

Standard Application Form

Form Approved: OMB No.
0920-0109 Exp. Date: xx/xx/20xx

version 9. 20190409

Import XML

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Before completing this document, please review the instructions as well as the NIOSH Standard Application Procedure for the Approval of Respirators under 42 CFR 84 for the specific class of respirator being submitted.

Section C.1: Project Reference Numbers

(C.1.A) What is your NIOSH-assigned Manufacturer Code?

(C.1.B) Does the manufacturer hold a current approval?

☐ Yes

☒ No

(C.1.C) Assign an unique reference number to this application, as directed by NIOSH

Section C.2: Type of Application

(C.2.A) Type of Application

☒ New

☐ Extension

☐ Quality Assurance Approval

☐ Correlation Testing Only

Refer to Section C.8 for Resubmittal

Section C.3: Manufacturer

(C.3.A) Manufacturer Name

Public reporting burden of this collection of information is estimated to average 229 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA(0920-0109). Do not send the completed form to this address.

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

Section C.5: Application Representative

1 (C.5.A) Status of Facility (C.5.B) Manufacturer Name (if different from C.3.A)

Approval Holder

(C.5.C) Has the organization submitted a request for approval of any respirator produced at this manufacturing site in the last three years?

☒ Yes

☐ No

(C.5.D) Official Title

Name of Representative

(C.5.E) Prefix

(C.5.F) Given

(C.5.G) Middle Initial

(C.5.H) Surname

(C.5.I) Suffix

Address of Representative

(C.5.J) Address Line 1

(C.5.K) Address Line 2

(C.5.L) City

(C.5.M) State

(C.5.N) Country

(C.5.O) Postal Code

(C.5.P) Telephone

(C.6.Q) Fax

(C.5.R) Email

(C.5.S) Shipping Number

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

Section C.6: Date of Application

(C.6.A) Date of Application

Section C.7: Type of Product

(C.7.A) Type of Product(s)

☐ Air-Purifying ☐ Atmosphere-Supplying ☒ Combination Air-Purifying and Atmosphere-Supplying

Note: By choosing “Combination Air-Purifying and Atmosphere-Supplying”, you indicate that all of the respirators you will describe perform both functions.

Section C.8: Specific Questions Pertaining to Submission

(C.8.A) Is this a resubmittal of a previous application?

☐ Yes ☒ No

(C.8.C) Is this an amended application?

☐ Yes ☒ No

(C.8.D) Is this submission the result of a field problem or site audit?

☐ Yes ☒ No

(C.8.F) Does this application contain any respirators intended for use in mines?

☐ Yes ☒ No

(C.8.G) Does this application depend upon the approval of an application already in progress?

☐ Yes ☒ No

(C.8.I) Is this application the result of a recall or retrofit program?

☐ Yes ☒ No

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

(C.8.J) Are you seeking approval for an Self-Contained Breathing Apparatus respirator?

☐ Yes

☒ No

(C.8.M) Is this a Chemical, Biological, Radiological, and Nuclear application?

☐ Yes

☒ No

(C.8.P) Is testing required?

☐ Yes

☐ No

(C.8.Q) Source of submitted samples

(C.8.R) Return tested equipment?

☐ Yes

☒ No

Section C.9: Reason for Application

(C.9.A) Reason for Application

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

Section MI: Model Information

1	(MI.A) Trade name 	(MI.B) Model Number(s)
	(MI.C) Remarks 	

Section R: Specific Respirator Model Description(s)

1	(R.A) Draft Approval Number 	(R.B) Associated Trade Name
	(R.C) Facepiece Type 	(R.D) Fit Type
	(R.E) Is this respirator fit-checkable? ☐ Yes ☒ No	(R.F) Does the respirator have an inhalation valve? ☐ Yes ☒ No
	(R.G) Does the respirator have an exhalation valve? ☐ Yes ☒ No	(R.H) Have the respirator's electric components been approved by MSHA for intrinsic safety? ☐ Yes ☐ No ☒ Not Applicable

Subsection R.AP: Questions Specifically for Air-Purifying Respirators

(R.AP.A) Type of AP Respirator 	(R.AP.B) Is the mask powered? ☐ Yes ☒ No	
(R.AP.C) How many filters? 	(R.AP.D) Are the filters replaceable? ☐ Yes ☐ No	(R.AP.F) Filter location
(R.AP.G) Does the respirator use cartridges or canisters? ☐ Cartridges ☐ Canisters	(R.AP.H) How many cartridges or canisters? 	
(R.AP.I) Can the cartridge or canister be replaced? ☐ Yes ☐ No	(R.AP.J) Cartridge or Canister location 	
(R.AP.K) Does the cartridge or canister have an ELSI (EOSL)? ☐ Yes ☐ No		

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

(R.AP.M) Does the respirator protection cover more than a one gas?

