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

The Standard Application Procedure for the Approval of Powered Air-Purifying Respirators and Chemical, Biological, Radiological, and Nuclear Powered Air-Purifying Respirators Under 42 CFR Part 84

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Introduction

This is a revision to the NIOSH *Standard Application Procedure for the Approval of Respirators* dated August 2015. It is intended to add clarity to the approval process under Title 42, *Code of Federal Regulations* (CFR) Part 84 (also known as 42 CFR 84). It is recommended that applicants review the entire document before submitting a respirator for approval.

This Standard Application Procedure (SAP) correlates with version 8 of the Standard Application Form.

NPPTL has developed individual instructions for each class of respirator. The information in this document pertain to the approval of Powered Air-Purifying Respirators (PAPRs) and Chemical, Biological, Radiological, and Nuclear Powered Air-Purifying Respirators (CBRN PAPRs). Please see the appropriate application for the type of respirator being submitted.

Schedule 14G

- **Tight-Fitting Powered Air-Purifying Respirators with or without High-Efficiency Filters that meet the Canister Requirements.**
- **Tight-fitting Powered Air-Purifying Respirators with Chemical, Biological, Radiological and Nuclear protection.**

Schedule 21C

- **Powered Air-Purifying Respirators with High-Efficiency Particulate Filters, Loose- Fitting or Tight-Fitting.**

Schedule 23C

- **Powered Air-Purifying Respirators with Chemical Cartridges or Combination Chemical Cartridges with High-Efficiency Filters; Loose-Fitting or Tight-Fitting.**
- **Loose-Fitting Powered Air-Purifying Respirators with Chemical, Biological, Radiological, and Nuclear Protection.**

Compliance with all instructions is essential for efficient processing of an application.

The information in Section 2 of this document provides specific step-by-step instructions to prepare an application for approval of a **Powered Air-Purifying Respirator** or **a CBRN Powered Air-Purifying Respirator**. The paragraphs are numbered to correspond with the sections of version 8 of the standard application form (SAF).

Additional guidance and information related to PAPRs and CBRN PAPRs is included in the sections that follow and should be used as a reference.

Section 1 General Information for Powered Air-Purifying Respirators and CBRN Powered Air-Purifying Respirators

Instructions for Preparing an Application Package for a Powered Air-Purifying or CBRN Powered Air-Purifying Respirator (14G, 21C, or 23C Approvals).

This guide applies strictly to Powered Air-Purifying Respirators (PAPRs) and CBRN Powered Air-Purifying Respirators (CBRN PAPRs). Please see the appropriate standard application procedure for submitting an application for a different class of respirator.

1.1 Getting Started

1.1.1 Who May Apply

An individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator may apply to NIOSH to become an approval holder (42 CFR Section 84.2). An organization may appoint an authorized representative to complete and submit the Standard Application Form (SAF) to NIOSH.

1.1.2 Approval

Approval is issued once NIOSH determines the product conforms to the requirements of 42 CFR Section 84.

1.1.3 Applicants Without a Three-character Manufacturer's Code

A prospective approval holder that has not applied for a NIOSH-Assigned three-character manufacturer's code will need to complete the Prospective Approval Holder Form and return it to the NIOSH NPPTL Records Room. To obtain the form, contact the NIOSH NPPTL Records Room at recordsroom@cdc.gov or (412) 386-4000.

1.1.4 Applicants Without NIOSH Approval

Prospective approval holders, without a NIOSH-Approved respirator, who have received a three-character manufacturer's code, may submit an initial application for a single new respirator along with a signed and approved company Quality Assurance Manual.

For prospective approval holders, once the application is accepted, reviewed, the respirator is tested, and a final review is successfully performed, a site qualification will be scheduled and conducted prior to the issuance of any approval. Please see the fee schedules for the cost of the site qualification. Other applications may be submitted with the initial application. However, subsequent applications will not be reviewed until the site qualification is completed and the initial application is approved.

The site qualification is only performed for new applicants (those without a NIOSH approval). Approval holders with joint NIOSH and Mine Safety and Health Administration (MSHA) approval have routine site audits conducted annually. NIOSH performs routine site audits for all approval holders every two years.

1.1.5 Where to Find the Standard Application Form

The standard application form, version 7 can be downloaded from the NIOSH NPPTL website. SAF versions 8 and 9 may be requested from the NPPTL Records Room once the manufacturer's code is issued.

1.1.6 Submitting the Application

Applications should be submitted on CD-R or DVD-R electronic media. Neither rewritable CDs **nor** thumb drives will be accepted. Due to computer security policies, NIOSH cannot accept thumb drives. Only one application per CD-R or DVD-R will be accepted. CD-Rs and DVD-Rs will be destroyed once the project is closed, unless a prepaid shipping label is sent with the media.

Compressed or "zip" files are recommended for applications submitted via email. Applicants that choose to email the attachments to NIOSH at recordsroom@cdc.gov risk having the information stripped by mail routers.

1.1.7 Documents to Submit with the Application

Checklists specific to the type of application being completed are included in Section 6. Fee schedules are included in Section 3. Tests required for the specific respirator type are included in Section 5.

Documents must be named in accordance with the prescribed naming convention, using an acceptable software package.

1.1.8 Submitting the Application and Associated Documents

The CD-R or DVD-R with the completed application form and associated documents, including the application fee check or pay.gov receipt, must be sent to:

NIOSH NPPTL
CV&SDB, Records Room
626 Cochrans Mill Road
Pittsburgh, PA 15236

1.1.9 Submitting Test Samples (Hardware)

NIOSH NPPTL
CV&SDB, Evaluation and Testing
626 Cochrans Mill Road
Pittsburgh, PA 15236

All boxes containing test samples (hardware) must be marked with the AAR# and include a packing slip.
If test samples (hardware) submitted for a series of applications must be identified for each project which it is to be used. For example, a facepiece that is to be used on three projects must have all three Applicant-Assigned Reference Numbers (AAR#s) on the packaging. If there are multiple containers, each container must be labeled with all the appropriate information. All sample components must be identified and labeled with their corresponding part numbers as listed on the assembly matrix.

If hardware is being sent to NIOSH for the testing of multiple projects, please include this information in the first application where testing will be performed and label the test samples (hardware) package with each AAR#.

1.2 Types of Applications

The types of applications include: New Approval Application, Extension of Approval Application, Quality Assurance Approval Application, Resubmission of New Approval Application, Resubmission of Extension of Approval Application, Amended Application, and Correlation Testing Only Application.

If there is any doubt about the appropriate type of application to submit, call the NIOSH NPPTL *Conformity Verification and Standards Development Branch (CV&SDB) at (412) 386-4000.*

Several screens of the Standard Application Form for New Approval Applications and Extension of Approval Applications identify the data fields that will be entered directly into the NIOSH Certified Equipment List (CEL). The product description should be short and succinct for an accurate reporting of the respirator in the CEL.

1.2.1 New Approval Application

- Used for new design, substantially different design, or different type or level of protection requested for an existing NIOSH-Approved respirator.
- NIOSH assigns a new testing and certification (TC) number for each new respirator system design that is approved.
- An application may be submitted for only **one** basic new respirator design per application.
- Applications containing more than one design will be denied.
    - For example, if an applicant submits a new PAPR with two new facepieces, a half-mask and full facepiece that use the same new filter, NIOSH requires two separate applications resulting in two new approvals because each facepiece represents a separate design and level of protection.
- New Approval applications must contain the following items or reference these items as described in detail in Sections 2 and 3 of this SAP.
    - NIOSH Standard Application Form.
    - Pretest Data.
    - Simplified Drawings.
    - Assembly Matrix.
    - Draft Approval Label(s).

- Quality Assurance Manual (Manual to be submitted separately as QA application after first approval).
- Product Quality Control Plan.
- a. Classification of Defects Document.
- b. Sampling Plan.
- Application Fee, $200.
- User Instructions.
- Test Samples (Hardware).

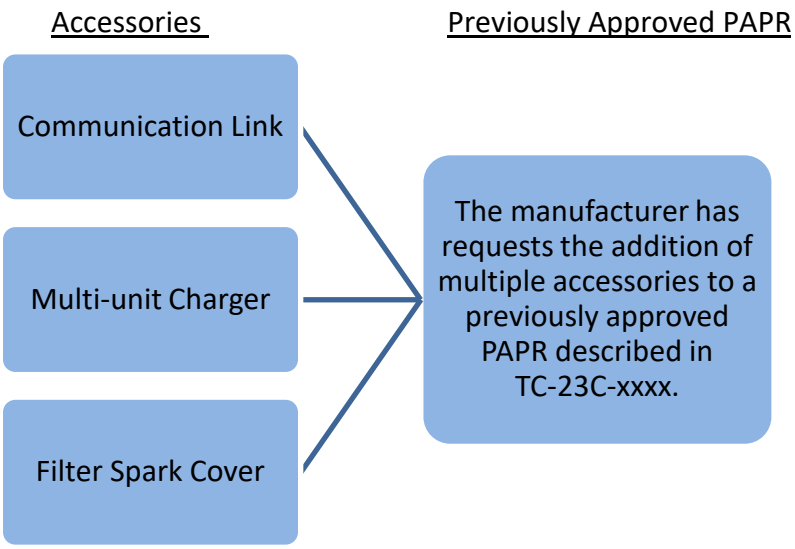
The following must be addressed in the "Reason for Application"

- If the respirator contains or has been treated with an antimicrobial or antiviral treatment, include supporting documentation indicating any EPA-identified human toxicity levels, or specific data and third-party certification that the treatment does not pose a hazard to the respirator user. Also include data supporting any claims being made about the treatment. See the September 24, 1981 letter to All Respirator Manufacturers.

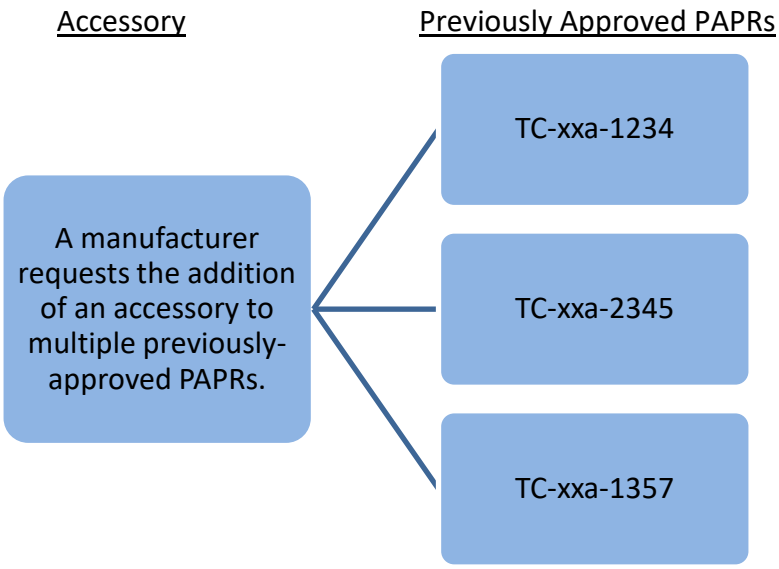
1.2.2 Extension of Approval Application

Submitted when:

- A critical or major characteristic affecting performance is altered on a previously approved respirator.
- A critical or major characteristic affecting design (including Quality Assurance provisions) is altered on a previously approved respirator.
- A new accessory is added to a previously approved respirator.
- A change is made to an approval label, assembly matrix, User Instructions, or drawings.
- All TC numbers affected must be listed in the "Reason for Application."
- All the TC numbers on a given assembly matrix apply to the extension, the assembly matrix may be referenced in lieu of listing the individual TC numbers.
- A product is made obsolete.
- The approval holder wants to add multiple accessories to one previously approved respirator.
- All TC numbers affected must be listed in the "Reason for Application."
- All of the TC numbers on a given assembly matrix apply to the extension, the assembly matrix may be referenced in lieu of listing the individual TC numbers.
- The approval holder wants to add multiple accessories to one previously approved PAPR.
- Requesting a private label approval of a previously approved respirator.



- An approval holder wants to add an accessory to multiple previously approved respirators.



Changes to minor characteristics not affecting performance or design which are not documented in the NIOSH approval records do not have to be submitted to NIOSH. A minor characteristic is an attribute, such as the size of the belt loops on the blower or component or specific screw or nut size, which is integral to the design but not a major contributor to the performance of the respirator. Approval holders are responsible for keeping all changes to minor characteristics on file and available for review at the request of NIOSH.

This includes any minor changes to any document that is part of the approval record. These changes should be submitted for an extension of approval at your earliest convenience.

Any changes to documents previously approved by NIOSH must be submitted to NIOSH. This includes minor changes to any document that is part of the approval record. These changes should be submitted as an Extension of Approval. Note that documents that are not up to date in their NIOSH record could result in a non-conformance during a site audit.

If the type or level of protection changes, a New Approval application must be submitted. For example, a PAPR with a particulate filter may be submitted and approved. The subsequent submission of the same PAPR with a chemical cartridge would be considered to be a new 'Type,' requiring a New Approval Applications and a new TC number being issued.

NIOSH <u>will not</u> assign new approval (TC) numbers for extensions of approval. New approvals can only be granted under an application for New Approval.

In addition, a New Approval Application is required and a different TC number will be issued for additions of a new respirator arrangement to a respirator family, model, or series such as a new facepiece on an existing PAPR model.

Extension of Approval applications must contain the following items or reference these items as described in detail in Sections 2 and 3 of this SAP.

- NIOSH Standard Application Form.
- Pretest data.
- Simplified Drawings.
- Assembly Matrix.
- Draft Approval Label(s).
- Product Quality Control Plan.
    - a. Classification of Defects Document.
    - b. Sampling Plan.
- Application Fee, $200.
- User Instructions.
- Test Samples (Hardware).

In the "Reason for Application": Describe exactly and completely the change(s) or addition(s) to the approved respirator(s) and how the change(s) will affect the previously approved respirator(s). Provide a succinct description of the previously approved respirator(s). For example, "An Extension of Approval to allow our 'xyz' alternate filter media to be used as an alternative on our Powered Air-Purifying Respirator, models 123, 456, and 789. No other respirators are affected. This request is for use of an alternate filter media only." The Extension of Approval Application must clearly indicate:

1. The affected respirator(s) by name, TC number, and part number. If multiple approvals are affected, the assembly matrix or matrices that contain these approvals may be listed in lieu of the TC numbers.
2. Complete details of the change(s) or addition(s).

3. Related documentation that has changed since the last approval (assembly matrix, inspection procedures, simplified drawings, draft approval label, product quality control plan, User Instruction).

Example of a Well-Written Reason for Extension of Approval Application:

Provides the model number, TC number, type of respirator, and what is being requested in a very descriptive manner. In this example, the request to allow an alternate filter media and the details are provided.

This Extension of Approval Application is for our model XXX PAPR with HE filter, [TC-21C-9999] to allow use of an alternate 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.

Specifies the change(s)

This request is for use of an alternate filter media only. No other components or processes are affected. Both filter media are mechanical and made of glass fiber filter paper and both pass the testing required to meet the criteria for HE protection.

States how the change(s) affect(s) the product

The current filter design with the DEF filter requires additional processing as part of the assembly procedure. The new filter material from ABC requires less processing and results in less scrapped filters.

Any time the approval holder makes a change to a critical or major characteristic, as defined in 42 CFR Part 84, affecting performance and/or design (including Quality Assurance provisions), the change must be submitted to NIOSH for approval. NIOSH will not assign new approval (TC) numbers for Extension of Approval Applications. New TC numbers can only be granted under a New Approval Application.

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

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

first time these items are listed on the matrix they will have a matrix code of “N” for new. Subsequent submittals will be designated with “R” for revision or redesign.

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

1.2.3 Quality Assurance Approval Application

- Current NIOSH approval holders may used this type of application to submit new or updated Quality Assurance (QA) Manuals. This type of application is limited to current approval holders.
- No other actions will be accepted under this type of application.
- QA Manual changes must include a revision history sheet showing the date and reason for revision.

Note: NIOSH will only accept Quality Assurance Applications that request updates to the QA Manual. No other requested actions will be accepted under a Quality Assurance Application. QA Applications will not be accepted until the requestor has at least one NIOSH-Approved product.

In the “Reason for Application” state the details of the changes to the QA Manual. Also, indicate the respirator(s) and manufacturing facility(ies) affected.
Quality Assurance Application submissions must not affect the performance or design of the respirator(s) and must not result in a different type or level of protection. If the change(s) impact(s) any of these aspects of the covered respirator(s), then applicants must submit an Extension of Approval application to address this (these) change(s).

1.2.4 Resubmission Application

- Resubmissions are only accepted when allowed by NIOSH.
- Used for hardware or documentation previously denied by NIOSH.

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

1.2.5 Amended Application

- Amended Applications are only accepted when requested by NIOSH.
- Used for open applications with an identified inaccuracy.
- Only the portion requested by NIOSH should be submitted.
- The AAR# and TN will remain the same.

1.2.6 Correlation Testing Only Application

Choose this type of application if the respirator is being submitted to be correlated with NIOSH Standard Testing Procedures (STPs). NIOSH will only perform correlation testing using one of the NIOSH Standard Test Procedures. The results of this testing cannot be used as pre-submission test data when submitting the respirator for NIOSH approval. An approval is not issued with a Correlation Testing Only Application. No approval will be issued with a Correlation Testing Only Application.

Independent or internal testing is still required prior to submittal of the application. Explain what testing is required, by STP number. NIOSH will only test the number of samples specified in the STP or 42 CFR Part 84. Specify the number of trials in the "Reason for Application" section.

1.3 Information for Powered Air-Purifying Respirators and CBRN Powered Air-Purifying Respirators

42 CFR Part 84 requirements for particulate filters allow for a limited number of multiple approvals of one filter.

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 a P100 as well as for a PAPR high-efficiency (HE) filtration level. However, the protections listed on the approval label for the filter may identify only the series and efficiency levels at which the filter is approved. The available multiple series efficiency levels are:

HE/P100

No other combinations are permitted with PAPRs. The same air-purifying filter can be used on a respirator as either a single filter or on a PAPR in a multiple or single filter configuration. If an applicant wants to show different series ratings based upon different configurations, different part numbers must be used for each configuration.

If a filter is identified using a single part number, the least protective class approved in either configuration will appear on the label.

If the approval holder wants to show different classifications based upon different configurations, different part numbers must be used for each configuration.

