CF - Continuous Flow SA - Supplied-Air

2. CAUTIONS AND LIMITATIONS

- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- D - Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G-7.1 Grade D or higher quality.
- E - Use only the pressure ranges and hose lengths specified in the User's Instructions.
- J - Failure to properly use and maintain this product could result in injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

[NOTE: All appropriate Cautions and Limitations must be listed in a separate section of the User Instructions. This includes air quality requirements, special use instructions, etc.]



Example Approval Label for SCBA RESPIRATOR



DOUBLE WING MANUFACTURING COMPANY
 ALMOST HEAVEN, WEST VIRGINIA, USA
 1-800-123-4567
 1900 SERIES SCBA

OPEN-CIRCUIT, PRESSURE DEMAND, ENTRY, SELF-CONTAINED BREATHING APPARATUS

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																					
TC-	Protection	Alternate Facepiece				Alternate Harness					Alternate Cylinder				Alternate Regulator			Accessories			Cautions & Limitations
		1	2	3	4	H 9 5	H 9 6	H 9 7	H 9 8	H 9 9	C 0 1	C 0 2	C 0 3	C 0 4	R 1 1	R 2 2	R 3 3	L E N S 1 0	A L A R M 5 0	C A S E 2 0	
13F-AARa	30 min/ 2216 psi/ SC/PD	X	X			X	X	X	X	X	X				X			X		X	IJM NOS
13F-AARb	30 min/ 4500 psi/SC/PD	X		X	X		X	X	X	X						X	X	X	X	X	IJM NOS
13F-AARc	45 min/ 4500 psi/SC/PD	X		X		X	X						X		X	X	X	X	X	X	IM NOS
13F-AARd	60 min/ 4500 psi/SC/PD	X						X	X					X		X	X	X	X	X	IJM NOS

1. PROTECTION

PD - Pressure-Demand

SC - Self-Contained

2. CAUTIONS AND LIMITATIONS

- I - Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by MSHA/NIOSH.
- J - Failure to properly use and maintain this product could result in injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

[NOTE: All appropriate Cautions and Limitations must be listed in a separate section of the User Instructions. This includes cold temperature limitations, air quality requirements, etc. that were listed on old Part 11 label.]



Example Approval Label for SCBA HARNESS

DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567

EASY-CARRY SCBA

OPEN-CIRCUIT, PRESSURE-DEMAND, ENTRY AND ESCAPE SELF-CONTAINED BREATHING
APPARATUS

TC-13F-XXX 30 MINUTE 2216 PSIG
TC-13F-YYY 30 MINUTE 4500 PSIG
TC-13F-ZZZ 45 MINUTE 4500 PSIG
TC-13F-AAA 60 MINUTE 4500 PSIG

(REFER TO THE APPROVED USER'S INSTRUCTIONS FOR THE COMPLETE LIST
OF COMPONENTS THAT MAKE UP THE APPROVED ASSEMBLY)

CAUTIONS AND LIMITATIONS

- I - Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by MSHA/NIOSH.
- J - Failure to properly use and maintain this product could result in injury or death.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

[NOTE: All appropriate Cautions and Limitations must be listed in a separate section of the User Instructions. This includes cold temperature limitations, air quality requirements, special use instructions, etc. that were listed on old Part 11 label.]



Example Approval Label for CHEMICAL SCRUBBER

DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567

CLEAN AIR SCRUBBER
CHEMICAL SCRUBBER CANISTER
TC-13F-XXX

CAUTIONS AND LIMITATIONS

1. Approved for use only in replacing or refilling chemical scrubber part number XXXXXX.
2. Not approved for use after the indicated expiration date.
3. Do not re-use scrubber material.

[NOTE: All appropriate Cautions and Limitations must be listed in a separate section of the User Instructions. This includes cold temperature limitations, air quality requirements, special use instructions, etc. that were listed on old Part 11 label.]

Example Label for ABBREVIATED FILTER and FILTERING FACEPIECE



Filter Version



Filtering Facepiece Version

NOTE:

The company name must be completely spelled out or a NIOSH acceptable abbreviation.

The part number (P/N) must be shown.

The protections provided by the filter must be accurately listed.

Multiple protection identifiers as listed on the full filter label are separated by a forward slash.

A lot number or other production tracking identifier must be provided on the respirator or container.

