NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2022-1040
February 2022

Subject: Effective Immediately - Prioritization of applications submitted by existing domestic approval holders and new domestic applicants for new approvals or extensions-of-approval for particulate filtering respirators, including Surgical N95 respirators. This prioritization does not include private-label requests.

This notice and NIOSH CA 2022-1041 supersede NIOSH CA 2021-1032

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

Subject: Effective Immediately - Prioritization of applications submitted by existing domestic approval holders, and new domestic applicants for approvals or extensions-of-approval for particulate filtering respirators, including Surgical N95 respirators. This prioritization does not include private-label requests.

This notice and NIOSH CA 2022-1041 supersede NIOSH CA 2021-1032

NIOSH CA 2021-1032, a Conformity Assessment Letter to Manufacturers (Letter) published in February 2021, offered prioritization guidance to address the overwhelming number of new applications submitted to the NIOSH Respirator Approval Program (Program) throughout 2020 and early 2021. In that Letter, the Program continued to prioritize applications seeking or modifying approval for half and full facepiece particulate filtering air-purifying respirators (APRs), including filtering facepiece respirators (FFRs), and powered air-purifying respirators (PAPRs) produced in the United States. The prioritization included domestic Surgical N95 FFRs (SN95s) applications described in NIOSH CA 2018-1010R1. The February 2021 letter also included a new policy prohibiting fraud and fraudulent statements in the application process.

The February 2021 Letter is superseded by this notice, NIOSH CA 2022-1040 (prioritization guidance), and NIOSH CA 2022-1041 (fraud and fraudulent statements).

This February 2022 Letter is updated to clarify that NIOSH will continue to prioritize applications for particulate filtering APRs (full and half facepiece), including FFRs, SN95s, and PAPRs, produced in the United States, with preference to domestic approval holders and new domestic applicants. NIOSH continues prioritizing applications submitted by existing approval holders since in the Program's experience existing approval holders are more likely to achieve and maintain approvals. However, applications from existing approval holders to offer private-label versions of a NIOSH-approved respirator will not be prioritized since this process does not increase the capacity of the approval holder to make and release NIOSH-approved respirators.

NIOSH will continue prioritizing the addition of manufacturing sites for all existing approval holders. This can increase the supply of all types of NIOSH-approved respirators, with or without particulate only protections. The process for adding sites requires two steps: 1) identifying the new location, typically accomplished using a quality assurance (QA) application; and 2) submitting an extension-for-approval application for the NIOSH-approved respirator(s) to be manufactured at the newly added manufacturing site.

The Program is not accepting applications for approval of APRs (including FFRs) with novel head suspensions, e.g., ear loops. NIOSH is focusing its resources on approving designs with traditional two head-strap suspensions, commonly used in respirator designs demonstrating the fit and protection required by Occupational Safety and Health Administration. Until NIOSH regulations in 42 C.F.R. Part 84 are updated to incorporate ASTM F3407-21, Standard Test Method for Respirator Fit Capability for Negative Pressure Half-Facepiece Particulate Respirators, into Subpart K, the Program does not have a defined performance standard against which to assess devices with novel head suspensions. NIOSH has indicated that plans to incorporate ASTM F3407-21 into Part 84, Subpart K are underway.

APPLICATION PRIORITY

NIOSH continues to focus on protecting healthcare personnel and all workers who rely on NIOSH-approved respirators during the COVID-19 Response by accepting and expediting applications to increase the supply NIOSH-approved particulate filtering respirators. Accordingly, NIOSH is prioritizing applications for new approvals and extension-of-approvals (except for private-label requests) for half and full facepiece APRs, including FFRs, SN95s, and PAPRs. Applicants and approval holders interested in applying for NIOSH Surgical N95 FFR approval MUST follow the guidance in NIOSH CA 2018-1010R1 and should expect approval timelines based on the order described below. NIOSH continues to prioritize QA application to increase an approval holder's production capacity.

