National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
Respirator Branch

STANDARD APPLICATION PROCEDURE

FOR THE

CERTIFICATION OF RESPIRATORS

UNDER 42 CFR 84

Revision 1, July 2005

Introduction

This document revises the NIOSH *Standard Application Procedures for the Certification of Respirators* dated January 2001. 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) for manufacturers and NPPTL staff. The text has also been revised to reflect NPPTL's move from Morgantown WV to Pittsburgh PA. The document has undergone extensive revision; changes have not been highlighted or otherwise marked due to the large number of changes. It is recommended that applicants review the entire document before submitting a respirator for approval.

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. It is imperative that each applicant invest the time necessary to become familiar with these instructions.

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

Additional guidance and requirements are published by NIOSH in *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 Respirator Branch at (412) 386-4000 or NPPTL@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

How to Contact the NPPTL Respirator Branch (RB)

Telephone: 412.386.4000

Fax: 412.386.4051

E-mail: NPPTL@cdc.gov

Pittsburgh mailing address for sending mail	NIOSH / NPPTL / Respirator Branch Records Room, Building 20 P.O. Box 18070 Pittsburgh, PA 15236
Pittsburgh shipping address for sending hardware	NIOSH / NPPTL / Respirator Branch Evaluation and Testing Section, Building 37 626 Cochrans Mill Road Pittsburgh, PA 15236

Check the status of your applications at
http://www.cdc.gov/niosh/status.html

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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 a manufacturer's test equipment and results to NIOSH's. Correlation testing requires a New application with the wording "Correlation Testing Only; product is not submitted for certification" 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.

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 manufacturer.

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 manufacturer 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's 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"

Fit - Conformance to (1) design and dimensions for correct insertion and connection of the components or major sub-assemblies making up the complete respirator assembly, as well as (2) proper seating of the respirator on the user's face and/or torso.

Form - Shape, structure, size, and outward appearance of the respirator.

Function - The ability to meet minimum performance requirements for the intended use.

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 form, fit, or function; 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 product in the form as offered to the user. See "Applicant."

Manufacturer's Code - A unique three-letter code assigned to each manufacturer 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 product, 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 manufacturer calls the part number since the manufacturer 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.

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

Private Packaging - A product that is repackaged and sold by a company that is not the manufacturer of the product. 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 manufacturer (see Section C.20).

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

Product Trade Name - Because of the way that manufacturers market and users reference certified products, 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).

Protections - 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 air supply capability (e.g., pressure, duration, demand flow, continuous flow, etc.).

Prototype – Is usually the initial production unit. 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 manufacturer's pre-testing to meet 42 CFR 84 minimum design and performance requirements. Products may be submitted for certification while in the prototype stage using a NEW application form. NIOSH may request samples made on regular production tooling and production quality control (Ref. 84.30 (c)). For *non-certification prototype testing* use a NEW application form and state "prototype testing only - product is not submitted for certification" in the 'Reason for Application.'

Quality Assurance - A planned and systemic pattern of all activities necessary to provide confidence that all products 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 manufacturer.

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 product 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 - Are composed of the exploded view drawing and the major sub-assembly drawings. Any additional drawings the manufacturer deems necessary for further clarification of a major sub-assembly or part may also be included in the application.

Standard Application Form - 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

CEL - Certified Equipment List

CFR - Code of Federal Regulations

CGA - Compressed Gas Association

DHHS - Department of Health and Human Services

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 – **T**esting and **C**ertification 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 manufacturer 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/saf.html.

The application software consists of (1) Application Forms located in file saf_v6.mdb and (2) Application Data located in file saf_data.mdb. Version 6 is the latest version, and applications that use earlier versions will not be accepted. When the application form has been completed, save the data file by selecting FILE, then SAVE AS, from the menu bar on the main menu screen. Save the data file using the file naming convention XXXnnnnnn.mdb 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.

The application data file and supporting documents may be submitted on the following electronic media: 3.5 inch diskettes, zip drive disks (100 MB), and 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.

Manufacturers 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 diskettes returned after the application is processed, you must submit a pre-paid, return shipping label with the diskettes. Your diskettes will be held by the Respirator Branch for as long as the project is open. If a pre-paid, return shipping label is not received with the diskettes, the diskettes will be destroyed after the project is closed.

In addition to the application file, the manufacturer must submit related project documents. These documents must be in English and saved with the following file-naming conventions. **PageMaker files will no longer be accepted.** 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	XXXnnnnnnnn.MDB
Pre-test data	Word Perfect, Adobe Acrobat, ASCII text, Excel, Microsoft Word, Quark Express	nnnnnnnPD.WPD, PDF, TXT, XLS, DOC, QXD
Drawings	Scanned file, AutoCAD, Adobe Acrobat, Corel Draw	nnnnnnnRa.TIF, DWG, DXF, PDF, CAL, GIF, PCX, CDR, JPG, BMP
Assembly Matrix	Excel	nnnnnnnnAMa.XLS
Draft approval labels	Excel	nnnnnnnnDLa.XLS
QA manual	Word Perfect, Adobe Acrobat, scanned file, Excel, Microsoft Word, ASCII text, Quark Express	nnnnnnnnQMa.WPD, PDF, TIF, XLS, DOC, TXT, QXD, plus one signed paper copy
Process Quality Control Plan	Word Perfect, Adobe Acrobat, scanned file, AutoCAD, Excel, Microsoft Word, ASCII text, Quark Express	nnnnnnnnPQP.WPD, PDF, TIF, DWG, XLS, DOC, TXT, QXD
Fees	Not Applicable	Paper only
Service Life Plan	Word Perfect, Adobe Acrobat, scanned file, Excel, Microsoft Word, ASCII text, Quark Express	nnnnnnnSLP.WPD, PDF, TIF, XLS, DOC, TXT, QXD
User's Instructions	Word Perfect, Adobe Acrobat, scanned file, Microsoft Word, ASCII text, Quark Express	nnnnnnnnnUIa.WPD, PDF, TIF, DOC, TXT, QXD
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 product may apply for approval. The manufacturer can prepare the application and documentation themselves or use an independent consultant. 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 products 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 / Respirator Branch
Records Room, Building 20
P.O. Box 18070
626 Cochrans Mill Road
Pittsburgh, PA 15236

Test samples must be sent to:
NIOSH / NPPTL / Respirator Branch
Evaluation and Testing Section, Building 37
626 Cochrans Mill Road
Pittsburgh, PA 15236

B.1.3 WEB SITE

Manufacturers 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/status.html.