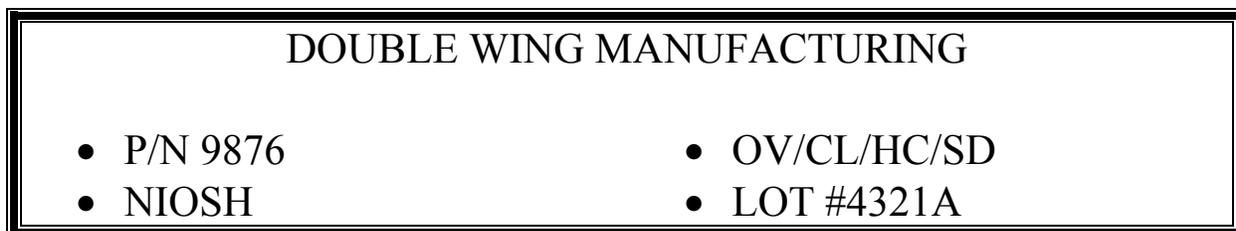
The word “NIOSH” must be shown in all capital letters.

For filtering facepiece respirators, the NIOSH approval number must be printed on the respirator as part of the abbreviated label.

All information must be provided in a legible typeface readable by the user. For filtering facepiece respirators, the information must be on the facepiece, exhalation valve cover or the head straps.

The P100 series of filters must be magenta in color.

Example Label for ABBREVIATED CARTRIDGE



NOTE:

The company name must be completely spelled out.

The part number (P/N) must be shown.

The protections provided by the cartridge must be accurately listed with each protection identifier as shown on the cartridge label and separated by a forward slash.

The word “NIOSH” must be portrayed in all capital letters.

A lot number (LOT #) or other production tracking identifier must be provided.

All information must be provided in a legible typeface readable by the user.

Color codes of cartridges for gases and vapors must meet the requirements of ANSI K13.1-1973 or ANSI Z88.7-2001. The applicable specification will be called out on the cartridge drawing.

Example Label for GAS MASK CANISTER

(NOTE: the full matrix label may also be used on the canister)



DOUBLE WING MANUFACTURING COMPANY
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567
LIST CANISTER PART NUMBER AND TRADE NAME
LIST PROTECTIONS



TC-14G-XXX
TC-14G-YYY
TC-14G-ZZZ
TC-14G-AAA

REFER TO THE APPROVED USER'S INSTRUCTIONS FOR THE COMPLETE LIST OF COMPONENT PARTS MAKING UP THE APPROVED ASSEMBLY

CAUTIONS AND LIMITATIONS

- A - Not for use in atmospheres containing less than 19.5 percent oxygen.
- B - Not for use in atmospheres immediately dangerous to life or health.
- C - Do not exceed maximum use concentrations established by regulatory standards.
- D - Air-line respirators can be used only when the respirators are supplied with respirable air meeting the requirements of CGA G-7.1 Grade D or higher quality.
- E - Use only the pressure ranges and hose lengths specified in the User's Instructions.
- G - If airflow is cut off, switch to filter and/or cartridge or canister and immediately exit to clean air.
- H - Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
- I - Contains electrical parts which have not been evaluated as an ignition source in flammable or explosive atmospheres by MSHA/NIOSH.
- J - Failure to properly use and maintain this product could result in injury or death.
- K - The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
- L - Follow the manufacturer's instructions for changing cartridges, canister and/or filters.
- M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O - Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P - NIOSH does not evaluate respirators for use as surgical masks.
- S - Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

[NOTE: The labels for gas mask respirators and canisters must appear in their entirety in the User Instructions]

SECTION H - LABEL FORMAT GUIDANCE & ISSUES

Labels for respirators, cartridges, and filters must be completed in the assembly matrix format shown in the preceding examples. The far left column must be the TC number. For initial submittals the TC number is the schedule and AAR# followed by an alpha character, exactly as in the assembly matrix. This links the approval label to the application and assembly matrix. Upon approval, NIOSH will insert the TC number. "TC-" can only appear in the column heading, not in the row. The second column from the left is for the protections. The far right column is for the Cautions and Limitations. The component columns must list all of the major sub-assemblies in any order that the applicant chooses.

Anytime more than one of the same major sub-assemblies for a respirator configuration are listed on the approval label, they must be identified as alternate components by adding "Alternate" to the column heading. The only character that may be used in the body of the approval label to designate an approved component is an X. If a component is offered as an accessory, the category must be labeled as "accessory" (e.g., "accessory spectacle kit").

Empty rows are not permitted. Approval labels must not be color coded.

