NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2020-1027
April 2020

Subject: Effective Immediately - In response to COVID-19 - NIOSH is accepting and prioritizing particulate filtering respirator approval applications submitted by existing approval holders and new domestic manufacturers/applicants

Supersedes NIOSH CA 2020-1024

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

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In response to the nation's effort to control the spread of coronavirus disease 2019 (COVID-19) outbreak, the National Institute for Occupational Safety and Health (NIOSH) Respirator Approval Program is accepting and prioritizing applications received for new approvals and extension of approvals submitted by existing approval holders and new domestic respirator manufacturers/applicants.

NIOSH is committed to protecting healthcare personnel and Americans preparing to return to work by accepting and expediting applications to increase the supply of NIOSH-approved particulate filtering (air-purifying) respirators and ensure quality products providing the intended protections are available. The applications accepted can include those seeking or modifying approval for filtering facepiece respirators (FFR), half mask and full facepiece air-purifying respirators (APR) and powered air-purifying respirators (PAPR). During the response, NIOSH is **not** accepting applications for approval of FFRs with novel head suspensions, e.g. ear loops.

Once approved, the respirators will be added to the NIOSH Certified Equipment List and will thus be covered under the FDA's clarification letter, and Emergency Use Authorization (EUA), dated March 28, 2020 for use by healthcare personnel.

NIOSH is also prioritizing Quality Assurance (QA) applications to facilitate FFR, APR, and PAPR production at additional manufacturing sites, in accordance with established and NIOSH-approved QA systems.

NIOSH is also developing procedures to conduct virtual domestic site qualification evaluations of new domestic manufacturing and quality management facilities, for applicants seeking their first NIOSH approval for an FFR, APR or PAPR.

The prioritization of domestic requests will impact NIOSH's ability to process requests received from new international respirator manufacturer for manufacturers codes, application and engineering reviews and related questions. Additionally, due to heightened concerns over counterfeiting, NIOSH will not respond to emails that lack recognizable company domains. Examples include emails that look like 3894634876@hotnet.net, or cv2009@vip.126.com, or 3272523865@qq.com. Inquiries for approval will only be responded to when received from an email address recognizably associated with a legitimate business or stakeholder.

Supplemental Information

FDA EUAs NOT Associated with NIOSH Approved Respirators

The FDA Emergency Use Authorizations website should be checked for the most up-to-date information. As of April 23, 2020, the FDA has issued three EUA's that do **NOT** require seeking NIOSH approval, NIOSH asks stakeholders interested in inclusion in these authorizations read and follow the information and guidance provided by the FDA.

For inclusion in Exhibit 1 Authorized Respirators:
Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators;
https://www.fda.gov/media/136403/download March 28, 2020, Imported other than China

For inclusion in Appendix A:
Manufacturers of Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators;
https://www.fda.gov/media/136664/download April 3, 2020, Imported China

Manufacturers of Face Mask:
https://www.fda.gov/media/137121/download April 18, 2020, Facemasks, non-surgical