REVISED April 13, 2020

NIOSH ASSESsMENT of LIMITED PUBLIC HEALTH EMERGENCY POWERED   
AIR-PURIFYING respirators

NPPTL Assessment to Support the COVID-19 Response

National Personal Protective Technology Laboratory

National Institute for Occupational Safety and Health

Centers for Disease Control and Prevention

Contents

[List of Acronyms 2](#_Toc36641146)

[NPPTL Limited PAPR Respirator Approvals 3](#_Toc36641147)

[Scope 3](#_Toc36641148)

[Prevailing Standard 4](#_Toc36641149)

[Handling of Received Hardware 5](#_Toc36641150)

[Documentation 6](#_Toc36641151)

[Testing 6](#_Toc36641152)

[Full NIOSH Respirator Label 7](#_Toc36641153)

[Abbreviated PAPR Filter Label 8](#_Toc36641154)

[APPENDIX A 10](#_Toc36641155)

# List of Acronyms

CDC – Centers for Disease Control and Prevention

CEL – Certified Equipment List

COVID-19 – Coronavirus Disease outbreak of 2019

NIOSH – National Institute for Occupational Safety and Health

NPPTL – National Personal Protective Technology Laboratory

PAPR – Powered Air-purifying Respirator

PHE – Public Health Emergency

PPE – Personal Protective Equipment

RAP – Respirator Approval Program

# NIOSH Limited PAPR Respirator Approvals

This document was previously dated April 3, 2020. The document was revised on April 11, 2020. The document was updated again on April 13, 2020.

The National Personal Protective Technology Laboratory (NPPTL) is responsible for completing the activities of the NIOSH Respirator Approval Program (RAP). The RAP has developed procedures for conducting a limited PAPR assessment in response to the COVID-19 pandemic, see Figure 1. These assessments include examining limited documentation provided by the applicant, conducting limited testing to verify the minimum performance of the PAPR and issuing a NIOSH PAPR Limited Public Health Emergency (PHE) approval.

Documentation and Hardware

Examined

Expedited

New Approval Application

Testing

Provisional

Limited 21 C PAPR Approval

**Figure 1: Diagram of successful NIOSH PAPR PHE respirator assessments**

# Scope

In response to the national COVID-19 emergency, this protocol establishes a method for achieving a limited NIOSH PAPR PHE approval for loose-fitting PAPR designs. This assessment was developed to communicate abbreviated NIOSH Standard Application Procedures and the documentation needed and methods used to issue the approval. This effort supports increasing the availability of respiratory protection to US healthcare workers due to the extraordinarily high respirator demand associated with COVID-19. Since the ability to fit test using a panel of human subject volunteers is challenging during the pandemic, NIOSH is including evaluation of facepiece fit within the scope of this process, but only for loose-fitting, PAPR100 class respirators. NIOSH approved 21C-PHXX PAPRs will be included in the Certified Equipment List (CEL) and thus still eligible for coverage under the FDA Emergency Use Authorization (EUA).

The NIOSH Limited Approval is for a unique, single configuration which may define alternate subcomponents (batteries, charger, depending on supply chains) as defined by the documentation package, submitted to and held by NIOSH. No extensions for approval will be accepted or issued. It will be understood that the PAPRs will have been manufactured using limited production runs. If a supplier needs to change components, the approval holder must submit a new limited approval package, and new samples for a new “Limited” approval number. An expedited process may be used to update User Instruction (UI) or label revisions, if necessary.

**This test plan remains active only for the duration of the Public Health Declaration. Any PAPR accepted by NIOSH for evaluation on or after the date of termination will have its evaluation completed using the conventional NIOSH approval process. Should any evaluations for limited approvals be in-process at the termination date, evaluation will be halted, and the applicant will be given the opportunity to withdraw the request. If approval is still desired, standard approval may be sought under normal procedures.**

# Prevailing Standard

Longstanding regulatory standards provide for NIOSH approval of PAPRs incorporating high-efficiency (HE PAPR-only) particulate filters which are incorporated into PAPRs. With the expected [April 14, 2020 interim final rulemaking](https://www.cdc.gov/niosh/npptl/respstandards/papr.html) on particulate-filtering respirators, requirements for the current HE class are unchanged; however, a new class of PAPR is established, PAPR100. PAPR100s tested to the new alternative testing and approval requirements have protections designated either series “PAPR100-N,” which is not for use against oil-based aerosols, or “PAPR100-P,” which is strongly resistant to oil aerosols.