Wording of the standard protections and Cautions and Limitations must always be identical to the NIOSH samples. Only appropriate Cautions and Limitations may be listed. For example, if only Cautions and Limitations A, C, and G apply, then only A, C, and G can be footnoted at the bottom of the label.

Caution and Limitation F only applies to PAPRs.

The abbreviated label mounted on the cartridge, filter, cartridge/filter combination or filtering facepiece must clearly indicate the approval holder's name, filter series (if a filter is included), gas or vapor protection, part number, lot number and word "NIOSH." Only on Filtering Facepieces does the TC number appear. The abbreviated label may list the two-letter codes for gases and vapors (see label examples) or the entire chemical name, but not a mix of codes and names. The same information is required for filtering facepieces, with one exception: the lot number need only appear on the container.

Gas mask canister labels or the SCBA harness label must clearly indicate the approval holder's name, address, and phone number, model/trade name, type of protection, TC number, duration-cylinder pressure-type data, appropriate Cautions and Limitations, reference to the User Instructions for major sub-assembly and component information, and DHHS and NIOSH logos.

The entire SCBA, SAR, or gas mask label must appear in the User Instructions.

Protections on SCBA approval labels, User Instructions and assembly matrices must list the cylinder operating pressure, rated service time, and self-contained code e.g., 2216 psi 30 min SC.

If all respirators on the label are of the same series or family, text may be added to identify the respirator series or family, e.g., continuous flow, pressure demand, positive pressure, Type C or Type CE, open circuit, closed circuit, etc. This heading is optional on all approval labels.

Non-NIOSH approval identifiers cannot be represented on any NIOSH labels. Applicants may use additional areas on the component to identify any other applicable approvals such as the European CE approval, but this information must be separated from the NIOSH approval label.

If the label will not fit on the container, it must be included inside the container. If the label is inserted, the container must say “NIOSH approved - see insert.” The insert may consist of the approval label or the User Instructions containing the approval label.

The statement “Time use restrictions may apply” refers to the potential limited filter life associated with degradation of the filter efficiency as the result of exposure to aerosols in the workplace. The service life is dependent upon the concentration, type of contaminant, and use conditions encountered in the workplace, and must be determined on a workplace basis. Specific recommendations have been published in *A NIOSH Guide to the SELECTION AND USE OF PARTICULATE RESPIRATORS CERTIFIED UNDER 42 CFR 84 - DHHS (NIOSH) Publication No. 96-101.* Call 1-800-35NIOSH to obtain a copy.

Since NIOSH tests against gases and vapors individually and not in mixed gas and vapor atmospheres or in a sequence of atmospheres, NIOSH assumes that the gases and vapors listed in the protection column of the approval labels are used against only one of the listed gases or vapors. Since NIOSH cannot test cartridges against mixed atmospheres, the applicant assumes the liability for use of the respirators in mixed atmospheres. An applicant may demonstrate to NIOSH that sorbents are effective in exposures to mixed gas and vapor atmospheres or serial exposures to different atmospheres by providing data to NIOSH satisfying the six criteria for mixed gas and vapor atmospheres as listed in the Notice to all Manufacturers, September 24, 1981. When the data has been received, reviewed and accepted by NIOSH, the approval holder is permitted to say in the User Instructions or respirator literature that they endorse the use of the cartridges in mixed gas and vapor atmospheres. You may not say that NIOSH endorses the use of the respirators in mixed gas and vapor atmospheres. The slash on the label in the protection column serves only as a divider between protections.

If the respirator is for *escape* only, the applicant must use the word *escape* on full approval labels. For example, “These escape-only respirators are approved only in the following configurations.” You may abbreviate *escape* in the protection column and must spell out the word *escape* in the legend. On abbreviated cartridge labels, *escape* must follow each gas and vapor listed. The only acceptable abbreviation for *escape* is “esc.” A list of allowable protections, cautions, and limitations can be found on page 44. No other codes are permitted on the NIOSH approval labels at this time.

APPENDIX



LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Sampling Procedures

The National Institute for Occupational Safety and Health (NIOSH) requires that respirator approval holders inspect and/or test samples of respirators and components as part of their quality control plans. This requirement is stated in Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84), specifically in §§ 84.41(b) through 84.41(i).

Some applicants or approval holders have had difficulty understanding how to select and use a sampling procedure which meets the requirements. This letter is intended to explain the practical use of common standard procedures acceptable to NIOSH.

