

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 Closed-Circuit Escape Respirators Under 42 CFR Part 84**

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## Introduction

This document 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 (SAF).

NPPTL has developed individual instructions for each class of respirator. The information in this document pertain to the approval of Closed-Circuit Escape Respirators. Please see the appropriate application for the class of respirator being submitted.

### Schedule 13G

- **Closed-Circuit Escape Respirator**

**NOTE: These instructions only cover Closed-Circuit Escape Respirators (CCERs) as defined in 42 CFR Subpart H.**

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 a **Closed-Circuit Escape Respirator**. The paragraphs are numbered to correspond with the sections of version 8 of the SAF

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

# Section 1 General Information for a Closed-Circuit Escape Respirator

## Instructions for Preparing an Application Package for a Closed-Circuit Escape Respirator (13G Approval).

**This guide applies strictly to Closed-Circuit Escape Respirators (CCERs). Please see the appropriate application and instructions 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 Part 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](mailto: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 \(QA\) 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 and Safety 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 three-character manufacturer's code is issued.

### **1.1.6 Submitting the Application**

Applications should be submitted on CD-R or DVD-R. 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](mailto: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 CCERs 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 Cochran's Mill Road  
Pittsburgh, PA 15236

### **1.1.9 Submitting Test Samples (Hardware)**

NIOSH NPPTL  
CV&SDB, Evaluation and Testing  
626 Cochran's Mill Road  
Pittsburgh, PA 15236

**All boxes containing test samples (hardware) must be marked with the AAR# and include a packing slip.**

Test samples (hardware) submitted for a series of applications must be identified for each project for which it is to be used. For example, a CCER that is to be used on three projects. One project with a mouthbit only, one with a mouthbit and visor, and one with a hood and mouthbit, must have all three [Applicant-Assigned Reference Numbers](#) (AAR#s) listed on the packaging. If there are multiple containers, each container must be labeled with all the appropriate information.

If test samples (hardware) are 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#. All sample components or respirators must be identified, and labeled with their corresponding part number as listed on the assembly matrix.

## 1.2 Types of Applications

The types of applications include: New Approval Application, Extension of Approval Application, Quality Assurance Approval Application, Amended Application, Correlation Testing Only Application, Resubmission of New Approval Application, and Resubmission of Extension of Approval 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 in 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 respirator with two different mouthbit arrangements, for example CAP 1 with mouthbit and hood and CAP 2 mining mouthbit only, that use the same family respirator package, NIOSH requires two separate applications resulting in two new approvals because each respirator represents a separate design and level of protection.

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

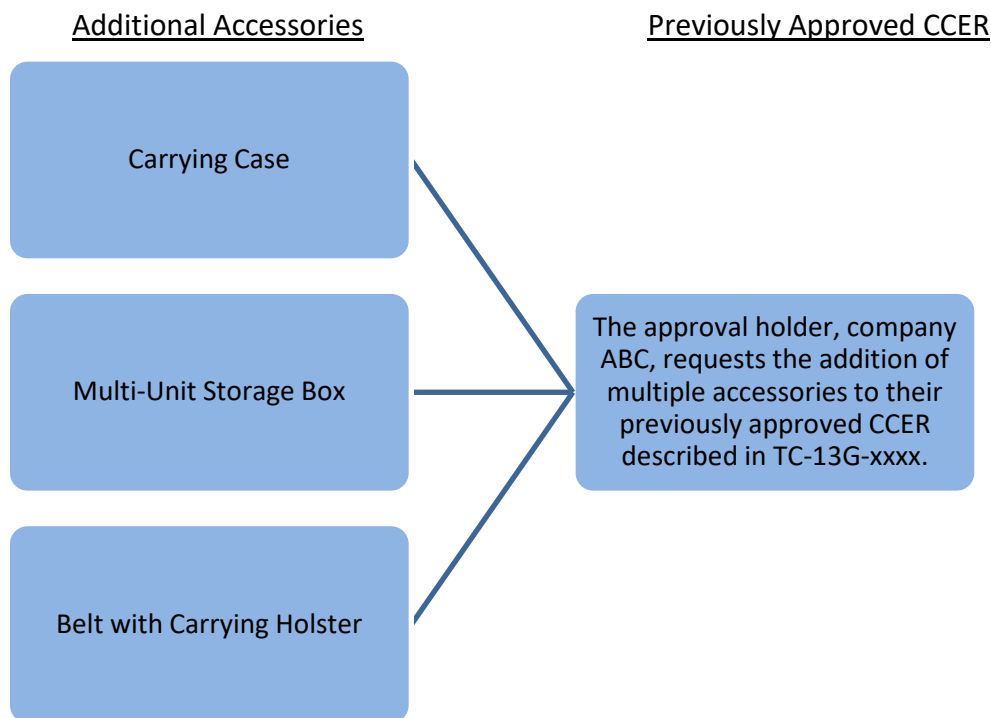
- NIOSH Standard Application Form.
- Pretest Data.
- Simplified Drawings.
- Assembly Matrix.
- Draft Approval Label(s).
- Quality Assurance Manual (Manual to be submitted separately as a QA Application after first approval).
- Product Quality Control Plan.
  - Classification of Defects Document.
  - Sampling Plan.
- Application Fee, \$200.

- Service Life Plan
- User Instructions.
- Test Samples (Hardware).

### 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 CCER.

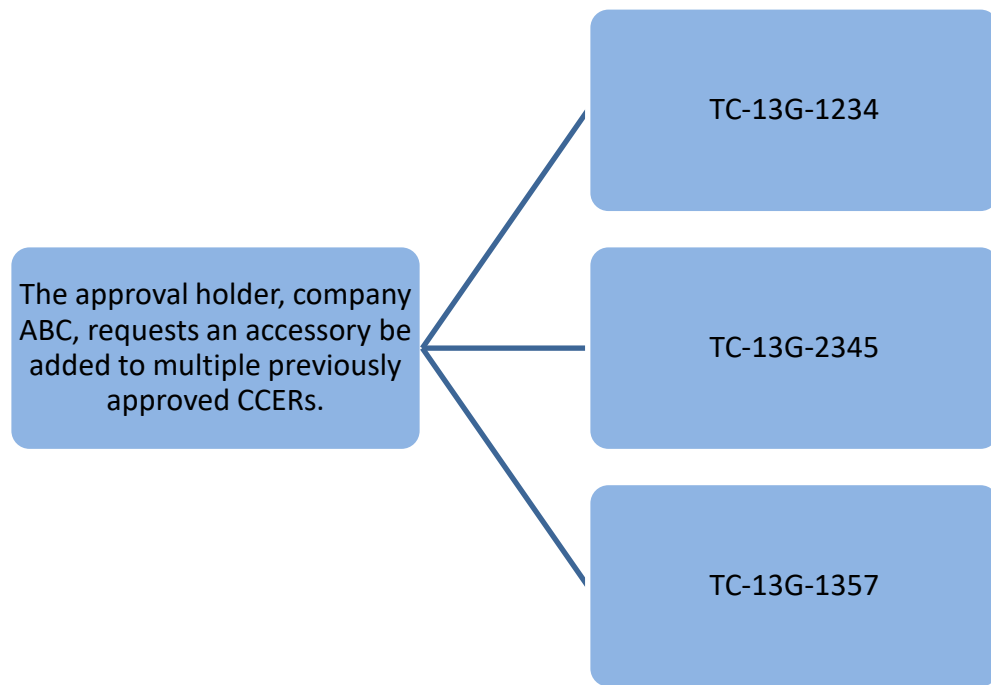


- An approval holder requests the addition of an accessory to multiple previously approved CCERs.

Additional Accessories

Previously Approved CCERs





Changes to minor characteristics not affecting performance or designs 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 a typographical error in a drawing. 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 as an extension of approval at your earliest convenience. NOTE: documents that are not up-to-date in the NIOSH records may be identified during a site audit and will result in a non-conformance.

If the type or level of protection changes, a New Approval Application must be submitted. For example, a CCER CAP 3 may be submitted and approved. The subsequent submission of the same respirator with a CAP 3 Mining would be considered a new 'Type' requiring a New Approval Application and a different TC number being issued.

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 face cover arrangement on an existing CCER model.

Extension of Approval Applications must contain the following items or reference 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 a QA Application after first approval).
- Product Quality Control Plan.
  - Classification of Defects Document.
  - Sampling Plan.
- Application Fee, \$200.
- Service Life Plan.
- User Instructions.
- Test Samples (Hardware).

**In the “Reason for Application”:** Describe exactly and completely the change or additions 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’ carrier to be used as an alternate to our ‘abc’ carrier on our CCER, models 123, 456, and 789. No other components are affected. This request is for use of an alternate carrier only." The Extension of Approval Application request 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 Instructions).

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 carrier assembly and the details are provided.**

This Extension of Approval is for our EZESC Closed-Circuit Escape Respirator family to allow an alternate carrying case. This case, part number 12345, will be an alternate carrying case for all approvals listed on the EZESC assembly matrix (EZESCAMrC.xls) which is included in our list of documents. The 12345 case allows greater mobility to the user than the original 67890 case. The internal dimensions and the materials are the same in both units. Test data is included to prove that the respirator performs the same regardless of which case is used.

**Specifies the change(s)**

This request is for use of an alternate carrying case only. No other components or processes are affected. Both carrying cases are made of high-density polyethylene and both pass the testing required to meet the criteria for CCERs.

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

The current carrying case design with the 12345 case has a limited mobility for users. The new carrying case 67890 provides a greater mobility while keeping the same internal dimensions and material as the original.

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 approvals 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.

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

**NOTE:** NIOSH will only accept QA Applications that request updates to the QA Manual. No other requested actions will be accepted under a QA 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.

QA approval 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 changes 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.