Requirements and test procedures in accordance with [42 CFR 84.](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=c9c15fd462ffe5c4f4e85b73f161b2e0&r=PART&n=42y1.0.1.7.67)

[NIOSH Standard Test Procedures](https://www.cdc.gov/niosh/npptl/stps/apresp.html)

[NIOSH Standard Test Procedures for PAPR 100 Class](https://wwwdev.cdc.gov/niosh/npptl/stps/aprespInterim.html)

[NIOSH Fee Schedule](https://www.cdc.gov/niosh/npptl/respcertfeescheduletables.html)

Per configuration requiring evaluation:

| Fee Type or Test | Citation | Applicable To | Amount | Due Date |
| --- | --- | --- | --- | --- |
| Application | 42 CFR §84.20(b)(1) | Both Classes | $200 per application submitted. | Upon receipt of any application request. To be submitted with application. |
| Approval | 42 CFR §84.20(b)(1) | Both Classes | $100 per each certificate of approval issued. | Upon receipt of the invoice. |
| 0001 Determination of Particulate Filter Penetration (PAPR) | | Both Classes | $150 | Upon receipt of the invoice. |
| 0012 Airflow Determination PAPR | | Both Classes | $150 | Upon receipt of the invoice. |
| 0025 Silica Dust Loading for PAPRs | | PAPR HE | $1200 | Upon receipt of the invoice. |
| 0010 Determination of Facepiece Fit for PAPR 100 Class | | PAPR100 | $1000 | Upon receipt of the invoice. |
| 0080 Determination of Particulate Filter Efficiency Level DOP for PAPR 100-P | | PAPR100 | $500 | Upon receipt of the invoice. |
| 0081 Determination of Particulate Filter Efficiency Level NaCl for PAPR 100-N | | PAPR100 | $1000 | Upon receipt of the invoice. |
| 0085 Determination of Low Flow Warning Device Sound Level for PAPR 100 Class | | PAPR100 | $500 | Upon receipt of the invoice. |
| 0087 Determination of Low Flow Warning Device Visibility for PAPR 100 Class | | PAPR100 | $500 | Upon receipt of the invoice. |
| 0088 Determination of Low Flow Warning Activation for PAPR 100 Class | | PAPR100 | $500 | Upon receipt of the invoice. |

Existing Approval Holders are encouraged to use their NIOSH Manufacturer’s Code when applying. New applicants manufacturing under the Defense Protection Act will be assigned a Manufacturer’s Code by NIOSH. Other new manufacturers are required to apply for and receive a Manufacturer’s Code.

# Handling of Received Hardware

Send hardware to NIOSH/NPPTL

Test samples (hardware) submitted for an expedited application must be identified. If there are multiple containers, each container must be labeled with all the appropriate information. All sample components must be identified and labeled with their corresponding part numbers as listed on the assembly matrix.

|  |
| --- |
| **NIOSH NPPTL CV&SDB, Evaluation and Testing**  **ATTN PAPR PH Testing Hardware**  **626 Cochrans Mill Road**  **Pittsburgh, PA 15236** |

Once hardware or paperwork is received by NPPTL, the task number (TN) will be assigned.

Hardware information (include in table provided in Appendix A):

A single supplier model name, or model number will be permitted, but not required.

*Make* – Make or brand or manufacturer of respirator (what are you calling it?)

*Model* – Model of respirator (if available)

*Number sent to NIOSH*

*Lot Number* – Lot Number assigned by manufacturer (if available)

*ExpDate* – Expiration date assigned by manufacturer (if available)

*Sample Number* – Number assigned by NPPTL to each respirator within a lot

Photographs of respirators will also be taken and stored.

