National Institute for Occupational Safety and Health
Respirator Branch

STANDARD APPLICATION PROCEDURES FOR THE CERTIFICATION OF RESPIRATORS

January 2001

Rev. 01/01

Introduction

These instructions should be read completely before submitting an application for approval of a respirator. The purpose of this document is to further streamline and improve the approval process under Title 42, Code of Federal Regulations (CFR) Part 84, 42 CFR 84 for manufacturers and NIOSH staff.

Compliance with all instructions is essential for efficient processing of an application. **Failure to follow these instructions completely may result in the rejection and return of your application. It is therefore imperative that each applicant invests 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, 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 at NIOSH's request.

Public reporting burden of this collection of information is estimated to average 227 hours per respirator approval application. These estimates include time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to DHHS Reports Clearance Officer; Paperwork Reduction Project (0920-0109); Rm 531-H, H.H. Humphrey Building.; 200 Independence Avenue, SW; Washington, D.C . 20201.

Form Approved: (Respirators)
OMB No. 0920-0109
Exp. Date: August 31, 2001

CONTACTS AT NIOSH

Respirator Branch

Richard Metzler, Chief, RB	(304) 285-5907	rwm0@cdc.gov
Kay Basile	(304) 285-5907	dkb1@cdc.gov
John R. (Ray) Wells	(304) 285-5907	ozw0@cdc.gov

Certification Team

Cathy Calvert	(304) 285-5935	cac3@cdc.gov
Michael Commodore	(304) 285-5748	mac5@cdc.gov
William (Gary)Fletcher	(304) 285-5748	wgf1@cdc.gov
Lee Hall	(304) 285-5852	wlh3@cdc.gov
Allen Harding	(304) 285-5967	awh2@cdc.gov
Judy Hudnall	(304) 285-6053	jbh1@cdc.gov
Darrell (Doug) Riffle	(304) 285-6356	dar2@cdc.gov
Sam Terry	(304) 285-5964	slt2@cdc.gov
Robert Thewlis	(304) 285-5798	ret0@cdc.gov
Kurt Vandestouwe	(304) 285-5735	khv1@cdc.gov
Charlie Wolfe	(304) 285-5747	cew9@cdc.gov
Jennie Wydo	(304) 285-5909	jvw1@cdc.gov

Quality Assurance Team

Linda Benson	(304) 285-5988	lrb4@cdc.gov
Matt Bowyer	(304) 285-5991	mqb2@cdc.gov
Susan B. Englehart (Records room)	(304) 285-5955	sfe5@cdc.gov
Kim Furrow (Records room)	(304) 285-5955	kcf6@cdc.gov
Bill Hoffman	(304) 285-5963	wah0@cdc.gov
Thomas McDowell	(304) 285-6337/6327 Lab	tom0@cdc.gov
Tim Merinar	(304) 285-5965	trm2@cdc.gov
Nancy Morgan	(304) 285-5961	nlm2@cdc.gov
Jeff Peterson	(304) 285-5960	jap3@cdc.gov
Sandra Poulson	(304) 285-6197	skp1@cdc.gov
Ronald Powelko	(304) 285-5966	rep6@cdc.gov
Gregory Spransy	(304) 285-6287	gcs3@cdc.gov

Policy Development Team

Roland Berry Ann	(304) 285-5956	rfb6@cdc.gov
John Dower	(304) 285-5954	jmd2@cdc.gov
Frank Palya	(304) 285-5788	fcp2@cdc.gov
Bob Stein	(304) 285-6049	rqs3@cdc.gov

http://www.cdc.gov/niosh/status.html

Respirator Branch Office (304) 285-5907

Fax: (304) 285-6030

Email: respcert@cdc.gov

Rev. 01/01

TABLE OF CONTENTS (page 1 of 2)

TABLE OF CONTENTS (page 2 of 2)

SECTION A – 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 the accessory is used or not.

Amended Application - A correction or amendment to an application presently in-house at NIOSH. Applications may be amended only at the request of NIOSH for the correction of inconsistencies detected during the NIOSH evaluation. Manufacturers are allowed 2 weeks to make corrections and submit an amended application. Failure to respond in 2 weeks will result in the application being denied.

Assembly Matrix - An assembly matrix is a table of major sub-assemblies and accessories, and should closely follow the format of the example shown in this manual in Section C.

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

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

Common Matrix - An assembly matrix that contains all of the information for a series of applications.

Component - See major sub-assembly

Correlation Testing - Testing requested for the purpose of comparing a manufacturer's test equipment to NIOSH equipment. For correlation testing use a new application form and in the "Reason for Application" section, include the wording, "Correlation Testing Only. The product is not submitted for certification."

Critical Characteristic - Is a feature of a product that, if not manufactured as approved, could have a direct adverse impact on safety (or health of the user) and for which testing or inspection is required prior to shipment to ensure conformity with the technical requirements under which the approval was issued.

Disposable Respirator - An air-purifying respirator for particulates and/or chemical gases and vapors where either the cartridge or filter is not designed to be replaced. The respirator is discarded when it is unsuitable for further use as defined by the manufacturer.

Exploded View Drawing - A drawing (see example in Section C.19 Drawings) showing all major sub-assemblies of the respirator. **The exploded view drawing must not contain dimensions, unless it is a filtering facepiece or disposable respirator.**

Family of Products - Is defined as a group of respirators sharing some common major sub-assembly such as a common facepiece (e.g., FastAir half mask, etc.). Each manufacturer determines the basis for grouping its respirator families.

Features - Descriptors that relate to the makeup, shape, proportions, outward appearance, prominent characteristics, or qualities but are not separate components or devices. Features may *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 - Means any component, major sub-assembly, or accessory that can normally be replaced by the user following user's instructions without any special knowledge, skills, abilities, or equipment (e.g., cartridges, regulators, hoses, etc.). Items, such as internal regulator components, would not be considered to be field-replaceable due to higher level of knowledge, skill, and training required for servicing.

Filtering facepiece - Is a type of N, R, or P series particulate respirator with the entire facepiece composed of the filtering media. The unit may or may not have an exhalation valve. This unit has no replaceable parts. See also Disposable Respirator.

Fit - Refers to 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 - Refers to the shape, structure, size, and outward appearance of the respirator.

Function - Addresses the capacity and method of operation of the respirator to meet minimum performance requirements for its intended use.

Intrinsically safe - Means incapable 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 - Are those components or sub-assemblies: (a) essential to the function and effective performance of the respirator; (b) that affect the respirator's form, fit, or function; and (c) which are normally field-replaceable items. Examples of major sub-assemblies are listed, but not limited to, those under Section C.20, Approval labels.

Model Numbers - A model number is not required to identify each unique configuration . *However, 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*, (i.e. a full facepiece, with model number "RX100" molded into the mask, must serve as the part number). If a product has both a part number and a model number, they both must appear in separate rows on the assembly matrix. No model numbers previously used for particulate filtering devices approved under 30 CFR Part 11 standards may be reused or carried over to devices or configurations to be approved under 42 CFR 84 standards, except for powered air-purifying respirators (PAPRs).

New design - Is defined as an entirely new product, component, or new arrangement of components (some of which may have been used on other previously approved respirators) constructed under specifications, or configurations, which NIOSH has not evaluated for this new 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 - NIOSH requires that the identifying number which is 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 number (where it appears on the component hardware) must also be shown on the drawings. This is the number referenced by users to identify respirator parts. It may not necessarily be what the manufacturer terms its part number since the manufacturer may use terms like catalog number, manufacturer number, production component number or other terms.

Pre-filter - Is an accessory item that removes coarse particles, situated in front of the main filter or cartridge 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. ***NOTE***: When pre-filters are used, the complete assembly must meet the resistance requirements of 42 CFR 84. Pre-filters may or may not 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.

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

Product Trade Name - Because of the way that manufacturers market and the way 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. (Ref. C.23)

Protections - A *different type of protection* is defined as protection against a different atmospheric contaminant (e.g., particulates, chlorine gas, ammonia gas, mercury vapor, IDLH, etc.). A *different level of protection* is defined by change in the type of facepiece (half mask, full facepiece) or mouthpiece, different filtering efficiency (such as N95 as opposed to N100) and/or different air supply capability (e.g., pressure, duration, demand flow, continuous flow, etc.).

Prototype - Initial production unit is 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 to be certified 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* complete a new application form and in the reason for application section, include the wording "prototype testing only. The product is not submitted for certification."

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.

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

Respirator - Is 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 (i.e. in the same bundle or package). There is a common assembly matrix that contains all of the information for the submitted series located in the last application of the series. Assembly matrices may not contain future submittals.

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 simplified drawings.

SECTION B -- General Information

B.1 HOW TO APPLY

NIOSH will accept only electronic applications that are completed using the NIOSH Standard Application Form software. The software is a Windows application and will be furnished to each manufacturer free of charge. Copies of the software on CD-ROM may be obtained by calling NIOSH at (304) 285-5907 or by downloading it from the website at http://www.cdc.gov/niosh/status.html.

The application form consists of the following:

Description	Electronic File Name
Application Forms: -New Approval - Extension of Approval - Quality Assurance	saf_v6.mdb
Application Data:	saf_data.mdb

To apply, use the NIOSH Standard Application Form software "saf_v6.mdb" and "saf_data.mdb". When an application form has been completed, the data file is saved by selecting FILE, then SAVE AS, from the menu bar on the main menu screen. The data file must be saved using the file naming convention XXXnnnnnnnnnnnn.MDB. The file-naming convention of the application file is XXXnnnnnnnnnnnn.mdb where XXX is the three-letter manufacturer code and the n's are a unique identifier of the manufacturer's choice. If a manufacturer code is unknown or has not been assigned, the manufacturer may contact the NIOSH records room to obtain a designated manufacturer code before preparing an application or select the option, "Not Listed". If "Not Listed" is selected, NIOSH will then assign a code to the manufacturer upon receipt of the application. The application data file and supporting documents may currently be submitted on the following electronic media: 3.5 inch diskettes, zip drive disks (100 MB), and CD-ROM. The revision level must be included in the file name for every controlled document file.

Manufacturers who submit via e-mail run the risk of losing data if 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 documents. These documents must be in English and saved with the following file-naming conventions to comprise a complete application. The only documents that will be accepted in paper form are the Quality Assurance Manual and the fee check.

XXX is the 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	XXXnnnnnnnnnnnn.MDB
Pre-test data	WordPerfect, Adobe Acrobat, ASCII text, PageMaker6, Excel, Microsoft Word, QuarkExpress	nnnnnnnnnnnnnnPD.WPD, PDF, PM6, XLS, TXT, DOC, QXD
Drawings	Scanned file, AutoCad, Adobe Acrobat, CorelDraw	nnnnnnnnnnnnnnRa.TIF, DWG, DXF, PDF, CAL, GIF, PCX, CDR
Assembly Matrix	Excel	nnnnnnnnnnnnnAMa.XLS
Draft approval labels	Excel	nnnnnnnnnnnnnDLa.XLS
Q/A manual	WordPerfect, Adobe Acrobat, scanned file, PageMaker6, Excel, Microsoft Word, ASCII text, QuarkExpress	nnnnnnnnnnnnnQMa.WPD, PDF, TIF, PM6, XLS, TXT, DOC, QXD and PAPER
Process Quality Control Plan	WordPerfect, Adobe Acrobat, scanned file, PageMaker6, AutoCad, Excel, Microsoft Word, ASCII text, QuarkExpress	nnnnnnnnnnnnnPQP.WPD, PDF, TIF, PM6, DWG, XLS, TXT, DOC, QXD
Fees	Not Applicable	Paper only
Service Life Plan	WordPerfect, Adobe Acrobat, scanned file, PageMaker6, Excel, Microsoft Word, ASCII text, QuarkExpress	nnnnnnnnnnnnnSLP.WPD, PDF, TIF, PM6, XLS, TXT, DOC, QXD
User's Instructions	WordPerfect, Adobe Acrobat, scanned file, Microsoft Word, ASCII text, QuarkExpress	nnnnnnnnnnnnnUIa.WPD, PDF, TIF, TXT, DOC, QXD
Hardware	Not Applicable	Not Applicable

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

B.1.1 WHO MAY APPLY ?

Only the manufacturer of the product may apply for approval. The manufacturer may prepare the application and documentation themselves or use an independent consultant. A **manufacturer** is defined as 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. A manufacturer does **not** include re-branders, re-packagers, wholesalers, retailers, distributors, or those who may add accessory items such as welding lenses. TC numbers will only be issued to manufacturers, and as such, these manufacturers are responsible for insuring that the quality and performance of all approved products offered to the market are equal to that originally evaluated and approved by NIOSH.

B.1.2 WHERE TO APPLY ?

Applications and samples must be sent under separate cover.

Applications must be sent to:
ATTN: Records Room
Respirator Branch
NIOSH, NPPTL
1095 Willowdale Road
Morgantown, WV 26505-2888

Samples must be sent to:
ATTN: Respirator Certification Team
Respirator Branch
NIOSH, NPPTL
1095 Willowdale Road
Morgantown, WV 26505-2888

B.1.3 WEB SITE

Manufacturers can inquire about the status of their projects, obtain copies of the Standard Application Form, Certified Equipment List, Logos, etc. 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 one time, however the inter-relationship(s) and the suggested processing order reflecting how the applications build upon each other must be called out in the approval history. **The applicant should be aware that under NIOSH processing procedures, no application in the series will be approved until processing of all applications in the series is completed.** See definition of series of applications. When a series of inter-related applications is submitted involving a common assembly matrix, only a single assembly matrix need be submitted to cover all applications.

Applications are processed in the order received. This is not necessarily the order tested. There are several testing queues and the products will be tested at the earliest available time in each queue.

The electronic standard application form for new approval and extension of approval identifies the data fields that are being entered directly into the NIOSH Certified Equipment List (CEL). These fields are in red and noted at the bottom of the screen of the application form. Please complete these fields for an accurate reporting of your product in the CEL.

If a manufacturer is in doubt about the appropriate type of application to submit, call NIOSH. (See Contacts at NIOSH for phone numbers)

B.2.1 NEW APPROVAL APPLICATIONS

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. A new TC number is assigned for each new respirator system design that is approved.

An approval 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 (i.e. if a manufacturer wants to submit 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).

Approval Schedules

This list of **NIOSH approval schedules** is provided to assist the manufacturer in creating the assembly matrix and labels. The following respirator class schedules will be assigned by NIOSH upon completion of the submission:

> *13F - Self-contained Breathing Apparatus (SCBA) for entry or escape, open circuit, closed circuit, or Self-contained Self-rescuers (SCSR), and combination escape only Self-contained Breathing Apparatus/Supplied Air (ESCBA/SAR) respirators.

*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-line Respirators (SAR), type C and CE, including demand, pressure demand, or continuous air 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.

This list is provided as a tool only and is not all inclusive. Unique respirators submitted for NIOSH 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.

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

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, P) or efficiency (100, 99, 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. It has been NIOSH

policy since the implementation of 42 CFR 84, that particulate filters previously approved under 30 CFR 11 may be physically unchanged and resubmitted under 42 CFR 84. Although these filters may be physically unchanged, the performance requirements, quality control measures governing critical and major characteristics, and approval label formats all must change. To separately distinguish the Part 11 and 42 CFR 84 filters, it is required that these filters have different part numbers. Also, NIOSH does not allow dual labeling and since Part 11 and 42 CFR 84 approvals have different labeling requirements, these filters must be packaged separately. The only exception is a filter that is approved for use on powered and non-powered respirators as an HE/P100. These will carry a dual label.

As always, when in doubt, call NIOSH and discuss the changes planned and your application submittal strategy before assembling and mailing the application. (See Contacts at NIOSH for phone numbers)

B.2.2 EXTENSION OF APPROVAL APPLICATIONS

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, will not have to be submitted to NIOSH. However, manufacturers remain responsible for keeping all changes to minor characteristics on file and available 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). Approval label, assembly matrix, user instructions, service life plans, and drawing changes are also considered extensions of approval. Alternate new items, such as two new alternate filter medias, require **separate** applications since each requires testing. The Manufacturer must list the NIOSH "TC" numbers of all approved products affected in the "Reason for Application". If **all** of the TC numbers on a given assembly matrix applies to the extension then the assembly matrix may be referenced instead of listing the individual TC numbers.

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

New TC numbers may be assigned for extensions of approval (excluding private labels) if the type or level of protection changes.

For an **extension of approval**: Describe **exactly** and **completely** the **change** or **additions** for which you are seeking approval and **what** and **how** it 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 product(s) affected (name, TC number and part numbers).
2. Complete details of the change.
3. Related documentation that has changed since the last approval (assembly matrix, 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. The accessories may not affect a change on the approval labels.

When changes are made that affect the user's instructions or service life plan, highlight or clearly note the items changed in the instructions or plan.

If multiple changes are being provided to users as an "upgrade kit" then the applicant must submit one application for one upgrade kit (e.g., an NFPA upgrade kit involving new head strap, backpack, harness straps, regulator, etc.).

B.2.3 QUALITY ASSURANCE APPROVAL APPLICATIONS

A **Quality Assurance Approval** is defined as a submission requesting approval of a change affecting some aspect of the **previously approved** quality assurance system manual for the corporation or company, or of the process quality control plan for a **previously approved** respirator system. Quality manual changes must include a revision change sheet showing the date and reason for revision changes.

When changes are made to the quality assurance manual or process quality control plan documentation, state exactly and completely the details of the change. Also indicate the products and manufacturing facilities affected. Quality assurance approval submissions must **in no way affect form, fit, or function and must not result in a different type or different level of protection**. If the changes do impact any of these aspects of the covered respirators, then only an Extension of Approval application is acceptable to NIOSH.

B.2.4 RESUBMITTAL OF APPROVAL APPLICATIONS

When the product has previously been evaluated and denied approval by NIOSH, indicate in the application form that the application is a resubmittal (i.e. select request type as Resubmittal of New or Resubmittal of Extension). The denial may have been due to a failure of the sample hardware to meet design or performance requirements, or due to the unacceptability of the quality assurance plan or other documentation submitted (see Section D).

A resubmittal must state, in the *Reason for Application* section, the modification that was made to address product or documentation deficiencies and demonstrate why the product or documentation now meets NIOSH requirements. Failure to provide this information will result in your application being returned, unprocessed. The applicant must also indicate the task number (TN) under which the product was previously denied. **When applications are denied, NIOSH does not retain the associated documentation or hardware.**

B.2.5 AMENDED APPLICATIONS

An amended application is submitted ONLY at NIOSH's request. This is for open applications that have some inaccuracy in part of the application. Manufacturers need only submit the portion of the application requested. In each case the application will retain the same Applicant-Assigned Reference Number and NIOSH-assigned Task Number. NOSH will provide instruction as to what documents must be submitted when requesting an amended application.

SECTION C -- SPECIFIC INSTRUCTIONS FOR PREPARING AN APPLICATION

Samples of the New and Extension of Approval Forms
Can Be Found in Section F

C.1 APPLICANT-ASSIGNED REFERENCE (AAR) NUMBER

The applicant (manufacturer) must assign a unique reference number of their choice for each application. The first 3 digits of this applicant-assigned reference number must be the NIOSH-assigned manufacturers' code. This number must also appear on each hardware sample package and on the payment check.

Never re-use applicant-assigned reference numbers, except for amended applications requested by NIOSH.

To obtain the task number, submit a stamped, self-addressed post card with the applicant-assigned reference number with each application or series of applications. NIOSH will note the assigned task number and promptly return the post card. Foreign manufacturers may send a completed fax form that will be faxed to them with the assigned task number.

Subsequent inquiries must refer to the NIOSH assigned task number (TN) or the 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, telephone number, facsimile (FAX) number, and e-mail address.

C.4 MANUFACTURING SITE(S)

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

C.5 APPLICATION REPRESENTATIVE

Please do not list every contact person you have for NIOSH. Only list one or two people who can assist us if we have questions about each specific application. If for company policy reasons you must list all of the NIOSH contacts, please list the appropriate contact person in the Reason for Application.

When the manufacturer is located outside of the United States, or a manufacturer hires a consultant to handle the application submission, the manufacturer 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. NIOSH reserves the right to obtain documentation directly from the manufacturer if necessary.

NOTE: NIOSH requires a formal letter designating the official contact be on file at NIOSH. Any time the manufacturer representative changes, NIOSH must be notified in writing.

C.6 DATE OF APPLICATION

State the date of the application in a MM/DD/YY format.

If the application, check, or samples are sent on different dates, processing will not begin until all of the items are received. These items must all be received within 2 weeks of each other or they will be returned.

C.7 TYPE OF PRODUCT

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

C.8 SPECIFIC QUESTIONS PERTAINING TO SUBMISSION

If you are submitting an amended application, please refer to Section B.2.5 for specific instructions.

If an application is submitted as a result of any type of field problem or non-conforming site or product audit, the yes box must be checked and the related task number field must be completed. If not applicable check the no box.

Is this device intended for mine use, a yes or no must be marked (new application only). More information is provided in C.12.

If 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. (Example: If a new facepiece was submitted for approval in an application 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.) If not applicable check the no box.

If this request is for a modification involving a recall or retrofit program, the yes box must be checked and a copy of the recall/retrofit notice must be submitted. If not applicable check the no box.

C.9 REASON FOR APPLICATION

Provide a complete, concise, descriptive reason for your application. Do not provide detailed information relating to product use or future developments of the product line. List the NIOSH "TC" numbers of all approved products affected by this application. If **all** of the TC numbers on a given assembly matrix apply to the extension then the assembly matrix may be referenced instead of listing the individual TC numbers. Do not list additional requests in the Approval History.

New and Extension of Approval applications must contain the following items **(content of each of these items is described in detail in Section C).** If one of the items is not submitted, the manufacturer must state a reason why the item was not submitted (i.e. has not changed since submission under 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

Quality Assurance Approval applications must state exactly and completely the details of the change, indicating the products and manufacturing facilities affected. Quality assurance approval submissions must in no way affect form, fit, or function and must not result in a different type or different level of protection.

Resubmittal applications must state, the modification that was made to address product or documentation deficiencies and demonstrate why the product or documentation now meets NIOSH requirements.

An Example 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.

C.10 APPROVAL HISTORY

This section may be used to provide additional information on approval history, and other pertinent information applicable to this application.

If this application is one of a series being submitted, review Section B-General Information and be sure to:

1. list the applicant-assigned reference numbers of related applications in a succinct manner
2. include a suggested processing order
3. if using a common assembly matrix, place it in the last application of the series and state the application in which it is located in the other applications within the series. See definition of series (of applications).