### **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. 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 Approval Label Protections and Cautions and Limitations for Closed-Circuit Escape Respirators**

### **PROTECTIONS**

CAP 1, 20 L – Capacity 1, 20 liters of O<sub>2</sub> minimum

CAP 2, L – X liters of O<sub>2</sub> minimum

CAP 3, L – Capacity 3, X liters of O<sub>2</sub> minimum

CAP 1, M - 20 L – Capacity 1, 20 liters of O<sub>2</sub> minimum, mining

CAP 2, M - L – X liters of O<sub>2</sub> minimum, mining

CAP 3, M - L – Capacity 3, X liters of O<sub>2</sub> minimum, mining

### **CAUTIONS AND LIMITATIONS**

- 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.
- 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.

\* For non-mining units that have electrical components that have not been evaluated for intrinsic safety by MSHA or other recognized approval organization.

## **Section 2    Specific Instructions for Preparing a Closed-Circuit Escape 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 New Approval Application, Extension of Approval Application, Resubmission of Extension of Approval Application, Quality Assurance Application Correlation Testing Only Application, or Amended Application.

#### **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**

- 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 NIOSH approval holders 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 (Section C.3 and Section 3.5)**

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 Atmosphere Supplying since this application applies only to Closed-Circuit Escape 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?

Yes or No.

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.

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

If yes, specify the applicable AAR# or TN.

*If the same respirator is being added as a private label, the second application 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.*



## 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 CEL.

**The following must be addressed in the “Reason for Application”:**

- 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 QA Manual and the respirator(s) and manufacturing facility(ies) affected. QA Approval 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 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.

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. A copy of the intrinsic safety

approval from MSHA must be included with the application. The application will not be accepted without the intrinsic safety approval.

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

Example of a Well-Written Approval History for a Closed-Circuit Escape Respirator:

The new case material is documented on revised specification sheet ZM-FL-A02 Rev A.

The change is documented in the CCER unit bill of materials (Item 2) on page 3 of drawing 103-01 Revision M.

This modification does not affect the respirator performance, but may affect the results of the environmental conditioning process. Happy Breathing Company has tested the respirator after conditioning and finds that the respirator still meet the requirements of 42 CFR Part 84 for performance. Happy Breathing Company has not changed any of the other respirator components since the components were granted NIOSH approval under TN-xxxxx. Happy Breathing Company is relying on the post conditioning test data accompanying this submission, AAR#ph24, to obtain this approval.

This change will be applicable to the model III respirator.

## **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 options. 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.

**NOTE:** Not applicable for CCERs.

Is this an SEI retrofit respirator?

Yes or No.

Is this a CBRN Application?

Yes or No.

Select Type of CBRN, if applicable.

Not Applicable.

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, or Correlation Test Sample.  
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, Helmet, or  
Tight-Fitting Full Facepiece with Neckdam Seal.

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.

### **Move to Air-Supplied Respirator Questions**

Type of Supplied-Air Respirator – Choose from dropdown options:  
Self-Contained Breathing Apparatus (SCBA), Supplied-Air Respirator (SAR), or Combination  
SCBA/SAR.

SCBA Type – Choose from dropdown options:  
Open-Circuit, Closed-Circuit, or Other Technology.

SCBA Use – Choose from dropdown options:  
Escape-only or Entry and Escape.

SAR Category – Choose from dropdown options:  
A, AE, A and AE, B, BE, B and BE, C, CE, C and CE, or Other.

Select the Rated Service Time (minutes):  
3, 5, 10, 15, 30, 45, 60, 120, 180, or 240.

Airflow – Choose from dropdown options:

Demand, Pressure-Demand, Continuous Flow, or Negative Pressure.

Breathing Gas – Choose from dropdown options:

Compressed Air, Compressed Oxygen, Compressed and Rich Air, Chemical Oxygen, Liquid Oxygen, or Other Technology.

Enter the Concentration of Oxygen in Breathing Gas (percentage).

Enter the Cylinder Rating (psi).

Regulator Mounting Location – Choose from dropdown options:

Belt, Chest, Facepiece, Back or Backpack, or Helmet.

Are the materials used in the construction which may be exposed to oxygen at pressures above atmospheric pressures, safe and compatible for their intended use?

Yes or No.

If a hose set is needed, click on Add Hose Set and provide the model number, hose type, shortest length, maximum length, other lengths, total sections, valve type, and pressure.

Also provide a description of the respirator(s).

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

### **Atmosphere-Supplying respirators only**

Confirm that any materials used in the construction of the respirator which may be exposed to oxygen pressures above atmospheric pressure are safe and compatible for intended use (e.g., exposure to elevated concentrations of oxygen). CBRN is not applicable to CCERs.

The term “Intended for Mine Use” identifies respirators to be used for emergency use in mines. NIOSH requires this information to determine if the application must be evaluated and approved by both NIOSH and the Mine Safety and Health Administration (MSHA). Any questions regarding the need for joint approval, please call NIOSH at 412-386-4000.

Note: If the respirator is to be used in underground mines and has electrical components, MSHA intrinsic safety approval must be received prior to submitting to NIOSH.

## **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 H through O](#) criteria).
  - [Subpart O](#) is a recent addition to 42 CFR 84. It is recommended that applicants unfamiliar with the subpart review the 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 applicants 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 of the related Closed-Circuit Escape Respirator configurations. This data must be representative of each complete respirator assembly seeking approval. For resistance testing, NIOSH will test and verify the highest and lowest resistance combinations reported by the applicant if multiple sizes or configurations are submitted.