This letter will not discuss statistical theory underlying acceptance sampling. If applicants or approval holders intend to use alternatives to the procedures described here, they must understand the concepts of acceptance sampling and process control. The use of more modern methods such as calculating process capability values (C_{pk}) or employing statistical process control (SPC) is encouraged where this is compatible with the approval holder's operations and provides equivalent assurance of respirator performance. Justification to demonstrate the equivalence of these procedures must be provided in the application seeking approval.

1. Selection of Sampling Procedures

1.1 Sampling by Variables. The standard sampling procedure specified in 42 CFR 84 is MIL-STD-414 [U.S. Department of Defense 1957]. This is a variable sampling plan, which means that the characteristic must be something that can be measured numerically on a continuous scale. Examples include the diameter of a hole in inches, the mass of a cartridge in grams, or the leakage of an exhalation valve in milliliters per minute. This procedure is only valid when the characteristic being measured has a statistically normal distribution over the population being sampled. The ANSI/ASQ Z1.9 standard [American National Standards Institute 2003b] is derived from MIL-STD-414, and NIOSH considers it to be equivalent.

1.2 Sampling by Attributes. The MIL-STD-105D sampling procedure [U.S. Department of Defense 1963] is explicitly accepted as an equivalent procedure in 42 CFR 84. This is an

attribute sampling plan, which means that each characteristic is simply checked to see whether it is acceptable. Due to its simplicity, this standard and its derivatives are by far the most common in use. It has the advantage that it can be applied to characteristics which do not involve a numerical measurement (such as visual checks) as well as to those that are measurable. No calculations are needed to determine acceptance, and the procedure is valid whether the Page 2 – Letter to All Respirator Manufacturers 9-2012 characteristic has a normal distribution or not. Typically the sample sizes will be larger than the corresponding variable sampling plan. Procedures derived from this standard, and which NIOSH considers to be equivalent, include MIL-STD-105E [U.S. Department of Defense 1989] and ANSI/ASQ Z1.4 [American National Standards Institute 2003a].

1.3 Zero-Defect Sampling by Attributes. Another attribute sampling plan which NIOSH accepts as equivalent is the Squeglia C=0 procedure [Squeglia 2008]. While not directly derived from MIL-STD-105E, its plans are matched to that procedure and provide an acceptable statistical assurance of lot quality. The chief difference is that in all cases, the lot is only accepted if there are zero defects found in the sample (C=0). This procedure usually requires fewer samples than MIL-STD-105D and related standards, and is the simplest to use of those listed in this letter. However, it is generally only suitable when defects in production are extremely rare.

1.4 Equivalent Standards. The ANSI/ASQ standards mentioned above are revised periodically. In general, NIOSH will consider later editions of a given procedure to be equivalent. There may also be other national or international standards based on MIL-STD-414 or MIL-STD-105D that can be considered equivalent. If such a standard is used, NIOSH may request a copy from the applicant to verify its equivalence.

1.5 Obtaining Sampling Procedure Documents. One feature of MIL-STD plans is that as works of the United States Government, they may be copied free of charge. Those mentioned can be downloaded from the Internet Archive at <http://www.archive.org/> and may be available elsewhere. However, all MIL-STD documents in this letter have been cancelled by the Department of Defense and are no longer maintained or revised. The corresponding ANSI/ASQ standards are successors to the MIL-STD documents and have various minor improvements and clarifications added. Copies of these standards may be purchased from the American Society for Quality, the American National Standards Institute, or others who deal in national standards.

2. Acceptable Quality Level (AQL)

- Meaning of AQL. The acceptable quality level is an indicator of the percent defective that can be considered satisfactory for a particular characteristic. Smaller AQL values mean that fewer defectives will be tolerated in an acceptable lot.
- Selection of AQL. The classification of defects document submitted with each application as required by 42 CFR 84.41(c) through 84.41(e) must identify the severity level of each characteristic. The AQL to be used for sampling is shown in the table below and is defined in 42 CFR 84.41(g). The AQL value does not depend on lot size or any other factor, and it is generally improper to modify the AQL for any reason other than the defect classification.

Defect Classification	AQL ^{1,2}
Major A	1.0
Major B	2.5
Minor	4.0

¹ These are called “index values” in the Squeglia C=0 procedure.

² It is acceptable to use a smaller (more stringent) AQL value.

2.3 Critical Characteristics. Characteristics identified as Critical in the classification of defects are not assigned an AQL and are not eligible for any form of sampling. Each item made must be 100% inspected as required by 42 CFR 84.41(f) and the entire lot rejected when a defect is found. Any plans to perform rework on the lot must be approved as part of the product quality plan.