An Example of a Well-Written Approval History:

> The new filter media is documented on the new specification sheet - ZM-FL-A02 Revision 0A.
>
> The change is documented in the mask's Bill of Materials (Item 2) on page 3 of the drawing 103-01 Revision 0M.
>
> 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. Therefore, 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 both private labels (YYY & ZZZ).

C.11 DESCRIPTION OF RESPIRATOR

A detailed description of the respirator is needed. On the application form for a NEW approval, this 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. For extensions a detailed narrative description is required.

C.12 INTENDED PROTECTION AND SAFE DESIGN

Air-purifying respirators only: State all contaminants for which approval is sought. Only gas masks (14G) can list "Acid Gas" as a protection. Chemical cartridges (23C or 84A) must identify the specific contaminants for which approval is sought (e.g., chlorine, chlorine dioxide, etc.). **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"** in the Standard Application Form is to identify respirators to be used for mine rescue and other emergency use in mines, including self-contained breathing apparatus (SCBA). This information is requested by NIOSH to assist in determining if the application must be jointly evaluated and approved by both NIOSH and the Mine Safety and Health Administration (MSHA)**. Please note that respirators to be used for mine rescue and other emergency use in mines must be co-approved by MSHA under Title 30 CFR Part 75.1714.**

C.13 PRE-TEST DATA AND STATEMENTS

Performance test data on the respirator must accompany each application.

- Specify components by part number used for test configuration.

- Show units of measure for all test data.
- Unit of measure must match 42 CFR 84 criteria.

Submit copies of actual test data with all results and conclusions. The following "RESPIRATOR TESTING SELECTION GUIDE" is provided for reference. 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.

If 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:

1. Demonstrating that the ESLI is a reliable indicator of sorbent depletion.
2. On the effects of any industrial chemical interference with the indicator.
3. On the shelf life of the indicator.
4. Affirming that the ESLI is visible to the user when worn.
5. 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 Label, Section C.20 for an example.)

NIOSH - RESPIRATOR BRANCH
RESPIRATOR TESTING SELECTION GUIDE

Item	RESPIRATOR TYPE	*NIOSH Test #	TITLE	TOTAL MATERIALS NEEDED
1	Chemical Cartridge, Subpart L, Non-powered Note: Adequate O2 necessary Note: concentration limitations	3 4 5/5A/6 7 33-48 or 62 60 61 Note: ESLI tested where used	Exhalation resistance Exhalation valve leakage Facepiece fit (IAA) Inhalation resistance Gas or vapor (as applies) ESLI visibility ESLI damage resistance	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 1 set 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 4 5/5A/6 7 33- 48 or 62 51-56 57-59 60 61 Note: ESLI tested where used	Exhalation resistance Exhalation valve leakage Facepiece fit (IAA) Inhalation Resistance Gas or vapor (as applies) DOP for Particulates NACL for Particulates ESLI visibility ESLI damage resistance	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 1 set 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 4 5/5A/6 7 33-48 or 50 60 61 Note: ESLI tested where used	Exhalation resistance Exhalation valve leakage Facepiece fit (IAA) Inhalation Resistance Gas or vapor (as applies) ESLI visibility ESLI damage resistance	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 1 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 4 5/5A/6 7 33-48 or 50 51-56 57-59 60 61 Note: ESLI tested where used	Exhalation resistance Exhalation valve leakage Facepiece fit (IAA) Inhalation Resistance Gas or vapor (as applies) DOP for particulates NACL for particulates ESLI visibility ESLI damage resistance	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 1 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 60 61 Note: ESLI tested where used	Exhalation resistance Exhalation valve leakage Inhalation Resistance DOP for particulates NACL for particulates ESLI visibility ESLI damage resistance	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 26 filters for each type Note: All combinations with an ESLI must be submitted to verify ESLI visibility and damage-resistance.

Rev. 01/01

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 25 30 33-48 or 62 60 61 Note: ESLI tested where used	DOP (dioctyl phthalate)- PAPR only Exhalation resistance Exhalation valve leakage Facepiece fit (IAA) Inhalation Resistance PAPR air flow PAPR Silica dust (for res) Sound level Gas or vapor (as applies) ESLI visibility ESLI damage resistance	3 complete respirator assemblies with components for assembling the highest & lowest resistance combinations 3 exhalation valve assemblies 1 set 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	118 121 123.1 124 125 126 Valve 128 130 131 132 133 139 145 148 **Note:** **146-Regulator Over Pressurization Test** **(is done on all belt mounted regulators only)**	Low Temperature Test Rated Service Time Test Gas Flow Test Remaining Service Life Indicator Test (IAA), Gas Tightness Test Bypass Flow, Test - Adj. Bypass Gas Pressure Gauge Test (Accuracy of gauge) Man Tests Weight Determination Test Inhalation Resistance Test Exhalation Resistance Test Maximum CO_2 Inspired Gas Test (CO_2 Dead Space) Alarm Sound Level Test Gauge Leakage of Gas Test	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 Valve 128 130 131 139 145 148 **Note:146-Regulator Over Pressurization Test** **(is done on all belt mounted regulators only)**	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 Gas Pressure Gauge Test (Accuracy of gauge) Man Tests Weight Determination Test Maximum CO_2 Inspired Gas Test (CO_2 Dead Space) Alarm Sound Level Test Gauge Leakage of Gas Test	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 Positive Pressure Test 121.1 Rated Service Time Test 124.1 Alarm Pressure 125 (IAA) Gas Tightness Test 127 Bypass Flow Test-Adj. Bypass Valve 128 Gas Pressure Gauge Test (Accuracy of gauge) 136 Gas Flow Test (Demand only) **or** 137 Gas Flow Test, (Constant flow with Demand) 131 Weight Determination Test 134 Breathing Bag Test 135 Breathing Resistance Test 136 Gas Flow Test (Demand only) **or** 137 Gas Flow Test, (Constant flow with Demand) 138 Safety Relief Valve Operation Test 139 Maximum CO_2 Inspired Gas Test (CO_2 Dead Space) 140 Man Tests 141 Man test 5 for Inspired Gas Test 143 Low Temperature Operation Test 145 Alarm Sound Level Test 148.1 Gauge Leakage of Gas Test 155 Man Test 6 for Liquified Gas **Note: Rated Service Time is tested during Man test 4 assuming all previous Man tests have been satisfactorily completed.**	2 complete units plus 1 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 (IAA) Gas Tightness Test 134 Breathing Bag Test 135 Breathing Resistance Test 138 Safety Relief Valve Operation Test 139 Maximum CO_2 Inspired Gas Test (CO_2 Dead Space) 140 Man Tests 141 Man test 5 for Inspired Gas Test 142 Vibration Test 143 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 1 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	118 121 123.1 125 128 130 131 132 133 139	Low Temperature Test Rated Service Time Test Gas Flow Test (IAA), Gas Tightness Test Gas Pressure Gauge Test (Accuracy of gauge) Man Tests Weight Determination Test Inhalation Resistance Test Exhalation Resistance Test Maximum CO_2 Inspired Gas Test (CO_2 Dead Space)	2 complete units plus one each of all accessories 3 cylinder gauges
12	SCBA -open circuit escape Pressure Demand	118 120 121 122 123 125 128 130 131	Low Temperature Test Positive Pressure Test Rated Service Time Test Exhalation Resistance Test Gas Flow Test (IAA), Gas Tightness Test Gas Pressure Gauge Test (Accuracy of gauge) Man Tests Weight Determination Test	2 complete units plus one each of all accessories 3 cylinder gauges
13	SCBA -open circuit escape Constant Flow	114 115 116 118 125.1 128 130 131 132 133 139	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) Man Tests Weight Determination Test Inhalation Resistance Test Exhalation Resistance Test Maximum CO_2 Inspired Gas Test (CO_2 Dead Space)	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 plus 112-Abrasive Blast, Quantitative Fit**	Exhalation valve leakage Strength of Hose and Coupling Test Tightness Test Nonkinkability 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

Item	RESPIRATOR TYPE	*NIOSH Test # TITLE	TOTAL MATERIALS NEEDED
15	Supplied Air Type C-CE Pressure Demand	4 Exhalation valve leakage 100 Strength of Hose and Coupling Test 101 Tightness Test 102 Nonkinkability Test 103 Gasoline Permeation Test 104 Air Regulating Valve Test (100,000 Cycles) 105.1 Airflow Test, Pressure Demand Class 106 Inhalation Resistance Test, 107 Exhalation Resistance Test 110 (IAA), Gas Tightness Test **Note:** **For Abrasive Blast, Type CE, Supplied-Air Respirators, perform all above tests 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
16	Supplied Air Type C-CE Constant Flow	4 Exhalation valve leakage 100 Strength of Hose and Coupling Test 101 Tightness Test 102 Nonkinkability 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 #2
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 or 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

* Tests selected may vary depending on design and intended use.

C.14 MODEL NUMBERS AND PRODUCT TRADE NAMES

A **product trade name** that uniquely identifies the respirator or family **is required**. This trade name will be listed in the NIOSH Certified Equipment List for public reference. In the electronic application (New only), the model number field can be blank, but the product trade name field must be completed before proceeding to the next data screen.

C.15 TEST SAMPLES AND HARDWARE

Submit a sufficient number of test samples (including facepieces) for testing at the time of application but under separate cover from the application. The manufacturer must list, in the application and on a packing slip shipped with the samples, the item (part number and description) and quantity submitted for testing.

The outside of each shipping container and packing slip should clearly indicate "**Test Samples**" along with the **name of the manufacturer** and the **applicant-assigned reference number** as explained under section "**C.1. -Applicant-assigned reference number"** and the part number and quantity of samples. The sample hardware must clearly show the part number on each item regardless of how it is packaged. This also applies to additional test samples requested by NIOSH. When additional samples are requested by NIOSH please mark the shipment to the attention of the NIOSH staff person requesting the additional samples. Also mark the **Applicant-assigned reference number,** NIOSH Task Number and state "additional samples". No cross-reference lists will be accepted.

Applicants must also submit **pre-paid return shipping labels or provide other return means** with the samples, for any materials that the manufacturer wants returned once testing is completed. State "Please return samples" on the packing slip. If NIOSH denies an application based upon documentation issues, it will return the application and all sample hardware. **NIOSH does not retain samples for 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 NIOSH as well as when the hardware is shipped from NIOSH back to the manufacturer.

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.** NIOSH may request additional samples for testing that could not have been anticipated by the applicant.

A **"Respirator Testing Selection Guide"** is provided in Section C.13 to assist the applicant in determining the minimum number of samples needed to be submitted for testing. NIOSH may require additional testing where evaluators deem it necessary or appropriate thus necessitating need for additional samples.

C.16 QUALITY ASSURANCE DOCUMENTATION

If a change is submitted under 42 CFR 84, NIOSH does not require a complete new quality assurance manual, just the revision(s) to applicable sections. This policy has not changed. Submit only the applicable sections that have been revised.

If you have previously had a Quality Manual approved, and there is no change, complete the required information on the SAF. If there are changes included in this submission, the following information is required.

The quality assurance documentation is divided into two sections:

1. Quality Assurance Manual
2. Product Quality Control Plan and Documentation

Any submittals for existing approvals under Part 11 must be made under 42 CFR 84 guidelines.

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.