B.2 INFORMATION COMMON TO ALL APPLICATIONS

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

Manufacturers 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 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 product in the CEL.

If there is any doubt about the appropriate type of application to submit, call NIOSH. See *How to Contact the NIOSH Respirator Branch (RB)* 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 manufacturer 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. Process Quality Control Plan
8. Fees
9. Service Life Plan (for self-contained self-rescuers only)
10. User's 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:

<u>Air-Purifying Respirators (filtering facepiece)</u>

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)

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)

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)

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 (SCSR only) and User's 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 manufacturer 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).

*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.

* 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.

* 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

A manufacturer 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 product. NIOSH assigns a new 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 a manufacturer submits a new product with two new facepieces, for example, a half-mask and full-facepiece that use the same new filter, NIOSH would require 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 manufacturer makes a change to a critical or major characteristic affecting form, fit, or function (including quality assurance provisions), the change must be submitted to NIOSH for approval. Changes to minor characteristics not affecting form, fit or function which are not documented in the NIOSH approval records do not have to be submitted to NIOSH. However, manufacturers remain responsible for keeping all changes to minor characteristics on file and available for review at NIOSH's request.

A manufacturer should 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 filter on **several** previously approved facepieces, but not for **several** new filters on **several** different facepieces. Changes to approval labels, assembly matrices, User's 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 Manufacturer 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 may assign new TC numbers for extensions of approval (excluding private labels) 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.

Describe **exactly** and **completely** the **change** or **additions** to the approved respirator and **how** they will affect the previously approved product(s). Provide descriptive information on the previously approved product(s). For example, "An extension of approval to allow our 'xyz' 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 products 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's 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's 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 "U" or "R."

B.2.4 QUALITY ASSURANCE APPROVALS

A **Quality Assurance Approval** is a submission requesting approval of a quality system, a change to some aspect of the **previously approved** quality assurance manual, or to the Process Quality Plan (PQP) for a **previously approved** respirator product line. 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 or PQP. Also indicate the products and manufacturing facilities affected. Quality assurance approval submissions must not affect form, fit, or function, 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.

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 product or documentation deficiencies, an explanation why the product 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. Manufacturers 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		

AG - Acid Gas (gas mask only)	AM - Ammonia	
CD - Chlorine Dioxide	CF - Continuous Flow	CL - Chlorine
CN - Chloroacetophenone	CO - Carbon Monoxide	CS - Chlorobenzylidene Malononitrile
DE - Demand	EO - Ethylene Oxide	ESC - Escape
FM - Formaldehyde	HC - Hydrogen Chloride	HF - Hydrogen Fluoride
HN - Hydrogen Cyanide	HS - Hydrogen Sulfide	MA - Methylamine
MV - Mercury Vapor	ND - Nitrogen Dioxide	OV - Organic Vapor
PD - Pressure-Demand	PH - Phosphine	SA - Supplied-Air
SB - Supplied-Air Abrasive Blast	SC - Self-Contained	SD - Sulfur Dioxide
TDI - Toluene-2,4-diisocyanate	VC - Vinyl Chloride	

[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'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'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.

S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's 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.

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 a manufacturer 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.

As always, when in doubt, call NIOSH and discuss your proposed changes and application submittal strategy before assembling and mailing the application. See *How to Contact the NIOSH Respirator Branch (RB)* in the front of this document for phone numbers.

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 manufacturer of their TN by email or manufacturer-supplied self-addressed stamped post card. 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 and FAX numbers, 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 product use or future product 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 products and manufacturing facilities affected. Quality Assurance approvals must in no way affect form, fit, or function, and must not result in a different type or different level of protection.

Resubmittals must state the modification that was made to address the original rejection / denial, and demonstrate that the product 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 does 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's 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 may be used to provide 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.

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 product selected. Both New approvals 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.

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).

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 mine rescue and other 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 Respirator Branch (RB)* in the front of this document for the phone number.

C.13 PRE-TEST DATA AND STATEMENTS

Respirator performance test data must accompany each application.

- 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: Manufacturer 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 manufacturer.

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 in the approval label. Also, the User's Instructions must contain a special section that is labeled S-Special or Critical User's 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 Part 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 certification 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 certification 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's 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 manufacturer, 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 manufacturer 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 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 manufacturer is responsible for all shipping costs. The manufacturer 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 manufacturers are required to have an approved Quality 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 Manual approved and there is no change, complete the applicable blocks on the SAF. If a previously-approved Quality 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 (PQP) 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 and/or assembled. 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 a particular product 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 product or product line, and whenever there are changes to the manufacturing process and 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 manufacturer 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 that show all inspection and test operations and identify each procedure by manufacturer-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 a manufacturer 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 form, fit, or function 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 manufacturer 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 manufacturer is responsible for identifying on product drawings the location of this required information on their product.

C.17 FEES

When testing will be performed, the manufacturer must **submit a separate check** in United States currency for the fee **with each application**. Each check must contain the applicant-assigned reference 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 the stale date must be 6 months or greater from issuance. There is no fee at this time for applications not requiring testing.

Respirator testing fees are as follows:

Respirator Type	Fee
1-hour or more SCBA	$3500
< 1-hour SCBA	$2750
Escape only SCBA	$2000
Gas mask and pesticide single hazard	$1100
Gas mask and pesticide type N (special use)	$4100
Supplied air	$750
Particulate, Type N, P, R or PAPR HE, including those with chemical cartridges	$1250
Chemical cartridge- one or more gases/vapors	$1150
Filtering Self-rescuer for CO only	$1100
Filtering Self-rescuer for all classes of gases	$4100

Alternate filtering media for filtering facepiece respirators require complete respirator testing and a fee of $1250.00

When a major sub-assembly is changed or added to a previously approved respirator, only the major sub-assembly and other affected components of the respirator may require testing. Depending on the nature of the change, NIOSH may require testing of the entire assembly as would be required for a new product. Only complete respirators are approved.