1.3.1 Approval Label Protections and Cautions and Limitations for PAPRs and CBRN PAPRs

PROTECTIONS

HE - High-Efficiency Particulate Air filter for Powered Air-Purifying Respirators
CBRN - Chemical, Biological, Radiological, and Nuclear

AG - Acid Gas (gas mask only)	AM - Ammonia	CD - Chlorine Dioxide
CL - Chlorine	CN - Chloroacetophenone	CO - Carbon Monoxide
CS - Chlorobenzylidene Malononitril		EO - Ethylene Oxide
ESC - Escape	FM - Formaldehyde	HC - Hydrogen Chloride
HF - Hydrogen Fluoride	HN - Hydrogen Cyanide	HS - Hydrogen Sulfide
MA - Methylamine	MV - Mercury Vapor	ND - Nitrogen Dioxide
OV - Organic Vapor	PH - Phosphine	SD - Sulfur Dioxide
TDI - Toluene-2, 4-diisocyanate	VC - Vinyl Chloride	

CBRN PAPR CAP 1, 2, 3 etc. - Capacity N Minutes

[**Note**: HS (esc) - Hydrogen Sulfide (escape-only) has been replaced with HS and ESC for new approvals OSHA 1910.134(d)(3)(3)(iii)(B)(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.
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.
H Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
I Contains electrical parts that may cause an ignition in flammable or explosive atmospheres.
J Failure to properly use and maintain this product could result in injury or death.
K The Occupational Safety and Health Administration regulations require gas-proof goggles to be worn with this respirator when used against formaldehyde.
L Follow the manufacturer's User Instructions for changing cartridges, canister and/or filters.
M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P NIOSH does not evaluate respirators for use as surgical masks.
S Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.
AA This respirator is to be used for escape-only and will protect against the inhalation of certain respiratory hazards.
BB Not for use for entry into atmospheres immediately dangerous to life or health.
CC For entry, do not exceed maximum use concentrations established by regulatory standards.
LL This respirator contains filter or cartridge components that are not approved for all protections in all configurations. Check the specific row on the NIOSH approval label to ensure proper use.

CBRN-SPECIFIC CAUTIONS and LIMITATIONS

R Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.
Y The respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.
Z If during use, an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air
QQ Use in conjunction with personal protective ensembles that provide appropriate levels of protection against dermal hazard. Failure to do so may result in personal injury even when the respirator is properly fitted, used, and maintained.
UU The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours.
VV PAPRS with TC-23C approvals may NOT be used for escape from IDLH atmospheres.

Section 2 Specific Instructions for Preparing a Powered Air-Purifying or CBRN Powered Air-Purifying Respirator Application Package

The paragraphs in this section are numbered to correspond to the different sections on version 8 of the Standard Application Form (SAF).

1 Project Reference Numbers (Section C.1)

Enter the three character NIOSH-Assigned manufacturer's code.
Check box if the applicant currently has a NIOSH-Approved product.
Assign a unique reference number to this application.

This reference number must start with the three character NIOSH-Assigned manufacturer's code.
There is no character limit on this reference number.
This number must appear on each hardware sample package and the payment.
Never reuse the Applicant-Assigned Reference Number (AAR#) except on Amended Applications requested by NIOSH.

NIOSH assigns a unique Task Number (TN) to each project. This number is emailed to the applicant once the application is received along with accompanying documents, check or payment confirmation, and test samples (hardware). All inquiries must refer to either the NIOSH-Assigned TN or the AAR#.

2 Type of Application (Section C.2)

Select from: New Approval Application, Resubmission of a New Application, Extension of Approval Application, Resubmission of Extension of Approval Application, Quality Assurance Application, Correlation Testing Only Application Amended Applications.

New Approval Application

- Used for new design, substantially modified design, or different type or level of protection requested for an existing NIOSH-Approved respirator.

Resubmission of New Approval Application

- Resubmission applications are only accepted when allowed by NIOSH.
- Used for previously denied applications.

Extension of Approval Application

- A change is made to any document that was evaluated by NIOSH as part of an approval.
- A critical or major characteristic affecting performance or design (including Quality Assurance provisions) is altered on a previously approved respirator.
- One new accessory is added to a previously approved respirator.
- A change is made to an approval label, assembly matrix, User Instructions, or drawings.
- A private label request is made.

- A product is made obsolete.

Resubmission of Extension of Approval Application

- Resubmission will only be accepted when allowed by NIOSH.
- Used for previously denied applications.

Quality Assurance Approval Application

- Choose this application for a new or updated QA Manual only.
- No other actions will be accepted under this type of application.

Correlation Testing Only Application

- Choose this type of application if the respirator is being submitted to be correlated with NIOSH Standard Test Procedures (STPs).
- The results of this testing cannot be used as pre-submission test data when submitting the respirator for NIOSH approval.
- Independent or internal testing is still required prior to submittal of the application.
- Explain what testing is required and indicate how many trials in the "Reason for Application."
- No approval will be issued with a Correlation Testing Only Application.

Amended Application

- Amended submissions are only accepted when requested by NIOSH.
- Used for open applications with an inaccuracy in the application.
- Only the portion requested by NIOSH should be submitted.
- The AAR# and TN will remain the same.

3 and 5 Prospective Approval Holder (Sections C.3 and C.5)

Enter the name of the prospective approval holder.

Status of Facility **Manufacturer/Approval Holder Name (if different than above).**

Check if the organization has submitted a request for approval for any respirator produced at this manufacturing plant in the last three years.

Applicant *– A person identified by the approval holder as completing and submitting the application.*

Primary Contact *– Person who will receive the approval or denial letter and all correspondence concerning the application.*

Only those persons identified to NIOSH by the manufacturer/approval holder as official company contacts should be listed on the application. Multiple contacts can be identified as required by the manufacturer/approval holder.

Enter Official Title.
Enter the first and last name, middle initial, and suffix for the applicant.
Enter the name of the prospective approval holder, if different from above.
Enter the manufacturing plant address.
Enter the manufacturing plant phone number.

Click “add contact” to add information for another person who can answer questions related to this application.

6 Date of Application (Section C.6)

Choose the date from the dropdown calendar. The NIOSH date of application is when the application is assigned a TN by NIOSH.

7 Type of Product (Section C.7)

Select Air-Purifying Respirator since this application applies only to Powered Air-Purifying Respirators.

8 Specific Questions Pertaining to Submission (Section C.8)

Is this a resubmittal of a previous application?

If Yes, enter the previous TN.

Is this an amended application?

Yes or No.

Is this submission application a result of field problem or site audit?

If Yes, enter the relevant TN(s).

Is the respirator intended for use in mines?

Not applicable.

Is this application dependent upon the approval of an application in process?

If Yes, specify the applicable AAR# or TN.

If the same PAPR unit is being added as a private label, the second application for the private label cannot be approved until the first application is approved.

If there are two or more applications that use the same assembly matrix, check the “yes” box and identify all subsequent applications in the Approval History. The second and subsequent applications using the same assembly matrix cannot be processed until the first application is approved. Additionally if a drawing is currently under review at NIOSH and a separate matrix is submitted, the current application should indicate that the project is dependent on the prior project and applicants should list the applicable TN.

9 Reason for Application (Section C.9)

Provide a complete, concise, descriptive reason for the application. Do not provide information relating to respirator use or future respirator development. This is the information that will appear in the Certified Equipment List (CEL).

The following must be addressed in the "Reason for Application":

- If the respirator contains or has been treated with an antimicrobial or antiviral treatment, include supporting documentation indicating any EPA identified human toxicity levels, or specific data and third party certification that the treatment does not pose a hazard to the respirator user. Also include data supporting any claims being made about the treatment. The documents should be included as part of the application.
- See letter to All Respirator Manufacturers dated September 24, 1981.
  - If making respirators obsolete, include the TC numbers and model numbers.

List the TC numbers of all approvals affected by the application. If all of the TC numbers on the assembly matrix apply to the extension, the assembly matrix may be referenced instead of the individual TC numbers.

If an Extension of Approval Application is the result of a field problem, site audit, or product audit, state that fact and list any associated task numbers (TN) here. Also list the Corrective Action Request (CAR) number associated with the application.

Please do not list "approval" as the "Reason for Application."

Quality Assurance approval applications must state the details of the change(s) to the Quality Assurance Manual and the respirator(s) and manufacturing facility(ies) affected. Quality Assurance Applications must not affect performance or design and must not result in a different type or level of protection.

Correlation Testing Only Applications must state which NIOSH Standard Testing Procedures is to be used and indicate how many trials are requested. Special correlation tests that are not consistent with a NIOSH Standard Testing Procedures will not be conducted unless previously agreed upon by NIOSH. An approval will not be issued with a Correlation Testing Only Application.

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

10 Approval History (Section C.10)

Provide additional information on Approval History and any other information pertaining to this application. Do not list additional requests in the Approval History.

If the application is one of a series being submitted, clearly list the AAR#s of all applications in the series.

Include a suggested processing order. Include an explanation of how the applications build upon each other. When using a common assembly matrix for the entire series of applications, place the assembly matrix in the last application of the series and reference the application in which it is located in all applications in the series. Applications in a series will not be approved until the entire series is complete.

List the application TN where the respirator was last tested by NIOSH.

Example of a Well-Written Approval History for a Powered Air-Purifying Respirator:

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

The change is documented in the cartridge's bill of materials (Item 2) on page 3 of drawing 203-01 Revision N.

This modification does not affect facepiece fit, but could affect the unit airflow. Happy Breathing Company has tested the PAPR being submitted as an extension of approval and found it still meets the requirements of 42 CFR Part 84 for breathing resistance, filter efficiency, and airflow. Happy Breathing Company has not changed any of the design construction of the cartridges since they were granted NIOSH approval under TN-xxxxx. Happy Breathing Company is relying on the submitted data and sample hardware accompanying this submission, AAR#ph24, to obtain this approval.

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

11 Description of Respirator (Section C.11)

Information for New Approval Applications and Extension of Approval Applications is entered in the SAF by selecting options from dropdown boxes. The respirator description fields vary based on the type of respirator selected. Both New Approval Applications and Extension of Approval applications require a detailed narrative description.

Is this a joint SEI (CBRN NFPA) submission?

Yes or No.

Not Applicable to PAPRs.

Is this an SEI retrofit respirator?

Yes or No.

Is this a CBRN Application?

Yes or No.

Is testing required?

Yes or No.

Return sample hardware?

Yes or No.
Note: If No NIOSH will dispose of the equipment.

Source of submitted samples – Choose from dropdown options:
Prototype, Regular Production Unit, Correlation Test Sample.
Note: If No testing is required, please provide the reason.

Facepiece type – Choose from the dropdown options:
Filtering Facepiece, Full Facepiece, Half-Mask, Quarter-Mask, Mouthpiece, Hood, or Helmet.

Fit – Choose from the dropdown options:
Tight-fit, Loose-fit, Both Tight- and Loose-fit, or Mouthbit.

Is this respirator fit checkable?
Yes or No.

If the respirator contains electrical components, have the components been approved by MSHA for intrinsic safety?
Yes, No, or Not Applicable.

Note: If this respirator is to be used for underground mine use and has electrical components, MSHA intrinsic safety approval must be received prior to submitting to NIOSH.

Does the respirator have an inhalation valve?
Yes or No.

Does the respirator have an exhalation valve?
Yes or No.

Type of AP Respirator – Choose from the dropdown options:
Particulate Filtering, Gas/Vapor Removing, Combination Gas/Vapor Removing and Particulate.

Mask Power – Choose from dropdown options:
Unpowered, Powered, Both Unpowered and Powered use.

How many filters?

Are the filters replaceable?
Yes or No.

Filter Location (particulate filtering only) – Choose from dropdown options:
Facepiece-Mounted, Chest-Mounted, Back-Mounted, Belt-Mounted, Hood-Mounted, Helmet-Mounted.

Does this respirator protection cover more than a single gas?
Yes or No.

Does the respirator use cartridges or canisters?

How many cartridges or canisters?

Cartridge or canister location – Choose from the dropdown options:
Facepiece-Mounted, Belt-Mounted, Chin-Mounted, Chest- Mounted, Chest and back-Mounted, Hood-Mounted, Helmet-Mounted.

Can the canister or cartridge be replaced?
Yes or No.

Does the canister or cartridge have an ESLI (EOSL)?
Yes or No.

12 Intended Protection and Safety Design (Section C.12)

Air-Purifying Respirators Only: State all protections for which approval is requested. NIOSH does not permit the use of any form of chromium-impregnated sorbent material for nuisance levels due to the suspected carcinogenic effects. Chemical cartridges (23C) must identify the specific contaminants for which approval is requested (e.g., chlorine, chlorine dioxide, etc.). Canister PAPRs (14G) can list specific contaminants for which approval is requested, or may use "Acid Gas" as a protection if the protection applies.

Note: If this respirator is to be used for underground mine use and has electrical components, MSHA intrinsic safety must be received prior to submitting to NIOSH.

Note: NIOSH does not permit the use of any form of chromium-impregnated sorbent material due to the suspected carcinogenic effects. In the case of CBRN PAPR respirators, identify the capacity level requested as CAP 1, 2, 3, or other.

13 Pre-Submission Performance Test Data and Statements (Section C.13)

Respirator pre-submission performance test data must accompany each application and must:

- Specify components used for test configuration by part number.
- Show units of measure for all test data (units of measure must match 42 CFR Part 84 Subparts I, J, K and KK criteria).
- Submit copies of actual test data with all results and conclusions.

To verify which tests need to be performed as part of the pre-submission testing, please refer to the "Respirator Test Selection Guide." NIOSH expects that the applicant will have performed each NIOSH test and any additional tests the applicants deem appropriate during the process of validating that the device meets NIOSH approval requirements.

Note for resistance testing:

Applicant data must include resistance values for all combinations of related Powered Air-Purifying Respirators. This data must be representative of each complete assembly (including facepiece) seeking approval. For resistance testing, NIOSH will test and verify the highest and lowest resistance combinations reported by the applicant.

Note for efficiency or penetration testing:
For PAPR high-efficiency (HE) filters, three samples will be test against DOP, refer to the Standard Testing Procedure for HE filters, STP-0001. The test is an instantaneous test only.

When an end-of-service-life indicator (ESLI) is included on a Powered Air-Purifying Respirator for a gas or vapor, include the following information:

- Demonstration of the ESLI as a reliable indicator of sorbent depletion,
- The effects of any industrial chemical interference with the indicator,
- The shelf life of the indicator,
- Affirmation of visibility of the ESLI to the user when worn, and
- Affirmation that the ESLI will withstand normal handling without damage.

Any respirator that has an ESLI should list caution "S" on the approval label. Also, the User Instructions must contain a special section that is labeled "S-Special or Critical User Instructions" where the ESLI information is contained. See *Approval Labels* in Section 7 for an example

14 Model Numbers and Product Trade Names (Section C.14)

The information provided in this field is how the product will appear in the Certified Equipment List.

A product trade name that uniquely identifies the respirator or family is required. This name will be listed in the Certified Equipment List for public reference. In version 8 of the SAF for a New Approval Application, the model number field can be blank but the product trade name field must be completed before proceeding to the next data screen. A product trade name may indicate a protection but it may not imply use. Model numbers previously used for particulate filtering devices approved under 30 CFR 11 standards may not be reused or carried over to devices or configurations to be approved under 42 CFR 84 standards.

15 Test Samples (Hardware) (Section C.15)

Regular production units submitted for approval must be the result of actual manufacturing processes [42 CFR Section 84.11(e)]. Applications will be denied if the test samples (hardware) provided for testing did not go through the manufacturer's normal assembly, inspection, and test processes. Applications may be denied even if the component that failed is not related to the "Reason for Application."

Use the Respirator Test Selection Guide to determine the minimum number of hardware samples required for testing. Submit a sufficient number of hardware samples for testing at the time of application. The hardware samples to be used for testing must be sent under a separate cover from the application. In the application and on the packing slip with the hardware samples, list the item by part number and description, and indicate the quantity submitted for testing. Include a copy of the User Instructions in the box or shipping container with the hardware samples to be used for testing.

The outside of each box or shipping container and packing slip(s) should clearly indicate "Test Samples/Hardware" along with the name of the applicant, AAR#(s), part number(s), and quantity(ies). The hardware samples to be used for testing and any additional hardware samples requested by NIOSH must clearly show the part number on each item, regardless of how it is packaged. If additional hardware samples to be used for testing are requested by NIOSH, mark the shipment to the attention of the NIOSH employee requesting the samples. Include the AAR#, TN, and state “Additional Test Samples” on the outside of the box or shipping container. Cross-referenced lists will not be accepted.

The applicant must submit prepaid return shipping labels or provide other return means with the hardware samples for any materials to be returned upon completion of testing. “Please Return Samples” should be indicated on the packing slip. If NIOSH denies an application based upon documentation issues, the application, and in most cases, all hardware samples will be returned.

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

The test sample hardware submitted with the application will be tested. No substitutions, additions, or deletions are permitted by the applicant once NIOSH receives the application.
If NIOSH evaluators determine a need for additional testing, additional test samples (hardware) may be requested.

Saving the Application

Once the application form has been completed, save the data file by selecting FILE, then SAVE AS, from the menu bar on the main menu screen.

Section 3 Supplemental Information for Preparing an Application for Powered Air-Purifying Respirators and CBRN Powered Air-Purifying Respirators

3.1 Quality Assurance Documentation

Understanding the requirements of 42 CFR Part 84 Subpart E and specific quality system characteristics as noted below are necessary to adequately develop and maintain Quality Assurance and quality control programs acceptable to NIOSH. Prior to obtaining any approvals under 42 CFR Part 84, all approval holders are required to have an approved Quality Assurance (QA) Manual on file at NIOSH.

If an organization has an approved Quality Assurance Manual and there is no change, complete the applicable blocks on the SAF. If a previously approved QA Manual is being revised, it is not necessary to submit the entire manual. In a separate QA application, submit only the sections that have been revised and an updated revision history sheet.

3.2 Quality Assurance Manual

Submit a Quality Assurance Manual that documents the following elements at a minimum:

A. Statement of Quality Assurance.
- Upper management approval of the QA Manual (usually a signature).
- A revision history sheet showing date and reason for revision.
- A Table of Contents.
- Management assurance that the QA system meets NIOSH requirements in 42 CFR Part 84 Subpart E.

B. Description of Management Responsibilities as they relate to:
- The company quality policy.
- Personnel/organization structure necessary to carry out these provisions.
- Verification of quality (internal auditing).
- Quality system review.
- International Standards Organization (ISO) Certification (if applicable).

C. Structure of Quality System.
- Identify how quality procedures and instructions are prepared and implemented.

D. Contract Review Activities (as applicable).

E. Design Control for aspects of safety, performance, and dependability of the product reliability programs.

F. Control of All Documents and Data (control of engineering drawings, documentations, and changes).

G. Quality in Purchasing.

H. Control of Customer-Supplied Product (control of purchased material to include incoming inspection).

I. Product Identification and Traceability.

J. Control of Production Processes (lot identification, control of processes, manufacturing, fabrication, and assembly work conducted in the plant).
K. All Areas of Inspection and Testing: Receiving, In Process, and Final Inspection.
L. Control of Inspection, Measuring, and Test Equipment.
M. Inspection and Test Status.
N. Control of Nonconforming Product.
O. Corrective and Preventive Actions (as applicable).
P. Inventory and Handling Controls.
Q. Control of Quality Records.
R. Internal Quality Audits (audit of final inspection of the completed product).
S. Training.
T. Servicing (as applicable).

Note: If the manual does not incorporate the specific elements within the document then the manual must link or list the Standard Operating Procedures (SOPs) for the various elements.

3.3 Product Quality Control Plan and Documentation

Product Quality Control Plan (PQP) documentation is required to be submitted as part of an application to demonstrate to NIOSH the applicant's process characteristics involved in controlling and monitoring the quality of the respirator being manufactured.

Items that must be submitted are the:

A. PQP flowcharts showing all inspection and test operations. Identify each procedure by AAR#. Inspection or test procedures must be clearly identified on the flow chart.
B. Sampling plan and classification of defects document as described in 42 CFR Section 84.41 (c), (d), (e), (f), (g), and (h).
C. Incoming, in process inspection, and test procedures for items listed on the assembly matrix.
D. Final inspection and test procedures for the complete respirator and items listed on the assembly matrix.
E. Simplified Powered Air-Purifying Respirator drawing.
F. Assembly matrix.