NIOSH will store documents and photos in the NPPTL DRIVE: 2020 LIMITED PAPR PHE

[\\cdc.gov\project\NIOSH\_PIT\_NPPTL\2020 LIMITED PAPR PHE\](file:///\\cdc.gov\project\NIOSH_PIT_NPPTL\2020%20LIMITED%20PAPR%20PHE\)

(link is not accessible to applicants)

# Documentation

Send electronic documents to [Recordsroom@cdc.gov](mailto:Recordsroom@cdc.gov)

NIOSH will accept and examine the following documents:

Application (form, Appendix A) states the contact information for the application, request for the Limited PAPR PHE Approval and a declaration and identification of the applicant’s quality control system.

Bill of materials

Drawings for only the level that we would normally think of as major subassemblies, part numbers, as defined by the applicant and can be identifiable. No top-level exploded view.

Summary of any testing completed – developmental, prototype testing or production QA testing, especially fit testing, if completed, since we are not conducting corn oil population fit test. NIOSH understands fit test data may be limited or not available. Pre-test data provided for the PAPR particulate filter penetration test (DOP) can be based on testing at the minimum design flow rate. NIOSH will test in accordance with STP 0001.

Draft Labels

User Instructions

# Testing

|  |  |  |
| --- | --- | --- |
| Test Description | Applicable to | Test Number |
| Determination of Particulate Filter Penetration (PAPR) Test | Both Classes | [TEB-APR-STP-0001](https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0001-508.pdf) |
| Determination of Air Flow PAPR Test | Both Classes | [RCT-APR-STP-0012](https://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-APR-0012-508.pdf) |
| Determination of Silica Dust Loading for PAPR Filters Test | PAPR HE | [RCT-APR-STP-0025](https://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-APR-0025-508.pdf) |
| Determination of Facepiece Fit with Loose Fitting Respiratory Inlet Coverings | PAPR100 | [CVB-APR-STP-0010](https://www.cdc.gov/niosh/npptl/stps/pdfs/CVB-APR-STP-0010-508.pdf) |
| Determination of Particulate Filter Efficiency Level Against Liquid Particulates (PAPR 100-P Series Only) | PAPR100 | [CVB-APR-STP-0080](https://www.cdc.gov/niosh/npptl/stps/pdfs/CVB-APR-STP-0080-508.pdf) |
| Determination of Particulate Filter Efficiency Level Against Solid Particulates (PAPR 100-N Series Only) | PAPR100 | [CVB-APR-STP-0081](https://www.cdc.gov/niosh/npptl/stps/pdfs/CVB-APR-STP-0081-508.pdf) |
| Determination of Low Flow Warning Device Sound Level (Design Dependent) | PAPR100 | [CVB-APR-STP-0085](https://www.cdc.gov/niosh/npptl/stps/pdfs/CVB-APR-STP-0085-508.pdf) |
| Determination of Low Flow Warning Device Visibility  (Design Dependent) | PAPR100 | [CVB-APR-STP-0087](https://www.cdc.gov/niosh/npptl/stps/pdfs/CVB-APR-STP-0087-508.pdf) |
| Determination of Low Flow Warning Device Activation  (Constant Flow Type) | PAPR100 | [CVB-APR-STP-0088](https://www.cdc.gov/niosh/npptl/stps/pdfs/CVB-APR-STP-0088-508.pdf) |

* For PAPR HE Class devices NIOSH will conduct testing in accordance with STP 0001, 0012 and 0025.
* For PAPR 100 Class devices NIOSH will conduct testing in accordance with STP 0001, 0010, 0012, 0080, 0081, 0085, 0087, and 0088 as applicable.
* The [noise level test](https://www.cdc.gov/niosh/npptl/stps/pdfs/RCT-APR-0030-508.pdf) may be required for either class, depending on the design.
* Due to the pandemic, NIOSH is not completing facepiece fit testing for the PAPR HE Class, but facepiece fit testing for the PAPR 100 Class will be required to assess the system.
* If a flow tube is used to demonstrate the PAPR HE has exceeded the minimum flow, the flow tube should be provided for verification.