Major sub-assembly testing fees are as follows:

Major sub-assembly	Fee
Facepiece (one size or more)	$450
Canister	$900
Cartridge	$600
Filter	$650
Hoses and airline quick disconnects	$250
Blower	$250
Harnesses	$100
Other not listed above	$100/day

C.18 ASSEMBLY MATRIX

An assembly matrix must be submitted electronically in Microsoft Excel 5.0 or 7.0 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 a manufacturer's 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 Users' Instructions. Schedule 13F approvals for SCSR's must also include the part number and revision level of the service life plan.

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 products and/or components 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** of an existing component where the part number has not changed.

- = a component designated by the manufacturer 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.

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.

U = **Upgrade/**retrofit kit. Is used to identify (1) the controlled drawing that contains the List of Materials for the upgrade/retrofit kit, and (2) the upgrade/retrofit User's Instructions.

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 Respirator Branch (RB)* 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

Manufacturers 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's 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 manufacturer 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

Manufacturers 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 form, fit, and function. For example, if an accessory would not affect form, fit or function, materials could be identified as plastic, metal, rubber, etc. But if the items did affect form, fit or function, 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 manufacturer controls all specifications for the component. If the manufacturer does not determine all specifications of the component, then the manufacturer must provide the name of the vendor. Per 42 CFR 84.42(c) and 84.43(c), the manufacturer is obligated to manufacture to the documentation in effect at the time the approval is issued.

C.20 Approval Labels and Private Label Notification

Approval labels used in final User's 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 manufacturer is responsible for inserting the logos during label production. Approval Labels may not contain future submittals or show unapproved assemblies.

If the respirator contains electrical components and the manufacturer wishes to list the product **on the NIOSH approval label** as intrinsically safe, first obtain intrinsic safety approval from the Mine Safety and Health Administration (MSHA) under Title 30, CFR, Part 18 and submit verification of such approval in the application.

Private Labeling vs. Private Packaging

Under **Private Labeling**, Manufacturer A may enter into an agreement to allow Company B to sell Manufacturer A's product as being manufactured by Company B. In doing so, all packaging, labeling, markings, User's Instructions and other marketing literature should reflect Company B. Such an approach appears to the user that the manufacturer of the product is Company B. No reference needs to be made to Manufacturer A. The product name, model numbers and part numbers may or may not be the same as that used by Manufacturer A. However, **the NIOSH TC number will not be changed**. Manufacturer A remains liable for product quality and all packaging, labeling, markings and other marketing literature which pertains to the NIOSH approval. Manufacturer A must insure 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 or a Private Label Notification Form. An Extension of Approval is necessary when the private labeler desires anything more than a name change at the top of the NIOSH approval label. If a part number or model number changes, an Extension of Approval must be submitted. The Private Label Notification Form is to be used where nothing changes on the product or documentation except the Company name on the NIOSH approval label.

Under **Private Packaging**, Manufacturer A may enter into an agreement to have its products sold by Company B whereby Company B puts the assembled product in a different or additional package. In doing so, the product name, model number, part number, product labeling, markings, user's instructions and other marketing literature must show Manufacturer A as being the manufacturer. 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 manufacturer. It is recommended that clarifiers be included on the packaging, for example, "Sold by Company B and Manufactured by Manufacturer A" or "Made by Manufacturer A for Company B." The NIOSH approval label will not be changed. Manufacturer A remains liable for product quality and all packaging, labeling, markings and other publicity that pertains to the NIOSH approval. Manufacturer A must insure that the private packager does not misrepresent the NIOSH approval. The Institute need not be notified of Private Packaging arrangements since this does not result in any changes to NIOSH documentation on file for the product.

C.21 User's Instructions

User's 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. Changes to the User's Instructions require an Extension of Approval. All User's Instructions and associated procedures such as maintenance requirements, inspection procedures, donning and doffing instructions, etc., that pertain to the product 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's 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's Instructions from the prior revision level.

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

User's 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's Instructions,** noted on the approval label and listed in the User's Instructions:

> Manufacturers 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 manufacturer 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's 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.

Special or critical user's instructions and/or specific use limitations will be reviewed to ensure they are correct and appropriate.

Requirements Specific to Air-Supplied Respirators

The approval labels must be included in the User's 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's Instructions.

Requirements Specific to Air-Purifying Respirators

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

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's 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 Self-Contained Self-Rescuers

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 product under intended use conditions. The service life plan is a separate document from the user's 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 manufacturer 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 manufacturer'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, manufacturers 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 manufacturers 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.

Manufacturers may not imply "use" for approved products. For example, packaging may not say "NIOSH-approved Paint Spray Respirator." It may say "NIOSH approved OV/P100 respirator; manufacturer 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.”

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. Manufacturers that follow the suggested guidelines listed above do not have to submit packaging changes to NIOSH. Manufacturers may refer to their products as surgical masks or any other name they desire, so long as they do not imply that their products 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’s 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.

File Name	Document Type	Description	Program
nnnnPD.xls	Pre-submission Test Data	Test Name	Excel 7.0
nnnnUIa.pdf	User's Instructions	Title of manual	Adobe Acrobat
nnnnSLP.wpd	Service Life Plan	Model Name/Number Rev. Number	WordPerfect 8
nnnnnra.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	Draft Approval Label	Model Name/Number	Excel 7.0
nnnnQMa.xls	Q/A Manual	Date (mm/dd/yy)	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's 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.

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 manufacturer stating the nature of the approval and will return final approval label files, if applicable, with the appropriate approval documentation. For manufacturers using consultants or authorized representatives, the final letter of certification and enclosed documentation will be sent directly to the manufacturer 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 manufacturer's U.S. or Canadian

address or authorized representative. Foreign manufacturers 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 a manufacturer 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's 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.
- Pretest 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 manufacturer'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.).

- Manufacturer's pre-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 has errors and/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 mis-numbered, or documents are otherwise incorrect.

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
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 Note: ESLI tested where used	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	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	118 121 122 123 124 125 126 128 140 132 139 145 148 155 146	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 Liquified 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
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 Liquified 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
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	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) 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 Liquified Gas NOTE: Rated Service Time is tested during Man Test 4, assuming that all previous Man Tests have been satisfactorily completed.	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)
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 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)	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)

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
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	118 120 121 123 125 128 140	Low Temperature Test Positive Pressure Test Rated Service Time Test Gas Flow Test (IAA), Gas Tightness Test Gas Pressure Gauge Test (Accuracy of gauge) 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
14	Supplied-Air Type C-CE Demand Subpart J	4 100 101 102 103 104 105.1 108 109 110 NOTE: For Abrasive Blast, Type CE, Supplied-Air Respirators, perform all above tests <u>plus</u> 112-Abrasive Blast, Quantitative Fit	Exhalation valve leakage Strength of Hose and Coupling Test Tightness Test Non-kinkability Test Gasoline Permeation Test Air Regulating Valve Test (100,000 Cycles) Airflow Test, Demand Class Inhalation Resistance Test Exhalation Resistance Test (IAA), Gas Tightness Test	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	4 100 101 102 103 104 105.1 106 107 110 NOTE: For Abrasive Blast, Type CE, Supplied-Air Respirators, perform all above tests <u>plus</u> 112-Abrasive Blast, Quantitative Fit	Exhalation valve leakage Strength of Hose and Coupling Test Tightness Test Non-kinkability Test Gasoline Permeation Test Air Regulating Valve Test (100,000 Cycles) Airflow Test, Pressure-Demand Class Inhalation Resistance Test, Exhalation Resistance Test (IAA), Gas Tightness Test	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

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

* 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 manufacturer'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.

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 product. 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 manufacturer's 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. List matches the protections listed in the SAF. See complete list of protections and Cautions and Limitations in Section C.20.

12. _____ Airline hoses must be listed under components instead of accessories.

13. _____ Key Box uses only the characters X, N, P, R, -, A, or U.

14. _____ Cylinders are only approved for one duration (30, 45, or 60 min).

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.

18. _____ SCSR's contain the Service Life Plan part number and revision level.

19. _____ Flow Indicator is listed for PAPR.

EXPLODED VIEW DRAWING

_____ Drawing contains all major sub-assemblies and accessories that appear on the assembly matrix (except the user's instructions and service life plan).

_____ The reference numbering on the exploded view drawing matches the reference numbering on the assembly matrix. All matrix assemblies are represented on the exploded view drawing and there are no extra assemblies on the exploded view drawing. For every reference number on the drawing there is a corresponding number on the matrix, and vice-versa.

_____ The drawing is properly titled, signed/initialed, numbered, dated, and contains a revision level.

_____ There are no reference dimensions on the drawing. The only exception is for filtering facepieces and disposable respirators.

+~+~+~+~+~+~+~+~+~+~+~+~+~+~+~+~+~+

ALL MAJOR SUB-ASSEMBLIES

_____ Numbered, titled, signed/initialed by an authorized representative, with an effective date.

_____ Reference dimensions - length, width, or diameter, as applicable

_____ Material specifications

_____ Part number location

_____ Serial number location, if applicable

_____ Critical and major characteristics are identified on drawing or is separate document..

_____ Inspection procedures or classification of defects are identified on the drawing or in additional documentation provided with the drawing.

SELF-CONTAINED BREATHING APPARATUS (page 1 of 2)

_____ 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

_____ 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 x 5 ÷ 3 = upper limit
highest pressure x .90 = lower limit

_____ Torque requirement for connection of cylinder valve to cylinder

_____ Cylinder construction (material(s) of construction, fiber reinforced, type of fiber)

_____ Full cylinder volume at operating pressure - Compressed Air Volume

_____ Markings on cylinder: compressed breathing air, compressed breathing oxygen, liquefied breathing air, or liquefied breathing oxygen, DOT marking requirements

_____ Pressure-gauge range has a scale reliable to within + or - 5% of full scale (minimum of five graduations empty, 1/4, ½, 3/4, full)

_____ 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.

_____ Procedure to assure proper gas mixture for refill purposes (percent oxygen). Applies to specialty gases only; does not apply to Grade D air.

_____ Specification and dimensions of outlet threads are identified.

Respiratory Inlet Covering (Facepiece or Hood)

_____ If a pressure demand valve, shows it is spring loaded

_____ Lens meets impact resistance GGG-M-125d Oct. 11, 1965 (amended July 30, 1969)

_____ Lens has statement if anti-fog is needed or not

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

SELF-CONTAINED BREATHING APPARATUS (page 2 of 2)

Backpack Harness Assembly

_____ Inspection procedures or classification of defects include a visual inspection of the buckles.

_____ Location of NIOSH harness label

Pneumatic Assembly/1st Stage Regulator

_____ 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)

_____ Type of connections on SAR hose (for an SCBA/SAR combination)

_____ Pressure-gauge range has a scale reliable to within + or - 5% of full scale (minimum of five graduations: empty, 1/4, ½, 3/4, full)

_____ When pressurized oxygen is used, gauge has the words “Oxygen” and “Use No Oil”

_____ 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)

_____ Statement as to how the remote pressure gauge is attached, i.e., loctite or torque.

_____ Parts list showing all parts and materials of the pneumatic assembly

Second Stage Regulator Assembly

_____ Parts list showing all parts and materials of the regulator

_____ 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)

_____ 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.

_____ Lens has statement of whether or not anti-fog is needed

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

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

Hose/Couplings

_____ 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".

Breathing Tube

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

+~+~+~+~+~+~+~+~+~+~+~+~+~+~+~+~+

FILTERING FACEPIECE

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

_____ Reference dimensions for facepiece, liner, valve, straps, and nosepiece.

_____ Material specification for filter media, valve, nosepiece, straps, liner

_____ Location of nosepiece, liner, straps and valve.

_____ Lot number location and code or date of manufacture

_____ Filter efficiency (N95, N99, N100, etc.) including nuisance protections

_____ Filters containing carbon layers include a statement that carbon is chromium free.

_____ Final filter media form is identified/shown (pleated, flat, etc.)

_____ Filtering mechanism is identified (electrostatic, mechanical or other)

_____ Vendor for filter material is identified if the filter specification is not determined by the respirator manufacturer.

_____ Elasticity and length of the straps, method of attachment. If staples or sonic welds are used to fasten straps, the drawing must clearly indicate whether or not the attachment point is within the breathing zone.

SELF-CONTAINED SELF-RESCUER (page 1 of 1)

_____ Firing mechanism

_____ Case seal information (assembly procedures), and a statement that it can be opened within 15 seconds

Regulator

_____ Parts list showing all parts and materials of the regulator

If the unit has a cylinder:

_____ 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

_____ Torque requirement for connection of cylinder valve to cylinder

_____ Cylinder construction (material(s) of construction, fiber reinforced, type of fiber)

_____ Full cylinder volume at operating pressure

_____ Markings on cylinder: compressed breathing air, compressed breathing oxygen, liquefied breathing air, or liquefied breathing oxygen, DOT markings.

_____ 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)

_____ 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).

_____ Procedure to assure proper gas mixture for refill purposes (percent oxygen)

_____ Specification and dimensions of outlet threads are identified.

_____ 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)

_____ Elasticity, length and method of attachment of straps

Filter - except filtering facepiece

_____ Material specifications and filtering mechanism for filter media

_____ Lot number location and code, or date of manufacture

_____ Filter efficiency (N95, N99, N100, etc.) include nuisance protections

_____ Final filter media form (pleated, flat, etc.)

_____ Vendor for filter material is identified if the filter material specification is not determined by the respirator manufacturer.

_____ Filters containing carbon layers include a statement that carbon is chromium free.

Cartridge or Canister

_____ Material specifications including each carbon, with fill volume and mesh

_____ Statement that the carbon is chromium free

_____ Lot number location and code, or date of manufacture

_____ Vendor for carbon material is identified if the carbon specification is not determined by the respirator manufacturer

_____ Location and material of End of Service Life Indicator (ESLI) -- ESLI's are required for MV, HS, CO, and EO.

_____ Color and markings conform to either ANSI K13.1-1973 or ANSI Z88.7-2001, and the applicable specification is identified.

_____ 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)

_____ Elasticity and length of the straps, method of attachment

Filter

_____ Material specifications for filter media

_____ Lot number location and code, or date of manufacture

_____ Filter efficiency, including applicable nuisance protections

_____ Final filter media form is identifiable (pleated, flat, etc.)

_____ Filtering mechanism is identified (electrostatic, mechanical or other)

_____ Filters containing carbon layers include statement that carbon is chromium free.

_____ Vendor for filter material is identified (only if the filter material specification is not determined by the respirator manufacturer).

Cartridge or Canister

_____ Material specifications including each carbon, with fill volume and mesh.

_____ Protections listed

_____ Lot number location and code, or date of manufacture

_____ Vendor for carbon material is identified (only if the carbon specification is not determined by respirator manufacturer).

_____ Filters containing carbon layers include a statement that carbon is chromium free.

_____ Location and material of End of Service Life Indicator, if used

_____ Color and markings conform to either ANSI K13.1-1973 or ANSI Z88.7-2001, and the applicable specification is identified.

Blower

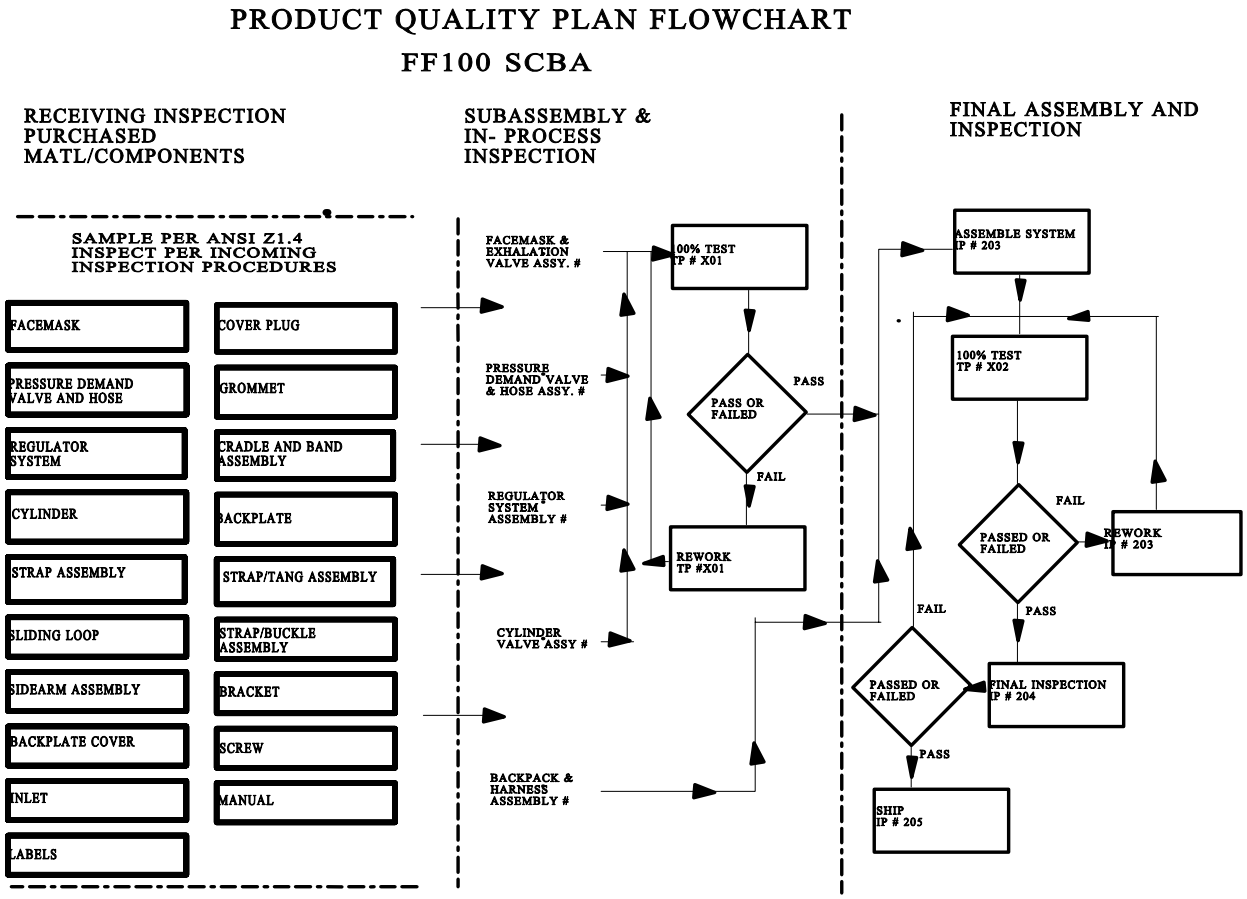
_____ Lot number location and code, or date of manufacture

