NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2021-1032
February 2021

Subject: Effective Immediately – In response to COVID-19 – Updated NIOSH fraud and fraudulent statements policy and prioritization for accepting and examining particulate filtering respirator approval applications, including Surgical N95 respirators, submitted by existing domestic and non-domestic approval holders, new domestic manufacturers/applicants, and new non-domestic manufacturers/applicants.

Supersedes NIOSH CA 2020-1031

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

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NIOSH issued an earlier version of this Conformity Assessment Letter to Manufacturers (CA 2020-1031) in August 2020 to address the overwhelming number of new applications submitted to the NIOSH Respirator Approval Program as well as the serious and ongoing attempts to defraud the Program.

The February 2021 version of this Letter provides new guidance on fraud and fraudulent statements.

The February 2021 version of this Letter also updates the prioritization order for accepting and examining particulate filtering respirator approval applications and clarifies NIOSH's definitions of "domestic manufacturer" and "non-domestic manufacturer."

FRAUD AND FRAUDULENT STATEMENTS

If the NIOSH Respirator Approval Program determines, at any time, that an applicant[1] or a third party acting on behalf of the applicant has engaged in any of the following:

- making any materially false, fictitious, or fraudulent statement or representation, including any omission or concealment of substantive fact in any application or application-related material or communication; or

- misrepresenting or misusing the NIOSH manufacturers' code, respirator approval number, or NIOSH title or logo,

the NIOSH Respirator Approval Program **will discontinue the processing of any current application for a certificate of approval from the applicant** for the duration of the HHS COVID-19 public health

[1] "Applicant" means an individual, partnership, company, corporation, association, or other organization that designs, manufactures, assembles, or controls the assembly of a respirator and who seeks to obtain a certificate of approval for such respirator. *See* 42 C.F.R. § 84.2.

emergency declaration first issued on January 31, 2020[2] and **will not process any new application for a certificate of approval from the applicant** for that same time period.

Information concerning suspected fraud related to the NIOSH Respirator Approval Program will be reported to the Department of Health and Human Services Office of Inspector General (OIG). Any person who knowingly and willfully makes any false statement, misrepresentation, concealment of fact, or any other act of fraud to obtain any benefit from the NIOSH Respirator Approval Program is subject to civil and/or administrative remedies as well as felony criminal prosecution and may, under appropriate criminal provisions, be punished by a fine or imprisonment or both pursuant to 18 U.S.C. § 1001.

Additionally, due to ongoing, heightened concerns over counterfeiting, NIOSH will not respond to emails that lack recognizable company domains. Examples include emails that look like 3894876@hotnet.net, cv2009@vip.126.com, or 3273865@qq.com. NIOSH will only respond to inquiries concerning an approval application or request from an email address recognizably associated with a legitimate business or stakeholder.

APPLICATION PRIORITY

In response to the nation's effort to control the spread of COVID-19, the NIOSH Respirator Approval Program is accepting and prioritizing applications received for new approvals and extension of approvals submitted by existing approval holders (both domestic and non-domestic manufacturers) and new domestic respirator manufacturers/applicants.

NIOSH considers **domestic respirator manufacturers** to be those whose design/development activities, quality assurance activities, and manufacturing sites are located inside the United States.

Manufacturers whose headquarters are located within the United States but whose design/development activities, quality assurance activities, and manufacturing sites are not within the United States are considered by NIOSH to be **non-domestic manufacturers**.

NIOSH is committed to protecting healthcare personnel and all workers who rely on NIOSH-approved respirators 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. Accordingly, NIOSH is prioritizing applications seeking or modifying approval for filtering facepiece respirators (FFRs), including half mask and full facepiece air-purifying respirators

[2] *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*.

(APRs), powered air-purifying respirators (PAPRs), and Surgical N95 FFRs described in NIOSH CA 2018-1010R1. Manufacturers/approval holders interested in applying for Surgical N95 FFR approval MUST follow the guidance in NIOSH CA 2018-1010R1 and should expect approval timelines based on the order described below.

For the duration of the current HHS COVID-19 public health emergency declaration, NIOSH is not accepting applications for approval of APRs (including FFRs) with novel head suspensions, *e.g.*, ear loops. NIOSH is focusing its resources to approve designs with traditional two head-strap suspensions, commonly used in respirator designs demonstrating the fit and protection required by OSHA.

Effective immediately and including applications accepted by NIOSH prior to publication of this notice, NIOSH will prioritize applications in the order described below:

1. Domestic approval holders submitting a new or an extension application, including a new or extension application using the SN95 Guidance. NOTE: This does NOT include claims about barrier performance based on ASTM F2100-20, *Standard Specification for Performance of Materials Used in Medical Masks*, or claims exceeding the threshold limitations defined in the NIOSH/FDA MOU.

2. Domestic and non-domestic approval holders submitting Quality Assurance (QA) applications to facilitate FFR, APR, and PAPR production at additional manufacturing sites, in accordance with established and NIOSH-approved QA systems.

3. New domestic applicants. NOTE: NIOSH has developed 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. Alternatively, NIOSH may use a contractor to conduct the site qualification visit.

4. Non-domestic approval holders submitting a new application using the SN95 Guidance. NOTE: This does NOT include claims about barrier performance based on ASTM F2100-20, *Standard Specification for Performance of Materials Used in Medical Masks*, or claims exceeding the threshold limitations defined in the NIOSH/FDA MOU.

5. New domestic applicants re-submitting a new application after a prior denial was issued by NIOSH. NIOSH has developed 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. Alternatively, NIOSH may use a contractor to conduct the site qualification visit.

6. Non-domestic approval holders submitting a new or extension application.

7. New non-domestic applicants submitting a new application using the SN95 Guidance, with priority given to products manufactured in Canada and Mexico. Timelines will depend on the ability to arrange and complete initial site qualification visits. NOTE: This does NOT include claims about barrier performance based on ASTM F2100-20, *Standard Specification for Performance of Materials Used in Medical Masks*, or claims exceeding the threshold limitations defined in the NIOSH/FDA MOU.

8. New non-domestic applicants, with priority given to products manufactured in Canada and Mexico. Timelines will depend on the ability to arrange and complete initial site qualification visits.

9. New non-domestic applicants re-submitting a new application after a prior denial was issued by NIOSH. Timelines will depend on the ability to arrange and complete initial site qualification visits.

Once NIOSH-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.

Requests for new manufacturer codes and other questions related to the NIOSH Respirator Approval Program from non-domestic manufacturers with no previous relationship to the Program will be answered as NIOSH resources allow.