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 Quality Assurance Manual;
- Quality Assurance revision change sheet showing date and reason for revision change;
- Quality Assurance Manual "table of contents";
- Management assurance that the Quality Control program meets NIOSH requirements.

B. Description of Management Responsibilities:
- Quality Policy
- Organization of Personnel
- Verification of Quality (Internal Auditing)
- Review of Quality System
- 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 Process

K. Three areas of Inspection and Testing
    - Receiving
    - In-process
    - 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

All applicants must submit a Product Quality Control Plan (PQP). Graphical flow charts are the best stable representation of an applicant's production processes. However, text form is acceptable. A PQP only needs to be submitted once for a particular product or product line.

The following quality control documentation, which must demonstrate the process characteristics involved in controlling and monitoring the quality of the respirator being manufactured and/or assembled, is required to be submitted as part of this application. The inspection and test procedures are required to meet the requirements outlined in the 42 CFR 84, Subpart E, sections 84.40, 84.41, 84.42, 84.43, or comparable sections of 42 CFR 84 and other sections which detail specific test requirements. These test requirements depend upon the respiratory protection provided by the respirator. The manufacturer is to 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:

A. PQP flowcharts will show all inspection, and test operations and identify each procedure by manufacturer-assigned documentation number. **Clearly identify the inspection or test procedure on your flow chart.**

B. Sampling plan and classification of defects document as described in Title 42 CFR 84.41 (c), (d), (e), (f), (g), (h).

C. In-process inspection procedures for those items listed on the Assembly matrix.

D. In-process test procedures for those items listed on the Assembly matrix.

E. Final inspection procedures for those items listed on the Assembly matrix and the completed respirator.

F. Final test procedures for those items listed on the Assembly matrix and the completed respirator.

G. Drawings and Assembly matrix.

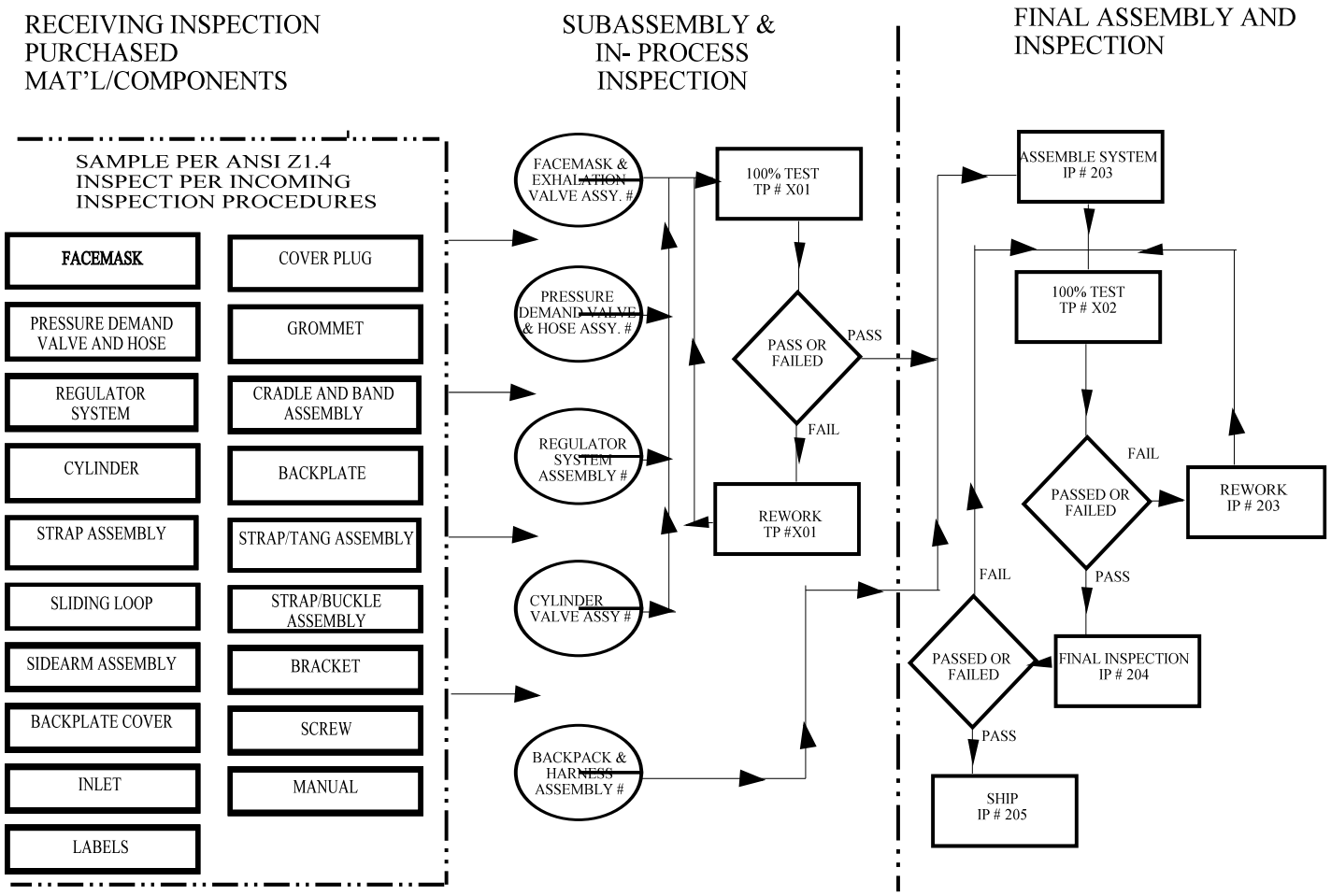
If inspection or test procedures were previously accepted, they need not be submitted again unless they have been changed.

The Institute reserves the right to request additional information in order to determine if an effective plan has been designed and is being implemented. This includes drawings.

Whether 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 upon request by NIOSH.

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 the location of a lot number or other traceability identifier on the product.

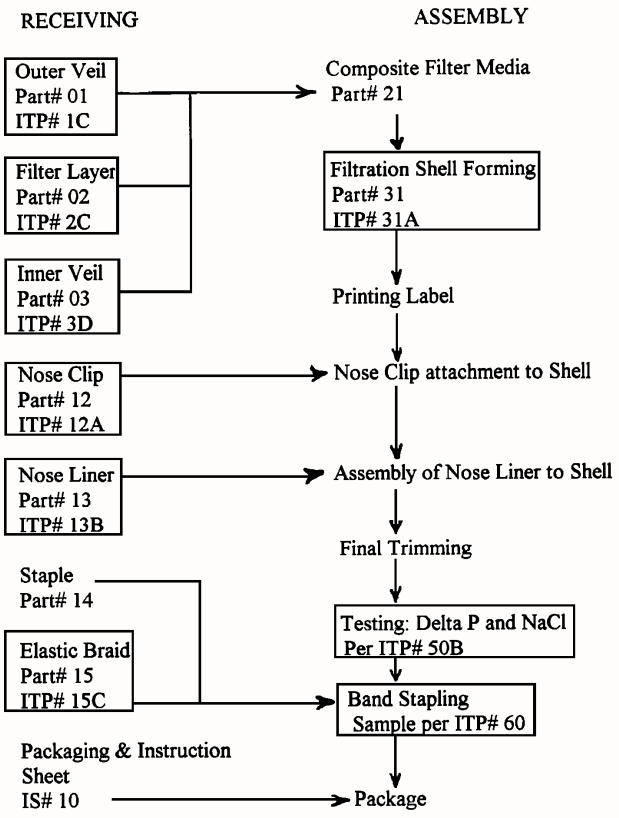
PRODUCT QUALITY PLAN FLOWCHART
FF100 SCBA



Rev. 01/01

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

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 as stated in **Section C.1. - Applicant-assigned reference number**. Processing will not begin until all items (application, check, and 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.

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 chem cart)	$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

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. However, please note the following:

A. Only complete respirators are approved.

B. Depending on the nature of the change, NIOSH may require testing of the entire assembly as would be required for a new product.

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

Fees for such major sub-assembly tests 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 format. An assembly matrix is a table of major sub-assemblies and accessories and must follow the format of the example. It 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 if the component is or is not part of the complete approved assembly.

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

When a manufacturer requests a new TC number, identify the rows within the TC number column as the schedule (Section B.), AAR#, and an alpha character. (Example:84A-MOR699a for the first line and 84A-MOR699b on the second line, etc.) "TC-" can only appear in the column heading and not in the 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.).

On the assembly matrix containing 13F approvals, there must be a column that lists the part number and revision level of the most current Users' Instructions. 13F approvals for SCSR must include part number and revision level of the service life plan.

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

Empty rows and/or columns within the body of the assembly matrix must be entirely empty and from 80 percent dark shaded to completely blacked out to clearly indicate no additional information is present. Columns with information shall not be shaded. Assembly matrices may not contain future submittals or show unapproved assemblies. **Please ensure that blank spaces on your assembly matrix are entirely blank and do not contain any unnecessary information, extra 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.

Anytime more than one of the same major sub-assemblies for a respirator configuration 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 approval. 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 = components that have been previously tested and approved by NIOSH **in this configuration**.

N = if a new TC number has been requested, "N" must appear in every column across the entire row. When an extension of approval is requested "N" should only appear in the column for the new component. For example, where only one component is new or new to the TC number, show "N" for the new component(s) only.

P = pending must be used for each component submitted in a prior application(s) currently under evaluation at NIOSH.

R = a component that is 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)**

A = accessory items - 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 the accessory is used or not. **The use of "o" or "x" is no longer acceptable to denote accessory items.**

An obsoleted item must be shown on the matrix as obsolete for the TC number/Part number combination at least once. After October, 2000, once you have submitted an assembly matrix with obsoleted items, you may drop these items from the matrix in future submissions.

It is strongly recommended that you color the rows and columns containing new or redesigned (N or R) components for easier review and evaluation. If nothing is marked "N" or "R" the applicant should reconsider whether an application for approval is required. In case of doubt, call NIOSH first. (Refer to NIOSH Contact List for phone numbers.)

Color is used for example purposes only and the numbering system corresponds to the numbering on the Assembly Matrix Check List on the page after the example.