2.4 Cross-References. See MIL-STD-414 section A4; ANSI/ASQ Z1.9-2003 sections A2.1, A4; MIL-STD-105D section 4; MIL-STD-105E sections 3.1, 4.4; ANSI/ASQ Z1.4-2003 section 4; Squeglia C=0 pages 3, 6.

3. Inspection Level

3.1 Meaning of Inspection Level. The inspection level decides the number of samples to be drawn for a particular lot size and determines the sampling plan’s ability to discriminate between conforming and nonconforming lots. Lower inspection levels increase the risk that a nonconforming lot will be accepted.

3.2 Selection of Inspection Level. The inspection level to be used is shown in the “normal” column of the table below and is defined in 42 CFR 84.41(h). As a special exception, NIOSH is permitted under 42 CFR 84.41(i) to allow a lower inspection level for destructive testing only. The minimum level NIOSH will accept under this exception is in the “destructive” column. Approval of a level lower than the “normal” level is entirely at NIOSH’s option and will only be granted if the rest of the inspection plan ensures adequate control over product quality.

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

¹ Only permitted with specific prior approval from NIOSH.

The Squeglia C=0 procedure does not use the concept of inspection levels and NIOSH treats it as equivalent to inspection level II of MIL-STD-105D.

3.3 Cross-References. See MIL-STD-414 section A7.1; ANSI/ASQ Z1.9-2003 section A7.1; MIL-STD-105D sections 9.2, 9.3; MIL-STD-105E sections 4.9.1, 4.9.2; ANSI/ASQ Z1.4-2003 sections 9.2, 9.3.

4. Normal, Reduced, and Tightened Inspection

4.1 Use of Switching Rules. Most sampling procedures referenced in this letter contain rules allowing reduced inspection under certain conditions. Reduced inspection may be used only when all conditions listed in the switching rules are met. This includes the requirement that production is not irregular or delayed. A history of lot acceptance at one manufacturing site

cannot be used to move to reduced sampling at another site. Approval holders may choose to stay at normal inspection even when conditions for reduced inspection are met. However, tightened inspection is not optional and must be used where specified by the rules. The Squeglia C=0 procedure does not recommend switching rules, and reduced inspection is not permitted by NIOSH for that procedure. Tightened inspection is not required for the Squeglia C=0 procedure.

4.2 Records to Support Reduced Inspection. To use reduced inspection, the approval holder must maintain inspection records showing that the conditions in the applicable procedure are met. Such records must be available for review during NIOSH on-site audits.

4.3 Cross-References. See MIL-STD-414 sections A8, B14, C14, D14; ANSI/ASQ Z1.9-2003 section A10; MIL-STD-105D section 8; MIL-STD-105E sections 4.6, 4.7, 4.8; ANSI/ASQ Z1.4-2003 section 8; Squeglia C=0 pages 14, 16.

5. Lots or Batches

5.1 Definition of Lot. Each procedure listed in this letter requires that product be grouped into inspection lots (the term “batch” means the same as “lot”). Each lot consists of product which has been manufactured under essentially the same conditions in the same production facility and at essentially the same time. For example, if a production line is shut down for a week for maintenance, it is wrong to consider product made before and after the shutdown as part of the same lot.

5.2 Selection of Samples from Lot. Each sample drawn from a lot must be representative of the lot. For example, when drawing a sample of 200 pieces from a lot of 10,000 it would be improper to select the first 200 respirators produced to use as the sample. As another example, if respirators being produced on five machines are being combined into an inspection lot, then one-fifth of the sample drawn must come from each machine. As noted in section 6.2 of this letter, each sample taken for double or multiple sampling must be representative of the whole lot.

5.3 Inspection Lot vs. Other Lot Designations. The grouping of finished respirators into lots for shipment or other purposes may differ from the grouping used for inspection. The lot number marked on the respirator or its container, as required by 42 CFR 84.33(g), does not necessarily need to be the same number used for inspection purposes. However, the approval holder must maintain traceability between lot numbering systems if more than one is used. For example, a shipping lot number must be traceable to the corresponding production lot number (or numbers).

5.4 Cross-References. See MIL-STD-414 sections A5, A7.2; ANSI/ASQ Z1.9-2003 sections A2.4, A5, A7.2; MIL-STD-105D sections 5, 7.2; MIL-STD-105E sections 3.12, 3.13, 4.3, 4.5.1; ANSI/ASQ Z1.4-2003 sections 5, 7.2; Squeglia C=0 page 2.

6. Specific Considerations for Attribute Plans

6.1 Following Arrows to Select Appropriate Sampling Plan. Where the sampling plan indicated leads to an arrow in the table, follow the arrow to the next available sampling plan. This will

point to a new code letter row in the table with the acceptance and rejection numbers and a new corresponding sample size to be used.

As an example, consider sampling of a lot of 200 pieces under MIL-STD-105D for a Major A characteristic at inspection level II. Code letter G is selected from Table I, and an AQL of 1.0 is used. An arrow pointing downward is contained in Table II-A for these conditions, indicating that code letter G is not available and code letter H must be used. This means that the appropriate sample size is 50 pieces, not 32, and that the lot is accepted if there are 0 or 1 defective pieces, and rejected if there are 2 or more defectives.

6.2 Single, Double, or Multiple Sampling. Most attribute procedures include double or multiple sampling plans (the Squeglia C=0 procedure only has single plans). Any of these options included in the procedure may be selected. Note that each sample drawn must be representative of the entire lot. Double and multiple sampling tend to require fewer samples when lot quality is either much better or much worse than the AQL. Single sampling is simpler to administer and apply correctly than double or multiple sampling and is the overwhelmingly popular choice.

As an example, consider a lot of 200 pieces under MIL-STD-105D for a Minor characteristic at inspection level II. Code letter G is selected from Table I, and an AQL of 4.0 is used. For single sampling, Table II-A indicates that the sample size is 32. The lot is accepted if there are 3 or fewer defective pieces, and it is rejected if there are 4 or more defectives. For double sampling, Table III-A is used instead and an initial sample of 20 would be drawn. The lot is accepted if there are 0 or 1 defectives, and it is rejected if there are 4 or more defectives. If there are 2 or 3 defectives, then a second sample of 20 is drawn from the lot and inspected. If after both samples (totaling 40 pieces) are inspected there are a total of 4 or fewer defectives, then the lot is accepted; if 5 or more defectives, then the lot is rejected. Multiple sampling (Table IV-A) works in a similar fashion, except that there are up to seven rounds of sampling to reach a decision.

6.2.1 Cross-References. See MIL-STD-105D sections 7.4, 9.5, 10.1.1, 10.1.2, 10.1.3; MIL-STD-105E sections 4.5.3, 4.9.4, 4.10.1.1, 4.10.1.2, 4.10.1.3; ANSI/ASQ Z1.4-2003 sections 7.4, 9.5, 10.1.1, 10.1.2, 10.1.3.

7. Specific Considerations for Variable Plans

7.1 Variability Unknown vs. Variability Known. A variability unknown method should normally be used. The variability known method may only be used when the production process is under strict control and the process parameters influencing final respirator performance are well understood. Data must be provided with the application for approval, available during on- site audits, and continuously updated to support the standard deviation value (σ) used.

7.2 Single Specification Limit vs. Double Specification Limit. This is selected on the basis of whether there is only one limit value (such as penetration less than or equal to 5%) or two limit values (such as cartridge mass between 95 and 105 grams) for the characteristic.

7.3 Standard Deviation Method vs. Range Method. Either method may be selected. The standard deviation method generally requires fewer samples, but more complex computations.

7.4 Form 1 vs. Form 2. The two forms are equivalent and either one may be selected. Form 2 is recommended as it yields figures which must be calculated anyway to satisfy the switching rules.

7.5 Cross-References. See MIL-STD-414 Introduction, section A6.2; ANSI/ASQ Z1.9-2003 Introduction, section A6.2.

8. Scope

8.1 Limitation to Approved Quality Control Plans. Approval holders may perform additional testing and inspection not listed in their approved quality control plans. Sampling for these additional inspections is not required to meet the requirements set forth in 42 CFR 84 and this letter. However, there must be a reasonable basis for selecting the sampling plans used.

8.2 Limitation to Required Testing. In some cases, applicants may wish to list testing and inspection in their quality control plans above that required by NIOSH for effective quality control of respirator performance. Sampling done for these additional inspections is not required to meet the requirements in 42 CFR 84 and this letter. Additional testing should be identified clearly, such as with the notation “additional inspection,” on documents submitted with the application to avoid delay and requests for clarification during processing. Any such testing listed in the approved quality control plan must be conducted as required by 42 CFR 84.42(c).