3.4 Fees

An application fee of $200 is required at the time of submission for all approval requests. Checks are to be made payable to NIOSH, dated less than 30 days prior to the submission date, and contain the AAR#. The specific AAR# for the application must be written on the check. Checks older than 30 days may be returned. Separate checks are required for each application submitted. Do not issue multiple application fees on one check. Otherwise, checks will be returned and application processing delayed.

NIOSH will not begin processing the request until all items (application, check, and test samples (hardware)) are received. If a domestic applicant utilizes Pay.Gov, send a copy of the Pay.Gov receipt to the NIOSH NPPTL Records Room to facilitate linking the payment to the approval request.

As part of the Initial Review Process, an estimate of the costs anticipated to be incurred during the evaluation will be provided. An email from the initial reviewer will be sent to the applicant towards the end of the Initial Review Phase.

This estimate is prepared based on the "Reason for the Application," the number of approvals affected, and the assigned tests. In the event other testing or other additional cost items are identified after the acceptance of the original estimate, the company will be contacted and an addendum to the estimate will be forwarded for acceptance.

Once the applicant has provided authorization to the initial reviewer via email, the evaluation can begin.

During the Final Review Phase, an invoice for all fees, including testing of equipment, incurred in the processing of an application will be generated. Invoices will contain specific payment instructions and identify authorized methods of payment, and will be provided to the approval holder for payment.

Respirator Approval Application-Based fees are as follows:

Administrative Fees:

Fee type	Legal citation	Amount	Due date
Application	42 CFR §84.20(b)(1)	$200 per application submitted.	Upon receipt of any application request. To be submitted with application.
Approval	42 CFR §84.20(b)(1)	$100 per each certificate of approval issued.	Upon receipt of the invoice.
Approval Modification	42 CFR §84.20(b)(1)	$50 per each certificate of approval modified.	Upon receipt of the invoice.
Site Qualification	42 CFR §84.20(b)(3)	• Existing approval holder, paper review: $400 per each request to inspect new production facility. • Prospective approval holders: ▫ One day domestic site visit - $2,500. ▫ One day international site visit - $7,500.	Upon agreement on the date of the site qualification.

Note: For any modification to an existing approval, such as changes to User Instructions or PQP, the approval modification fee will be charged for all the approvals affected by this change. For example, if the User Instructions are revised due to a change in a specific respirator, but the same User Instructions

are used on a family of respirators (example: family consists of 20 approvals), the approval modification fee of $50 will be charged for all the approvals under that family of respirators (20 X $50 = $1,000).

Testing fees will be charged in accordance with the following fee tables and will be due upon receipt of the invoice. The final letter (approval or denial) will be issued to the primary contact once all reviews are complete. The invoice is to be paid within 30 days after receipt.

3.5 Powered Air-Purifying Respirators and CBRN Powered Air-Purifying Respirators Test Fees

All of these tests may not apply to the specific type of respirator being submitted. These apply only to Powered Air-Purifying Respirators.

Air-Purifying Respirator Fees:

0001 Determination of Particulate Filter Penetration (PAPR)	$150.00
0003 Exhalation Resistance	$150.00
0004 Exhalation Valve Leakage	$300.00
0005 IAA Fit Test	$1,800.00
0005* Qualitative Fit Testing	$1,800.00
0005A IAA Fit Test for Full Facepiece	$1,800.00
0006 IAA Fit Test for Half-Masks	$1,800.00
0007 Inhalation Resistance	$150.00
0012 Airflow Determination PAPR	$150.00
0014 Leakage of Drink Tubes and Accessories	$300.00
0025 Silica Dust Loading for PAPRs	$1,200.00
0030 Noise Level in PAPRs with Hoods or Helmets	$450.00
0033C Ammonia Service Life Testing PAPR Cartridges	$750.00
0033D Ammonia Service Life Testing PAPR Canisters	$750.00
0034 Carbon Monoxide Service Time	$750.00
0035 Chlorine Service Time Testing	$750.00
0036 Chlorine Dioxide Service Time Testing	$750.00
0037 CN Service Time Testing	$2,400.00
0038 Ethylene Oxide Service Time Testing	$450.00
0039C Formaldehyde Service Time PAPR Cartridges	$750.00
0040 Hydrogen Chloride Service Time Testing	$500.00
0041 Hydrogen Cyanide	$1,800.00
0042 Hydrogen Fluoride Service Time Test	$750.00
0043C Hydrogen Sulfide Service Time Testing PAPR Cartridges	$750.00
0044 Mercury Vapor Service Time Testing	$2,400.00
0045C Methylamine Service Time Testing PAPR Cartridges	$450.00
0045D Methylamine Service Time Testing PAPR Canisters	$450.00
0046C Organic Vapor (CCL4) Service Time PAPR Cartridges	$450.00

0046D Organic Vapor (CCL4) Service Time PAPR Canisters	$450.00
0047 Phosphine Service Time Testing	$750.00
0048C Sulfur Dioxide Service Time Testing PAPR Cartridges	$450.00
0048D Sulfur Dioxide Service Time Testing PAPR Canisters	$450.00
0050 CS Service Time Testing	$2,400.00
0060 Determination of End-of-Service-Life Indicator Drop	$300.00
0061 Determination of End-of-Service-Life Indicator Visibility	$300.00
0062 Nitrogen Dioxide Service Time Testing	$750.00
0063 CO_2 Volume Tight-Fitting PAPR Running	$300.00
0064 CO_2 Volume Tight-Fitting PAPR Unit Off	$300.00
0065 Breath Response PAPR Airflow Resistance	$300.00
0066 Determination of End-of-Service-Life Indicator	$300.00
0067 Qualitative Fit Test, Bitrex or Saccharine	$1,800.00

* Quantitative fit testing, using corn oil, may be performed in place of the qualitative fit testing performed with IAA, at the request of the applicant.

New Site Qualification Fee, existing manufacturer	$400.00

Powered Air-Purifying CBRN Respirators:

0501 Cyclohexane (Set of 9 Canisters) Tight-Fitting	$1,000.00
0502 Cyanogen Chloride (Set of 9 Canisters) Tight-Fitting	$2,400.00
0503 Hydrogen Cyanide (Set of 9 Canisters) Tight-Fitting	$2,400.00
0504 Phosgene (Set of 9 Canisters) Tight-Fitting	$1,400.00
0505 Hydrogen Sulfide (Set of 9 Canisters)Tight-Fitting	$800.00
0506 Sulfur Dioxide (Set of 9 Canisters) Tight-Fitting	$800.00
0507 Ammonia (Set of 9 Canisters) Tight-Fitting	$1,000.00
0508 Nitrogen Dioxide (Set of 9 Canisters) Tight-Fitting	$1,200.00
0509 Phosphine (Set of 9 Canisters) Tight-Fitting	$1,000.00
0510 Formaldehyde (Set of 9 Canisters) Tight-Fitting	$1,000.00
0511 Cyclohexane (Set of 9 Canisters) Loose-Fitting	$1,000.00
0512 Cyanogen Chloride (Set of 9 Canisters) Loose-Fitting	$2,400.00
0513 Hydrogen Cyanide (Set of 9 Canisters) Loose-Fitting	$2,400.00
0514 Phosgene (Set of 9 Canisters) Loose-Fitting	$1,400.00
0515 Hydrogen Sulfide (Set of 9 Canisters) Loose-Fitting	$800.00
0516 Sulfur Dioxide (Set of 9 Canisters) Loose-Fitting	$800.00
0517 Ammonia (Set of 9 Canisters) Loose-Fitting	$1,000.00
0518 Nitrogen Dioxide (Set of 9 Canisters) Loose-Fitting	$1,200.00
0519 Phosphine (Set of 9 Canisters) Loose-Fitting	$1,000.00
0520 Formaldehyde (Set of 9 Canisters) Loose-Fitting	$1,000.00
0550 GB[1] (SMARTMAN) Qualifier LAT(QLAT) Only	$9,142.00
0550 GM[1] (SMARTMAN) Remainder LAT (RLAT)	$9.142.00

0551 HD[1] (SMARTMAN) QLAT Only	$9,142.00
0551 HD[1] (SMARTMAN) RLAT Only	$9,142.00
0550/0551[1] Aerosol process TDA-99M (SMARTMAN) Only	$600.00
0552 Laboratory Respirator Protection Level (LRPL) Tight-Fitting	$20,000.00
0552 Partial LRPL Tight-Fitting	$16,000.00
0553 Laboratory Respirator Protection Level (LRPL) Loose-Fitting	$20,000.00
0553 Partial LRPL Loose-Fitting	$16,000.00

Note: [1] Testing Performed at RDECOM.

For CBRN PAPRs, tests 1, 3, 4, 7, 12, 14 (as configured), 25 and 30 (for hoods only) may also be performed.

A single payment (check or pay.gov) for multiple invoices is allowed. Include the AAR#s for each associated application on the check or the pay.gov receipt so they will be properly credited. Separate payments (check or pay.gov) will also be allowed for each application invoice. For application fee invoices, included the TN number(s) associated with the payment. To indicate a final payment for a specific application(s), add an -F after the TN number(s) (TN-nnnn-F).

3.6 Annual (Fixed) Certification (Approval) Fees

Annual (fixed) certification (approval) fees will be invoiced to approval holders who hold active or obsolete certificates of approval. Invoices will be sent in September with payment due by October 30 of the applicable year. Invoices will itemize the number of manufacturing sites and approvals and apply the fees per the following table:

Respirator Certification Fee Schedule A—Annual (Fixed) Fees

Fee Type	Legal Citation	Amount	Due Date
Maintenance of Product Performance (product audit)	42 CFR §84.20(b)(5)	• Annual fee: $761 per each approval holder. • Variable fee: as billed by NIOSH based on the respirators chosen to be tested each year.	October 30 of applicable year.
Records Maintenance	42 CFR §84.20(b)(1)	$50 per every listed[1] approval on file with NIOSH on July 1st of each year.	October 30 of applicable year.
Quality Assurance Maintenance (Site Audit)	42 CFR §84.20(b)(4)	• Annual fee: $3,000 per every manufacturing site registered with NIOSH. • Variable fee:[2] ▫ 1 day domestic audit - $2,500 per site. ▫ 2 day domestic audit - $5,000 per site. ▫ 1 day international audit - $7,500 per site. ▫ 2 day international audit - $10,000 per site.	October 30 of applicable year.
Maintenance of Testing and Approval Facilities	42 CFR §84.20(b)(2)	$34 per every listed[1] approval on file with NIOSH on July 1st of each applicable year.	October 30 of applicable year.

Maintenance of Test Equipment	42 CFR §84.20(b)(2)	$36 per every active[3] approval on file with NIOSH on July 1st of each applicable year.	October 30 of applicable year.

1. "Listed" approvals include all active and obsolete approvals. The Certified Equipment List (CEL) reflects the current listed approvals maintained by NIOSH.
2. Applies to design as well as manufacturing sites.
3. Does not include obsolete approvals.

Checks are to be made payable to NIOSH, must be dated less than 30 days prior to the submittal date, and must reference the AAR#, TN, or NIOSH invoice number.

3.7 Pay.Gov Instructions

Domestic applicants may use the electronic fees transfer program known as Pay.Gov.

Note: Prior to making any payment of respirator approval fees, applicants must establish an account with Pay.Gov.

A. Follow the web link provided below:
   a. Pay.Gov homepage: https://pay.gov/paygov/homepage.
B. On the center of the web page click on the link "Click here to register" to start the process or go to the web page address provided below:
   a. Registration: Pay.gov - Register for a Pay.gov Account.
   b. Read the User Responsibility Statement, fill in the box, and select accept.
   c. Select the "Continue with Self Enrollment" tab.
   d. Complete the required fields in the Online Self Enrollment form and then select "submit."
   e. Use Pay.Gov username and password to log into the Pay.Gov system from the homepage.
   f. Access the forms necessary to submit payments online using this process.
C. Fee Payment User Instructions.
   a. Open the Pay.Gov homepage.
   b. Locate the "User Fee Form."
      i. Go to the Find Public Forms section below the login.
      ii. Search for forms by three options:
         1. Form Name.
         2. Agency Name.
         3. Search Public Forms.
      iii. Use one of three links listed on the six forms in the system for the Centers for Disease Control and Prevention (CDC).
         1. Form Name: CDC Royalty BMLA and User fee Form.
            a. Select CDC User Fee Form.
         2. Agency Name: CDC Royalty BMLA and User Fee Form.
            a. Select CDC User Fee Form.
         3. Search Forms: CDC Royalty BMLA and User Fee Form.
            a. Select CDC User Fee Form.
         4. Click on the form name to open the online fillable form.
      iv. Complete the Online CDC User Fee Form.
         1. Complete all mandatory blocks marked with asterisks.
         2. Under CDC Invoice Number, enter the three digit Applicant-Assigned Reference Number (AAR#).
            a. If payment is for an existing Task Number (TN), enter the associated TN.
         3. For "Payment Options," select the "NIOSH User Fee" from the three choices.

4. Enter a short description in the comments block regarding the payment. Add any specific identifying information regarding the submission that may help in processing the payment.

c. When submitting the form, users will be prompted to enter their Automated Clearing House (ACH) debit information.

D. Currently Pay.Gov accepts payment directly by the Automated Clearing House (ACH) feature or through credit or debit cards as follows:

a. Credit Cards: Visa, MasterCard, American Express, and Discover.

b. Debit Cards: Visa and MasterCard processed only.

Note: More in-depth instructions and information can be found at Pay.Gov homepage.

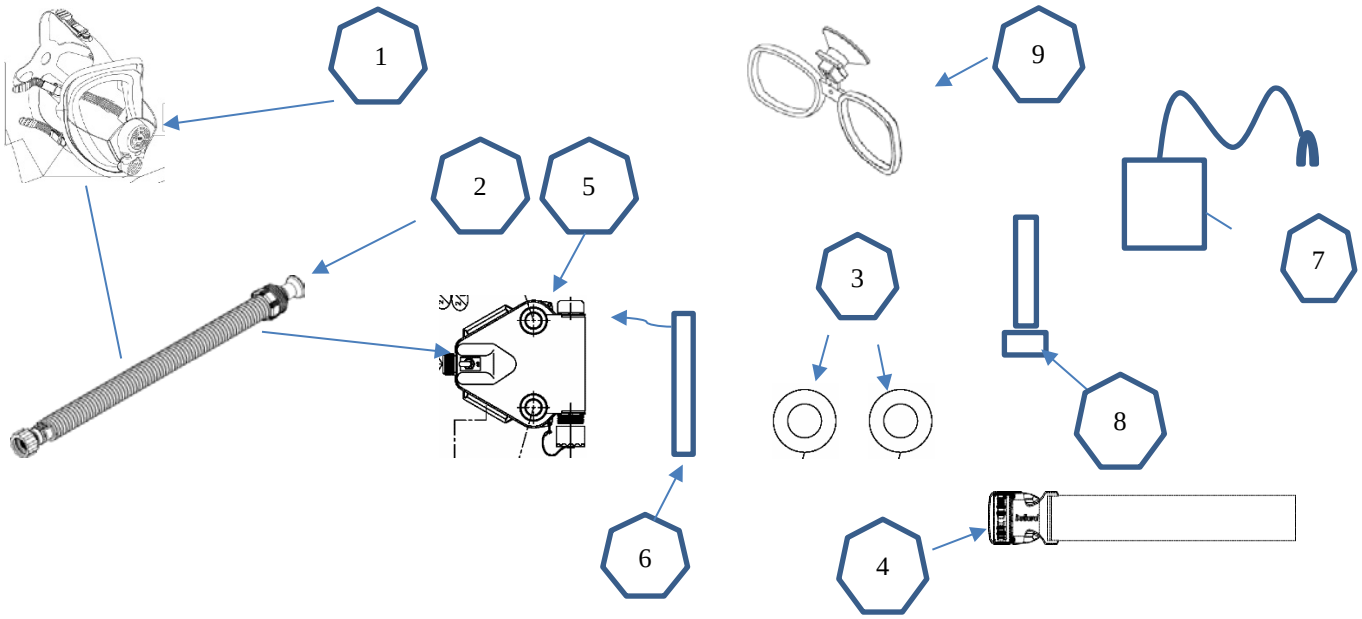
3.8 Drawings for a Powered Air-Purifying Respirator and a CBRN Powered Air-Purifying Respirator

All drawings must be in English. Drawings are accepted in Adobe PDF, ProEngineer, Autodesk, Smart Draw, and Corel Draw. Drawings should be named using a unique identifier of the organization's choice, R for drawing, the revision level (e.g., a, b, c, etc.), and the file extension representing the software program (e.g., XXXnnnnRa.dwg). However, it is suggested that applicants also use their three character manufacturer's code in the drawing filenames (XXXnnnnRa.dwg). All engineering and CAD drawings must be saved and submitted in full view mode. All engineering and CAD drawings must be submitted in black and white. The signature blocks on each submitted drawing must contain the initials or signature of the preparer and approver along with the approval date for the drawing revision.

3.8.1 Exploded-View Drawing and Major Subassembly Drawing for a PAPR and a CBRN PAPR

For Powered Air-Purifying Respirators, the exploded-view drawing must be included along with the major subassembly drawings. The major subassembly drawings must include all the respirator components with critical or major dimensions, materials, and characteristics as listed on the Powered Air-Purifying Respirator drawing checklist. User Instructions do not need to be illustrated on the exploded-view drawing. Do not include future submittals or unapproved assemblies on the exploded-view drawing.

3.8.2 Example of an Exploded-View Drawing for a Powered Air-Purifying Respirator



3.8.3 Material Specifications on Drawings for a PAPR and a CBRN PAPR

For material specifications, use the criteria of affecting performance or design.
For example, if an accessory would not affect the performance or design, materials could be identified as plastic, metal, rubber, etc. However, if the items do affect performance or design, they would be identified as aluminum, butyl rubber, etc.
The phrase "or equivalent" should not be used.

3.9 Component Vendors

If the applicant controls all specifications for the component, the component vendors do not need to be specified. If the applicant does not determine all specifications of the component, then the applicant must provide the name of the vendor. In accordance with 42 CFR Sections 84.42 (c) and 84.43 (c) the approval holder is obligated to manufacture to the approved documentation. NIOSH reserves the right to revoke, for cause, any certificate of approval where it is found that the applicant's quality control test methods, equipment, or records do not ensure effective quality control over the respirator for which the approval was issued. See the April 7, 2005 Letter to All Manufacturers on "Clarification of Supplier and Subcontractor Relationships" for additional information.