The matrix must list all major sub-assemblies and accessories. The component row is for a general heading of the major sub-assemblies shown (example high pressure hose, low pressure hose, etc. might have the category heading of alternate hoses). Anytime more than one of the same major sub-assemblies is listed it must be identified as alternate components by stating "alternate" in the column heading. (7)

Key Box (14)

Matrix must list the manufacturer's name and address. (2)

The first column on the left must list the applicant assigned reference number. The second column from the left must list the TC numbers. When a manufacturer requests a new TC number, identify the rows within the TC number column as the schedule, AAR#, and an alpha character. (Example:84A-MOR699a for the first line and 84A-MOR699b on the second line, etc.) "TC-" can only appear in the column heading and not in the matrix row. The third from the left is the protection column. (9) (10) (11)

To reference the major sub-assemblies from the assembly matrix to the exploded view drawing, an identifying numbering system shall be used and must match exactly (e.g., the facepiece is shown as item 1a, 1b and 1c on the assembly matrix and is correspondingly shown as items 1a, 1b, and 1c on the exploded view drawing.) The manufacturer may use dotted lines around major sub-assemblies on an exploded view drawing to group the smaller parts together into one sub-assembly. (4)

The top right corner of the assembly matrix must list the task number or applicant assigned reference number of the previously approved or pending assembly matrix. Do not reference denied projects. If it has not been previously submitted indicate "new". The top right corner of the assembly matrix must also list the exploded view drawing number that corresponds to the assembly matrix submitted in this application. (12)(13)

The row along the bottom of each component column is for the NIOSH task number where the component was last tested (if new, indicate as N). This is where the component itself was tested and passed the most critical performance elements. For example give the task number of where the facepiece fit tests were performed, not where the facepiece was resistance tested in combination with a filter or cartridge. Do not reference denied projects. (8)

The number stamped on the component and shown on the label is the number that must appear in the part number row of the assembly matrix. Part numbers are mandatory on the matrix, and model numbers are optional (if you have them , they should appear). (5)

The matrix must be titled and show the date or revision level. (1)

The drawing number and revision level shown on the assembly matrix must match the major sub-assembly drawing on file at NIOSH or be included in the application. (3)

A description of the part must be listed in a column above the revision level of the drawing. (6)

(14) KEY
X - CURRENTLY APPROVED IN THIS CONFIGURATION
N - NEW COMPONENT OR CONFIGURATION
- - OBSOLETED
R - REDESIGN
P - PENDING
A - ACCESSORY

EXAMPLE ASSEMBLY MATRIX

(2) DOUBLE WING MANUFACTURING
ST. XAVIER, ALMOST HEAVEN, USA
1-800-123-4567

(12) TN or AA R# of previously approved or pending matrix ____________
(13) Exploded view drawing number ____________

(1) Rev or Date of Assembly Mx

(1) RESPIRATOR FAMILY APPROVAL MATRIX

(9) APPL. ASSY REF #	(10) NIOSH APPROVAL NUMBER, TC-	(11) PROTECTION																						
		(4)	1						2				3								4			
		(7) COMPONENT	ALTERNATE FACEPIECE						ALTERNATE ADAPTOR				ALTERNATE CARTRIDGES								FILTERS			
		(4)							A	B	C	D	B	B	B	B	B	B	B	D	C	C	C	C
		(6) DESCRIPTION	FULL FACEPIECE-SMALL	FULL FACEPIECE-SM STL	FULL FACEPIECE-MEDIUM	FULL FACEPIECE-MED STL	FULL FACEPIECE-LARGE	FULL FACEPIECE-LG STL	PLUG	HOLDER	FULLFACE ADAPTOR	ADAPTOR	ORGANIC VAPOR	CHLORINE	OV/CL/HC/SD	ORGANIC VAPOR	CHLORINE	OV/CL/HC/SD	AMMONIA/METHLAMINE	FORMALDEHYDE/P100	N95	N100	R99	P100
		(3) REV	D	C	R	G	D	C	C	C	A	C	E	G	F	B	B	C	B	B	F	A	A	A
		(3) DRG NO	8614	8619	1295	2417	8616	8617	6441	1232	7901	3445	1114	1115	1116	8523	8524	8525	8526	8527	8702	8700	8701	8636
		(5) PART NO	8618-4	8619-2	1295-5	2417-5	8616-8	8617-5	6441-7	1232-9	7901-0	3445-3	1114-9	1115-5	1116-4	8523-5	8524-4	8525-1	8526-9	8527-7	8700-5	8700-0	8701-9	8636-5
		MODEL	2001Sm	2001Sms	2001	2001S	2001L	2001LS	2000	1999	701	502	1998	1989	1952	61	62	63	64	65C	2001F10	2001F11	2001F12	20
	19C-199	DGSA	X	X	X	X	X	X	X															
	19C-238	PDSA	X	X	X	X	X	X	X															
	19C-239	CFSA	X	X	X	X	X	X	X															
	23C-690	OV/CL/HC/SD	X	X	X	X	X	X		X	X				X			X						
	23C-692	AM/MA	X	X	X	X	X	X		X	X								X					
	23C-693	OV/SA/CE	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												
	84A-1095	FM/P100	X	X	X	X	X	X			X									X				
N/2718a	84A-N/2718a	N95	P	P	P	P	P	P			P										P			
	84A-1610	N100/SA/PD	X	X	X	X	X	X	X		X											X		
	84A-1210	R99/SA/CE	X	X	X	X	X	X	X		X												X	
	84A-0808	P100	X	X	X	X	X	X			X													X
	84A-0809	P100/OV	X	X	X	X	X	X		X	X		X			X								X
N/2719a	84A-N/2719a	N95/CL	N	N	N	N	N	N		N	N			N			N				N			
(8) NIOSH task number where component was LAST used (if new, indicate as "N"):			04128	04128	04128	04128	04128	04128	05978	06166	05509	05509	05512	05590	06162	05646	05647	05648	05649	05650	N/2718a	9400	9401	09208

(9) APPL. ASSY REF #	(10) NIOSH APPROVAL NUMBER, TC-	(11) PROTECTION																			
		(4)	6		7		8		9			10									5
		(7) COMPONENT	RETAINER		ALT AIRLINE ADAPTOR		ALTERNATE BRTH TUBE		REGULATOR			ALTERNATE HOSES / LENGTHS									ACCESSORY
		(4)	B	B	A	B			E	F	G	F	F	F	F	F	F	G	G	G	B
		(6) DESCRIPTION	RETAINER	RETAINER	AIRLINE ADAPTOR	AIRLINE ADAPTOR	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	F	F	D	D	A	D	G	E	B	K	K	M	A	A	A	F	F	J	B
		(3) DRG NO	4494	4516	1278	1278	6445	2517	1217	3267	3268	5637	5633	5757	7722	7723	7724	1376	1377	4584	1118
		(5) PART NO	4494-3	802916	1278-2	1278-5	6445-3	2517-3	1217-0	3267-1	3268-9	5637-7	5633-5	5757-1	7722-0	7723-8	7724-5	1376-4	1377-2	4584-5	1118-0
		MODEL	20017287	20017288	20013187	20011010	20013188	20013188	20013062	20013194	20013195	2001335-25	2001335-50	2001335-100	200035-25	200035-50	200035-100	200020-25	200020-50	200020-100	7255
	19C-199	DGSA			X		X	X	X			X	X	X	X	X	X				
	19C-238	PDSA			X		X	X			X							X	X	X	
	19C-239	CFSA			X		X	X		X		X	X	X	X	X	X				
	23C-690	OV/CL/HC/SD																			A
	23C-692	AM/MA																			A
	23C-693	OV/SA/CE			X		X	X	X			X	X	X	X	X	X				
	23C-694	CL/SA/CF			X		X	X			X							X	X	X	
	84A-1095	FM/P100																			
N/2718a	84A-N/2718a	N95	P																		
	84A-1610	N100/SA/PD	X		X	X	X	X			X							X	X	X	
	84A-1210	R99/SA/CE	X		X	X	X	X	X			X	X	X	X	X	X				
	84A-0808	P100	X																		
	84A-0809	P100/OV	X																		
N/2719a	84A-N/2719a	N95/CL	N																		
(8) NIOSH task number where component was LAST used (if new, indicate as "N"):			05054	06088	05489	05054	05491	05491	05592	05789	05790	06262	06263	06264	06265	06266	06067	06268	06269	06270	6120

Assembly Matrix Checklist

___ Title and date or revision level (1)

___ Manufacturer name and address (2)

___ Revision level of drawings must reflect the current revision level on file at NIOSH or a new drawing must be submitted. (3)

___ Numbering system used for major sub-assemblies shown on the matrix and exploded view drawing must match (4)

___ Part numbers (Model numbers optional). The number marked on the component is the number that must appear in the part number row of the Assembly Matrix. (5)

___ Description of product (full facepiece-small). Features that describe the respirator cannot be listed on the matrix as a separate column. Ffeatures associated with specific model numbers may be coupled together in the description (e.g., Model 1201-Low Flow) (6)

___ Top row must be category (facepiece, adaptor, etc.). Accessories must be included on the assembly matrix. If more than one of the same sub-assemblies, does it say alternate in the column heading? (7)

___ Bottom row must be for the NIOSH task number where component was last tested...if new indicate N (8)

___ First column from left is manufacturer's Applicant Assigned Reference number (AAR#) (9)

___ Second column from left is TC number(s) If requesting a new TC number does it show the AAR# followed by an alpha character? Is "TC-" only listed in the category heading? (10)

___ Third column from left is list of protections. See complete list of protections and cautions and limitations in Section C20 (11)

___ Empty rows and/or columns 80% shaded or blacked out (no shading in columns with information)

___ Airline hoses must be listed under components instead of accessories

___ Cylinders are only approved for one duration (30, 45, 60 min) (if applicable)

___ TN# or applicant assigned reference number of the previously approved or pending matrix is located in the top right corner (12)

___ Current exploded view drawing number is located in the top right corner (13)

___ 13F approvals must list User's Instructions, part number, and revision level

___ SCSR's must list Service Life Plan part number and revision level

___ Flow Indicator for PAPR

___ Key Box (14) you must only use the characters listed

C.19 Drawings

All drawings must be in English. All engineering and CAD drawings must be saved and submitted in full view mode, preferably in black and white.

There should be only two levels of drawings submitted for an application. The first level is the exploded view drawing. The second level is for major sub-assemblies.

Exploded View Drawing

Manufacturers must submit an **exploded view drawing** (see attached example) showing all major sub-assemblies of the respirator assembly. **The signature blocks on each submitted drawing must contain the initials of the preparer and approver along with the approval date for the drawing revision. The exploded view drawing must not contain dimensions, unless it is a filtering facepiece or disposable respirator.**

