NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2021-1036
July 2021

Subject: Immediate Information for NIOSH-Approval Holders having Public Health Emergency (PHE) Approvals issued during the COVID-19 Response, and the forthcoming NIOSH revocation of these PHE approvals

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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1) SUMMARY

Throughout 2020, NIOSH issued limited, temporary Public Health Emergency (PHE) approvals for N95 filtering facepiece respirators (FFRs) and powered air-purifying respirators (PAPRs). **NIOSH is informing the holders of those PHE approvals about the forthcoming NIOSH revocation of these approvals. PHE approvals will be revoked upon expiration of the public health emergency declaration first issued by the HHS Secretary on January 31, 2020.**[1]

On April 9, 2021, CDC updated its "Strategies for Optimizing the Use of N95 Respirators." These updates include an acknowledgement that the supply and availability of NIOSH-approved respirators have increased significantly over the last several months. The updates to the guidance as summarized on the CDC website include:

- For conventional capacity strategies
  - Added language on extended use of N95 respirators as source control
  - Added language on use of respirators with exhalation valves
- For contingency capacity strategies
  - Added a strategy to prioritize respirators for healthcare personnel (HCP) who are using them as PPE over those HCP who are only using them for source control
  - For extended use of N95 respirators as PPE, clarified that N95 respirators should be discarded immediately after being removed
- For crisis capacity strategies
  - Removed the strategy of using non-NIOSH-approved respirators developed by manufacturers who are not NIOSH-approval holders
  - Highlighted that the number of reuses should be limited to no more than five uses (five donnings) per device by the same HCP to ensure an adequate respirator performance
  - Removed decontamination of respirators as a strategy with limited re-use
  - Emphasized that facemasks for caring for a patient with suspected or confirmed SARS-CoV-2 infection should only be used for certain scenarios as a last resort if respirators are severely limited

[1] *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx for the most current *Renewal of the Determination that a Public Health Emergency Exists Nationwide as the Result of the Continued Consequences of Coronavirus Disease 2019 (COVID-19) Pandemic*.

- Removed the table "Suggested well-fitting facemask or respirator use, based upon distance from a patient with suspected or confirmed SARS-CoV-2 infection and use of source control"

During the COVID-19 response, one crisis and contingency strategy included the use of NIOSH-approved FFRs and PAPRs identified as PHE Approvals. As described in each NIOSH PHE approval letter, the N95 FFR or PAPR PHE approval was granted and effective on a limited and temporary basis.

In anticipation of the end of the declared public health emergency and the concomitant revocation of the PHE approvals, if the PHE approval holder intends to provide a smooth transition for PHE respirator users, the PHE approval holder may submit a new approval application to obtain a conventional NIOSH approval. An application for a new NIOSH approval must be submitted and approved by NIOSH through the respirator approval process described in 42 CFR Part 84, NIOSH Conformity Assessment Notice NIOSH CA 2021-1034R1, and the NIOSH Standard Application Procedures.

The table below provides a summary of the FDA, NIOSH, and OSHA dispositions regarding NIOSH PHE approvals. The agencies continue to collaborate to establish post-COVID-19 solutions to optimize the respiratory protection options available in healthcare settings during conventional operations.

Respirator Type	PRE-COVID PHE USE			DURING COVID PHE USE			POST-COVID PHE USE		
	FDA	NIOSH	OSHA	FDA	NIOSH	OSHA	FDA	NIOSH	OSHA
PHE N95 FFR	PHE devices did not exist			✓	✓	✓	X	X	X
PHE PAPR				✓	✓	✓	X	X	X

2) AUTHORITY

42 C.F.R. Part 84, Approval of Respiratory Protective Devices

3) REFERENCES

Letter from RADM Denise M. Hinton, FDA, to Dr. Robert Redfield, CDC, March 11, 2020, to clarify Emergency Use Authorization ("EUA") issued by the Food and Drug Administration ("FDA") on March 2, 2020

Letter from RADM Denise M. Hinton, FDA, to Dr. Robert Redfield, CDC, March 28, 2020, authorizing emergency use of NIOSH-approved air-purifying respirators for use in healthcare settings by HCP to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3)

Authorization for Medical Products for Use in Emergencies, 21 U.S.C. § 360bbb-3

Approval of Respiratory Protective Devices, 42 C.F.R. Part 84

NIOSH Conformity Assessment Notice (CA 2021-1034R1), June 2021, Summarized information about NIOSH Respirator Approval Program (i) Basic Application Procedures (ii) Quality Assurance Requirements and (iii) Supplier or Subcontractor Agreements

Standard Application Procedure for the Approval of Air-Purifying Filtering Facepiece Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Powered Air-Purifying Respirators and Chemical, Biological, Radiological and Nuclear Powered Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2