3.10 Assembly Matrix

- An assembly matrix is a diagram of the major subassemblies and accessories. It must be submitted electronically in Microsoft Excel 97 or later formats and it must be formatted as shown in the example (7.3). The assembly matrix cannot be part of the exploded-view drawing.
- Powered Air-Purifying Respirators can have multiple subassemblies. The assembly matrix should show individual columns for each subassembly of the Powered Air-Purifying Respirator, including chargers, airflow indicators (if included), all accessories, and the User Instructions.
- An "X" placed in the wrong box on a label or assembly matrix could delay the approval process. Please verify the placement.
- Only one assembly matrix is necessary for a series of applications involving a common assembly matrix. This assembly matrix must be submitted with the last application in the series.
- The AAR# for the application that contains the assembly matrix must be identified in the Approval History section of each application in the series.
- When a new TC number is being requested, identify the rows for the new TC number using the numbering convention of "schedule#, AAR#, alpha character" in the TC number column. For example, for a Powered Air-Purifying Respirator where the schedule# is 23C and the AAR# is MOR699, the TC number cell for the first row of the new approval would be 23C-MOR699a. The second row would be numbered 23C-MOR699b, the third row would be numbered 23C-MOR699c, etc.
- "TC-"can only appear in the column heading; do not use "TC-" in the assembly matrix row.
- Features that describe the respirator cannot be listed on the assembly matrix as a separate column.
- Features associated with specific model numbers may be coupled together in the description column heading (e.g., Model 1201-EZ Flow, Model 1202-EZ Flow, etc.).

- The listing of User Instructions on Powered Air-Purifying Respirator assembly matrices is mandatory.
- More than one assembly matrix may be submitted with an application, if relevant.
- Columns with new information or revised information may be lightly shaded.
- Future submissions or unapproved assemblies should not be shown on the assembly matrices.
- Blank cells need to be entirely blank. They should not contain any unnecessary information, spaces, embedded characters, hidden rows or columns, etc.
- The complete respirator or the respirator components listed on the assembly matrix must exactly match those illustrated on the exploded-view drawing.

Some components may be an accessory on one approval and a required component on another.
If a component is an accessory, this must be explained in the "Reason for Application."
If this information is not clearly stated, NIOSH will consider the component required.
The assembly matrix must list all major subassemblies and accessories.

The NIOSH evaluation status for each component or subassembly must be indicated as follows:

X = An existing component or respirator that has been previously tested and approved by NIOSH in this configuration.

N = A new component or respirator. If a new TC number has been requested, "N" must appear in every column across the entire row. If an Extension of Approval is requested, "N" should only appear in columns for respirators or components new to the approval.

P = Pending. A component or respirator submitted in an earlier application that is currently being evaluated by NIOSH.

R = A redesign or revision to an existing component or respirator where the part number has not changed. "R" is used to indicate a change to any associated document with that component.

- = A component or respirator designated by the approval holder as obsolete. Do not use "double dash." An obsolete item must be shown on the matrix as obsolete for the TC number/part number combination at least once. Once organizations have submitted an assembly matrix with obsolete items, they may drop these items from the matrix in future submissions. If obsoleting an approval, dash marks must appear in every block that a component for that approval was marked.

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

For easier review and evaluation, it is recommended that applicants lightly shade the rows and columns containing new (N), revised, or redesigned (R) components.

If no cells are marked N or R, the applicant should reconsider whether an application for approval is required. If in doubt, call NIOSH NPPTL *Conformity Verification and Standards Development Branch at (412) 386-4000.*

3.11 Approval Labels and Private Labels

Approval labels used in User Instructions, on packaging, or on devices must be legible. Labeling requirements vary based on the type and intended use of the respirator. See example label formats for Powered Air-Purifying Respirators. The list of protections must be in the same order and identical to the matrix. Submit draft versions of the appropriate labels.

Labels must be submitted for all New Approval Applications, and for Extension of Approval Applications when the components change. Labels must be created in Excel (97 or later) and follow the format of the examples. Accessories may be listed on the approval label, but are not required. NIOSH will accept draft labels with the location of the Health and Human Services (HHS) and NIOSH logos noted. Logos are available on the NIOSH NPPTL homepage. The applicant is responsible for inserting the logos during label production. Approval labels may not contain future submittals or show unapproved assemblies.

3.12 List of NIOSH Cautions and Limitations by Respirator Type

PAPR (HE filter only): A, B, C, F, I*, J, L, M, N, O, P, S*, AA*, FF*
PAPR (G/V cartridge only): A, B, C, F, H, I*, J, K*, L, M, N, O, S*, FF*
PAPR (G/V cartridge & HEPA): A, B, C, F, H, I*, J, K*, L, M, N, O, P, S*, FF*
PAPR Gas Mask: A, F, H, I*, J, L, M, N, O, P, S*, BB, CC, FF*
CBRN PAPR (loose-fit 23C) A, B, C, F, H, I*, J, L, M, N, O, R, S*, Y, GG, QQ, UU, VV
CBRN PAPR (tight-fit 14G) A, F, H, I*, J, L, M, N, O, R, S*, Y, Z, BB, CC, GG, UU, VV

* **Note**:

- I — Applies if the respirator contains electrical components and the intrinsic safety has not been evaluated and approved by MSHA or a recognized independent laboratory.
- K — When used with half-mask, gas proof goggles are required for formaldehyde.
- S — With unique or unusual design or critical operation requirements or a private label version.
- AA — Depending on use or design such as a mouthbit.

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

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

3.13 Private Labeling Versus Private Packaging

Private Labeling

Approval Holder A enters into an agreement to allow Company B to sell Approval Holder A's respirator as being manufactured by Company B. All packaging, labeling, markings, User Instructions, and literature should indicate Company B. This approach appears to the user that the approval holder of the

respirator is Company B. The only reference to the actual approval holder is in a Special Instructions "S" section. The respirator name, model number, and part number may or may not be the same as what is used by Approval Holder A. The NIOSH TC number will not be changed. Approval Holder A remains responsible for the respirator quality and all packaging, labeling, markings, and literature pertaining to the NIOSH approval. Approval Holder A must ensure that the private labeler does not misrepresent the NIOSH approval. Private labeling is always submitted to NIOSH by the approval holder for approval.

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

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

> *The model/part number "respirator type" has been manufactured by Company (Approval Holder A) for private label Company B under TC-XXY-nnnn.*

Private Packaging

Approval Holder A enters into an agreement to have its respirators sold by Company B. Company B puts the assembled respirator in a different or additional package. The respirator name, model number, part number, respirator labeling, markings, User Instructions, and literature show Approval Holder A as the approval holder. The packaging may represent Company B and its catalog or other reference number. However, this packaging must be done in a manner which does not mislead the user to think Company B is the approval holder. Clarifiers, such as "Sold by Company B and Manufactured by Approval Holder A" or "Made by Approval Holder A for Company B" must be included on the packaging. The NIOSH approval label will not be changed. Approval Holder A remains responsible for respirator quality and all packaging, labeling, markings, and literature that pertains to the NIOSH approval. Approval Holder A must ensure that the private packager does not misrepresent the NIOSH approval. NIOSH does not need to be notified of private packaging arrangements (no application needs to be submitted).

Note: Private packaging does not result in any changes to NIOSH documentation on file for the approved respirator configuration. User Instructions and NIOSH approval labels provided on or with the package must not be changed. Approval labels and the package artwork are part of the NIOSH documentation and therefore must not be changed to remain a private packaging arrangement.

For both private labeling and private packaging arrangements, the approval holder is responsible for notifying the private label or private packaging company of any changes in approval status, such as stop sale, rescission, or revocation.

3.14 User Instructions

User Instructions must be submitted to NIOSH for Powered Air-Purifying Respirators. User Instructions may be listed on the assembly matrix for Powered Air-Purifying Respirators, but are not required.

An Extension of Approval Application is required for changes to the User Instructions. User Instructions and associated procedures such as maintenance requirements, inspection procedures, and donning and doffing instructions that pertain to the respirator submitted for approval must be submitted as a complete package. When there is a change, NIOSH will not accept only the amended pages. A complete User Instructions document must be submitted indicating what has been changed either by highlighting the changed items or a cover page listing the page numbers and detailing the paragraphs that were updated. The file description for the User Instructions must clearly and specifically identify the model or product line and revision level. Bold, underline, or otherwise indicate all changes to the User Instructions from the prior revision level. When an approval has a design or performance issue, corrections to the User Instructions is not adequate to address the issue.

For cautions and limitations "S," Special or Critical User Instructions**,** noted on the approval label and listed in the User Instructions:

- Approval holders have discretion in what is identified as special cautions or limitations. To be "special" the specific attribute of the respirator must go beyond the standard cautions and limitations and be unique or unusual for the class of respirator.
- If the approval holder states "Special or Critical User Instructions or specific use limitations apply," the Special or Critical User Instructions must be readily identified within a separate section of the User Instructions with the heading, "*S - Special or Critical User Instructions.*"
- Examples of special or critical instructions are special donning procedures, service life limitations, and private labeled respirators.

For private label respirators, the "S" Special or Critical User Instructions section in the private label holder's User Instructions will state:

> *"The model/part number "respirator type" has been manufactured by Approval Holder A (Company) for private label Company B under TC-84A-nnnn."*

If Special or Critical User Instructions or specific use limitations are stated, these items will be reviewed to ensure the items are correct and appropriate.

For all tight-fitting respirators that must be fit tested prior to use, the following the Occupational Safety and Health Administration (OSHA) reference must be included in the User Instructions:

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

For all Powered Air-Purifying Respirators that include a nuisance level odor removal layer in the filter or other design, the following must be included in the User Instructions under a Special "S" titled listing:

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

Requirements Specific to Powered Air-Purifying Respirators and CBRN Powered Air-Purifying Respirators
The approval label may be located on the container or box or inserted in the package or in the User Instructions.

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

3.15 Packaging Art Work and Carton Design

In accordance with 42 CFR Section 84.33, the applicant will submit full scale reproductions of approval labels and markings, and a sketch or description of the method of application and position on the harness, container, canister, cartridge, filter, or other component, together with the instructions for use and maintenance of the respirator.

Approval labels will include the HHS and NIOSH logos, the applicant's name and address, the approval number assigned by NIOSH, and, where appropriate, restrictions or limitations on use of the respirator. When additional labels, markings, or instructions are required, the applicant will be notified. Approval labels and markings will only be used by the applicant to whom the labels were issued.

Legible reproductions or abbreviated forms of the label approved by NIOSH for use on each respirator will be attached to or printed on the following locations:

Respirator Type	Label Type	Location
Gas Mask	Entire	Mask container and canister.
Particulate Respirator	Entire	Respirator container and filter container.
	Abbreviated	Filters.
Chemical-Cartridge Respirator	Entire	Respirator container, cartridge container, and filter containers (where applicable).
	Abbreviated	Cartridges and filters and filter containers.

When companies receive and accept a NIOSH approval, the companies are agreeing to manufacture, inspect, and test the respirator as they stated in their documentation as approved by NIOSH. The company will maintain the Product Quality Control Plan, as submitted and approved, and will not deviate from this plan. The plan will only be changed after the company submits a request to NIOSH and this plan change is reviewed and approved by NIOSH.

Each respirator, respirator component, and respirator container will, 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.

NIOSH-Approved Powered Air-Purifying Respirators advertised and marketed as "Surgical Masks" or "Medical Respirator" and used in the healthcare industry cannot identify medical claims. NIOSH does not approve surgical masks or medical respirators.

Approval holders may not imply "use" for approved respirators.
Package advertising that is not permitted includes phrases such as:

"NIOSH-Approved Welding Respirator."

A trade name implying use, such as "Medi-Ready Powered Air-Purifying Respirator."

Packaging may include a phrase such as: "NIOSH-Approved Powered Air-Purifying Respirator; recommended by the approval holder for lacquer paints."

3.16 Summary of Related Documents

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

Filename:
XXX represents the three character NIOSH-Assigned manufacturer's code and should only appear on the application.
nnnn represents the unique characters chosen by the applicant.
The filename with extension must be listed, using Specific file naming conventions.
Spaces must not be used in filenames.
Filenames are derived from the controlled document number, not the AAR#.
For example, the filename for drawing 10222 revision A should be 10222Ra.dwg.
For future submissions of the same document, the only change to the filename will be to the revision level; the next submission of the drawing above would be 10222Rb.dwg. Files submitted using the AAR# as filenames will be returned.

Document Type:
Pretest data, drawing, assembly matrix, draft approval label, QA Manual, PQP, service life plan, User Instructions, etc.

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

Software program extension:
The software program (including version) used to create the file.
nnnn = unique identifying characters.
a, b, c, etc. = revisions.
.xml, .xls, etc. = program used to create file.

In addition to the application file, the manufacturer must submit related project documents. These documents must be in English and saved with the following file-naming conventions. Any files created in a language other than English will be returned unprocessed**.**

3.17 File Naming Conventions

Required Documents	Naming Convention Abbreviation	Acceptable Software Packages	File Naming Convention Format
Application Form	-	Microsoft Access Java Adobe Acrobat	XXXnnnn.MDB XXXnnnn.XML XXXnnnn.PDF
Pretest Data	PD	Adobe Acrobat Excel Microsoft Word	nnnnPD.PDF nnnnPD.XLS nnnnPD.XLSX nnnnPD.DOC nnnnPD.DOCX
Drawings	R followed by revision level (if applicable)	Adobe Acrobat AutoCAD Scanned file	nnnnRa.PDF nnnnRb.DWG nnnnRc.TIF nnnnRd.GIF nnnnRe.JPG nnnnRf.BMP (a-f indicate various revision levels)
Assembly Matrix	AM followed by revision level (if applicable)	Excel	nnnnAMa.XLS nnnnAMb.XLSX
Draft approval labels	DL followed by revision level (if applicable)	Excel	nnnnnDLa.XLS nnnnDLb.XLSX
Quality Assurance (QA) Manual	QM followed by revision level (if applicable)	Adobe Acrobat Scanned file Excel Microsoft Word	nnnnQMa.PDF nnnnQMb.TIF nnnnQMc.XLS nnnnQMd.XLSX nnnnQMe.DOC nnnnQMf.DOCX Plus one signed paper copy (a-f indicate various revision levels)
Product Quality Control Plan (PQP)	PQP followed by revision level (if applicable)	Adobe Acrobat Scanned file AutoCAD Excel Microsoft Word	nnnnPQP.PDF nnnnPQP.TIF nnnnPQP.DWG nnnnPQP.XLS nnnnPQP.XLSX nnnnPQP.DOC nnnnPQP.DOCX
Fees	-	Paper or PAY.GOV only	Paper or PAY.GOV only
Service Life Plan	SLP followed by revision level (if applicable)	Adobe Acrobat Scanned file Excel Microsoft Word	nnnnSLP.PDF nnnnSLP.TIF nnnnSLP.JPG nnnnSLP.BMP nnnnSLP.PNG nnnnSLP.XLS nnnnSLP.XLSX nnnnSLP.DOC nnnnSLP.DOCX
User Instructions	UI followed by revision level (if applicable)	Adobe Acrobat Scanned file Microsoft Word	nnnnUIa.PDF nnnnUIb.TIF nnnnUIc.DOC nnnnUId.DOCX (a-d indicate various revision levels)

- If “zipped” files are submitted, provide the individual filename, description, and program for each working file contained in the zipped file.
- If there is more than one User Instruction or assembly matrix, list them in the assembly matrix by name.
- If NIOSH has requested replacement files, give the replacement files the same name as the original files.
- Send replacement files only at the request of NIOSH, and send them directly to the NIOSH employee requesting the files. The requestor is responsible for having the corrected files posted to your project.
- NIOSH will only accept replacement or new files that have been requested by NIOSH.
- NIOSH will only accept single documents under a single file name. Multiple documents under a single file name will not be accepted and the application may be denied.

Section 4 Approvals and Denials

4.1 Approval Documentation

If the respirator complies with all of the requirements outlined in these procedures and 42 CFR 84, NIOSH will grant an approval and assign a TC number.

All submitted documentation and supporting test data will become part of the approval record. Applicants may use consultants or authorized representatives as contacts for the application. Foreign companies may provide a U.S. contact as a consultant or authorized representative. These contacts may submit applications either by request of the company's primary contact or in place of the company primary contact. NIOSH will send a letter to the applicant's primary contact stating the nature of the approval and will return final approval label files, if applicable, with the appropriate approval documentation. For applicants using consultants or authorized representatives, the final letter of approval and enclosed documentation will be sent directly to the applicant with a copy of the approval letter to the consultant or authorized representative. All approval documentation and application discussions will be done through the company's primary contact.

When application approval labels and assembly matrices contain rows of information for approvals other than the ones evaluated in the individual application under review, approval letters will indicate that only the approvals indicated (or marked or requested) under the individual application are granted.

4.2 Denial Documentation

If the respirator fails to meet the requirements of 42 CFR Part 84, the application will be denied and all documentation, CD-Rs or DVD-Rs, and sample hardware will be returned or destroyed. NIOSH will not retain documentation or sample hardware for any respirator that has failed to meet all of the requirements. If NIOSH denies an application based upon documentation issues, the application, CD-Rs or DVD-Rs, and all sample hardware will be returned to the applicant's U.S. or Canadian address or authorized representative. It is recommended that foreign applicants 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.

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

4.3 Denial Prior to Assignment of a Task Number

Some of the reasons applications will not be accepted and will be denied prior to issuance of a TN include:

- An application is assigned a previously used AAR#.
- A major section of the application such as the assembly matrix, QA Manual, PQP, approval labels, pretest data, User Instructions, or drawing package is missing, is in an unacceptable file format, or uses an unacceptable file naming convention.

- Sample hardware, application package, and payment are not received within two weeks of one another.
- Shipping boxes contain sample hardware associated with different applications and without separate packaging to indicate what sample hardware goes with each application.
- 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).
- The respirator is for underground mine use and has electrical components, but has not received MSHA intrinsic safety approval or the MSHA approval document has not been included with the application.
- A complete file list is not included in the related documents section of the application.

4.4 Denial of a Project Undergoing NIOSH Evaluation

Some of the reasons why applications may be denied after issuance of a TN include:

- Assembly matrix, exploded-view drawing, approval labels, or major subassembly drawings are incorrect (content or format) or show unapproved assemblies.
- Pre-submission test data is not complete. For example, it does not include total resistance on the complete assembly or all assemblies involved in the submittal(s).
- Sample hardware submitted does not match subassembly drawings, part numbers, or the assembly matrix drawing.
- Drawings are not in accordance with the documentation control procedures stated in the applicant's Quality Assurance Manual.
- Additional information requested by NIOSH is not received within two weeks of the date requested.
- The application is for a new or unique respirator which cannot be approved under current regulations for which there is no existing NIOSH policy (e.g. a PAPR in combination with an SCBA, PAPR in combination with an APR).
- Applicant's pre-submission test data indicates that the respirator would fail the NIOSH regulatory test requirements or the appropriate pretest data is not submitted with the application.
- The official submission either (1) requested approval of two respirators of different basic designs (includes submitting a filter media and alternate in the same application) or (2) requested a New Approval and an Extension of Approval in the same application.
- The Standard Application Form (SAF) has errors, deficiencies, or is incorrect.
- Items on the assembly matrix do not correspond exactly to the "Reason for Application," drawing revision levels are wrong, components on the exploded-view drawing are improperly numbered or documents are otherwise incorrect.
- Protection or intended use claims have not been requested or approval has not been obtained from other governing agencies (such as MSHA for mine use (along with MSHA intrinsic safety) or intrinsic safety from recognized laboratories.)
- QA documentation does not have sufficient inspections identified, is missing required inspection steps, or inspections identified are not sufficient to meet the NIOSH requirements.
- The Quality Assurance Application includes other documents, such as a PQP or inspection procedures, in addition to or instead of the Quality Assurance Manual.

4.5 Respirator Certification (Approval) Program Decision Review Process

NIOSH NPPTL has a structured Decision Review Process that enables applicants to request a review of decisions regarding NIOSH NPPTL policy statements, test procedures, and test results pertaining to ongoing respirator approval activities.