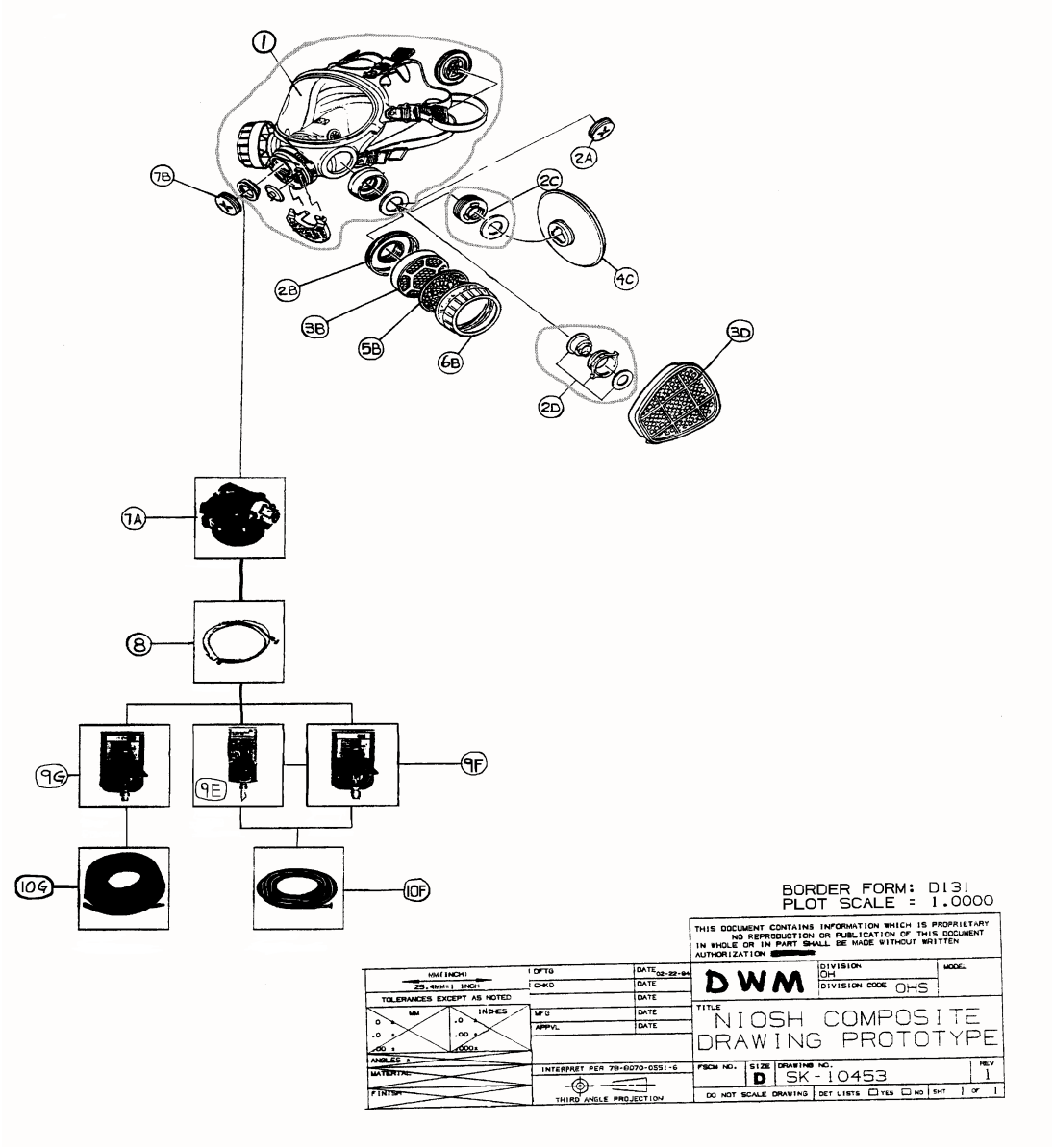
The exploded view drawing may not contain future submittals or show unapproved assemblies.

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. (e.g., The facepiece is shown as Item 1 on the assembly matrix and is correspondingly shown as 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 (example: facepiece vs facepiece with side window) it has to be shown separately as 1a, 1b, etc.

The only exception is the 13F user's instructions and the service life plan do not need to be illustrated on the exploded view drawing.

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

EXPLODED VIEW DRAWING FOR EXAMPLE ASSEMBLY MATRIX



EXPLODED VIEW DRAWING
CHECKLIST

This is only a checklist and may not be all inclusive

___All major sub-assemblies and accessories that appear on the assembly matrix must be on the exploded view drawing except user's instructions and the service life plan.

___Component numbering on the exploded view drawing for referencing to assembly matrix is accurate and inclusive.

___Titled, numbered, dated, revision level.

___Does not contain dimensions. The exception is for filtering facepiece and disposable respirators.

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 a new major sub-assembly drawing is not required.

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

All major sub-assembly drawings must contain all of the items called out on the checklists.

All drawings must be in compliance with the manufacturer's document control system.

For referencing major sub-assemblies from the assembly matrix to the major sub-assembly drawings, the drawing numbers, and revision level numbers shown on both must match exactly.

Major sub-assemblies must have identifying numbers permanently marked on them. The number on the major sub-assembly must appear in the part number row of the assembly matrix. **Note: the location of the part numbers must be included on the major sub-assembly drawings.**

Please label each controlled document with a specific name. The name of the file is to be derived from the document number not the applicant-assigned reference number. The document file name should be retained and used for future submittals with only the revision level changed to indicate a change to the document file. For example, a drawing is 10-10222 revision A. The file name should be 10222Ra.dwg. On another submittal that uses the same drawing but the drawing has increased to a higher revision level the file name would be 10222Rb.dwg. See the file-naming conventions in Section B.11 and description in Section C.24. Files submitted using the applicant-assigned reference number as file names will be returned.

Material Specifications on Drawings

For material specifications, use the criteria of affecting form, fit, and function. For example, an accessory would not affect form, fit or function so materials could be identified as plastic, metal, etc. For items affecting form, fit or function, it would be necessary to specify stainless steel 480 or butyl rubber, etc. Protections must be listed on the cartridge and filter drawings including nuisance protections.

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). In addition, the specific model or part number must be identified. It cannot say "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.

Major Sub-Assembly Drawing Checklist
This is only a checklist and may not be all inclusive
SELF-CONTAINED BREATHING APPARATUS (page 1 of 4)

___ 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

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation

___ 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

___ Construction of cylinder (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). Specialty gases only. Does not apply to Grade D air

___ Outlet threads meets the requirements of ANSI/CGA V-1 1994

SELF-CONTAINED BREATHING APPARATUS (page 2 of 4)

Respiratory Inlet Covering (Facepiece or Hood)

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation (exhalation valve, lens, faceseal, etc.)

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

___ Lens has statement on 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 nosecup assembly is needed.

Backpack Harness Assembly

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation, including at least a visual inspection on the buckles

___ Location of NIOSH harness label

Pneumatic Assembly/1st Stage Regulator

___ Reference dimensions (length, diameter)

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation (valves, hose, gauge, pressure reducer, alarm, clamps on the breathing tube, etc.)

___ 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 if it is a 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 the 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 to how the remote pressure gauge is attached (examples: loctite or torque)

___ Parts list required showing all parts & materials that make up the pneumatic assembly.

SELF-CONTAINED BREATHING APPARATUS (page 4 of 4)

Second Stage Regulator Assembly

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Serial number location (if applicable)

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation (diaphragm, hoses, springs, etc.)

___ Parts list required showing all parts and materials that make up the regulator

___ If a belt mounted regulator assembly, a pressure relief valve is required...statement to diaphragm over pressurization requirement

___ Failure mode analysis demonstrating either that the regulator can only fail open, or include a manual bypass on all entry units. This would be with pre-test data--not on drawings.

Other Component Drawings (Adaptors, Retainers, Accessories, Breathing Tubes, Connectors, Nosecups, Voice Transmitters, Plugs, Lenses, etc.)

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

Major Sub-Assembly Drawing Checklist
This is only a checklist and may not be all inclusive
SUPPLIED AIR RESPIRATOR (page 1 of 3)

Respiratory Inlet Covering (Facepiece/Hood/Helmet)

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation

___ Lens has statement on impact resistance GGG-M-125d, Oct. 11, 1965 (amended July 30, 1969) (except types B, BE, C, and CE)

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

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

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation

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

SUPPLIED AIR RESPIRATOR (page 2 of 3)

Hose/Couplings

___ Reference dimensions (length, diameter)

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation

___ 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). In addition, the specific model or part number must be identified. **It cannot say "or equivalent".**

Belt

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation

SUPPLIED AIR RESPIRATOR (page 3 of 3)

Breathing Tube

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation (make sure there is a method for checking clamps on the breathing tube)

Other Component Drawings (Adaptors, Retainers, Accessories, Breathing Tubes, Connectors, Nosecups, Voice Transmitters, Plugs, Lenses, etc.)

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing

Major Sub-Assembly Drawing Checklist
This is only a checklist and may not be all inclusive

SELF-CONTAINED SELF-RESCUER (page 1 of 2)

___ Reference dimensions

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Location of part number

___ Location of serial number

___ Critical and major characteristics

___ Inspection procedures or classification of defects on drawing or in documentation

___ Firing mechanism

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

Other Component Drawings (Adaptors, Retainers, Accessories, Breathing Tubes, Connectors, Nosecups, Voice Transmitters, Plugs, Lenses, etc.)

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

SELF-CONTAINED SELF-RESCUER (page 2 of 2)

Regulator

___ Parts list required showing all parts and materials that make up 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

___ Construction of cylinder (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 marking requirements)

___ 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 it 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)

___ Outlet threads meets the requirements of ANSI/CGA V-1 1994

___ For compressed oxygen units, the drawing should specify that the cylinder is to be charged with oxygen meeting the requirements of the US Pharmacopeia for pure oxygen [84.79(b)]

Major Sub-Assembly Drawing Checklist
This is only a checklist and may not be all inclusive

FILTERING FACEPIECE (page 1 of 2)

Note- A single drawing may serve as the exploded view and major sub-assembly drawing for Filtering Facepieces

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions (facepiece, liner, valve, straps, nosepiece)

___ Materials (filter media, valve, nosepiece, straps, liner)

___ Location of nosepiece, liner, straps and valve

___ Part number location on facepiece

___ Lot number location and code

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

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

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

___ Filtering mechanism (electrostatic, mechanical or other)

___ Vendor for filter material (only if specification is not determined by respirator manufacturer)

___ Elasticity and length of the straps, method of attachment

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

FILTERING FACEPIECE (page 2 of 2)

Other Component Drawings (Adaptors, Retainers, Accessories, Breathing Tubes, Connectors, Nosecups, Voice Transmitters, Plugs, Lenses, etc.)

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

Major Sub-Assembly Drawing Checklist
This is only a checklist and may not be all inclusive

NEGATIVE PRESSURE AIR-PURIFYING RESPIRATOR
EXCEPT FILTERING FACEPIECE (page 1 of 2)

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

___ Reference dimensions (including suspension system, inhalation & exhalation valves)

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Inspection procedures, and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

___ Elasticity, length and method of attachment of straps

Filter- except filtering facepiece

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications & filtering mechanism for filter media

___ Drawing identifies location of part number

___ Lot number location and code

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

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

__ Vendor for filter material (only if specification is not determined by respirator manufacturer)

___ Filters containing carbon layers must include a statement that carbon is chromium free

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing

NEGATIVE PRESSURE AIR-PURIFYING RESPIRATOR
EXCEPT FILTERING FACEPIECE (page 2 of 2)

Cartridge or Canister

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

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

___ Statement that the carbon is chromium free

___ Drawing identifies location of part number

___ Lot number location and code

___ Vendor for carbon material (only if specification is not determined by respirator manufacturer)

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing

___ Location and material of End of Service Life Indicator (ESLI) if used. ESLI's are required for MV, HS (not for escape), CO, EO.

___ Color and markings conform to ANSI K13.1, 1973

___ Protections listed

Other Component Drawings (Adaptors, Retainers, Accessories, Breathing Tubes, Connectors, Nosecups, Voice Transmitters, Plugs, Lenses, etc.)

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

Major Sub-Assembly Drawing Checklist
This is only a checklist and may not be all inclusive

POWERED AIR-PURIFYING RESPIRATOR (page 1 of 3)

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

___ Reference dimensions (including suspension system, inhalation and exhalation valves)

___ Material specifications

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Drawing identifies location of part number

___ Inspection procedures, and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

___ Elasticity and length of the straps, method of attachment

Filter

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications for filter media

___ Drawing identifies location of part number

___ Lot number location and code

___ Filter efficiency. Include nuisance protection

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

___ Filtering mechanism (electrostatic, mechanical or other)

___ Filters containing carbon layers must include a statement that the carbon is chromium free.

___ Vendor for filter material (only if specification is not determined by respirator manufacturer)

___ Inspection procedures, and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing

POWERED AIR-PURIFYING RESPIRATOR (page 2 of 3)

Cartridge or Canister

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

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

___ Protections listed

___ Drawing identifies location of part number

___ Lot number location and code

___ Vendor for carbon material (only if specification is not determined by respirator manufacturer)

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

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

___ Location and material of End of Service Life Indicator if used.

___ Color and markings conform to ANSI K13.1, 1973, if applicable

Blower

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Lot number location and code

___ Inspection procedures and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

___ Intrinsic safety certification (if intended for mine use)

POWERED AIR-PURIFYING RESPIRATOR (page 3 of 3)

Battery

__ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Inspection procedures, and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

___ Cadmium, lithium, etc. (type must be called out)

Other Components

___ Numbered, titled, signed or initialed by an authorized representative, effective date of the revision

___ Reference dimensions

___ Material specifications

___ Drawing identifies location of part number

___ Inspection procedures, and classification of critical and major characteristics on drawing or in documentation attached as page 2 to the drawing.