9. Common Errors

9.1 Selection of Inadequate Inspection Levels. The minimum acceptable inspection level is described in section 3.2 of this letter. If a product quality control plan does not specify inspection levels, NIOSH assumes that the level in the “normal” column of the table will be used. Use of lower levels without specific approval, whatever the reason, is a failure to conform to NIOSH requirements and can result in revocation of approval under 42 CFR 84.43(c).

9.2 Selection of Plan Based on Desired Sample Size. It is entirely improper to choose a desired sample size and work backwards to identify a proposed AQL and inspection level which will yield this result. To do so reflects a fundamental misunderstanding of the basis for sampling plans. The appropriate AQL and inspection level are stated in sections 2.2 and 3.2 of this letter.

9.3 Selection of Defect Classification Based on Desired AQL. As in 9.2, the defect classification drives the selection of AQL, not the other way around. Each defect must be classified based solely on the definitions in 42 CFR 84.41(d).

9.4 Modification of AQL or Inspection Level Based on Lot Size or Other Factors. The AQL and inspection level are chosen by the criteria in sections 2.2 and 3.2 of this letter. Approval holders are free to use higher inspection levels if greater discrimination is desired, or to use lower (more stringent) AQLs if a smaller percent defective is desired. However, these should not be modified based on lot size or inspection history, as provisions already exist to account for those factors. Changing AQL values or inspection levels is likely to result in a statistically invalid plan.

9.5 Inappropriate Use of Reduced Inspection. As described in section 4.1 of this letter, reduced inspection is permitted only when all conditions of the relevant procedure are met. When there are significant delays or changes in production processes, approval holders must revert to normal inspection. It will be considered a nonconformance during NIOSH on-site audits if the records described in section 4.2 of this letter are not available.

9.6 Incorrect Sample Size When Following Arrows in Sampling Tables. When using attribute sampling, be careful when following arrows in the sampling plan tables. A different sample size must be used to correspond with the new code letter as described in section 6.1 of this letter.

9.7 Improper Drawing of Samples. Each sample drawn must be representative of the entire lot as described in section 5.2 of this letter. The typical method is to select samples at random. However, other methods (such as every tenth piece) may be used so long as the sample is not biased in any way as a result. If a lot contains multiple sublots, the sample must contain a proportional number of pieces from each subplot.

10. References

American National Standards Institute [2003a]. Sampling procedures and tables for inspection by attributes. Milwaukee, WI: American Society for Quality, American National Standard ANSI/ASQ Z1.4-2003.

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U.S. Department of Defense [1957]. Sampling procedures and tables for inspection by variables for percent defective. Washington, DC: Office of the Assistant Secretary of Defense (Supply and Logistics), Military Standard MIL-STD-414 (including Notice 1, 8 May 1968).

U.S. Department of Defense [1963]. Sampling procedures and tables for inspection by attributes. Washington, DC: U.S. Government Printing Office, Military Standard MIL-STD-105D (including Change Notice 2, 20 March 1964).

U.S. Department of Defense [1989]. Sampling procedures and tables for inspection by attributes. Washington, DC: Department of Defense, Military Standard MIL-STD-105E.

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For further information regarding sampling, contact Vance Kochenderfer via electronic mail at vck6@cdc.gov or by telephone at 412-386-4029. General inquiries may be directed to the Technology Evaluation Branch at npptl@cdc.gov or 412-386-4000.

Sincerely yours,

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November 15, 2000

LETTER TO ALL MANUFACTURERS

Subject: Attachment of Headband Straps on Filtering Facepiece Respirators

Since April 1, 1997, the NIOSH position regarding punctures caused by staples has been: "Any filtering facepiece exhibiting holes around staples, in the breathing zone, through which light can be clearly observed shall be rejected. The justification for this rejection is that these holes are large enough to easily allow penetration of respirable particulates." Manufacturers have been required to institute quality control measures to reduce the size of punctures caused by staples so visible light will not pass.

Several product audits and recent research conducted by manufacturers and NIOSH have caused NIOSH to reconsider this policy. The research has shown that filtering facepiece respirators containing small punctures caused by staples, even punctures large enough to pass light, can still meet the maximum penetration requirement specified in 42 CFR, Part 84 for which these products were approved. Conversely, product audits have shown that sonic welds used to fasten straps can cause the respirator to fail to meet the maximum penetration requirement specified in 42 CFR, Part 84 for which these products were approved. NIOSH has considered the new data and is implementing a change in interpretation incorporating the new perspective on the impact of all fastenings in filtering facepieces.