☐ Yes

☐ No

Subsection R.AS: Questions specifically for Atmosphere-Supplied Respirators

(R.AS.A) Type of supplied-atmosphere respirator

(R.AS.B) Regulator Mounting Location

(R.AS.C) SAR Category

(R.AS.D) Airflow

(R.AS.E) SCBA Type

(R.AS.F) SCBA Use

(R.AS.G) Breathing Gas

(R.AS.H) Breathing gas specification or oxygen concentration

(R.AS.I) Cylinder Rating

(R.AS.J) Units

(R.AS.K) Are the materials used in the construction which may be exposed to oxygen at pressures above atmosphere pressures, safe and compatible for the intended use?

☐ Yes

☒ No

(R.AS.L) Rated Service Time (minutes)

Hose

1

(R.AS.M) Hose Type

(R.AS.N) Model Number

(R.AS.O) Total Sections

(R.AS.P) Valve Type

(R.AS.Q.A) Shortest Length

(R.AS.Q.B) Units

(R.AS.R.A) Maximum Length

(R.AS.R.B) Units

(R.AS.S.A) Pressure

(R.AS.S.B) Units

(R.AS.T) Other Lengths

Add another Hose

Intended Protections

(R.I) Gas Vapor Protections

1

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

(R.J) Unlisted Gas Vapor Protection

1

(R.K) Particulate Protections

1

(R.L) Description of the respirator

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

Section C.13: Pretest Data

(C.13.A) Air-Purified Respirator Pretests

1

(C.13.B) Air-Supplied Respirator Pretests

1

(C.13.C) Other Pretest(s)

1

Section C.15: Test Samples and Hardware

(C.15.A) Part Number

1

(C.15.B) Item

(C.15.C) Quantity

Section C.16: Quality Assurance Documents (Controlled Documents)

(C.16.A) Title

1

(C.16.B) Revision Level

(C.16.C) Document Date

(C.16.D) Has this document been previously accepted by NIOSH?

☐ Yes

☒ No

(C.16.F) If in process, under which reference number was the document previously submitted?

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

Section C.17: Fees

Standard Application Fee:

\$200

Pay.Gov was used? ☐ Yes ☒ No

(C.17.A) Check Amount

(C.17.B) Check Number

(C.17.C) Check Issue Date

Section C.24: Summary of Related Documents

(C.24.A) File Name

Choose File...

1

(C.24.B) Creation Program

(C.24.C) Document Type

(C.24.D) Description

Standard Application Form

Form Approved: OMB No. 0920-0109

version 9. 20190409

Checklist

- | | |
|--|---|
| ☐ Quality assurance manual | ☐ Check |
| ☐ Product quality control plan | ☐ User instructions |
| ☐ Assembly matrix | ☐ Packaging art |
| ☐ CGA thread specifications | ☐ Special gas data |
| ☐ Burst disc pressure range (SCBA only) | ☐ End of service life indicator (EOSL or ESLI) data |
| ☐ DOT approval documentation | ☐ List of related documents |
| ☐ Lens meets GGG-M-125d requirement | ☐ All test data sufficient to demonstrate compliance with 42 CFR part 84 |
| ☐ Exploded-view drawing | ☐ TC numbers are entered into "(C.9.A) Reason for Application" |
| ☐ Major components drawings | |

Draft Approval Labels

- | | |
|--|--|
| ☐ Approval label draft: Air-Purifying Respirator | ☐ Approval label draft: SCBA (in manual) |
| ☐ Approval label draft: Cartridge or Canister | ☐ Approval label draft: SCBA harness |
| ☐ Approval label draft: Filter | ☐ Approval label draft: SAR (in manual or on packaging) |
| ☐ Approval label draft: Abbreviated Cartridge or Canister | ☐ Approval label draft: Scrubber Label |
| ☐ Approval label draft: Abbreviated Filter | |

I certify that the information contained in this application is correct and that if approved, no further changes will be made to the product(s) without prior written approval of the National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory and CVSD branch.

Initials of Authorized Representative: