Centers for Disease Control and Prevention

Promoting productive workplaces through safety and health research NIOSH

NIOSH Conformity Assessment Letter to Manufacturers

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

Supersedes NIOSH CA 2020-1027

This notice has been superseded. For the latest NIOSH guidance on this topic, please see the updated notice: https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformitymanuf/CA-2021-1032.html

NIOSH CA 2020-1031
August 2020

In response to the nation's effort to control the spread of coronavirus disease 2019 (COVID-19), 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 (FFRs), including Surgical N95 FFRs described in NIOSH CA 2018-1010R1, half mask and full facepiece air-purifying respirators (APRs), and powered air-purifying respirators (PAPRs). During the COVID-19 response period, NIOSH is not accepting applications for approval of 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.

NIOSH has posted updated guidance ("SN95 Guidance", NIOSH CA 2018-1010R1) for manufacturers/approval holders interested in applying for Surgical N95 FFR approval under the consolidated NIOSH and FDA MOU. Applicants MUST follow the guidance and should expect approval timelines based on this notice.

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 2100-19 , 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 international 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: 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. International approval holders submitting a new application using the SN95 Guidance. NOTE:This does NOT include claims about barrier performance based on ASTM 2100-19 , Standard Specification for Performance of Materials Used in Medical Masks, or claims exceeding the threshold limitations defined in the NIOSH/FDA MOU .
5. International approval holders submitting a new or extension application.

6. New international 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 2100-19 , Standard Specification for Performance of Materials Used in Medical Masks, or claims exceeding the threshold limitations defined in the NIOSH/FDA MOU .
7. New international 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.
8. New international 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.

The prioritization listed above will further impact NIOSH's ability to process requests received from new international respirator manufacturers for manufacturers' codes and to answer their questions related to the Approval Program. 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 for approval received from an email address recognizably associated with a legitimate business or stakeholder.

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Page last reviewed: August 21, 2020