NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2023-1061
July 2023

Subject: Effective Immediately—NIOSH Respirator Approval Program Returns to Conventional Operations.

This notice supersedes NIOSH CA 2022-1040

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

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This notice applies to applications submitted to the National Institute for Occupational Safety and Health (NIOSH) for approval under the Respirator Approval Program, 42 C.F.R. Part 84. Due to increased demand and decreased supply of NIOSH Approved® respirators during the COVID-19 Public Health Emergency (PHE), NIOSH prioritized applications for the approval of air-purifying particulate filtering respirators. The COVID-19 PHE, declared under Section 319 of the Public Health Service (PHS) Act, expired on May 11, 2023, and the supply and availability of this type of NIOSH Approved respirators have increased significantly since the PHE was originally declared. **Therefore, effective immediately, NIOSH is returning to conventional operations and will no longer prioritize respirator approval applications by type of respirator.**

CONVENTIONAL APPLICATION PROCESSING

Effective immediately, and including applications accepted by NIOSH prior to publication of this notice, NIOSH is returning to conventional operations and is reviewing applications accordingly, regardless of the type of respiratory protection for which the applicant is seeking approval. NIOSH encourages approval holders and applicants to review the application order described below.

Application Order:

1) Approval holders submitting a new application or an application for an extension of approval for any type of respiratory protection, including air-purifying and atmosphere (air)-supplying protections. Quality Assurance 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. Applications to request correlation testing remain the lowest priority for NIOSH.
2) New respirator applicants submitting their first application.

3) New respirator applicants re-submitting their first application after a prior denial was issued by NIOSH.

The timeline for completing the review of a new respirator applicant request for approval will depend on the resources available to conduct the initial site qualification visit. NIOSH is conducting in-person or virtual site qualification evaluations of an applicant's manufacturing and quality management facilities when English is the primary language used at those facilities. NIOSH will begin to conduct in-person site qualification evaluations of an applicant's manufacturing and quality management facilities, where English is NOT the primary language, as resources allow, and NIOSH may use a third party to conduct the site qualification visit.

NIOSH reminds approval holders and applicants that air-purifying particulate respirator applications that include a novel head suspension, e.g., ear loops, will not be accepted. The Respirator Approval Program does not presently have a defined performance standard against which to assess devices with novel head suspensions. As indicated in the Fall 2022 Unified Agenda, NIOSH intends to incorporate a new performance standard into Part 84 to allow NIOSH to test the fit characteristics of non-powered, air-purifying, particulate respirators during the approval process; however, those efforts remain ongoing.

Applicants and approval holders interested in applying for NIOSH Surgical N95® filtering facepiece respirator approval should follow the guidance in NIOSH CA 2018-1010R1.0 and should expect the application review to begin based on the information provided above.

AUTHORITY and REFERENCES

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

Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap | HHS.gov

COVID-19: Renewal of Determination that a Public Health Emergency Exists (hhs.gov)

NIOSH Conformity Assessment Letter to Manufacturers (CA 2018-1010R1.0) | 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

Fall 2022 Unified Agenda, Respirator Fit Capability Test Standard, Filter Shelf Life, and Application Requirements for Air-Purifying Particulate Respirators