Untested hardware will be maintained at NIOSH as a matter of record. NIOSH reserves the option to request additional tests, based on the PAPR design. The need for additional testing will be clearly communicated to the applicant to expedite the process.

|  |
| --- |
| **Testing hardware needed per configuration evaluated** |
| PAPR HE - TWO complete PAPR systems minimum  PAPR 100 – TEN complete PAPR systems minimum |
| TEN complete PAPR filters or TEN complete PAPR filter systems |
| PAPR HE - ONE Flow tube |

# Full NIOSH Respirator Label

Includes the acronym NIOSH or NIOSH logo (below)

Listing of major subassembly parts

Full Respirator Label must be affixed to the respirator

Name and contact information

Approval numbers will be assigned as 21C-PHXX

Labeled protection will be “PHE particulate filtering respirator”

Protection, Cautions and Limitations

**PROTECTION**

**As applicable to each approval**

|  |
| --- |
| HE - High-Efficiency Particulate Air filter for Powered Air-Purifying Respirators |

|  |
| --- |
| PAPR100-N - Particulate Air Filter for Powered Air-Purifying Respirators (99.97% filter efficiency level) Effective against particulate aerosols free of oils; time use restrictions may apply. |

|  |
| --- |
| PAPR100-P - Particulate Air Filter for Powered Air-Purifying Respirators (99.97% filter efficiency level) Effective against all particulate aerosols. |

**CAUTIONS and LIMITATIONS**

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

B Not for use in atmospheres immediately dangerous to life or health.

C Do not exceed maximum use concentrations established by regulatory standards.

F Do not use Powered Air-Purifying Respirators if airflow is less than four cfm (115 lpm) for tight-fitting facepieces or six cfm (170 lpm) for hoods and/or helmets.

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

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

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

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

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

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

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

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

PH The limited PAPR approval will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act, or the EUA is revoked under Section 564(g) of the Act, or until such time that the approved configuration can no longer be maintained whichever may be shorter.

# Abbreviated PAPR Filter Label

Includes the acronym NIOSH or NIOSH logo (below)

Name and contact information

Abbreviated Filter Label must be magenta colored

Marked NIOSH HE, NIOSH PAPR 100-P, or NIOSH PAPR 100-N

Label will be affixed to the respirator filter or cartridge body.

 

Example label is described below.

|  |
| --- |
| HHS logo National Institute for Occupational Safety and Health NIOSH logo  Approval: TC-21C-PHXX  Assigned to: Company name and address (phone number)  Powered Air Purifying Respirator for Public Health Emergency  Protections: High Efficiency (HE) or 100P or 100N Particulate Filtration Level  **Read and understand UI prior to use.**  **User must adhere to all C&L in the UI.**  The following Cautions and Limitations spelled out in the UI apply:  **A, B, C, F, I, J, L, M, N, O, P, S, PH**  The respirator identified above by approval number and model consists of the following components parts:  1111, 2222, 3333, 4444, 5555  Only those replacement components specified and supplied by the approval holder may be used to maintain operational status. Substitution of any component with any other parts will result in a non-approved configuration. |

# APPENDIX A

|  |  |
| --- | --- |
| **EXPEDITED PAPR PHE APPLICATION FORM** | |
| **Sender Name and Contact Information** | Name:  Company or NIOSH Code:  Phone:  Email:  Address: |
| **Request for the Limited PAPR PHE Approval** | |
| **Product Name and Class/Series** |  |
| **Model Number** |  |
| **Lot Number** |  |
| **Manufacturing Year/Expiration Date (if available)** |  |
| **Quality System Identification and Attestation** |  |
| **Summary of Documents Provided** |  |
| **Summary of Hardware Provided**  **Shipping Method**  **Expected Arrival NIOSH** |  |
| **Additional Contact information**  **(optional)** | Name:  Phone:  Email:  Address (if different): |
|  | **Sign and date** |