_____ Intrinsic safety certification (if intended for mine use)

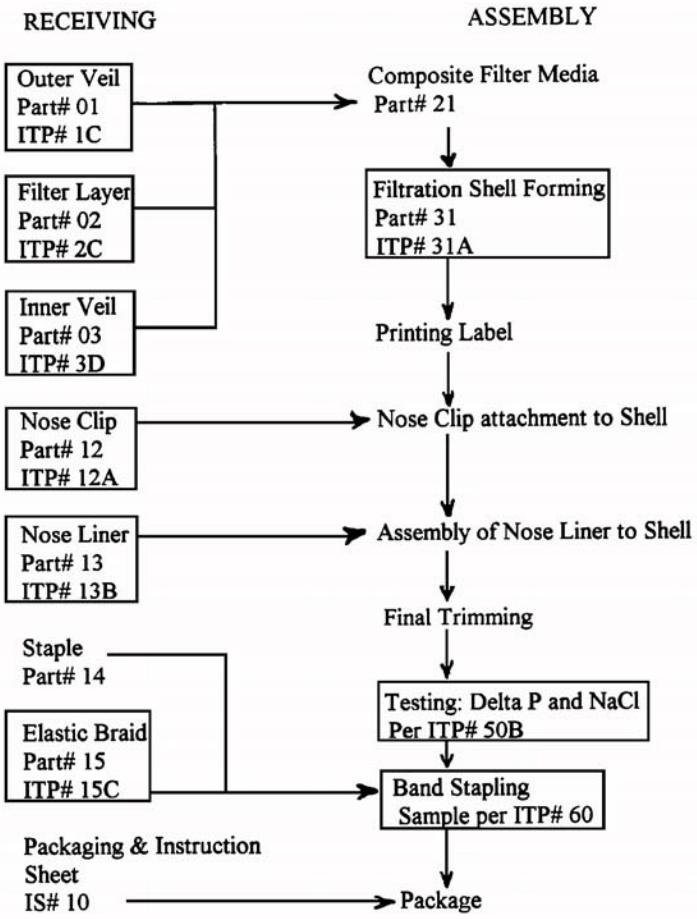
Battery

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

SECTION – G DOCUMENT EXAMPLES



PRODUCT QUALITY PLAN FLOWCHART
Model XY01 Filtering Facepiece



XYZ Respirator Co.

Approvals:	Production Engr	QA Mgr	General Mgr

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

-- SAMPLE PRIVATE LABEL NOTIFICATION FORM –

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Respirator Branch
P. O. Box 18070
626 Cochrans Mill Road
Pittsburgh, PA 15236

PRIVATE LABEL NOTIFICATION FORM

NOTE: See Section C20 to determine if this form can be used

The manufacturer and approval holder provides the following information to NIOSH regarding intent to "private label" certain NIOSH-approved products, or to update status.

New: _____ Discontinued: _____ Modified: _____

Approval Holder Information:

Manufacturer/Approval Holder: _____

Certification/Approval Numbers:	Model or Trade Name(s):
_____	_____
_____	_____
_____	_____
_____	_____

Private Label Vendor Information:

Vendor Name: _____

Address:_____

City: _____ State:_____

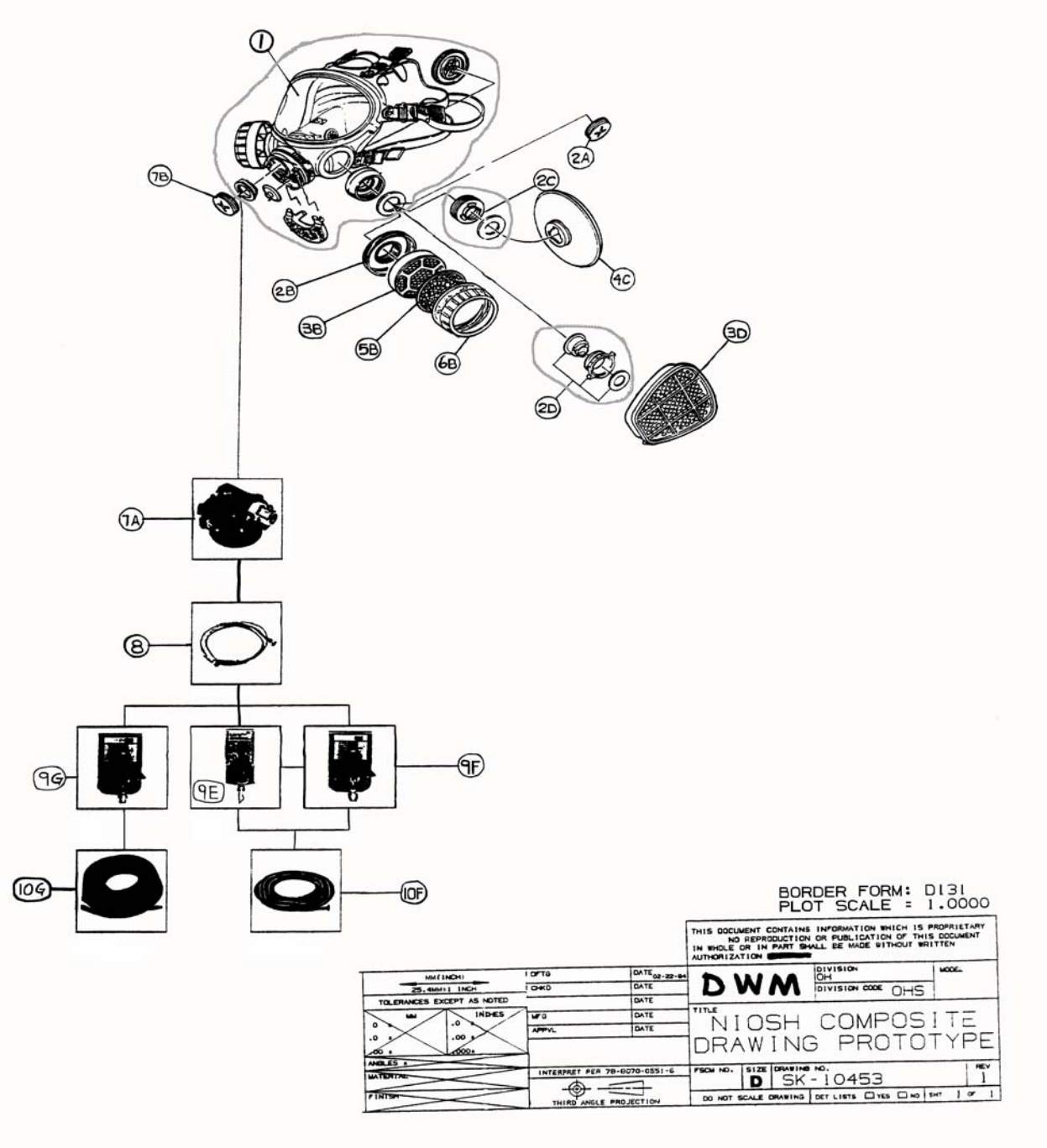
Country: _____ Zip/Postal Code:_____

Phone: _____ FAX: _____

_____ _____

Date Signature of Manufacturer's Authorized Representative

-- SAMPLE EXPLODED VIEW DRAWING –



EXAMPLE ASSEMBLY MATRIX

(The numbers in parentheses correspond to the Assembly Matrix Checklist in Section F)

(13) KEY
X= CURRENTLY APPROVED IN THIS CONFIGURATION
N = NEW COMPONENT OR CONFIGURATION
- = OBSOLETED
R= REDESIGN
P= PENDING
A=ACCESSORY
U = Upgrade/Retrofit Kit

(2) DOUBLE WING MANUFACTURING
ALMOST HEAVEN, WEST VIRGINIA, USA
1-800-123-4567

TN or AAR# of previously approved/pending matrix (15)
Exploded view drawing number/revision (16)

(1) RESPIRATOR FAMILY APPROVAL MATRIX

(4)		1						2				3								4				6		7		8		9			10								5
(7)	COMPONENT	ALTERNATE FACEPIECE						ALTERNATE ADAPTER				ALTERNATE CARTRIDGES								ALTERNATE FILTERS				ALTERNATE RETAINER		ALTERNATE AIRLINE ADAPTER		ALTERNATE BREATHING TUBE		ALTERNATE REGULATOR			(12) ALTERNATE HOSES / LENGTHS									ACCESSORY
(4)								A	B	C	D	A	A	A	B	B	B	C	D	A	B	A	B			A	B	A	B	A	B	C	A	B	C	A	B	C	
(6)	DESCRIPTION	FULL FACEPIECE-SMALL	FULL FACEPIECE-SM SIL.	FULL FACEPIECE-MEDIUM	FULL FACEPIECE-MED SIL.	FULL FACEPIECE-LARGE	FULL FACEPIECE-LG SIL.	PLUG	HOLDER	FULLFACE ADAPTER	ADAPTER	ORGANIC VAPOR	CHLORINE	OV/CL/HC/SD	ORGANIC VAPOR	CHLORINE	OV/CL/HC/SD	AMMONIA/METHYLAMINE	FORMALDEHYDE/P100	N95	N100	R99	P100	RETAINER	RETAINER	AIRLINE ADAPTER	AIRLINE ADAPTER	BREATHING TUBE	BREATHING TUBE	ARV	HIGH PRESS. CONNECTOR	LOW PRESS. CONNECTOR	HI PRESSURE HOSE	HI PRESSURE HOSE	HI PRESSURE HOSE	HI PRESSURE HOSE-YELLOW	HI PRESSURE HOSE-YELLOW	HI PRESSURE HOSE-YELLOW	LOW PRESSURE HOSE	LOW PRESSURE HOSE	LOW PRESSURE HOSE	PREFILTER WITH RETAINER
(3)	REV	D	C	R	G	D	C	C	C	A	C	E	G	F	B	B	C	B	B	F	A	A	A	F	F	D	D	A	D	G	E	B	K	K	M	A	A	A	F	F	J	B
(3)	DRWG #	8614	8619	1295	2417	8616	8617	6441	1232	7901	3445	1114	1115	1116	8523	8524	8525	8526	8527	8702	8700	8701	8636	4494	4516	1278	1278	6445	2517	1217	3267	3268	5637	5633	5757	7722	7723	7724	1376	1377	4584	1118
(5)	PART #	8618-4	8619-2	1295-6	2417-6	8616-8	8617-6	6441-7	1232-9	7901-0	3445-3	1114-9	1115-6	1116-4	8523-6	8524-4	8525-1	8526-9	8527-7	8700-5	8700-0	8701-9	8636-6	4494-8	802916	1278-2	1278-5	6445-8	2517-3	1217-0	3267-1	3268-9	5637-7	5633-6	5757-1	7722-0	7723-8	7724-6	1376-4	1377-2	4584-5	1118-0
(9) AAR#	(10) NIOSH APPROVAL NUMBER, TC-	(11) PROTECTION	MODEL #	2001Sm	2001SmS	2001	2001S	2001L	2001LS	2000	1999	701	502	1998	1989	1952	61	62	63	64	65C	2001F10	2001F11	2001F12	20	20017287	20017288	20013187	20011010	20013188	20013188	20013062	20013194	20013195	200135-25	200135-50	200135-100	200035-25	200035-50	200035-100	200020-25	200020-50	200020-100	7255
	19C-199	DE/SA		X	X	X	X	X	X	X																		X		X	X	X			X	X	X	X	X	X				
	19C-238	PD/SA		X	X	X	X	X	X	X																		X		X	X			X							X	X	X	
	19C-239	CF/SA		X	X	X	X	X	X	X																		X		X	X		X		X	X	X	X	X	X				
	23C-690	OV/CL/HC/SD		X	X	X	X	X	X		X	X			X			X																										A
	23C-692	AM/MA		X	X	X	X	X	X		X	X							X																									A
	23C-693	OV/SA/DE		X	X	X	X	X	X	X	X	X	X			X												X		X	X	X			X	X	X	X	X	X				
	23C-694	CL/SA/CF		X	X	X	X	X	X	X	X	X	X															X		X	X		X							X	X	X	
	84A-1695	FM/P100		X	X	X	X	X	X			X								X																								
M2718a	84A-M2718a	N95		P	P	P	P	P	P			P									P					P																		
	84A-1610	N100/SA/PD		X	X	X	X	X	X	X		X										X				X		X	X	X	X		X							X	X	X	
	84A-1210	R99/SA/DE		X	X	X	X	X	X	X		X											X			X		X	X	X	X	X			X	X	X	X	X	X				
	84A-0808	P100		X	X	X	X	X	X			X												X	X																		
	84A-0809	P100/OV		X	X	X	X	X	X		X	X		X			X							X	X																		
M2719a	84A-M2719a	N95/CL		N	N	N	N	N	N		N	N			N							N				N																		
(8) NIOSH TN where component last tested (if new, indicate as "N"):				04128	04128	04128	04128	04128	04128	05978	06166	05509	05509	05512	05590	06162	05646	05647	05648	05649	05650	N	9400	9401	09208	05054	06088	05489	05054	05491	05491	05592	05789	05790	06262	06263	06264	06265	06266	06067	06268	06269	06270	06120