Section 5 Powered Air-Purifying and CBRN Powered Air-Purifying Respirator Test Selection Guide

Item	Respirator Type	*NIOSH Test #	Title	Total Materials Needed
6	PAPR with particulate and/or chemical cartridge or canister Powered air-purifying	TEB-APR-STP-0001	Determination of Particulate Filter Penetration (PAPR)	3 complete respirator assemblies with components for assembling the highest and lowest resistance combinations 3 exhalation valve assemblies 3 sets OV cartridges 10 filters or filter/cartridge combinations plus 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.
		TEB-APR-STP-0003	Determination of Exhalation Resistance	
		TEB-APR-STP-0004	Determination of Exhalation Valve Leakage	
		TEB-APR-STP-0005, 0005a, and 0006	Determination of Qualitative Isoamyl Acetate Facepiece Fit Test	
		TEB-APR-STP-0007	Determination of Inhalation Resistance	
		RCT-APR-STP-0012	Determination of Airflow For Powered Air-Purifying Respirators	
		RCT-APR-STP-0014	Determination of Leakage of Drinking Tube and Accessories for Respirator Facepieces	
		RCT-APR-STP-0025	Determination of Silica Dust Loading Test for Powered Air-Purifying Respirator Filters	
		RCT-APR-STP-0030	Determination of Noise Level Test, Powered Air-Purifying Respirator with Hoods or Helmets	
		TEB-APR-STP-0033A	Determination of Ammonia Service Life Test, Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0033B	Determination of Ammonia Service Life Test, Air-Purifying Respirators with Canisters	
		TEB-APR-STP-0033C	Determination of Ammonia Service Life Test, Powered Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0033D	Determination of Ammonia Service Life Test, Tight-Fitting Powered Air-Purifying Respirators with Gas Mask Canister(s)	
		RCT-APR-STP-0034	Carbon Monoxide Service Life	
		RCT-APR-STP-0035	Determination of Chlorine Service Life	
		RCT-APR-STP-0036	Determination of Chlorine Dioxide Service Life	
		RCT-APR-STP-0037	Determination of a-Chloroacetophenone (CN) Service Life	
		RCT-APR-STP-0038	Determination of Ethylene Oxide Service Life	
		TEB-APR-STP-0039A	Determination of Formaldehyde Service Life Test, Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0039B	Determination of Formaldehyde Service Life Test, Air-Purifying Respirators with Canisters	

		TEB-APR-STP-0039C	Determination of Formaldehyde Service Life Test, Powered Air-Purifying Respirators with Cartridges	
		RCT-APR-STP-0040	Determination of Hydrogen Chloride Service Life	
		RCT-APR-STP-0041	Determination of Hydrogen Cyanide Service Life	
		RCT-APR-STP-0042	Determination of Hydrogen Fluoride Service Life	
		TEB-APR-STP-0043A	Determination of Hydrogen Sulfide Service Life Test, Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0043B	Determination of Hydrogen Sulfide Service Life Test, Air-Purifying Respirators with Canisters	
		TEB-APR-STP-0043C	Determination of Hydrogen Sulfide Service Life Test, Powered Air-Purifying Respirators with Cartridges	
		RCT-APR-STP-0044	Determination of Mercury Vapor Service Life	
		TEB-APR-STP-0045A	Determination of Methylamine Service Life Test, Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0045B	Determination of Methylamine Service Life Test, Air-Purifying Respirators with Canisters	
		TEB-APR-STP-0045C	Determination of Methylamine Service Life Test, Powered Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0045D	Determination of Methylamine Service Life Test, Tight-Fitting Powered Air-Purifying Respirators with Gas Mask Canister(s)	
		TEB-APR-STP-0046A	Determination of Organic Vapor (Carbon Tetrachloride) Service Life Test, Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0046B	Determination of Organic Vapor (Carbon Tetrachloride) Service Life Test, Air-Purifying Respirators with Canisters	
		TEB-APR-STP-0046C	Determination of Organic Vapor (Carbon Tetrachloride) Service Life Test, Powered Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0046D	Determination of Organic Vapor (Carbon Tetrachloride) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators with Gas Mask Canister(s)	
		RCT-APR-STP-0047	Determination of Phosphine Service Life	

		TEB-APR-STP-0048A	Determination of Sulfur Dioxide Service Life Test, Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0048B	Determination of Sulfur Dioxide Service Life Test, Air-Purifying Respirators with Canisters	
		TEB-APR-STP-0048C	Determination of Sulfur Dioxide Service Life Test, Powered Air-Purifying Respirators with Cartridges	
		TEB-APR-STP-0048D	Determination of Sulfur Dioxide Service Life Test, Tight-Fitting Powered Air-Purifying Respirators with Gas Mask Canisters	
		RCT-APR-STP-0050	Determination of O-Chlorobenzylidene Malononitrile (CS) Service Life	
		RCT-APR-STP-0060	Determination of End-of-Service-Life Indicator Drop	
		RCT-APR-STP-0061	Determination of End-of-Service-Life Indicator Visibility	
		RCT-APR-STP-0062	Determination of Nitrogen Dioxide Service Life	
		RCT-APR-STP-0063	Determination of Facepiece Carbon Dioxide and Oxygen Concentration Levels - Tight Fitting, Powered Air-Purifying Respirators, With the Blower Unit Running	
		RCT-APR-STP-0064	Determination of Facepiece Carbon Dioxide and Oxygen Concentration Levels - Tight-Fitting, Powered Air-Purifying Respirators, with the Blower Unit Off	
		RCT-APR-STP-0065	Determination of Airflow Resistance - Breath-Responsive, Powered Air-Purifying Respirators	
		RCT-APR-STP-0066	Determination of End-of-Service-Life Indicator (ESLI)	
		Note: ESLI tested where used.		
		* Actual tests selected may vary depending on design and intended use.		
Item	**Respirator Type**	***NIOSH Test #**	**Title**	**Total Materials Needed**
21	CBRN PAPRs	TEB-APR-STP-0001	Determination of Particulate Filter Penetration (PAPR)	4 complete respirators for live agent testing qualifying 6 complete respirators for live agent testing remaining after environmental conditioning 4 power adapters for live agent testing qualifying (QLAT) 6 Power adapters for live agent testing remaining (RLAT) 102 canisters (tight-fitting) or cartridges (loose-fitting) 49 complete respirators for bench testing loose-fitting 43 complete respirators for bench testing tight-fitting
		TEB-APR-STP-0003	Determination of Exhalation Resistance	
		TEB-APR-STP-0004	Determination of Exhalation Valve Leakage	
		TEB-APR-STP-0005, 0005a, and 0006	Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit Test	
		TEB-APR-STP-0007	Determination of Inhalation Resistance	
		RCT-APR-STP-0012	Determination of Airflow For Powered Air-Purifying Respirators	

		RCT-APR-STP-0014	Determination of Leakage of Drinking Tube and Accessories for Respirator Facepieces	
		RCT-APR-STP-0025	Determination of Silica Dust Loading Test for Powered Air-Purifying Respirator Filters	
		RCT-APR-STP-0064	Determination of Facepiece Carbon Dioxide and Oxygen Concentration Levels - Tight-Fitting, Powered Air-Purifying Respirators, with the Blower Unit Off	
		CET-APRS-STP-CBRN-0311	Laboratory Durability Conditioning Process for Environmental, Transportation and Rough Handling Use Conditions on Chemical, Biological, Radiological, and Nuclear (CBRN) Respiratory Protective Devices (RPD) Standard Conditioning Procedure (SCP)	
		CET-APRS-STP-CBRN-0312	Determination of Field of View for Full Facepiece Chemical, Biological, Radiological, and Nuclear (CBRN) Respiratory Protective Devices (RPD)	
		TEB-CBRN-APR-STP-0313	Determination of Communication Performance Test for Speech Conveyance and Intelligibility of Chemical, Biological, Radiological, and Nuclear (CBRN) Full Facepiece Air-Purifying Respirator	
		CET-APRS-STP-CBRN-0314	Determination of Lens Fogging on Full Facepiece Chemical, Biological, Radiological, and Nuclear (CBRN) Air-Purifying Respirator	
		TEB-CBRN-STP-0501	Determination of CBRN Organic Vapor (Cyclohexane) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0502	Determination of CBRN Acid Gases (Cyanogen Chloride) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0503	Determination of CBRN Acid Gases (Hydrogen Cyanide) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0504	Determination of CBRN Acid Gases (Phosgene) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 canisters)	

		TEB-CBRN-STP-0505	Determination of CBRN Acid Gases (Hydrogen Sulfide) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0506	Determination of CBRN Acid Gases (Sulfur Dioxide) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0507	Determination of CBRN Base Gases (Ammonia) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0508	Determination of CBRN Nitrogen Oxide Gases (Nitrogen Dioxide) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0509	Determination of CBRN Hydride Gases (Phosphine) Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-CBRN-STP-0510	Determination of CBRN Formaldehyde Service Life Test, Tight-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0511-CBRN	Determination of CBRN Organic Vapor (Cyclohexane) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0512-CBRN	Determination of CBRN Acid Gases (Cyanogen Chloride) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0513-CBRN	Determination of CBRN Acid Gases (Hydrogen Cyanide) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0514-CBRN	Determination of CBRN Acid Gases (Phosgene) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0515-CBRN	Determination of CBRN Acid Gases (Hydrogen Sulfide) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	

		TEB-APR-STP-0516-CBRN	Determination of CBRN Acid Gases (Sulfur Dioxide) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0517-CBRN	Determination of CBRN Base Gases (Ammonia) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0518-CBRN	Determination of CBRN Nitrogen Oxide Gases (Nitrogen Dioxide) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0519-CBRN	Determination of CBRN Hydride Gases (Phosphine) Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		TEB-APR-STP-0520-CBRN	Determination of CBRN Formaldehyde Service Life Test, Loose-Fitting Powered Air-Purifying Respirators (PAPR) (Set of 9 Canisters)	
		NPPTL-STP-CBRN-PAPR-0550 +	Determination of CBRN Powered Air-Purifying Respirator (PAPR) Performance During Dynamic Testing Against the Chemical Agent Vapor Sarin (GB) Chemical, Biological, Radiological, and Nuclear (CBRN)) GB (SMARTMAN) Qualifier LAT(QLAT) only 1 +	
		NPPTL-STP-CBRN-PAPR-0550 +	Determination of CBRN Powered Air-Purifying Respirator (PAPR) Performance During Dynamic Testing Against the Chemical Agent Vapor Sarin (GB) Chemical, Biological, Radiological, and Nuclear (CBRN) GB (SMARTMAN) Remainder LAT (RLAT) 2 trials +	
		NPPTL-STP-CBRN-PAPR-0551 +	Determination of CBRN, Powered Air-Purifying Respirator (PAPR) Performance During Dynamic Testing Against Chemical Agent Distilled Sulfur Mustard (HD) Vapor and Distilled Sulfur Mustard (HD) Liquid Chemical, Biological, Radiological, and Nuclear (CBRN) HD (SMARTMAN) QLAT only1 +	

		NPPTL-STP-CBRN-PAPR-0551 +	Determination of CBRN, Powered Air-Purifying Respirator (PAPR) Performance During Dynamic Testing Against Chemical Agent Distilled Sulfur Mustard (HD) Vapor and Distilled Sulfur Mustard (HD) Liquid Chemical, Biological, Radiological, and Nuclear (CBRN) HD (SMARTMAN) RLAT only 2 trials +	
		TEB-CBRN-APR-STP-0552	Determination of Laboratory Respirator Protection Level (LRPL) Values for CBRN Tight-Fitting Powered Air-Purifying Respirator (PAPR)	
		TEB-CBRN-APR-STP-0553	Determination of Laboratory Respiratory Protection Level (LRPL) Values for CBRN Loose-Fitting Powered Air-Purifying Respirator (PAPR)	
		+Tests performed at RDECOM		
		* Actual tests selected may vary depending on design and intended use.		

Note: All test procedures are located on the NIOSH NPPTL website: https://www.cdc.gov/niosh/npptl/stps/respirator_testing.html

Section 6 Powered Air-Purifying Respirator and CBRN Powered Air-Purifying Respirator Checklists

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

6.1 NIOSH Respirator Application Checklist

1. _____ The AAR# is unique to the application.
2. _____ All the applicable sections of the SAF are complete.
3. _____ The "Reason for Application" accurately reflects why the application is being submitted (e.g., New Approval, Extension of Approval, Quality Assurance Approval, Correlation Testing Only, Resubmission of New Approval, Resubmission of Extension of Approval, or Amended Application).
4. _____ The NIOSH TN where this (these) respirator(s) were last tested has been identified.
5. _____ All the files included with the application are listed in the SAF.
6. _____ All the files supplied are in the acceptable file formats.
7. _____ All the files are properly identified/listed in the SAF.

Test Samples (Hardware)

8. _____ Shipped under a separate cover.
9. _____ The individual test samples (hardware) for evaluation are identified with the AAR# and part numbers as listed on the assembly matrix.
10. _____ The individual test samples (hardware) for evaluation are referenced on the assembly matrix.
11. _____ The shipping container/box is marked with the associated AAR# and/or TN.
12. _____ The testing samples (hardware) package includes a packing slip identifying the items and quantity(ies) shipped.

Fees

13. _____ The application fee check or electronic funds transfer (Pay.Gov) receipt for $200 is included.
14. _____ The fee check is dated less than 30 days before the submission date of the application.
15. _____ The check is payable to NIOSH.
16. _____ The check includes the EIN, if a U.S. company or subsidiary.
17. _____ The check includes the AAR#.

Assembly Matrix

18. _____ The assembly matrix matches what is listed in the "Reason for Application" section of the SAF.
19. _____ The assembly matrix and SAF represent the actual configuration of the new or modified approval. All applications, except QA Applications, require an assembly matrix.

20. _____ The “Reason for Application” accurately reflects what is being requested (e.g., New Approval, Extension of Approval, Quality Assurance Approval, Correlation Testing Only, Resubmission of New Approval, Resubmission of Extension of Approval, or Amended Application).
21. _____ R’s are placed in the boxes that are associated with any change to the referenced components, including drawings, PQP’s, inspection procedures, or any other documents.

Drawings

22. _____ The necessary new or revised drawings are included in the application documents.
23. _____ The revision levels on all drawings match those listed on the assembly matrix.
24. _____ Item numbers on the exploded-view drawing match the item numbers on the assembly matrix.
25. _____ All required information is present on the Powered Air-Purifying Respirator drawings, as indicated on the appropriate checklists.

Labels

26. _____ All applicable draft approval labels are included with the application (respirator, along with other labels as required).
27. _____ The assemblies identified on the label match those identified on the matrix (or matrices) with the possible exception of accessories and User Instructions.
28. _____ The abbreviated labels, primary company, and private label company, if applicable, are listed and shown on page two of the applicable drawings.
29. _____ All the part numbers on the approval labels match the part numbers listed in the assembly matrix.

Cautions and Limitations

30. _____ All appropriate cautions and limitations statements are identified on the individual approvals.
31. _____ All cautions and limitations statements referred to on the approvals are stated on the label(s).

User Instructions

32. _____ The User Instructions include all the required information e.g., OSHA 1910.134 statement on fit testing, donning instructions, assembly instructions, additional warnings and cautions, private label statement (as required), name and contact information of the appropriate company.

Final Review of Application Documents

33. _____ All documents have been verified for the correct revision numbers and the revision levels match what is listed in version 8 of the SAF.
34. _____ Pre-submission testing indicating that all performance requirements specified in 42 CFR Part 84 is provided in the application and is complete.

6.2 Exploded-View Drawing Checklist for a PAPR and a CBRN PAPR

1. _____ Drawing contains all major subassemblies and accessories that appear on the assembly matrix (except the User Instructions).
2. _____ Parts that are obsolete from the matrix should not appear on the exploded-view drawing.
3. _____ The reference numbering on the exploded-view drawing matches the reference numbering on the assembly matrix. All matrix assemblies are represented on the exploded-view drawing and there are no extra assemblies on the exploded-view drawing. For every reference number on the drawing there is a corresponding number on the matrix, and vice versa.
4. _____ The drawing is properly titled, signed/initialed, numbered, dated, and contains a revision level.
5. _____ There are no reference dimensions on the drawing.

6.3 All Major Subassemblies for a PAPR and CBRN PAPR

1. _____ Numbered, titled, signed/initialed by an authorized representative, with an effective date and revision level.
2. _____ Dimensions: length, width, or diameter, as applicable are referenced.
3. _____ Material specifications or vendor part number is listed.
4. _____ Part number location is listed.
5. _____ Serial number location, if applicable, is listed.
6. _____ Critical and major characteristics must be identified on the drawing or on a separate document.
7. _____ Inspection procedures or classification of defects are identified on the drawing or in additional documentation provided with the drawing.
8. _____ Expiration date is indicated, if applicable.

6.4 Specific Components Checklist for a Powered Air-Purifying Respirator and a CBRN Powered Air-Purifying Respirator Respiratory Inlet Covering (Half-Mask, Full Facepiece, Hood, Helmet)

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

Filter

1. _____ Material specifications for filter media are listed.
2. _____ Lot number location and code, or date of manufacture is listed.
3. _____ Filter efficiency, including applicable nuisance protections is listed.
4. _____ Final filter media form is identifiable (pleated, flat, etc.) is listed.
5. _____ Filtering mechanism is listed (electrostatic, mechanical or other).
6. _____ Filters containing carbon layers include statement that carbon is chromium free.
7. _____ Vendor for filter material is listed (only if the filter material specification is not determined by the respirator manufacturer).
8. _____ HE filter labels are either magenta or purple; the abbreviated label color needs to be identified on the drawing.

Cartridge or Canister

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

Blower

1. _____ Lot number location and code, or date of manufacture is listed.
2. _____ Intrinsic safety certification is listed (as designed).

Battery

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

6.5 Private Label Checklist for a Powered Air-Purifying Respirator and a CBRN Powered Air-Purifying Respirator Checklist

1. _____ An assembly matrix showing private label version under current approval (TC) number is included.
2. _____ If private label PAPR is a different model/part number than primary approval holder's number, part number and description are in a new separate column on the matrix.
3. _____ If the private label is the same model/part number as the primary approval holder's model/part number, the approval holder name and private label company name are in the description column of the primary Powered Air-Purifying Respirator model/part number.
4. _____ The private label abbreviated label is included on page two of the applicable drawing.
    - A. _____ Abbreviated label must appear on the PAPR filter or cartridge only and include the following items:
        - a. Private label company name.
        - b. NIOSH is printed in block letters.
        - c. Appropriate approval (TC) number (for 14G canisters only).
        - d. Protection, (HE, CL, HC, etc.).
        - e. Model or part number.
        - f. The lot or date code is included on label or packaging.
    - B. _____ A draft of the full private label approval label is included and includes cautions and limitations special "S."
    - C. _____ Private label User Instructions are included.
    - D. _____ "S" Special User Instructions section is required with the statement: Model nnnn Powered Air-Purifying Respirator has been manufactured by approval holder xxx for private label company yyyy under TC-23C-nnnn.
    - E. _____ Contact information and a contact person must be identified either in the application or on a separate sheet.

6.6 Assembly Matrix Checklist for a Powered Air-Purifying Respirators and a CBRN Powered Air-Purifying Respirators

This checklist corresponds to the Example Assembly Matrix in Section 7.3

1. _____ The title of the document is indicated on the top of the page.
2. _____ The assembly matrix has the following information in the top right corner of the page:
    a. Title.
    b. Applicant's name and address.
3. _____ The following is indicated below the key box:
    a. Date.
    b. Revision level, if applicable.
4. _____ New drawings submitted with the application or the drawing revision level reflects the current revision level on file at NIOSH. If the drawing has changed from what is currently on file at NIOSH, the altered drawing needs submitted with the appropriate revision level noted. If the drawing is within another application at NIOSH, this information must be identified in the "Reason for Application" section.
5. _____ The numbering system used for assemblies shown on the matrix and exploded-view drawing match.
6. _____ The part number marked on the component must appear in the part number row (model numbers optional).
7. _____ Features that describe the respirator are not listed as a separate column on the matrix. Features associated with specific model numbers may be coupled together in the description (e.g., Model 1201 with Nuisance OV).
8. _____ Top row **(A)** must be a general category, i.e., facepiece, etc. Accessories must be included. "Alternate" will be in the column heading if there are more than one of the same assemblies.
9. _____ The NIOSH TN **(B)** where the component was last tested is listed in the bottom row. If new, indicate N.
10. _____ The AAR# **(C)** appears in the first column from the left.
11. _____ The TC number **(D)** appears in the second column from left.
    a. A new TC number is listed in the proper format: schedule# and AAR# followed by an alpha character.
    b. List "TC-" only in the category heading.
12. _____ The list of protections **(E)** appears in the third column from left.
    a. Verify the list matches the protections listed in the SAF. See the complete list of protections and cautions and limitations.
13. _____ The key box **(F)** must use only the characters X, N, P, R, -, or A.
14. _____ TN/AAR# of the previously approved/pending matrix **(G)** is noted above the right-hand side of the table.
15. _____ Current exploded-view drawing number **(H)** and revision is located directly below the TN/AAR# of the previously approved/pending matrix.
16. _____ A column for the part number/revision level of the User Instructions must be used.
17. _____ Flow indicator is listed for PAPR.

Section 7 - Document Examples for a Powered Air-Purifying Respirator and a CBRN Powered Air-Purifying Respirator

7.1 a Example of a Product Quality Control Plan for a PAPR (non-CBRN)

Double Wing Manufacturing, Pittsburgh, PA **Product Quality Plan (PQP)**

DWPA Powered Air-Purifying Respirator **Revision A, Date: 10/18/2016**

Item	Description	Inspection	Class	Location	AQL	Test Method	Recorded Results
1	Full Facepiece	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
		Facepiece Leak Test	Major A	Assembly Station	100%	TP-00LT	
		Valve Leak Test	Major B	Assembly Station	2.5%	TP-00VL	
2	Breathing Tube	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
		Flow Test	Minor	Assembly Station	4%	TP-00BT	
3	Blower	Flow Test	Major A	Assembly Station	100%	TP-00FC	Assembly Station
4	Battery and Charger	Assembly Correct	Major A	Assembly Station	1%	Visual	Assembly Station
		Charging Test	Major B	Assembly Station	2.5%	TP-00CT	
		Capacity Test	Major B	Assembly Station	2.5%	TP-00CAT	
5	Belt	Assembly Correct	Minor	Incoming Inspection	4%	Visual	Purchasing
6	Filter	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
		Filter Efficiency	Major A	Assembly Station	1%	TP-00DOP	Testing Station
		Silica Dust Test	Audit, destructive	Outside Lab	3 Units every 6 months,	TP-00SDT	QA
7	Cartridge	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
		Service Time	Major A, destructive	QC Lab	1%	TP-00OV	QC Lab
8	Flow Tube	Flow Measurement Correct	Major B	QC Lab	2.5%	TP-00FT	QC Lab
8	Accessory, Spectacle Kit	Assembly Correct	Minor	Incoming Inspection	4%	Visual	Incoming Inspection

7.1 b Example of a Product Quality Control Plan for a CBRN Powered Air-Purifying Respirator

Double Wing Manufacturing, Pittsburgh, PA **Product Quality Plan (PQP)**

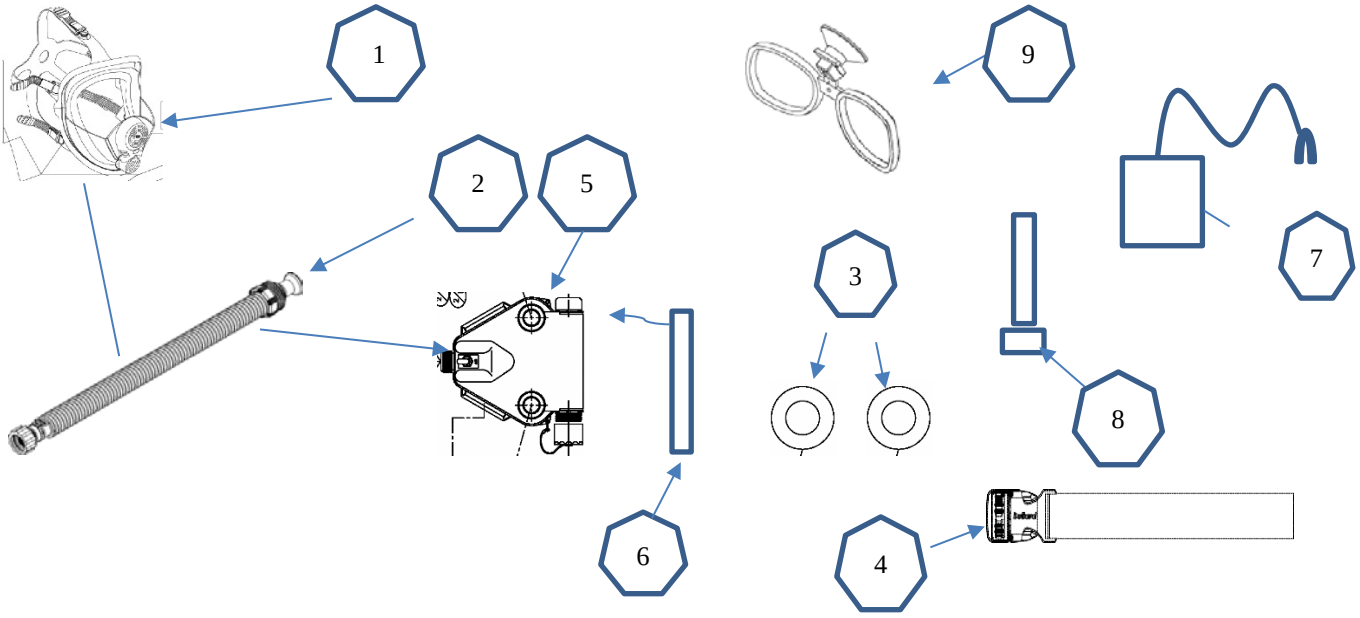
DWPA Powered Air-Purifying Respirator or CBRN PAPR **Revision A, Date: 10/18/2016**

Item	Description	Inspection	Class	Location	AQL	Test Method	Recorded Results
1	Full Facepiece	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
		Facepiece Leak Test	Major A	Assembly Station	100%	TP-00LT	
		Valve Leak Test	Major B	Assembly Station	2.5%	TP-00VL	
2	Breathing Tube	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
		Flow Test	Minor	Assembly Station	4%	TP-00BT	
3	Blower	Flow Test	Major A	Assembly Station	100%	TP-00FC	Assembly Station
4	Battery and Charger	Assembly Correct	Major A	Assembly Station	1%	Visual	Assembly Station
		Charging Test	Major B	Assembly Station	2.5%	TP-00CT	
		Capacity Test	Major B	Assembly Station	2.5%	TP-00CAT	
5	Belt	Assembly Correct	Minor	Incoming Inspection	4%	Visual	Purchasing
6	Filter	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
		Filter Efficiency	Major A	Assembly Station	1%	TP-00DOP	Testing Station
		Silica Dust Test	Audit, destructive	Outside Lab	3 Units every 6 months,	TP-00SDT	QA
7	Cartridge or Canister	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
	CBRN Only Cartridge or Canister	Service Time	Major A, destructive	QC Lab	1%	TP-00OV	QC Lab
8	Flow Tube	Flow Measurement Correct	Major B	QC Lab	2.5%	TP-00FT	QC Lab
8	Accessory, Spectacle Kit	Assembly Correct	Minor	Incoming Inspection	4%	Visual	Incoming Inspection

7.2 Example of an Exploded-View Drawing for a Powered Air-Purifying Respirator or a CBRN PAPR

Item	Description	Part Number
1	Full Facepiece	1000
2	Breathing Tube	943XX
3	Cartridge/Filter	1001
4	Belt	567BT
5	Blower	987BL
Item	**Description**	**Part Number**
6	Battery	321BAT
7	Charger	543CH
8	Flow Tube	765FT
9	Accessory, Spectacle Kit	678AS
*	User Instructions	100UI

Approved	Double Wing Manufacturing, Pittsburgh, PA		
Drawing: DWW 10/18/2016	Part Number:	Title: DWPR PAPR Exploded-View	
Release: DDW 10/18/2016	Scale: NTS	Revision: 0	Drawing Number LWM001PR



7.3 a Example of an Assembly Matrix for a Powered Air-Purifying Respirator (Non-CBRN)

Key: **(F)**
X = currently approved in this configuration
N = new component of configuration
"-" = obsolete
R = redesign or revision
P = pending
A = Accessory

Double Wing Manufacturing
123 Manufacture Lane
Pittsburgh PA 15236, USA
Phone: 412 555 1212

(G) TN or AAR# of previously approved or pending matrix: N/A
N/A see exploded-view drawing for each respirator configuration
(H) Exploded-view drawing number: DWM001PR

Date: March 20, 2018

(A)			**Item**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**x**
			Component	**Facepiece**	**Breathing Tube**	**Canister**	**Belt**	**Blower**	**Battery**	**Charger**	**Flow Tube**	**Accessories**	**Instructions**
			Description	Full Facepiece Piece	Standard Breathing Tube	Canister in Packaging	Standard Belt	Motor Blower	Rechargeable Battery	Standard Charger	Flow Tube	Kit	Instructions
			Revision	1	0	0	0	1	0	1	1	1	10
			Drawing Number	FPP 1011	BT002	OVC 001	BLT005	BLW 4000	UBAT1	CH 0003	FR001	SPK001	N/A
Applicant-Assigned Approval Number **(C)**	NIOSH Approval Number TC **(D)**	Protection 1 **(E)**	Model / Part Number	1000	943XX	1991	567BT	987BL	321BAT	543Ch	965FT	678AS	100U1
LMW-OOPR	14G-100	CL/ HC/ OV/ HE		N	N	N	N	N	N	N	N	N	N
NIOSH task number where component was last tested. If new, indicate as "N"			**(B)**	10101	N	N	10101	N	N	N	10101	10101	N

7.3 b Example of an Assembly Matrix for a CBRN Powered Air-Purifying Respirator

Key: **(F)**
X = currently approved in this configuration
N = new component of configuration
"-" = obsolete
R = redesign or revision
P = pending
A = Accessory

Double Wing Manufacturing
123 Manufacture Lane
Pittsburgh PA 15236, USA
Phone: 412 555 1212

(G) TN or AAR# of previously approved or pending matrix: N/A
N/A see exploded-view drawing for each respirator configuration

(H) Exploded-view drawing number: LWM001PR

Date: March 20, 2018

(A)			Item	1	2	3	4	5	6	7	8	9	x
			Component	**Facepiece**	**Breathing Tube**	**Canister**	**Belt**	**Blower**	**Battery**	**Charger**	**Flow Tube**	**Kit**	**Instructions**
			Description	Full Facepiece	Standard Breathing Tube	Canister in Packaging	Belt	Motor Blower	Rechargeable Battery	Standard Charger	Flow Tube	Kit	CBRN User Instructions
			Revision	1	0	0	0	1	0	1	1	1	10
			Drawing Number	FPP 1011	BT002	OVC 001	BLT005	BLW 4000	UBAT1	CH 0003	FR001	SPK001	N/A
Applicant-Assigned Approval Number **(C)**	NIOSH Approval Number TC **(D)**	Protection 1 **(E)**	Model / Part Number	1000	943XX	1991	567BT	987BL	321BAT	543Ch	965FT	678AS	100U1
LMW-OOPR	14G-200	CBRN PAPR CAP 1		N	N	N	N	N	N	N	N	N	N
NIOSH task number where component was last tested. If new, indicate as "N"			**(B)**	10101	N	N	10101	N	N	N	10101	10101	N

7.4 a Example of an Approval Label for a Full Facepiece Powered Air-Purifying Respirator (Non-CBRN)

Double Wing Manufacturing Company
456 John Denver Way
Almost Heaven WV 26303, USA
1-800-123-4567
DWPR PAPR

This respirator is approved only in the following configurations:

TC	Protection 1	Cartridge Filter	Alternate Facepiece			Alternate Breathing Tubes			Blower	Battery	Belt	Cautions and Limitations[2]
		1001	1000	2000	3000	94325	94350	943100	3021	3022	3025	
23C-AARa	OV/HE	X	x			x			x	x	x	A B C F H I J L M N O P
23C-AARb	OV/HE	X		x		x	x		x	x	x	A B C F H I J M N O P
23C-AARd	OV/HE	X			x	x	x	x	x	x	x	A B C F H I J L M N O P S

1 **PROTECTION**

HE - High-efficiency particulate filter for Powered Air-Purifying Respirators
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.
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.
H Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
I Contains electrical parts that may cause an ignition in flammable or explosive atmospheres.
J Failure to properly use and maintain this product could result in injury or death.
L Follow the manufacturer User Instructions for changing cartridges, canister and/or filters.
M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

P NIOSH does not evaluate respirators for use as surgical masks.

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

7.4 b Example of an Approval Label for a Full Facepiece CBRN Powered Air-Purifying Respirator

Double Wing Manufacturing Company
456 John Denver Way
Almost Heaven WV 26303, USA
1-800-123-4567
DWPR PAPR

This respirator is approved only in the following configurations:

TC-	Protection 1	Canister in packaging	Alternate Facepiece			Alternate Breathing Tubes			Blower	Battery	Belt	Cautions and Limitations[2,3]
		1001	1000	2000	3000	94325	94350	943100	3021	3022	3025	
14G-AARa	CBRN PAPR Cap 1	x	x			x			x	x	x	A F H I J L M N ORSYZ BB CC GG UU VV
14G-AARb	CBRN PAPR Cap 1	x		x		x	x		x	x	x	A F H I J L M N ORSYZ BB CC GG UU VV
14G-AARd	CBRN PAPR Cap 1	x			X	x	x	x	x	x	x	A F H I J L M N ORSYZ BB CC GG UU VV

1 PROTECTION

CBRN - Chemical, Biological, Radiological and Nuclear
PAPR Cap 1 - Capacity meets minimum 15 minute test time

2 CAUTIONS and LIMITATIONS

A Not for use in atmospheres containing less than 19.5 percent oxygen.

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.

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

I Contains electrical parts that may cause an ignition in flammable or explosive atmospheres.

J Failure to properly use and maintain this product could result in injury or death.

L Follow the manufacturer User Instructions for changing cartridges, canister and/or filters.

M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.

N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.

O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

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

BB Not for use for entry into atmospheres immediately dangerous to life or health.

CC For entry, do not exceed maximum use concentrations established by regulatory standards.

3 CBRN CAUTIONS and LIMITATIONS

R Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.

Y The respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.

Z If during use, an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air.

GG Direct contact with CBRN agents requires proper handling of the respirator after use. Correct disposal procedures must be followed.

UU The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours.

VV PAPRS with TC-23C approvals may NOT be used for escape from IDLH atmospheres.

7.5 Example of an Approval Label for a Powered Air-Purifying Respirator Filter

Double Wing Manufacturing Company
456 John Denver Way
Almost Heaven WV 26303 USA
1-800-123-4567
Halo Filter

This filter is approved only in the following configurations:

TC Number	Protection 1	HE Filter	Alternate Facepiece			Alternate Breathing Tube			Cartridge	Blower	Battery	Belt	Cautions and Limitations 2
		HALO	1000	2000	3000	94325	94350	94351	1001	3021	3022	3025	
23C-300	OV/HE	x	x	x		x	x	x	x	x	x	x	A, B, C, H, I, J, M, N, O, P
23C-400	OV/HE	x			X	x	x	x	x	x	x	x	A, B, C, H, I, J, L, M, N, O, P, S

1 **PROTECTION**

HE - High-efficiency particulate filter for Powered Air-Purifying Respirators
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.
H Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
I Contains electrical parts that may cause an ignition in flammable or explosive atmospheres.
J Failure to properly use and maintain this product could result in injury or death.
L Follow the manufacturer User Instructions for changing cartridges, canister and/or filters.
M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P NIOSH does not evaluate respirators for use as surgical masks.
S Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

7.6 Example of an Approval Label for a Powered Air-Purifying Respirator Chemical Cartridge

Double Wing Manufacturing Company
456 John Denver Way
Almost Heaven WV 26303 USA
1-800-123-4567

This cartridge is approved only in the following configurations:

TC Number	Protection 1		Cartridge	Alternate Facepiece			Alternate Breathing Tube			HE Filter	Blower	Battery	Belt	Cautions and Limitations 2
			1001	1000	2000	3000	94325	94350	94351	HALO	3021	3022	3025	
23C-200	OV		x	x			x				x	x	x	A, B, C, F, H, I, J, M, N, O
23C-300	OV/HE		x		x		x			x	x	x	x	A, B, C, F, H, I, J, M, N, O, P
23C-400	OV/HE		x			x	x	x		x	x	x	x	A, B, C, F, H, I, J, L, M, N, O, P, S

1 **PROTECTION**

HE - High-efficiency particulate filter for Powered Air-Purifying Respirators
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.
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.
H Follow established cartridge and canister change schedules or observe ESLI to ensure that cartridges and canisters are replaced before breakthrough occurs.
I Contains electrical parts that may cause an ignition in flammable or explosive atmospheres.
J Failure to properly use and maintain this product could result in injury or death.
L Follow the manufacturer User Instructions for changing cartridges, canister and/or filters.
M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
P NIOSH does not evaluate respirators for use as surgical masks.
S Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

7.7 Example of an Abbreviated Filter Label for a Powered Air-Purifying Respirator

Note: CBRN PAPRs cannot have an abbreviated filter label

Filter Version

Note:
The company name must be completely spelled out or a NIOSH acceptable abbreviation used. Please contact NIOSH for acceptability of abbreviation.
The part number 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. See example on drawing 7.8.
A lot number or other production tracking identifier must be provided on the respirator or container.
The word “NIOSH” must be shown in all capital letters.
All information must be provided in a legible typeface readable by the user.
The HE series of filters must be magenta or purple in color.

7.8 Example of an Abbreviated Cartridge Approval Label for a Powered Air-Purifying Respirator Chemical Cartridge

DOUBLE WING MANUFACTURING

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

Note:
The company name must be completely spelled out.

The part number must be shown.

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

The word "NIOSH" must be listed in capital letters.

A lot number or other production tracking identifier must be provided.

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

Color codes of cartridges for gases and vapors must meet the requirements of ANSI K13.1-1973 or ANSI Z88.7-2001. The applicable specification will be called out on the cartridge drawing.
See January 17, 2008 Letter to All Manufacturers.

7.9 a Example of a Label for a Powered Air-Purifying Respirator Full Facepiece Canister (non CBRN)

Double Wing Manufacturing Company
456 John Denver Way
Almost Heaven WV 26303 USA
1-800-123-4567

List canister part number and trade name
List protections
TC-14G-1234
TC-14G-2345
TC-14G-3456
TC-14G-4567
Refer to the approved User 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.

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.

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 may cause an ignition in flammable or explosive atmospheres.

J Failure to properly use and maintain this product could result in injury or death.

L Follow the manufacturer's instructions for changing cartridges, canister and/or filters.

M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.

N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.

O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

P NIOSH does not evaluate respirators for use as surgical masks.

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

BB Not for use for entry into atmospheres immediately dangerous to life or health.

CC For entry, do not exceed maximum use concentrations established by regulatory standards.

Note: The labels for gas mask respirators and respirators with canisters must appear in their entirety in the User Instructions.

7.9 b Example of a Label for a CBRN Powered Air-Purifying Respirator Full Facepiece Canister

Double Wing Manufacturing Company
456 John Denver Way
Almost Heaven WV 26303 USA
1-800-123-4567

List canister part number and trade name
CBRN PAPR CAP 1

TC-14G-1234
TC-14G-2345
TC-14G-3456
Refer to the approved User 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.

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.

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 may cause an ignition in flammable or explosive atmospheres.

J Failure to properly use and maintain this product could result in injury or death.

L Follow the manufacturer's instructions for changing cartridges, canister and/or filters.

M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.

N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.

O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.

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

BB Not for use for entry into atmospheres immediately dangerous to life or health.

CC For entry, do not exceed maximum use concentrations established by regulatory standards.

CBRN CAUTIONS and LIMITATIONS

R Some CBRN agents may not present immediate effects from exposure, but can result in delayed impairment, illness, or death.

Y The respirator provides respiratory protection against inhalation of radiological and nuclear dust particles. Procedures for monitoring radiation exposure and full radiation protection must be followed.

Z If during use, an unexpected hazard is encountered such as a secondary CBRN device, pockets of entrapped hazard or any unforeseen hazard, immediately leave the area for clean air.

GG Direct contact with CBRN agents requires proper handling of the respirator after use. Correct disposal procedures must be followed.

UU The respirator should not be used beyond eight (8) hours after initial exposure to chemical warfare agents to avoid possibility of agent permeation. If liquid exposure is encountered, the respirator should not be used for more than two (2) hours.

VV PAPRS with TC-23C approvals may NOT be used for escape from IDLH atmospheres.

Note: The labels for gas mask respirators and respirators with canisters must appear in their entirety in the User Instructions.

Section 8 - Label Format Guidance

- Labels for Powred Air-Purifying Respirators and CBRN Air-Purifying Respirators must be completed in the assembly matrix format shown in the preceding examples.
- The TC number is listed in the far left column. For initial submittals, the TC number is the schedule# and AAR# followed by an alpha character, exactly as in the assembly matrix. This links the approval label to the application and assembly matrix. Upon approval, NIOSH will insert the TC number. "TC-" can only appear in the column heading, not in the row.
- Protections are the second column from the left.
- Cautions and limitations are the far right column.
- The component columns must list all of the major subassemblies and accessories and can be in any order that the applicant chooses.
- Anytime more than one of the same subassemblies for a respirator configuration is listed on the approval label, the subassemblies must be identified as alternate components by adding "Alternate" to the column heading. X is the only character that may be used in the body of the approval label to designate an approved component.
- If a component is offered as an accessory, the category must be labeled as "accessory" (e.g., "Accessory Cover").
- Empty rows are not permitted. Approval labels must not be color coded.
- 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 only cautions and limitations A, C, and J apply, then only A, C, and J can be footnoted at the bottom of the label.
- Caution and limitation F only applies to PAPRs.
- The abbreviated label mounted on Powered Air-Purifying Respirators must clearly indicate the approval holder's name, filter series (if a filter is included), gas or vapor protection, part number, lot number, and the acronym "NIOSH" mounted on the cartridge, filter, or cartridge/filter combination.
- The abbreviated label may list either the two letter codes for gases and vapors (see label examples) or the entire chemical name. However, the abbreviated label must not have a mix of codes and names.
- Canister labels must clearly indicate the approval holder's name, address, and phone number, model/trade name, type of protection, TC number, appropriate cautions and limitations, reference to the User Instructions for major subassembly and component information, and the HHS and NIOSH logos. The entire gas mask respirator label must appear in the User Instructions.
- If all respirators on the label are of the same series or family, text may be added to identify the respirator series or family, e.g., LWPA PAPR. This heading is optional on all approval labels.
- Non-NIOSH approval identifiers cannot be represented on any NIOSH labels. Applicants may use additional areas on the component to identify any other applicable approvals such as the European CE approval. However, this information must be separated from the NIOSH approval label.

- If the label will not fit on the container, it must be included inside the container. If the label is inserted, the container must say "NIOSH-Approved - see insert." The insert may consist of the approval label or the User Instructions containing the approval label.
- NIOSH only tests against gases and vapors individually and therefore the applicant assumes the liability for use of the respirators in mixed 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. An applicant may demonstrate to NIOSH that sorbents are effective in exposures to mixed gas and vapor atmospheres or serial exposures to different atmospheres by providing data to NIOSH satisfying the six criteria for mixed gas and vapor atmospheres as listed in the Notice to all Manufacturers, September 24, 1981. When the data has been received, reviewed, and accepted by NIOSH, the approval holder is permitted to state that they endorse the use of the cartridges in mixed gas and vapor atmospheres in the User Instructions or respirator literature. The approval holder may not state 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.
- 'Escape' may be abbreviated in the protection column but must be spelled out in the legend. On abbreviated cartridge labels, *escape* must follow each gas and vapor listed. "Esc" is the only acceptable abbreviation for *escape*.

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-5200
Fax: 412-386-4089

September 24, 2012

LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Sampling Procedures

The National Institute for Occupational Safety and Health (NIOSH) requires that respirator approval holders inspect and/or test samples of respirators and components as part of their quality control plans. This requirement is stated in Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84), specifically in §§ 84.41(b) through 84.41(i). Some applicants or approval holders have had difficulty understanding how to select and use a sampling procedure which meets the requirements. This letter is intended to explain the practical use of common standard procedures acceptable to NIOSH.

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

1. Selection of Sampling Procedures

1.1 Sampling by Variables. The standard sampling procedure specified in 42 CFR Part 84 is MIL-STD-414 [U.S. Department of Defense 1957]. This is a variable sampling plan, which means that the characteristic must be something that can be measured numerically on a continuous scale. Examples include the diameter of a hole in inches, the mass of a cartridge in grams, or the leakage of an exhalation valve in milliliters per minute. This procedure is only valid when the characteristic being measured has a statistically normal distribution over the

population being sampled. The ANSI/ASQ Z1.9 standard [American National Standards Institute 2003b] is derived from MIL-STD-414, and NIOSH considers it to be equivalent.

1.2 Sampling by Attributes. The MIL-STD-105D sampling procedure [U.S. Department of Defense 1963] is explicitly accepted as an equivalent procedure in 42 CFR Part 84. This is an attribute sampling plan, which means that each characteristic is simply checked to see whether it is acceptable. Due to its simplicity, this standard and its derivatives are by far the most common in use. It has the advantage that it can be applied to characteristics which do not involve a numerical measurement (such as visual checks) as well as to those that are measurable. No calculations are needed to determine acceptance, and the procedure is valid whether the Page 2 – Letter to All Respirator Manufacturers 9-2012 characteristic has a normal distribution or not. Typically the sample sizes will be larger than the corresponding variable sampling plan. Procedures derived from this standard, and which NIOSH considers to be equivalent, include MIL-STD-105E [U.S. Department of Defense 1989] and ANSI/ASQ Z1.4 [American National Standards Institute 2003a].

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

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

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

2. Acceptable Quality Level (AQL)

- Meaning of AQL. The acceptable quality level is an indicator of the percent defective that can be considered satisfactory for a particular characteristic. Smaller AQL values mean that fewer defectives will be tolerated in an acceptable lot.

• Selection of AQL. The classification of defects document submitted with each application as required by 42 CFR Section 84.41(c) through 84.41(e) must identify the severity level of each characteristic. The AQL to be used for sampling is shown in the table below and is defined in 42 CFR Section 84.41(g). The AQL value does not depend on lot size or any other factor, and it is generally improper to modify the AQL for any reason other than the defect classification.

Defect Classification	AQL[1,2]
Major A	1.0
Major B	2.5
Minor	4.0

[1] These are called "index values" in the Squeglia C=0 procedure.
[2] It is acceptable to use a smaller (more stringent) AQL value.

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

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

3. Inspection Level

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

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

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

[1] Only permitted with specific prior approval from NIOSH.

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

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

4. Normal, Reduced, and Tightened Inspection

4.1 Use of Switching Rules. Most sampling procedures referenced in this letter contain rules allowing reduced inspection under certain conditions. Reduced inspection may be used only when all conditions listed in the switching rules are met. This includes the requirement that production is not irregular or delayed. A history of lot acceptance at one manufacturing site cannot be used to move to reduced sampling at another site. Approval holders may choose to stay at normal inspection even when conditions for reduced inspection are met. However, tightened inspection is not optional and must be used where specified by the rules. The Squeglia C=0 procedure does not recommend switching rules, and reduced inspection is not permitted by NIOSH for that procedure. Tightened inspection is not required for the Squeglia C=0 procedure.

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

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

5. Lots or Batches

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

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

5.3 Inspection Lot vs. Other Lot Designations. The grouping of finished respirators into lots for shipment or other purposes may differ from the grouping used for inspection. The lot number

marked on the respirator or its container, as required by 42 CFR Section 84.33(g), does not necessarily need to be the same number used for inspection purposes. However, the approval holder must maintain traceability between lot numbering systems if more than one is used. For example, a shipping lot number must be traceable to the corresponding production lot number (or numbers).

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

6. Specific Considerations for Attribute Plans

6.1 Following Arrows to Select Appropriate Sampling Plan. Where the sampling plan indicated leads to an arrow in the table, follow the arrow to the next available sampling plan. This will point to a new code letter row in the table with the acceptance and rejection numbers and a new corresponding sample size to be used.

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

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

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

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

7. Specific Considerations for Variable Plans

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

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

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

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

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

8. Scope

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

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

9. Common Errors

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

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

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

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

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

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

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

10. References

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

American National Standards Institute [2003b]. Sampling procedures and tables for inspection by variables for percent nonconforming. Milwaukee, WI: American Society for Quality, American National Standard ANSI/ASQ Z1.9-2003.

Squeglia NL [2008]. Zero acceptance number sampling plans. 5th ed. Milwaukee, WI: American Society for Quality.

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

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

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

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

Sincerely yours,

Heinz W. Ahlers
Chief, Technical Evaluation Branch
National Personal Protective Technology Laboratory

Department of Health and Human Services **Public Health Service**

Centers for Disease Control
National Institute for Occupational
Safety and Health – ALOSH
944 Chesnutt Ridge road
Morgantown, WV 26505

September 24, 1981

To All Respirator Manufacturers

1. Data on desorption of gases and vapors from the sorbent including a flow-temperature study at low and high temperatures and humidities: Data should be sufficient to demonstrate that the desorbed level of gases and vapors will not be harmful to the wearer.
2. Data on desorption in the impregnating agents used in the cartridge/canister including a flow-temperature study at low and high temperatures and humidities: Data should be sufficient to demonstrate safe levels of desorbed agents.
3. A list of catalytic products produced in the reaction of the sorbent with the contaminant gases and vapors, their concentrations and their toxicities.
4. Data on the toxicity of the impregnating agent(s) sufficient to insure that there is no creation of hazard to the wearer.
5. Family of breakthrough time curves and low and high temperatures, humidities and concentrations.
6. Data on the effects of the commonly found industrial interferences which could impair the ability of the respirator to protect the wearer (i.e., decreased service life).

We recognize the above list is by no means all-inclusive. This is our attempt to itemize the types of information needed in order to determine the intrinsic safety of the respirator. All other information regarding wearer safety would aid NIOSH in their evaluation and would be welcomed in the application.

For further technical information regarding these requirements, please contact the Testing and Certification Branch.

Sincerely yours,

Nancy Bollinger
Supervisory Chemist
Air-Purifying Respirator Section
Testing and Certification Branch
Division of Safety Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236-0070
Phone: 412-386-5200
Fax: 412-386-4089

January 17, 2008

LETTER TO ALL INTERESTED PARTIES

SUBJECT: Colors for Respirator Element Labeling

The color coding requirements of labels for canisters and cartridges as a means for secondary identification are referenced in paragraphs 84.113 and 84.193 of 42 CFR 84, respectively. The standard incorporated by reference is ANSI K-13.1 - 1973: American National Standard for identification of air-purifying respirator canisters and cartridges. It has been communicated to NIOSH that standard samples of colors specified for respirator labeling are not available. This letter includes information for the colors specified in 42 CFR 84 relevant to accessing reference colors. Equivalent designations for these colors in several color-defining systems are provided in Tables 1 and 3, as an attachment. Acceptable tolerances for each specified color are also provided in Table 2, as an attachment. Some resources for obtaining standards, reference colors and translation into other color systems are available in the additional notes.

Any questions concerning this letter should be directed to the National Personal Protective Technology Laboratory, Policy and Standards Development Branch at 412-386-5200.

Sincerely,

Jonathan V. Szalajda

Branch Chief, Policy and Standards Development National Personal Protective Technology Laboratory

Table 1 - Colors Specified for Secondary Designation of Air-Purifying Elements[a]

ISCC-NBS colors assigned in ANSI K13.1			Munsell Notations assigned in ANSI/AIHA Z88.7-2001	Equivalent designations for centroid color in other colorsystems						
Color Assigned	Centroid Color Name	Centroid Color Number		Nearest PANTONE ® Color[b]	CIE[c]			RGB[d]		
					Y	x	y	R	G	B
Red	Vivid red	11	5R 4/14	200 C	11.70	0.5711	0.3057	188	25	55
Orange	Vivid orange	48	5YR 7/14	1375 C	41.99	0.5252	0.4168	255	144	17
Brown	Deep Yellowish brown	75	10YR 3/6	1405 C	6.391	0.4842	0.4712	94	67	0
Yellow	Vivid yellow	82	2.5Y 8/14	116 C	57.62	0.4842	0.4712	255	189	0
Olive	Light olive	106	7.5Y 5/6	105 C	19.27	0.4199	0.4551	138	121	45
Green	Vivid green	139	2.5G 5/10	356 C	19.27	0.2565	0.4705	0	140	82
Blue	Strong blue	178	2.5PB 4/10	301 C	11.70	0.1805	0.1888	0	101	170
Purple	Strong purple	218	7.5P 4/8	259 C	11.70	0.3066	0.2228	129	77	136
White	White	263	N 9.5/	Cool Gray 1C	87.8	0.3100	0.3150	247	238	252
Gray	Medium gray	265	N 5.5/	423 C	23.95	0.3100	0.3150	138	133	141
Black	Black	267	N 0.75/	Black C	0.86	0.3100	0.3150	24	23	25

[a] Refer to ANSI K13.1-1973 and ANSI Z88.7-2001 for specific designations

[b] Values were obtained through "ask a question" at http://www.pantone.com/pages/pantone/index.aspx. CIE equivalents for CIE illuminant D50 were also provided and are included in Table 3.

[c] Obtained from ASTM D 1535-07 Table 2 for Munsell Notations in column 4. Another source is http://www.cis.rit.edu/mcsl/online/munsell_data/all.dat . Values are for CIE illuminant C-2º.

[d] sRGB, scaled to 255, estimates obtained from calculator available at www.easyrgb.com using CIE values in this table.

[e] 42 CFR 84.179 (b) (3) states the color, magenta, which is considered equivalent to purple *e.g.* NIOSH TB Respiratory Protection Program in Health Care Facilities, DHHS (NIOSH) Publication No. 99-143 p. 52.

Table 2 - Ranges for Colors specified in ANSI K13.1—1973

ISCC-NBS colors with ranges in Munsell Notation				
Centroid Color Number	Centroid Munsell Notation[a]	Range [b]		
		Hue	Value	Chroma
11	5R 3.9 /15.4	1-7R " " 7R-9R "	≤ 3.5 3.5 ← [c] 5.5 5.5 ← 6.5 ≤ 3.5 3.5 ← 4.5	≥ 11 ≥ 13 ≥ 15 ≥ 11 ≥ 13
48	4.1YR 6.5 /15	2-7YR	≥ 4.5	≥ 14
75	8.8YR 3.1 /5	8YR-1Y	≤ 3.5	≥ 5
82	3.3Y 8 /14.3	1-7Y	≥ 5.5	≥ 11
106	8.2Y 5.1 /5.6	4-7Y 7Y-9Y " 9Y-2GY "	4.5-5.5 4.5-5.5 5.5←6.5 4.5-5.5 5.5←6.5	≥ 3 ≥ 3 3-5 ≥ 3 3-5
139	3.2G 4.9 /11.1	3-9G	1.2-8.6	≥ 11
178	2.9PB4.1 /10.4	9B-5PB 5-7PB	3-5.5	9.-13
218	6.5P 4.3 /9.2	3-9P	3.5-5.5	9.-13
263	2.5PB 9.5 /0.2	all	≥ 8.5	≤ 0.5
265	3.3GY 5.4 /0.1	all	4.5-6.5	≤ 0.5
267	2.5PB 0.8 /0	all	≤ 2.5	≤ 0.5

[a] Values were obtained from http://www.anthus.com/Colors/Cent.html.

[b] Ranges were taken from charts in Chapter 13, Color: Universal Language and Dictionary of Names, by K. L. Kelly and D. B. Judd. National Bureau of Standards, Spec. Publ. 440, Dec. 1976.

[c] An arrowhead indicates boundary not included in range: *i.e.* 3.5 < value ≤ 5.5.

Table 3 - CIE Equivalents for Pantone® Colors given in Table 1

Nearest PANTONE® Color	CIE		
	Y D5 0	x D5 0	y D5 0
200 C	12.36	0.5985	0.3179
1375 C	44.12	0.5387	0.4198
1405 C	6.69	0.5039	0.4384
116 C	60.36	0.4957	0.4705
105 C	20.09	0.4405	0.4680
356 C	19.84	0.2785	0.5107
301 C	11.51	0.1988	0.2347
259 C	11.87	0.3500	0.2623
Cool Gray 1C	87.80	0.3457	0.3585
423 C	23.98	0.3457	0.3585
Black C	0.86	0.3457	0.3585

DEPARTMENT OF HEALTH & HUMAN SERVICE Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
P.O. Box 18070
Pittsburgh, PA 15236
Phone: 412-386-4000
Fax: 412-386-4051
April 7, 2005

LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Clarification of Supplier and Subcontractor Relationships

Background

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

Definitions

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

Supplier:
A supplier produces components or subassemblies under their own quality system for delivery to the approval holder. The approval holder confirms the acceptability of incoming goods by accepting a Certificate of Compliance and inspecting incoming goods to ensure compliance with all product design, performance, and Quality Assurance criteria (drawings and engineering control). The approval holder releases the product for distribution and sale.