NIOSH will accept applications for approval of filtering facepiece respirators with fastenings that attach headband straps within the breathing zone, provided the applicant's quality system includes controls to assure the fastenings do not prevent the respirator from meeting the maximum penetration requirement specified in 42 CFR, Part 84.

This requirement can be met one of two ways.

- For designs where the strap attachments are always placed on sealed edges or otherwise obviously outside the breathing zone (for example, on a tab), the fastening procedure/process is to be classified as a Major B characteristic in the Quality Control Plan.
- For designs where the strap attachments are not always placed on sealed edges or not otherwise obviously outside the breathing zone, the fastening procedure/process is to be classified as a Major A characteristic in the Quality Control Plan. Test data are to be

included with the application demonstrating any accepted fastenings in the breathing zone do not prevent the respirator from meeting the maximum penetration requirement specified in 42 CFR, Part 84 for which the respirator is approved.

When the respirator design includes the placement of staples within the breathing zone (option (2) above), the user instructions shall also be required to include information explaining the acceptability of punctures due to the stapling process. In conjunction with the existing use conditions that limit filter use to consideration of hygiene, damage and breathing resistance, the user instructions shall include statements that: (A) filtering facepieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred, and (B) enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage. The user instructions are also to provide information that the respirator has been tested and small punctures around the staples are normal and do not interfere with the respirator compliance with Part 84 approval requirements.

Sincerely yours,

Richard W. Metzler
Chief, Respirator Branch
Division of Respiratory Disease Studies



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LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Clarification of Supplier and Subcontractor Relationships

Background

National Institute for Occupational Safety and Health (NIOSH or the Institute) approval holders have established relationships with suppliers and subcontractors who are manufacturing components or subassemblies for approved respirator configurations. A growing number of approval holders wish to ship NIOSH-approved respirators directly from a subcontractor to distribution centers or customers, and replacement parts directly to a repair center. The Institute has identified two possible approval holder relationships with suppliers and subcontractors. Listed below are the responsibilities and requirements NIOSH has established for these relationships.

Definitions

Approval Holder: The party of record to whom certificates of approval have been issued. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support.

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.

Subcontractor Relationship Responsibilities

The approval documentation on file at NIOSH must demonstrate that the following criteria have been met for NIOSH recognition of a subcontractor.

- As with all other NIOSH approvals, the approval holder maintains responsibility for all aspects of the approval: control over product drawings, material specifications, parts lists, and manufacturing processes; control over the requirements for final inspection and testing; and approval of any changes to the above.
- The approval holder must assure that a subcontractor has demonstrated the ability to supply product that consistently meets the established release criteria, and has adequate quality systems and procedures in place to assure product quality on an ongoing basis.
- The approval holder must establish and maintain active involvement and influence over subcontractor quality systems. This can be demonstrated in many different ways. One example of this involvement and influence can be exhibited by participating in the subcontractor's management reviews (as defined by ISO 9001, 2000, section 5.6) required by the subcontractor's Quality System. A second example is participation in the subcontractor's Material Review Board.
- The approval holder's methods for maintaining active involvement and influence over their subcontractor's quality system needs to be documented in a plan or procedure that suits the individual situation and manufacturing complexity of the secured goods. This plan or procedure must be formally submitted to NIOSH.
- The approval holder will maintain copies of subcontractor quality records that demonstrate compliance with NIOSH performance requirements. It is important to assure that, in the event of a broken relationship, both the Approval Holder and NIOSH have continued access to those records.
- All submissions related to the approval must be made by an authorized representative of the approval holder. The subcontractor's Quality Manual and related quality system documents must represent how the approval holder establishes and maintains active involvement and influence over the subcontractor's quality system. This information must be specifically indicated and documented as part of a Quality Assurance Application. As with all Quality Manuals, a process must be established and followed for ongoing resubmission of the Quality Manual and related quality system documents in the event of significant changes, and on a periodic basis, per NIOSH requirements.
- All subcontractor relationships must be listed as an approval holder's manufacturing site, with a designated point of contact, on the NIOSH Standard Application Form (SAF) for direct shipment from the subcontractor to be acceptable under the NIOSH Approval.

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- h. All manufacturing sites for NIOSH-approved products, including subcontractor facilities, will be audited by NIOSH on a regular basis. The Institute will not contact the subcontractor directly, but will always work through the approval holder's designated representative for the specific manufacturing site.

Sincerely yours,

Heinz W. Ahlers
Acting Branch Chief
Respirator Branch
National Personal Protective Technology Laboratory