(1) Rev. F, 9/15/2003

-- Example Approval Label --
-- FILTERING FACEPIECE --

NIOSH

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 users 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]
		1000	HALO	ARCH	WING	CROWN	1001	1002	1003	1004	1005	94355	94355	94355	
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'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'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.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's 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															
		ALTERNATE FACEPIECE					ALTERNATE CARTRIDGE					ALTERNATE HOSES			ALTERNATE REGULATOR			CAUTIONS AND LIMITATIONS
	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'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'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.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

-- Example Approval Label --
-- 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
		1001	1000	2000	3000	4000	5000	HALO	WIND	GATE	GLORY	CROWN	943-25	943-50	943-1000	3021	3022	3025	
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'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.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

-- Example Approval Label --
-- 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
		CROWN	10000	20000	30000	40000	50000	1001	1002	1003	1004	1005	9430-25	9430-50	9431100	30211	30222	30225	
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	ABCDEGHJKLMNOP
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'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'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.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning

-- Example Approval Label --
-- 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	MODEL	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's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

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

-- Example Approval Label --
-- 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
		1000	2000	3000	4000	H95	H96	H97	H98	H99	C001	C002	C003	C004	R111	R222	R333	LENS10	ALARM50	CASE20	
13F-AARa	30 min/ 2216 psi/ SC/PD	X	X			X	X	X	X	X	X				X			X		X	IJMNOS
13F-AARb	30 min/ 4500 psi/SC/PD	X		X	X		X	X	X	X						X	X	X	X	X	IJMNOS
13F-AARc	45 min/ 4500 psi/SC/PD	X		X		X	X						X			X	X	X	X	X	IMNOS
13F-AARd	60 min/ 4500 psi/SC/PD	X						X	X					X		X	X	X	X	X	IJMNOS

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 - ever 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.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

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

-- Example Approval Label –
-- SCBA and Combination SCBA/SAR RESPIRATOR --

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

1955 Series SCBA
OPEN-CIRCUIT, PRESSURE-DEMAND, ENTRY AND ESCAPE, SELF-CONTAINED BREATHING APPARATUS
and
OPEN-CIRCUIT, PRESSURE-DEMAND, ENTRY AND ESCAPE, COMBINATION SELF-CONTAINED BREATHING APPARATUS AND TYPE C SUPPLIED-AIR RESPIRATOR

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

Respirator Components																							
TC-	Protection	Alternate Facepiece			Alternate Harness						Alternate Cylinder				Alternate Hoses			Alternate Regulator			Accessories			Cautions & Limitations
		1000	2000	3000	4000	H95	H96	H97	H98	H99	C001	C002	C003	C004	25	50	100	R111	R222	R333	LENS10	ALARM50	CASE20	
13F-AARa	30 min. 2216 psi SC/PD	X	X			X	X	X	X	X	X							X			X		X	IJMNOS
13F0-AARb	30 min. 4500 psi SC/PD	X		X	X		X		X	X		X							X	X	X	X	X	IJMNOS
13F0-AARc	45 min. 4500 psi SC/PD	X		X		X	X						X						X	X	X	X	X	IJMNOS
13F-AARd	60 min. 4500 psi SC/PD	X						X	X					X					X	X	X	X	X	IJMNOS
13F-AARc	30 min. 2216 psi SC/SA/PD	X	X			X	X	X	X	X	X				X	X	X	X			X		X	DEIJMNOS

1. PROTECTION

PD - Pressure-Demand SC - Self-Contained SA - Supplied-Air

2. CAUTIONS AND LIMITATIONS

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.

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's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

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

-- Example Approval Label --
-- 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's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

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

-- Example Approval Label –
-- 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's Instructions. This includes cold temperature limitations, air quality requirements, special use instructions, etc. that were listed on old Part 11 label.]

-- Example Label --
-- ABBREVIATED FILTER and FILTERING FACEPIECE --

NOTE:

The company name must be completely spelled out.

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 product or container.

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

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 --
-- ABBREVIATED CARTRIDGE --

DOUBLE WING MANUFACTURING

- P/N 9876
- NIOSH
- OV/CL/HC/SD
- LOT #4321A

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 --
-- 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'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.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

[NOTE: The labels for gas mask respirators and canisters must appear in their entirety in the User's 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 manufacturer name, filter series (if a filter is included), gas or vapor protection, part number, lot number and word "NIOSH." No TC number may 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 two exceptions: the lot number need only appear on the container, and the manufacturer may include the TC number if desired.

Gas mask canister labels or the SCBA harness label must clearly indicate the manufacturer 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's 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's Instructions.

Protections on SCBA approval labels, User's 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. Manufacturers may use additional areas on the component to identify any other applicable approvals such as the European CN 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's 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 manufacturer assumes the liability for use of the respirators in mixed atmospheres. A manufacturer 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 manufacturer is permitted to say in the User's Instructions or product 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.