Subcontractor:
The approval holder may authorize a subcontractor to release NIOSH- approved respirators directly from their facility for distribution and sale, or to release components and subassemblies directly to an authorized repair center. The approval holder maintains responsibility for, and control of, product design, performance, configuration management, manufacture, quality, and support by maintaining influence over, and active involvement in, the subcontractor's quality system. As such, the subcontractor's facility is considered to be a manufacturing site for the approval holder.

Subcontractor Relationship Responsibilities

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

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

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

Sincerely yours,

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

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 the respirator's ability to meet the requirements of 42 CFR Part 84. The approval remains effective whether or not the accessory is used.

Alternate Contact - A contact designated by the prospective approval holder that can interface with NIOSH regarding applications and other NIOSH business such as audits and product investigations.

Amended Application - An application submitted at NIOSH's request that shows changes to correct an inaccuracy detected during the NIOSH application evaluation. The Applicant-Assigned Reference Number (AAR#) and Task Number (TN) will remain the same.

Applicant - The individual, partnership, company, corporation, association or organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval for such respirator.

Applicant-Assigned Reference Number (AAR#) - A unique identifying number of the applicant's choosing. The number must start with the three character manufacturer's code. The AAR# must never be reused.

Approval - A certificate or formal document issued by the Institute (in this instance NIOSH) stating that an individual respirator or combination of respirators has met the minimum requirements of this part (42 CFR 84), and that the applicant is authorized to use and attach an approval label to any respirator, respirator container, or instruction card for any respirator manufactured or assembled in conformance with the plans and specifications upon which the approval was based, as evidence of such approval.

Approval Holder - The entity to which a certificate or formal document has been issued by NIOSH stating that an individual respirator or combination of respirators has met the minimum requirements of 42 CFR Part 84. The approval holder is authorized to use and attach an approval label to any respirator, respirator container, or instruction card for any respirator manufacturers or respirator assembled in conformance with the plans and specifications upon which the approval was based.

Approval Labels - The label that is attached to the respirator, container, instructions, or packaging once approved by NIOSH. All major subassemblies in the approved respirator configuration must be on the approval label. Accessories may be listed on the approval label, but are not required.

Assembly Matrix - A diagram of all major subassemblies and accessories that apply to approvals in a respirator family. Components are identified by category, description, drawing number and revision, part number, and applicability to the listed approvals.

Authorized Representative - The person responsible for completing and submitting the Standard Application Form to NIOSH. This person can be an employee of the prospective approval holder or an independent consultant hired by the company to complete the Standard Application Form. Designated

by prospective approval holder to interface with NIOSH regarding applications and other NIOSH business such as audits, and product investigations.

Belt Mounted - An air-purifying canister, chemical cartridge, or particulate filter or an air-supplied regulating valve or regulator that is mounted on the user's belt with an adaptor.

Canister - A gas or vapor removing component which meets the requirements of 42 CFR Part 84, subpart I, Tables 5, 6, and 7 only. Canisters may incorporate particulate filters and can be used for escape from immediately dangerous to life or health environments, which sufficient oxygen. Usually approved with under schedule 14G respirators.

Cartridge - A gas or vapor removing component which meets the requirements of 42 CFR Part 84, subpart L, Table 11. Cartridges may incorporate particulate filters. Cartridges cannot be used in immediately dangerous to life or health environments and are usually part of 84A or 23C approval schedules.

Chest and Back Mounted - Canisters fastened to a user's body, either on the back or chest, that have a breathing tube running from the canister to the facepiece inlet.

Chin Mounted - A canister, cartridge, or filter mounted on the full facepiece. Chin-style gas masks typically have a medium-sized (250-500 cm^3) canister rigidly attached to a full facepiece.

Combination Particulate Filtering and Gas/Vapor Removing - Cartridges and canisters that protect the user from both particulates and gases and vapors.

Common Assembly Matrix - An assembly matrix (diagram) that contains all of the information for a series of applications. A common assembly matrix should be found in the last application of the series. Also, a suggested processing order and an explanation as to how the applications interrelate must be in the Approval History, if applicable. In addition, assembly matrices should not contain information for future submissions. *(See "Series of Applications").*

Component - Essential parts to a respirator that provide function and effective performance of the product. *(See "Major Subassemblies").*

Controlled Document - Documents signed, released, and placed in an applicant's document control system.

Correlation Testing - Testing conducted to compare an applicant's test equipment and results to NIOSH's. The applicant must submit a new application with the wording "Correlation testing only; respirator is not submitted for approval" in the "Reason for Application" section.

Critical Characteristic - A feature that, if not manufactured properly, could have an adverse impact on the safety or health of the user. 100% testing or inspection is required prior to shipment to ensure conformance with all technical requirements of the approval.
As defined in 42 CFR Part 84: "Critical" A defect that judgement and experience indicate is likely to result in a condition immediately hazardous to life or health for individuals using or depending upon the respirator.

Critical User Instructions - Instructions that are important to operate a particular respirator. For instance, checking the service life indicator on a CCER is a critical user instruction.

Delist - Respirator listing is removed from the Certified Equipment List when NIOSH approval is rescinded or revoked.

Design - The overall specification for the respirator that includes materials, physical envelope and shape, manufacturing processes, and Quality Assurance requirements.

Discontinued - See obsolete.

Exploded-View Drawing - A drawing of the complete respirator assembly showing all major subassemblies and accessories and their proximity to one another.

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

Facepiece - A respirator component designed to provide a gas-tight or dust-tight fit with the face and may include headbands, valves, and connections for canisters, cartridges, filters, or respirable gas source.

Facepiece Mounted - A canister, cartridge, or filter mounted on the facepiece.

Features - Descriptors that relate to the makeup, shape, proportions, outward appearance, prominent characteristics, or qualities of the part, but are not separate components or devices. Do not list features 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 Part 84, subparts K or KK.

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

Filtering Facepiece - An N, R, or P class particulate respirator where the entire facepiece is composed of the filtering media. The unit may have an exhalation valve, but has no replaceable parts.

Full Facepiece - A type of facepiece that covers a user from the hairline to below the chin.

Gas/Vapor Removing Respirator - A type of respirator that provides protection against specific gases and vapors.

Half-Mask - A type of facepiece that fits over the nose and under the chin and is used to protect users from toxic materials.

Hardware - Regular production units submitted for approval must be the result of actual manufacturing processes.

Hazardous Atmosphere - Any atmosphere that contains toxic or disease producing gas, vapor, dust, fume, mist, or pesticide, that is either immediately or not immediately dangerous to life or health. Also, any oxygen-deficient atmosphere.

Helmet - A rigid protective headgear incorporated into the design of a respirator that covers the user's head and possibly the user's neck.

Helmet Mounted - A canister, cartridge, or filter mounted on the helmet.

Hood - A light, flexible device covering only the head and neck, or head, neck, and shoulders of a user.

Hood Mounted - A canister, cartridge, or filter mounted on the hood.

Immediately Dangerous to Life or Health - Conditions that pose an immediate threat to life or health or conditions that pose an immediate threat of severe exposure to contaminants, such as radioactive materials, which are likely to have adverse cumulative or delayed effects on health.

Inactive - See obsolete.

Intrinsically Safe - Not capable of releasing enough electrical or thermal energy under normal or abnormal conditions to cause ignition of a flammable mixture such as methane or natural gas or air comprised of an easily ignitable composition.

Major Subassemblies - Those components or subassemblies (1) that are essential to the respirator's function and effective performance; (2) that affect the respirator's performance or design; and (3) which are field-replaceable items.

Manufacturer's Code - A unique three-letter code assigned to each approval holder by NIOSH.

Model Number - An identifier of a product given by the manufacturer. A model number is not required to identify each unique configuration.

Mouthpiece - A respirator component that is held in the teeth with a clamp to close the nostrils that provides a gas-tight or dust-tight fit with the mouth.

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

Not Immediately Dangerous to Life or Health - Any hazardous atmosphere which may produce physical discomfort immediately, chronic poisoning after repeated exposure, or acute adverse physiological symptoms after prolonged exposure.

Nuisance Level Contaminants - Contaminants where the concentration in the atmosphere is below the established PEL (OSHA permissible exposure limit) or REL (NIOSH recommended exposure limit), whichever is lower. Nuisance level protection capability is not evaluated by NIOSH.

Obsolete - A respirator is considered obsolete when it is no longer manufactured or supported by the approval holder. However the NIOSH approval is still listed and the respirators can still be used until the units can no longer be maintained in an approved configuration. Approval remains active and is shown in the CEL as obsolete.

Part Number - The unique number referenced by users to identify respirator parts. The identifying number located on the component must match the part number shown on all labels (abbreviated and full) and on the assembly matrix. The location of the part number on the component hardware must be shown on the drawings. Applicants sometimes refer to the part number as catalog number, manufacturer number, production component number, among other terms.

Particulate Filtering Respirator - A type of respirator that protects users against solid particles or liquids such as dusts, fumes, and mists by trapping the particles with its fibers. The filters are classified by NIOSH as N, R, or P accompanied by either 95 (95%), 99 (99%), or 100 (99.97%) to indicate filtration levels.

Permissible Exposure Limit (PEL) - An OSHA permissible exposure concentration limit based on health data evaluation. Users working in contaminate levels below this concentration are not required by OSHA to have respiratory protection.

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

Pre-Submission Test Data - Respiratory performance test data must accompany each application and must specify components used for test configuration by part number, show units of measure for all test

data (matching 42 CFR Part 84 criteria), and submit copies of actual test data with all results and conclusions.

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

Primary Contact - The person designated by the prospective approval holder to receive all official NIOSH correspondence, including but not limited to approval and denial letters, manufacturers meeting notices, and notices seeking input for standards development. If this person changes, it is the responsibility of the manufacturer to notify NIOSH, in writing, of the person taking over this responsibility. The preference is for the Primary or Alternate Contact to make the notification to NIOSH prior to the change. Alternatively, a corporate officer may notify NIOSH.

Private Label - A respirator labeled as belonging to an organization that is not the approval holder. Private-labeled respirators are assigned the same TC number issued to the approval holder for the original product. Only the approval holder can apply for a private label.

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

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

Product Trade Name - A name that uniquely identifies a respirator or respirator family. A product trade name is required because of the way approval holders market and users reference certified respirators. The product trade name must not imply use for a specific hazard.

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

Prototype - Defined as a respirator or component that (a) involves a new design produced using rapid prototyping methods, temporary tooling, non-production tooling, or regular production tooling in a new fashion, and (b) has demonstrated by the applicant's pre-testing to meet 42 CFR Part 84 minimum design and performance requirements. Respirators may not be submitted for approval while in this defined prototype stage (limited production tooling and processes). NIOSH will request samples made on regular production tooling and production quality control (Ref. 84.30 (c)) if the approval holder

request approval. For non-approval prototype testing use a new application form and state "Prototype Testing Only - Respirator is Not Submitted for Approval" in the "Reason for Application."

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

Quality Assurance (QA) Manual - Documents the approval holder's quality systems including the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management and policy. Hard copies with original approval signatures need submitted and will be retained in NIOSH's files.

Quarter-Mask - A type of facepiece that covers the mouth and nose where the lower sealing surface rests between the mouth and chin. Quarter-masks are most commonly found on dust and mist respirators.

Recommended Exposure Limit (REL) - A NIOSH recommended exposure concentration limit based on health data evaluation. Users working in contaminate levels below this concentration are not required by OSHA to have respiratory protection.

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

Rescission - The approval holder voluntarily requests the certificate of approval be withdrawn for a product. The approval is no longer valid. Respirators in the field are no longer NIOSH-Approved. Respirators are not listed in the CEL.

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

Resubmission of an Application - Resubmission of a previously denied application. Resubmitted applications receive a new task number (TN) and are placed at the end of the application processing queue. All documentation must be updated to the current dates and revision levels.

Revocation - NIOSH reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of 42 CFR Part 84. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval. The approval is no longer valid. Respirators in the field are no longer NIOSH-Approved. Respirators are not listed in the CEL.

SEI Retrofit - An update or correction to a suspected performance or design issue to a self-contained breathing apparatus (SCBA) that is approved by NIOSH and the Safety Equipment Institute. This type of SCBA is approved jointly by NIOSH and SEI for use in firefighting operations.

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

Service Life Plan - A document that contains information on the reliability engineering methodology and appropriate service life dates that users may rely on for determining safe and reliable performance of the respirator under intended use conditions.

Simplified Drawings - Exploded-view and major subassembly drawings that accompany the application. Any additional drawings necessary for clarification of a major subassembly or part may also be included.

Standard Application Form (SAF) - The electronic form used to submit respirator approval requests to NIOSH.

Subcontractor - The entity contracted to produce products under the direction/oversite of the prospective approval holder.

Supplier - The entity that produces components or subassemblies under their own quality system for delivery to the approval holder.

User Instructions - Detailed instructions provided to the user that describes how to properly inspect, don, and use the product.

ACRONYMS

AAR# - Applicant-Assigned Reference Number

ABMS - Automated Breathing Metabolic Simulator

AP - Air-Purifying

APRS - Air-Purifying Respirator Section

AQL - Acceptable Quality Level

AS - Air-Supplied

ASR - Air-Supplied Respirator **(See SAR)**

BMS - Breathing Metabolic Simulator

CAR - Corrective Action Request

CBRN - Chemical, Biological, Radiological, and Nuclear

CCER - Closed-Circuit Escape Respirator

CEL - Certified Equipment List

CFR - Code of Federal Regulations

CGA - Compressed Gas Association

CV&SDB - Conformity Verification and Standards Development Branch

EBSS - Emergency Breathing Support System

EIN - Employer Identification Number

ESLI - End-of-Service-Life Indicator

EOSTI - End-of-Service-Time Indicator

ETB - Evaluation and Testing Branch

HHS - Department of Health and Human Services

HSBG - Human Subject Breathing Gas

IDLH - Immediately Dangerous to Life or Health

LRPL - Laboratory Respirator Protection Level

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

NFPA - National Fire Protection Association

NIOSH - National Institute for Occupational Safety and Health

NPPTL - National Personal Protective Technology Laboratory

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

PAPR - Powered Air-Purifying Respirator

PEL - Permissible Exposure Limit (OSHA)

PQP - Product Quality Control Plan

QA - Quality Assurance

REL - Recommended Exposure Limit (NIOSH)

RPD - Respiratory Protective Devices

RPU - Regular Production Unit

SAF - Standard Application Form

SAP - Standard Application Procedure

SAR - Supplied-Air Respirator

SCBA - Self-Contained Breathing Apparatus

SCP - Standard Conditioning Procedure

SCSR - Self-Contained Self-Rescuer

SOP - Standard Operating Procedure

STP - Standard Test Procedure

TC Number - Testing and Certification Number; the NIOSH approval number designation

TN - Task Number; a unique number assigned by NIOSH to each application

Revision History

Date	Section	Action
15-Dec-17	**Section 1** 1.1.9 Submitting Test Samples	**Added:** *All sample components must be identified and labeled with the corresponding part number as listed on the assembly matrix.*
15-Dec-17	**Section 1** 1.2.2 Extension of Approval Application	**Added second paragraph below the second drawing:** *Any changes to NIOSH-approved records (documents) must be submitted to NIOSH. This includes any minor changes to any document that is part of the approval record. These changes should be submitted for an extension of approval at your earliest convenience. NOTE: Documents that are not up-to-date in the NIOSH records could be identified during a site audit and result in a non-conformance.*
15-Dec-17	**Section 1** 1.2.3 Quality Assurance Approval Application	First bullet. **Changed from:** Used for new or updated Quality Assurance (QA) Manuals only. **To:** *Current NIOSH approval holders may use this type of application to submit new or updated Quality Assurance (QA) Manuals. This type of application is limited to current approval holders*.
15-Dec-17	**Section 2** 9 (Section C.9) Reason for Application	Third paragraph. **Added:** *Also, list the Corrective Action Request (CAR) number associated with the application.*
15-Dec-17	**Section 2** 2 (Section C.11) Description of Respirator	After the 10th entry "If the respirator contains electrical components, have the components been approved by MSHA for intrinsic safety? **Added:** ***NOTE:*** *If this respirator is to be used in underground mines and has electronics, MSHA intrinsic safety approval must be received prior to submitting to NIOSH.*
15-Dec-17	**Section 3** 3.1 Quality Assurance Documentation	Second paragraph. Third sentence. **Added:** *in a separate QA application,*
15-Dec-17	**Section 3** 3.5 Powered Air-Purifying Respirators	**Added:** *For CBRN PAPRs, tests 1, 3, 4, 7, 12, 14 (as configured), 25 and 30 (for hoods only) may also be performed.*

15-Dec-17	**Section 3** 3.5 Powered Air-Purifying Respirators	**Deleted:** Do not issue a single payment (check or pay.gov) for multiple invoices. Separate payments (check or pay.gov) are required for each application invoice received. Include the AAR# on the payment so it is properly credited.**Added:** A single payment (check or pay.gov) for multiple invoices is allowed. Include the AAR#s for each associated application on the check or the pay.gov receipt so they will be properly credited. Separate payments (check or pay.gov) will also be allowed for each application invoice. For application fee invoices, included the TN number(s) associated with the payment. To indicate a final payment for a specific application(s), add an -F after the TN number(s) (TN-nnnn-F).
15-Dec-17	Section 3 3.6 Annual Fixed Certification Fees	Deleted: Only one application per check.
15-Dec-17	**Section 3** 3.12 List of NIOSH Cautions and Limitations	**Special Cautions and Limitations Notes. For K. Added:** *for formaldehyde.*
15-Dec-17	**Section 3** 3.12 List of NIOSH Cautions and Limitations	**Added sentence to last paragraph:** *If the respirator is for underground use, MSHA intrinsic safety approval must be received prior to submitting to NIOSH.*
15-Dec-17	**Section 3** 3.13 Private Labeling	Third paragraph. **Added:** *A specific section titled* "S-Special …"
15-Dec-17	**Section 3** 3.14 User Instructions	**First paragraph. Second sentence. Changed to read:** User Instructions *must* be listed and *are required* to be listed on the assembly matrix for Supplied-Air Respirators.
12-Mar-18	**Section 3** 3.16 Summary of Related Documents	**Added at the end:** *In addition to the application file, the manufacturer must submit related project documents. These documents must be in English and saved with the following file-naming conventions. Any files created in a language other than English will be returned unprocessed.*
15-Dec-17	**Section 3** 3.17 File Naming Conventions	**Added an additional bullet to end of bulleted list:** *NIOSH will only accept single documents under a single filename. Multiple documents under a single filename will not be accepted and the application may be denied.*

15-Dec-17	**Section 4** 4.3 Denial Prior to Assignment of a Task Number	Eleventh bullet: **Added:** *along with MSHA intrinsic safety*
15-Dec-17	**Section 6**6.1Test Samples	**Item 9. Added:** *as listed on the assembly matrix.*
15-Dec-17	**Section 6** 6.1 Labels	**Item 28. Added:** *applicable*
15-Dec-17	**Section 6** 6.5 Private Label Checklist	**Item 4. Added:** *applicable*
20-Mar-18	**Section 7** 7.3 a Example of an Assembly Matrix for a PAPR (non CBRN)	**Table. Added** *a row to the table.*
20-Mar-18	**Section 7** 7.3 b Example of an Assembly Matrix for a CBRN PAPR	**Table. Added** *a row to the table.*
15-Dec-17	**Appendix** Acronyms	**Added:** *CAR – Corrective Action Request*