Effective immediately and including applications accepted by NIOSH prior to publication of this notice, NIOSH will prioritize applications in the order described in items 1-9 below, with priority given to domestic approval holders and new domestic applicants:

Domestic respirator applicants are those whose design/development activities, quality assurance activities, purchasing, and manufacturing sites are ALL located within the United States.

Domestic approval holders are those whose corporate headquarters and some or all manufacturing are located within the United States and have achieved at least one NIOSH respirator approval. Private label assignees located within the United States are not approval holders since the NIOSH approval is achieved and maintained by the approval holder. Private label assignees are those with a contractual relationship with the approval holder. This allows them to sell the NIOSH respirators manufactured and labeled for them by the approval holder. The approval holder indicates that they are a private label assignee in the user instructions.

Non-Domestic respirator applicants are those whose headquarters or other activities, such as design and development activities, quality assurance activities, purchasing, or manufacturing are completed

outside of United States. Within this notice, NIOSH does not consider those with headquarters only within the United States to be domestic applicants. They are considered non-domestic applicants.

1. Domestic approval holders submitting a **new or an extension** application (except for private-label requests) for an FFR, APR, PAPR, or SN95.

2. Any approval holder submitting a **QA application** to facilitate production at an additional manufacturing site, in accordance with established and NIOSH-approved QA systems. QA applications to add manufacturing sites located in countries with U.S. Department of State travel advisories may not be approved due to the difficulty in conducting site visits in those countries.

3. New domestic applicants submitting **their first application (new)** for an FFR, APR, PAPR, or SN95. NOTE: NIOSH is conducting virtual domestic site qualification evaluations of new domestic manufacturing and quality management facilities for applicants seeking their first NIOSH approval. Alternatively, NIOSH may use a contractor to conduct the site qualification visit.

4. New domestic applicants **re-submitting a new** application for an FFR, APR, PAPR, or SN95 after a prior denial was issued by NIOSH. NIOSH is conducting virtual domestic site qualification evaluations of new domestic manufacturing and quality management facilities, for applicants seeking their first NIOSH approval. Alternatively, NIOSH may use a contractor to conduct the site qualification visit or may conduct the site qualification using federal employees.

5. Non-domestic approval holders submitting **a new or extension** application (except for private-label requests) for an FFR, APR, PAPR, or SN95.

6. New non-domestic applicants submitting their first application (**new**) for an FFR, APR, PAPR, or SN95 with priority given to products manufactured in Canada and Mexico. Timelines will depend on the ability to arrange and complete initial site qualification visits.

7. New non-domestic applicants, **re-submitting a new** application for an FFR, APR, PAPR, or SN95 after a prior denial was issued by NIOSH, 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. Approval holders submitting a request for **a new or extension** application for other types of respiratory protection not directly related to the COVID-19 Response, e.g., air-supplied respirators and respirators that protect against chemical, biological, radiological, and nuclear (CBRN) hazards.

9. Approval holders **submitting a request for an extension of approval to offer a private-label versions of a NIOSH approved respirator.**

Once NIOSH-approved, new approvals will be added to the NIOSH Certified Equipment List. Respirators that offer particulate only protections will continue to be covered under the Food and Drug Administration's clarification letter and Emergency Use Authorization (EUA), dated July 12, 2021 for use by healthcare personnel.

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

REFERENCES

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

NIOSH Conformity Assessment Letter to Manufacturers (CA 2020-1030) | NPPTL | NIOSH | CDC

ASTM International, Standard Test Method for Respirator Fit Capability for Negative-Pressure Half-Facepiece Particulate Respirators, F3407-21.

NIOSH Science Blog, Overview of the ASTM F3407 Standard Test Method for Respirator Fit Capability.

The Development of Regulatory Requirements for Respirator Fit Capability Test Standards for Air-Purifying, Half-Facepiece Particulate Respirators RIN 0920-AA77.