C.20 Approval Labels and Private Label Notification

Product approval labeling requirements will vary based upon the type and intended use of the respirator. Attached are example label formats for various types of respirators. Prepare a draft version of the appropriate label(s) with everything correct using Excel. If you are not able to submit draft labels under these conditions you must obtain pre-authorization from NIOSH for each application. When reproduced inside final User's Instructions, on packaging, or on devices, each approval label must be legible. It is expected that this may require more than a single sheet of paper but legibility must be maintained.

Labels must be submitted for all new approvals or extensions of approval that necessitate a label revision (i.e.,component listing change). Labels must be submitted with the application following the format of the examples in this package and must be in Excel file format. All major sub-assemblies necessary to make up the approved respirator configuration must be on the approval label. Accessories may be listed on the approval label if the manufacturer desires, but are not required. However, accessories must appear on the assembly matrix. Due to the large size of the files with the NIOSH and DHHS logos imbedded, NIOSH will accept labels with only the location of the logos noted. NIOSH will hold the manufacturer responsible for inserting the logos at the time of label production. Be sure to include all appropriate labels (see Approval Label examples). All labels must be fully legible. **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 as intrinsically safe **on the NIOSH approval label**, the manufacturer must obtain **prior** intrinsic safety approval from the Mine Safety and Health Administration (MSHA) under Title 30, CFR, Part 18 and submit verification of such approval in their application.

To assist NIOSH in the review of the final label, the list of protections must be in the same order and identical in every way to the matrix.

Private Labeling vs. Private Packaging

Under **Private Labeling**, a manufacturer (Manufacturer A) may enter into an agreement to allow another company (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.

Application to Private Label is accomplished in two ways, 1) An extension of approval or 2) Private Label Notification Form. An extension of approval is necessary when the private labeler desires anything more than the name changed at the top of the NIOSH approval label. For example, if a part number or model number changes then 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**, A manufacturer (Manufacturer A) may enter into an agreement to have its products sold by another Company (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 it's 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". 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 documentation on file for the product at NIOSH.

Major sub-assemblies which must be contained 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)

<u>Air-Purifying Respirators (negative pressure)</u>

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 and required on assembly matrix.
6. Hoses
7. Adapters
8. Accessories (optional on approval label, required on assembly matrix)

<u>Powered Air-Purifying Respirators (PAPR)</u>

1. Facepiece (hood, helmet)
2. Cartridge (including filter/cartridges when permanently bonded together)
3. Canisters
4. Filters

5. Unclassified prefilter are optional on approval labels and 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 drawing)

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 drawing)

Self-Contained Breathing Apparatus

1. Facepiece (including hood, helmet, etc.)
2. Breathing tube
3. Regulator assembly or flow control valve or orifice
4. Pneumatic assembly
5. Harness and backpack assembly
6. Cylinder and valve assembly
7. Accessories (optional on approval label, required on assembly matrix drawing)
8. Service life plan and user's instructions on assembly matrix

Combination

All in each category above.

Label format issues:

1. **Entire labels for respirators, cartridges, and filters** must be completed in the assembly matrix format shown in the attached examples. The left most column must be the TC number. During initial submittals, list the applicant-assigned reference number in the left most column, followed by an Alpha character, (same format as used on Assembly matrix). This will relate the approval label to the application(s) and to the assembly matrix. Upon approval, NIOSH will replace the applicant-assigned reference number with the TC number. "TC-" can only appear in the column heading and not in the label row. The second column from the left must be for the protection. The last column (far right) is for the cautions and limitations. The component columns must list all of the major sub-assemblies. Applicants may list the major sub-assemblies in any order that they choose.

2. Anytime more than one of the same major sub-assemblies for a respirator configuration is listed on the approval label and/or assembly matrix row, they must be identified as alternate components by stating “Alternate” in the column heading. Only an "X" may be used in the body of the approval label to designate the approved component parts of an assembly. Likewise, if a component (such as a spectacle kit) is offered as an accessory, the category must be labeled as “accessory” (e.g., “accessory spectacle kit").

3. Empty rows within the table of the approval label are not permitted. Empty columns must be from 80 percent dark shaded to completely blacked out to clearly indicate no additional information is present. Approval labels must not be color coded.

4. Wording of the standard protections and cautions and limitations must be identical to the NIOSH samples. Only appropriate cautions and limitations may be listed. For example, if the only pertinent cautions and limitations are A, C, and G, then only A, C, and G can be footnoted at the bottom of the label. However, the wording and the letter designation will not change. For example, Caution C – “Do not exceed maximum use concentrations established by regulatory standards” is always Caution C on every label.

5. Caution H: Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.

7. Caution and Limitation F only applies to PAPRs.

8. The **abbreviated label mounted on the cartridge, filter, cartridge/filter combination or filtering facepiece** must clearly indicate the manufacturer name, the filter series (if a filter is included), the gas or vapor protection, the part number, the lot number and the word "NIOSH." No TC number may appear. The abbreviated label may list either the 2 letter codes for gases and vapors (see label examples) or the entire chemical name but not a mix of codes and names. For filtering facepieces, the same information is required except the lot number need only appear on the container and the manufacturer may include the TC number if desired.

9. The **harness label mounted on self-contained breathing apparatus or gas mask canister labels** must clearly indicate the manufacturer information (name, address, phone number), the model or trade name, the type of protection, the TC number, the duration-cylinder pressure-type data, the appropriate cautions and limitations, a reference to the User’s Instructions for major sub-assembly and component information, and the DHHS and NIOSH logos.

   The entire SCBA, SAR, or gas mask label must appear in the user’s instructions.

10. The Protection column on SCBA approval labels, printed in the user’s instructions and assembly matrices, must list operating pressure of the cylinder, rated service time, and show self-contained code (e.g., 2216 psi, 30 min, SC).

11. **S-Special or Critical User's Instructions" noted on the approval label and listed in the User's Instructions**: Manufacturers have some discretion in what they would identify as special caution or limitations. However the caution or limitation must go beyond the standard cautions and limitations and be unique or unusual for the class of respirator. If the manufacturer states that special or critical User's Instructions and/or specific use limitations apply, they must be readily identified within a separate *S-Special or Critical User's Instructions* section in the user's instructions (e.g., SCBA cold temperature use limitations, special donning procedures, service life limitations, etc.) with the instructions immediately following. All respirators with End-of-Service life Indicators must show caution and limitation S.

12. 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.), if all respirators on the label are of the same series or family, (as per the included label sample). This heading is optional on all types of respirator approval labels.

13. Non-NIOSH approval identifiers cannot be represented either on the NIOSH abbreviated labels or the complete NIOSH approval label. Manufacturers may use additional areas on the component to identify any other applicable foreign approvals such as the European CN approval, but this information must be separated from the NIOSH approval label.

14. If the label will not fit on the outside of the container, it must be included as an insert inside the container. If the label is inserted, the container must say "NIOSH approved - See Insert." The insert may consist of the approval label only or the User's Instructions containing the approval label.

15. On 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 developed by NIOSH with input from the public and published in the 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.

16. **"AND" or "OR" for the gases and vapors listed in the protection column of the approval labels**. Since NIOSH tests against gases and vapors individually, and not in mixed gas and vapor atmospheres or not 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. A manufacturer may demonstrate to NIOSH that sorbents are effective in exposures to mixed gas and vapor atmospheres or serial exposures to different atmospheres. To do this, the manufacturer must provide data to NIOSH satisfying the six criteria for mixed gas and vapor atmospheres as listed in the

Notice to all Manufacturers, September 24, 1981. Since NIOSH cannot test cartridges against mixed atmospheres, the manufacturer assumes the liability for use of the respirators in mixed atmospheres. 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 the manufacturer endorses 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.

17. 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."

18. A list of allowable protections, cautions, and limitations is on the next page. No other codes are permitted on the NIOSH approval labels at this time.

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Respirator Branch
1095 Willowdale Road
Morgantown, West Virginia 26505-2888

PRIVATE LABEL NOTIFICATION FORM

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

This manufacturer and approval holder is providing the following information to NIOSH regarding its intent to "private lab" certain of our 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

COMPLETE LIST OF ALLOWED STANDARD PROTECTIONS, CAUTIONS AND LIMITATIONS FOR APPROVAL LABELS

1. PROTECTION

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	FM- Formaldehyde	HC- Hydrogen chloride
HF- Hydrogen fluoride	HN- Hydrogen cyanide	HS(esc)- Hydrogen sulfide (escape only)
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	VC- Vinyl chloride	ESC - Escape

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
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 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 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 of

FILTERING FACEPIECE APPROVAL LABEL

Double Wing Manufacturing Company
St. Xavier, Almost Heaven, 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 of RESPIRATOR APPROVAL LABEL

DOUBLE WING MANUFACTURING COMPANY
ST. XAVIER, ALMOST HEAVEN, USA
1-800-123-4567
1000 HALF-MASK RESPIRATOR FAMILY

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																		
TC-	PROTECTION[1]	FACEPIECE	FILTER				CARTRIDGE					ALTERNATE HOSES/ LENGTH			REGULATOR			CAUTIONS AND LIMITATIONS[2]
		1000	HALO	ARCH	WING	CROWN	1001	1002	1003	1004	1005	9435-25	9435-50	9435-100	3021	3022	3025	
84A-AARa	N95/CL/MV	X	X							X								ABCHJLMNOPS
84A-AARb	R95/AM/MA	X		X				X										ABCHJLMNOP
84A-AARc	R95/OV	X		X			X											ABCHJLMNOP
84A-AARd	P99/OV/SA/CF	X			X		X					X	X	X	X			ABCDEGHJLMNOP
84A-AARe	R100/OV/SA/CF	X				X	X					X	X	X			X	ABCDEGHJLMNOP
23C-AARf	FM	X									X							ABCHKLMNO
23C-AARg	CL/ HC/SD/HS(esc)/SA/PD	X							X				X			X		ABCDEGHJLMNO

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
CL-Chlorine
CF-Continuous Flow
FM-Formaldehyde
HC-Hydrogen chloride
HS-Hydrogen sulfide (escape)
MV-Mercury vapor
MA-Methylamine
OV- Organic vapor
PD-Pressure Demand
SA-Supplied-air
SD-Sulfur dioxide

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.
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 of FILTER LABEL