## **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.

## **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 as listed on the assembly matrix, 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 a Closed-Circuit Escape Respirator Application

### 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 QA 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 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 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. 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 Closed-Circuit Escape 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](https://www.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
<b>Application</b>	42 CFR §84.20(b)(1)	\$200 per application submitted.	Upon receipt of any application request. To be submitted with application.
<b>Approval</b>	42 CFR §84.20(b)(1)	\$100 per each certificate of approval issued.	Upon receipt of the invoice.
<b>Approval Modification</b>	42 CFR §84.20(b)(1)	\$50 per each certificate of approval modified.	Upon receipt of the invoice.
<b>Site Qualification</b>	42 CFR §84.20(b)(3)	<ul style="list-style-type: none"><li>Existing approval holder, paper review:<ul style="list-style-type: none"><li>\$400 per each request to inspect new production facility.</li></ul></li><li>Prospective approval holders:<ul style="list-style-type: none"><li>One day domestic site visit - \$2,500.</li><li>One day international site visit - \$7,500.</li></ul></li></ul>	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 Closed-Circuit Escape Respirator Test Fees

All of these tests may not apply to the specific type of respirator being submitted. These apply only to Closed-Circuit Escape Respirators.

<b>New Site Qualification Fee, Existing Manufacturer</b>	<b>\$400.00</b>
----------------------------------------------------------	-----------------

#### Test Fees for New and Unspecified Tests:

All Closed-Circuit Escape Respirator (CCER) testing	\$500/day for testing plus actual costs for test subjects and required medical coverage. \$100/day per human test subject. \$1300/day for doctor and medical staff.
-----------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------

A single payment (check or pay.gov) for multiple invoices is allowed. Include the AAR#s for each associated application on the check and the pay.gov receipt so they will be properly credited. Separate payments (check or pay.gov) will also be allowed for each application invoice.

### 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 (Approval) Fee Schedule A—Annual (Fixed) Fees

Fee Type	Legal Citation	Amount	Due Date
<b>Maintenance of Product Performance (Product Audit)</b>	42 CFR §84.20(b)(5)	<ul style="list-style-type: none"> <li>Annual fee: \$761 per each approval holder.</li> <li>Variable fee: as billed by NIOSH based on the respirators chosen to be tested each year.</li> </ul>	October 30 of applicable year.
<b>Records Maintenance</b>	42 CFR §84.20(b)(1)	\$50 per every listed <sup>1</sup> approval on file with NIOSH on July 1 <sup>st</sup> of each year.	October 30 of applicable year.

<b>Quality Assurance Maintenance (Site Audit)</b>	42 CFR §84.20(b)(4)	<ul style="list-style-type: none"> <li>• Annual fee: \$3,000 per every manufacturing site registered with NIOSH.</li> <li>• Variable fee:<sup>2</sup> <ul style="list-style-type: none"> <li>▫ 1 day domestic audit - \$2,500 per site.</li> <li>▫ 2 day domestic audit - \$5,000 per site.</li> <li>▫ 1 day international audit - \$7,500 per site.</li> <li>▫ 2 day international audit - \$10,000 per site.</li> </ul> </li> </ul>	October 30 of applicable year.
<b>Maintenance of Testing and Approval Facilities</b>	42 CFR §84.20(b)(2)	\$34 per every listed <sup>1</sup> approval on file with NIOSH on July 1 <sup>st</sup> of each applicable year.	October 30 of applicable year.
<b>Maintenance of Test Equipment</b>	42 CFR §84.20(b)(2)	\$36 per every active <sup>3</sup> approval on file with NIOSH on July 1 <sup>st</sup> 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](#).

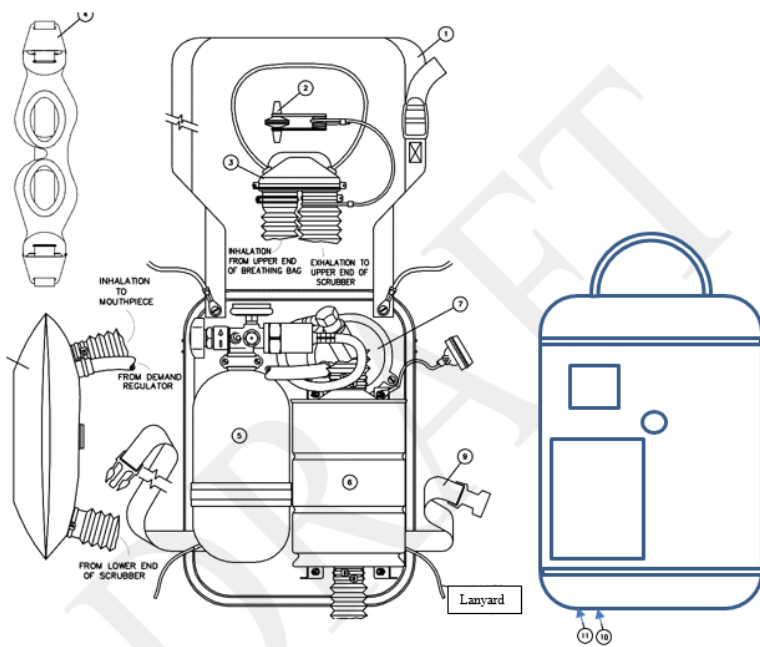
### 3.8 Drawings for a Closed-Circuit Escape Respirator

All drawings must be in English. Drawings are accepted in Adobe PDF, ProEngineer, Autodesk, Smart Draw, and Corel Draw. Drawings should be named by 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., nnnnRa.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 for a Closed-Circuit Escape Respirator

For Closed-Circuit Escape Respirators, the exploded-view drawing is the major subassembly drawing and must include the complete respirator with critical or major dimensions, materials, and characteristics as listed on the [Closed-Circuit Escape 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. Major subassemblies can be submitted for CCERs but are not required.

#### 3.8.2 Example of an Exploded-View Drawing for a Closed-Circuit Escape Respirator



#### 3.8.3 Material Specifications on Drawings for a Closed-Circuit Escape Respirator

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, the items 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 control 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 in accordance with 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 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](#). The assembly matrix cannot be part of the exploded-view drawing.
- 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 Closed-Circuit Escape Respirator where the schedule# is 13G, followed by the AAR# MOR699, and the TC number cell for the first row (a) of the new approval, the numbering convention would be 13G-MOR699a. The second row would be numbered 13G-MOR699b, the third row would be numbered 13G-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 Closed-Circuit Escape Respirator assembly matrices is required.
- The listing of the service life plan on Closed-Circuit Escape Respirator assembly matrices is required.
- 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. The cells 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 to be used indicating 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 or redesigned (N or R) components. If no cells are marked N or R, the applicant should reconsider whether an application for approval is required. If in doubt, call NIOSH 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 Closed-Circuit Escape 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 a New Approval and for an Extension of Approval 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 for a Closed-Circuit Escape Respirator**

CCER: I\*, J, M, N, O, S\*

**\* Notes:**

- I Applies if the respirator is not intended for mine use, contains electrical components and intrinsic safety has not been evaluated and approved by MSHA or a recognized independent laboratory.
- S With unique or unusual design or critical operation requirements or a private label version.

If the respirator contains electrical components and the applicant wants to list the respirator as intrinsically safe on the NIOSH approval label, the applicant must obtain intrinsic safety approval from MSHA under [Title 30 CFR Part 18](#) or a recognized independent laboratory before submitting the application to NIOSH. The verification of intrinsic safety must be submitted with the application. If the respirator is for underground mine 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 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 package 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 Closed-Circuit Escape Respirators. User Instructions must be listed on the assembly matrix for Closed-Circuit Escape Respirators. 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 to indicate all changes to the User Instructions from the prior revision level. When an approval has an issue or a 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-13G-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 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.*

#### Requirements Specific to Closed-Circuit Escape 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.

If a “Moisture Indicator” is used, applicants must include a description that denotes what the indicator changes or colors signify and if the unit can be used.

### **3.15 Service Life Plan for a Closed-Circuit Escape Respirator**

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

- Storage life of the various components based on intended use and environment.
- Chemical and physical component deterioration over time.
- The useful life of elastomers including facepiece, O-rings, breathing tubes, and seals.
- Packaging design specs to eliminate deformation and enhance timely deployment.
- Carrying characteristics which include expected daily shock and vibration assault.
- Life expectancies of chemical adsorbents and filter media with expected moisture effects and degeneration over time.
- Inspection procedures which address daily and periodic validation of condition to assure acceptability for emergency use.

- Specific shelf, deployment, or carrying life as applicable and interdependency.
- Intrinsic safety characteristics, if applicable.
- Acceptable end user maintenance versus return to approval holder for service.
- Allowable conditions of use including applicable regulations governing use.
- Other characteristics to the specific CCER design required to determine the weakest links and expected acceptable performance over the approved service life of the unit.
- Description of how units will be date marked to clearly identify when the unit is to be removed from service. The date used can be the manufacturing date, deployment date, or terminal end-of-service-life date.

The service life plan must be listed on the assembly matrix. The service life plan must be based upon, and include, solid reliability engineering data that clearly shows component parts are good for the requested service life. This data can be manufacturer data, accelerated aging test data, literature review data, or data derived from actual field experience with similar components of the same material. An example would be the case seal gasket of similar design and same material that has been used on an existing escape unit under similar expected conditions.

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

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

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

### 3.16 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
-----------------	------------	----------

Self-Contained Breathing Apparatus	Entire	Harness assembly and canister (where applicable).
------------------------------------	--------	---------------------------------------------------

When a company receives and accepts a NIOSH approval, the company agrees to manufacture, inspect, and test the respirator as it stated in the documentation as approved by NIOSH. The company will maintain the PQP 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.

Approval holders may not imply “use” for approved respirators.

Package advertising that is not permitted includes phrases such as:

“NIOSH-Approved Escape All Respirator.”

A trade name implying use, such as “Smoke Escape Respirator.”

Packaging may include a phrase such as: “NIOSH-Approved Closed-Circuit Escape Respirator; recommended by the approval holder for use when escaping from an underground mine.”

### 3.17 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.

### 3.18 File Naming Conventions

Required Documents	Naming Convention Abbreviation	Acceptable Software Packages	File Naming Convention Format
Application Form	-	Adobe Acrobat Microsoft Access Java	XXXnnnn.PDF XXXnnnn.MDB XXXnnnn.xml
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	nnnnDLa.XLS nnnnDLb.XLSX
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 Instructions or assembly matrix, list each 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 the replacement files directly to the employee requesting the files. The requestor is responsible for having the corrected files posted to the 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. 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. Applicants may use consultants or authorized representatives as contacts for the application. These contacts may submit applications either by request of the company primary contact or in place of the company primary contact. Foreign companies may provide a U.S. contact as a consultant or authorized representative. 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 still be done through the company 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 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 maintain 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, approval labels, pretest data, User Instructions, or drawing package is missing, 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., smoke hoods, etc.).
- 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 submittal either (1) requested approval of two respirators of different basic design (includes submitting a CCER with chemical oxygen and an alternate with bottled oxygen 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 mining (along with MSHA intrinsic safety)).
- 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 certification activities.

## Section 5 Respirator Tests for a Closed-Circuit Escape Respirator

Item	Respirator Type	*NIOSH Test #	Title	Total Materials Needed
25	CCERs, 42 CFR Part 84 Subpart O	<a href="#">TEB-CCER-STP-0600</a>	Determination of Gasoline Permeation	CAP 1 versions – 32 with mining use – 34. CAP 2 versions – 17 with mining use – 19. CAP 3 versions – 17 with mining use – 19. Spare units should be available and can be included with the required units listed.
		<a href="#">TEB-CCER-SOP-0601</a>	SOP for Environmental Treatments	
		<a href="#">TEB-CCER-STP-0602</a>	Determination of Capacity, BMS	
		<a href="#">TEB-CCER-STP-0603</a>	Determination of Performance, BMS	
		<a href="#">TEB-CCER-STP-0604</a>	Determination of Capacity, Minimum Temperature, BMS	
		<a href="#">TEB-CCER-STP-0610</a>	Determination of Wearability, Human Subjects	
		<a href="#">TEB-CCER-STP-0611</a>	Evaluation of Donning, Human Subjects	
		<a href="#">TEB-CCER-STP-0612</a>	Determination of Capacity, Human Subjects	
		<a href="#">TEB-CCER-STP-0613</a>	Determination of Performance, Human Subjects	
		<a href="#">TEB-CCER-STP-0614</a>	Assessment of Stressors, Human Subjects Tests	
		<a href="#">TEB-CCER-STP-0615</a>	Man Test 4 for Use in Underground Mines	
		<a href="#">TEB-CCER-SOP-0616</a>	SOP for Human Subject Work Rate (VO <sub>2</sub> )	
		* Actual tests selected may vary depending on design and intended use.		

## Section 6 Closed-Circuit Escape 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 applicants review their documents using these checklists prior to submitting them 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 a New Approval, Resubmission of an 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.
8. \_\_\_\_\_ Is the respirator to be used for underground mine use? Does it have electrical components, and has the respirator received MSHA intrinsic safety approval prior to submitting to NIOSH.

#### **If Test Samples (Hardware) shipped under separate cover**

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

#### **Fees**

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

#### **Assembly Matrix**

19. \_\_\_\_\_ The assembly matrix matches what is listed in the “Reason for Application” section of the SAF.
20. \_\_\_\_\_ The assembly matrix and SAF represent the actual configuration of the new or modified approval.
21. \_\_\_\_\_ The “Reason for Application” accurately reflects what is being requested (e.g., New Approval, Extension of Approval, Quality Assurance Approval, Correlation Testing Only Approval, Resubmission of a New Approval, Resubmission of an Extension of Approval, or Amended Application).

22. \_\_\_\_\_ 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**

23. \_\_\_\_\_ The necessary new or revised drawings are included in the application documents.
24. \_\_\_\_\_ The revision levels on all drawings match those listed on the assembly matrix.
25. \_\_\_\_\_ Item numbers on the exploded-view drawing match the item numbers on the assembly matrix.
26. \_\_\_\_\_ All required information is present on the Closed-Circuit Escape Respirator drawings, as indicated on the appropriate checklists.

#### **Labels**

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

#### **Cautions and Limitations**

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

#### **User Instructions**

33. \_\_\_\_\_ The User Instructions include all the required information e.g., 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**

34. \_\_\_\_\_ All documents have been verified for the correct revision numbers and the revision levels match what is listed in the SAF.
35. \_\_\_\_\_ 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 Closed-Circuit Escape Respirator**

1. \_\_\_\_\_ Drawing contains all major subassemblies and accessories that appear on the assembly matrix (except the User Instructions and service life plan).
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 except if the exploded-view drawing is the only drawing required.

### 6.3 All Major Subassemblies Checklist for a Closed-Circuit Escape Respirator

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 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.

#### Regulator

1. \_\_\_\_\_ Parts list shows all parts and materials of the regulator.

#### If the unit has a cylinder:

1. \_\_\_\_\_ The documentation for the cylinder lists the burst disc pressure or states that it meets the CGA-1-1.1.6.3. Requirement is 90 to 100% of 5/3 service pressure:
  - Cylinder fill pressure  $\times 5 \div 3$  = upper limit.
  - Highest pressure  $\times .90$  = lower limit.
2. \_\_\_\_\_ Torque requirement for connection of cylinder valve to cylinder is listed.
3. \_\_\_\_\_ Cylinder construction (material(s) of construction, fiber reinforced, type of fiber) are listed.
4. \_\_\_\_\_ Full cylinder volume at operating pressure is listed.
5. \_\_\_\_\_ Markings on cylinder must include compressed breathing air, compressed breathing oxygen, liquefied breathing air, or liquefied breathing oxygen as required by the U.S. DOT.
6. \_\_\_\_\_ Pressure gauge range has a scale reliable to within + or - 5% of full scale (minimum of five graduations empty, 1/4, 1/2, 3/4, full).
7. \_\_\_\_\_ Where pressurized oxygen is used, the gauge must have the words "Oxygen" and "Use No Oil." If respirator is a closed-circuit unit with oxygen, all materials must be compatible for use with oxygen ([42 CFR Section 84.86](#)).
8. \_\_\_\_\_ Procedure to assure proper gas mixture for refill purposes (percent oxygen) is included.
9. \_\_\_\_\_ Specification and dimensions of outlet threads are marked.
10. \_\_\_\_\_ For compressed oxygen units, drawing specifies that cylinder is to be charged with oxygen meeting requirements in 42 CFR 84.79(b) and methods of determining this level can be found in the U.S. Pharmacopeia for pure oxygen.



## 6.4 Private Label Checklist for a Closed-Circuit Escape Respirator

1. \_\_\_\_\_ An assembly matrix showing private label version under current approval (TC) number is included.
2. \_\_\_\_\_ If private label CCER 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 Closed-Circuit Escape Respirator model/part number.
4. \_\_\_\_\_ The private label abbreviated label is included on page two of the drawing.
  - A. \_\_\_\_\_ Abbreviated label must include the following items:
    - a. Private label company name.
    - b. NIOSH is printed in block letters.
    - c. Appropriate approval (TC) number.
    - d. Protection (CAP 1, CAP 2, etc.).
    - e. Model or part number.
    - f. Operating instructions.
    - g. The lot or date code is included on the 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 Closed-Circuit Escape Respirator has been manufactured by approval holder xxx for private label company yyyy under TC-13G-nnnn.
  - E. \_\_\_\_\_ Contact information and a contact person must be identified either in the application or on a separate sheet.

## 6.5 Assembly Matrix Checklist for Closed-Circuit Escape 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. \_\_\_\_\_ The service life plan part number and revision level for CCERs is included.

## Section 7 - Document Examples for a Closed-Circuit Escape Respirator

### 7.1 Example of a Product Quality Plan for a Closed-Circuit Escape Respirator

Double Wing Manufacturing, Pittsburgh, PA

Product Quality Plan (PQP)

DWER Closed-Circuit Escape Respirator

Revision A, Date: 10/21/2015

Item	Description	Inspection	Class	Location	AQL	Test Method	Recorded Results
1	Bag Assembly	Assembly Correct	Critical	Assembly Station	100%	Visual	Assembly Station
		Bag Leak Test	Critical	Assembly Station	100%	TP-00BT	
2	Cylinder Assembly	Assembly Correct	Critical	Assembly Station	100%	Visual	Assembly Station
		Volume	Major A	Assembly Station	1%	TP-00CT	
3	Scrubber Assembly	Assembly Correct	Critical	Assembly Station	100%	Visual	Assembly Station
		CO2 Scrubbing Test	Major A	Assembly Station	1%, destructive	TP-00ST	
4	Breathing Tube	Assembly Correct	Major A	Assembly Station	1%	Visual	Assembly Station
5	Case Assembly	Assembly Correct	Major A	Assembly Station	100%	Visual	Assembly Station
1	Assembly	Assembly Correct	Critical	Assembly Station	100%	Visual	Assembly Station
2	Unit Final Inspection Testing	Capacity Level Testing	Major A	QC Lab	1% destructive	TP-00FT	QC Lab

Technical drawing of the SCBA unit showing internal components and external features. The drawing includes a side view of the unit with numbered callouts (1-11) and a top-down view of the unit. The side view shows the following components:

- 1: Top of the unit (hood)
- 2: Pressure gauge
- 3: Breathing bag
- 4: Mouthpiece
- 5: Demand regulator
- 6: Lower end of the scrubber
- 7: Upper end of the scrubber
- 8: Lanyard
- 9: Lower end of the scrubber
- 10: Upper end of the scrubber
- 11: Mouthpiece

The top-down view shows the unit with a carrying handle and a carrying strap. The unit is labeled "SCBA" and "Lanyard".

CCER

### 7.3 Example of an Assembly Matrix for a Closed-Circuit Escape Respirator



<b>(F)</b> Key: X=Currently Approved in this Configuration N=New Component or Configuration "- "=Obsolete R=Redesign P=Pending	Double Wing Manufacturing 123 Manufacture Lane Pittsburgh, Pennsylvania, USA Phone: 412-555-1212
-----------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------

Date: August 15, 2015

**(G)** TN or AAR# of previously approved or pending matrix: n/a

Revision: 1

**(H)** Exploded-view drawing number: n/a; See simplified drawing of each unit.

CCER Respirator LW1000 Approval Matrix								
			1		2	3	4	
			<b>(A)</b> Respirator		Case	Service Life Plan	User Instructions	
			Description	Escape Respirator	Escape Respirator Mining	Carrying Case	Service Life Plan	User Instructions
			Revision	0	0	0	1	1
			Drawing Number	LWM001	LWM002	LWM004	N/A	N/A
AAR# <b>(C)</b>	NIOSH Approval Number, TC- <b>(D)</b>	Protection <b>(E)</b>	Model/ Part Number	123456	123457	CC001	N/A	N/A
LWM101	13G-0010	SC/ESC/ CAP 1-20L		X			R	R
LWM102	13G-0011	CAP 1-M-20L			R		R	R
NIOSH Task Number Where Component was Last Tested (If			<b>(B)</b>	TN-16000	TN-16001	TN-16000	N/A	N/A

## 7.4 Example of an Approval Label for a Closed-Circuit Escape Respirator



Double Wing Manufacturing Company  
Almost Heaven, West Virginia, USA

1-800-123-4567

LWM001 CCER

Closed-Circuit Escape Respirator



These respirators are approved only in the following configurations:

TC-	Protection <sup>1</sup>	Model	Escape Respirator	Escape Respirator, Mining	Carrying Pouch	Cautions and Limitations <sup>2</sup>
			100101	100121	1001CP	
13G-AARa	SC/ESC/CAP 1-20L	LWM001	X		X	I J MN OS
13G-AARb	SC/ESC/CAP 1-M-20L	LWM001M		X	X	J MN OS

### 1. PROTECTIONS

SC - Self-Contained

ESC - Escape-Only

CAP 1-20L - Capacity, 20 Liters

M - Mining

### 2. CAUTIONS AND LIMITATIONS

- 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.
- M All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O Refer to User Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- S Special or critical User Instructions and/or specific use limitations apply. Refer to User Instructions before donning.

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

## 7.5 Example of an Abbreviated Approval Label for a Closed-Circuit Escape Respirator



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



**TC-13G-XXXX Cap 1 20L**  
**TC-13G-YYYY Cap 1 M 20L**

Models CCR-1 and CCR-2  
Closed-Circuit Escape Respirators

### Operating Instructions:

1. Open unit by lifting the red tab and removing the top cover.
2. Remove unit from bottom cover by pulling the black neck strap up.
3. Insert mouthpiece into mouth.
4. Place nose clip securely on nose.
5. Exhale into unit and breathe normally to escape.
6. Place neck strap around neck.
7. Put goggles on and adjust as necessary.

Refer to the approved User Instructions for the complete list  
of components that make up the approved assembly.

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

## Section 8 - Label Format Guidance

- Labels for Closed-Circuit Escape 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 submissions, 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 J, M, and N apply, then only J, M, and N can be footnoted at the bottom of the label.
- The abbreviated label mounted on Closed-Circuit Escape Respirators must clearly indicate the approval holder's name, location, product model or trade name, approval number, protections, part number, and lot number. The entire CCER must appear in the User Instructions.
- The entire canister for a Closed-Circuit Escape 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., closed-circuit, CAP1, etc. This heading is optional on all approval labels.
- Non-NIOSH approval identifiers cannot be represented on any NIOSH labels. Applicants may use additional areas on the component to identify any other applicable approvals such as the European CE approval. However, this information must be separate 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.

If the respirator is for *escape*-only, the applicant must use the word *escape* on full approval labels.

For example, "These escape-only respirators are approved only in the following configurations."

'Escape' may be abbreviated in the protection column, but must be spelled out in the legend.



## **APPENDIX**



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  
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 <sup>1,2</sup>
Major A	1.0
Major B	2.5
Minor	4.0

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

<sup>2</sup> 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 <sup>1</sup>
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

<sup>1</sup> 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 ( $\sigma$ ) 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 subplot.

## **10. References**

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

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](mailto:vck6@cdc.gov) or by telephone at 412-386-4029. General inquiries may be directed to the Technology Evaluation Branch at [npptl@cdc.gov](mailto:npptl@cdc.gov) or 412-386-4000.

Sincerely yours,  
Heinz W. Ahlers  
Chief, Technical Evaluation Branch  
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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.

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- 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<sup>3</sup>) 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 pretesting 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

**SEI** - Safety Equipment Institute

**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