DOUBLE WING MANUFACTURING COMPANY
ST. XAVIER, ALMOST HEAVEN, USA
1-800-123-4567

CROWN FILTER

THIS FILTER IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																			
TC-	PROTECTION[1]	FILTER	ALTERNATE FACEPIECE					CARTRIDGE					ALTERNATE HOSES/ LENGTH			REGULATOR			CAUTIONS AND LIMITATIONS[2]
		CROWN	1000	2000	3000	4000	5000	1001	1002	1003	1004	1005	943-25	943-50	943-100	3021	3022	3025	
84A-AARa	P100	X	X																ABCJLMNOP
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			ABCDEGHJLMNOPS
84A-AARe	P100/FM/SA/CF	X			X	X	X		X				X	X	X			X	ABCDEGHJKLMNOP
84A-AARf	P100/CL/HC/SD	X			X	X	X			X									ABCHJLMNOP
84A-AARg	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
CL-Chlorine
FM-Formaldehyde
HC-Hydrogen chloride
HS-Hydrogen sulfide (escape)
MA-Methylamine
OV- Organic vapor
PD-Pressure demand
SA-Supplied-air
SD-Sulfur dioxide

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 occur.
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 of CHEMICAL CARTRIDGE LABEL

DOUBLE WING MANUFACTURING COMPANY
ST. XAVIER, ALMOST HEAVEN, USA
1-800-123-4567
1001 CARTRIDGE

THIS CARTRIDGE IS APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																		
TC-	PROTECTION [1]	CARTRIDGE	ALTERNATE FACEPIECE					FILTER					ALTERNATE HOSES/ LENGTH			ALTERNATE REGULATOR			CAUTIONS AND LIMITATIONS [2]
		1001	1000	2000	3000	4000	5000	HALO	WIND	GATE	GLORY	CROWN	943-25	943-50	943-100	3021	3022	3025	
23C-AARa	OV	X	X																ABCHJLMNO
84A-AARb	OV/N95	X		X				X											ABCHJLMNOP
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
84A-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	

CF-Continuous flow DE-Demand SA-Supplied air OV-Organic Vapor

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 of SUPPLIED-AIR RESPIRATOR LABEL

Company Name
Company Address

1-800-XXX-XXXX

MODEL or TRADE NAME

TYPE C AND CE CONTINUOUS FLOW SUPPLIED-AIR RESPIRATOR

APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

Respirator Components														
TC-	Protection[1]	Model	Facepiece	Hood or Helmet		Cape	Quick Disconnect	Hose 25'	Hose 50'	Breathing Tube	Visor	Inner Lenses	Outer Lenses	Cautions and Limitations[2]
			T2000	T1000	T28-61	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.

[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 of
SCBA RESPIRATOR LABEL

RESPIRATOR MANUFACTURING COMPANY
ADDRESS, CITY, STATE, USA

800-123-4567
MODEL OR TRADE NAME

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

THESE RESPIRATORS ARE APPROVED ONLY IN THE FOLLOWING CONFIGURATIONS:

RESPIRATOR COMPONENTS																				
TC -	PROTECTION [1]	Alternate FACEPIECE				Alternate HARNESS					CYLINDER				Alternate REGULATOR			ACCESSOR-IES			CAUTIONS AND LIMITATION [2]
		1000	2000	3000	4000	H95	H96	H97	H98	H99	C001	C002	C003	C004	R111	R222	R333	LENS-100	ALARM-50	CASE-200	
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	X	IJMNOS
13F-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

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.

[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 of
SCBA & Combination SCBA/SAR
RESPIRATOR LABEL

RESPIRATOR MANUFACTURING COMPANY
ADDRESS, CITY, STATE, USA 1-800-123-4567

MODEL OR TRADE NAME
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 [1]	Alternate FACEPIECE				Alternate HARNESS					CYLINDER				Alternate HOSES			Alternate REGULATOR			ACCESS-ORIES			CAUTIONS AND LIMITATION [2]
		1000	2000	3000	4000	H95	H96	H97	H98	H99	C001	C002	C003	C004	25	50	100	R111	R222	R333	LENS-100	ALARM-500	CASE-2000	
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	X	IJMNOS
13F-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-AARe	30min 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.

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 of SCBA HARNESS LABEL

RESPIRATOR MANUFACTURING COMPANY
ADDRESS, CITY, STATE, USA
1-800-123-4567

MODEL OR TRADE NAME
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 MANUAL FOR THE COMPLETE LIST OF COMPONENT PARTS 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 users instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
S- Special or critical users instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

[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 of CHEMICAL SCRUBBER LABEL

RESPIRATOR MANUFACTURING COMPANY
ADDRESS, CITY, STATE, USA
1-800-123-4567

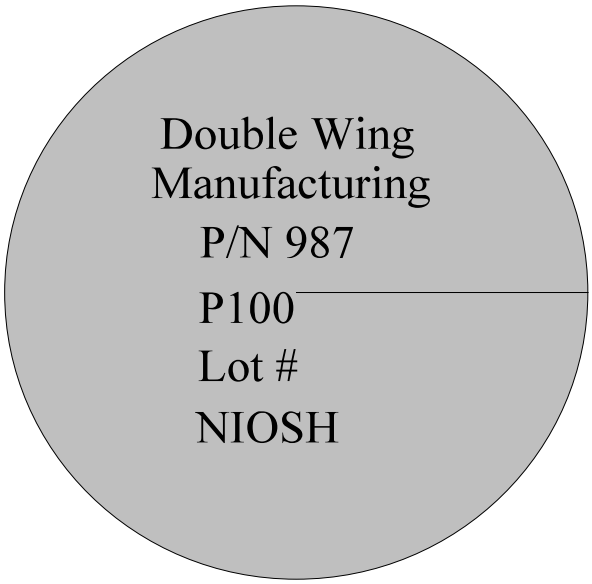
MODEL OR TRADE NAME
CHEMICAL SCRUBBER CANISTER
TC-13F-XXX

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.

[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 of
ABBREVIATED FILTER LABEL and
FILTERING FACEPIECE LABEL



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.

The word "NIOSH" (all capitals) must be shown.

A lot number (LOT #) or other production tracking identifier must be provided either on the product or container.

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 of
ABBREVIATED CARTRIDGE LABEL

DOUBLE WING MANUFACTURING
P/N 9876 OV/CL/HC/SD
NIOSH 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" (all capitals) must be portrayed.

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 ANSI K13.1-1973, Table 1 where applicable.

Example of GAS MASK CANISTER LABEL

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

DOUBLE WING MANUFACTURING COMPANY
ST. XAVIER, ALMOST HEAVEN, USA
1-800-123-456
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.

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

C.21 User's Instructions

General Requirements

All user instructions and associated procedures such as maintenance requirements, inspection procedures, donning and doffing, etc., that pertain to the product for which approval is sought must be submitted as a complete document. 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).

The entire user's instructions must be submitted. NIOSH will not accept only the amended pages.

Please bold, underline or otherwise clearly note all changes in the user's instructions that have changed from the prior revision level. This will facilitate the NIOSH review process.

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

User's instructions sheets for retrofit or conversion kits approved for use on NIOSH-approved respirators must reference the specific applicable NIOSH approval numbers.

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 they must go beyond the standard cautions and limitations and be unique 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***. (i.e., SCBA cold temperature use limitations, special donning procedures, service life limitations, hose lengths, number of connections, pressure ranges, end of service life indicators, etc.).

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 user's instructions for 13F approvals must be listed in a column on the assembly matrix.

The approval labels must be included in the user's instructions for supplied-air 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

For air-purifying respirators, the entire approval label may be on the container, as an insert in the box, or an insert in the user's instructions.

The user's instructions may or may not containing the approval label.

The following end of service life indicator information must be included in the user's instructions for all respirators equipped with passive end of service life indicators. **This wording, or similar 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 either the respirator, cartridges, facepiece or the indicator. If you cannot readily see the indicator, do not wear the respirator.

Add any other additional information necessary to explain the color change or any other operation mechanism of the ESLI.

C.22 Service Life Plan Limited To All Self-Contained Self-Rescuers

For 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 to be a separate document from the user's instructions. Some of the technical details for consideration must include:

- storage life of the various components based on intended use and environmental conditions
- component deterioration with time, both chemically and physically
- the useful life of elastomers including o-rings; breathing tubes; 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 degeneration over time and moisture effects
- inspection procedures which address daily and periodic validation of condition to assure as acceptable 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 identify clearly when the unit is to be removed from service. It 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. (Example- breathing tube of similar design and 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 any of the NIOSH-compatible formats of manufacturer's choice.

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.

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.

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.).

Regarding NIOSH approved particulate respirators advertised and marketed as "Surgical Masks," the following guidelines that should be used in preparing the packaging and advertising of particulate respirators used in the health care industry.

Package advertising that uses 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 of the product. While these individual

phrases, used by 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. Therefore, 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. Also NIOSH does not recognize N95 respirators as being "high efficiency" respirators, therefore this advertising is misleading and not permissible.

Manufacturers may not imply "use" approval. For example, packaging may not say "NIOSH approved Paint Spray Respirator". It may say "NIOSH approved OV/P100 respirator. Manufacturer A recommended for lacquer paints." Additionally, the tradename may not imply use, such as "Paintspray Plus". This also applies to private labelers and private packagers.

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, along with the instructions for use should be listed on a different panel from the two containing the word "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 use in context with the term "NIOSH approval" or "NIOSH approved".

The Institute has recently seen an increase in applications asking for NIOSH approval of sales literature, advertising and packaging. While 42 CFR 84 does contain packaging requirements, 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

The applicant must provide a complete and accurate listing of all new and/or revised files that pertain to the current application or series of applications. 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. (See Section B for file-naming conventions.) Spaces must not be used in file names.

Document Type: [Pre-test data, drawing, assembly matrix, draft approval label, Q/A manual, process quality control plan, service life Plan, user's instructions]

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.

Examples are shown below.

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 an applicant opts to submit "zipped" files, they must provide the individual file name, description, and program for each working file contained in the zipped file name.

If you have more than one user's instruction or more than one matrix, call them out by their individual titles/names.

When sending replacement files, give the replacement files the same name as the originals so that they will automatically overwrite. It becomes very confusing to have an incorrect document and a correct document in the same file listing with different names. Only send in information if it was requested by NIOSH and send directly to the requestor. The requestor is responsible for having the corrected files posted to your project.

NOTE: Failure to provide this complete and accurate file listing shall result in cancellation of the project with immediate return to the applicant.

SECTION D –APPROVAL AND FAILURE DOCUMENTATION

If the respirator meets or exceeds all of the requirements outlined in these procedures and specified under 42 CFR 84, NIOSH will grant an approval and assign an 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 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 as specified within 42 CFR 84 or the Standard Application Procedures (SAP), the application will be denied and all documentation, diskettes and sample hardware submitted with the application will be returned or destroyed. The Institute will not maintain any submitted 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, it will return the application, diskettes and all sample hardware 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** (e.g., assume a manufacturer submits a 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.

NIOSH CRITERIA FOR DENIAL OF APPLICATIONS

As part of the general information to ensure quality applications, NIOSH is providing the following list of reasons why applications will not be accepted before a TN number will be assigned:

- 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, pretest data, users instruction or drawing package is missing or 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 received 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 within the related documents section of the applications.

As part of the general information to ensure quality applications, NIOSH is providing the following list of reasons why applications will be denied:

- Assembly matrix 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.
- Application 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: requested approval of two respirators of different basic designs (includes submitting a filter media and alternate in the same application) or 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 drawing do not correspond exactly to the reason for application, appropriate drawings, components on the exploded view drawing, or are otherwise incorrect (except service life plan and user's instructions).