NIOSH Conformity Assessment Notice

NIOSH CA 2019-1012
February 2019

NIOSH Respirator Approval Contents and Meaning

Supersedes
March 17, 2006 Respirator User Notice – Meaning of NIOSH Approvals
May 15, 2015 Letter to All Respirator Manufacturers – NIOSH Respirator Certificate of Approval, Approval Labels and User Instructions

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

Subject: NIOSH Respirator Approval Contents and Meaning

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1 SUMMARY

The National Institute for Occupational Safety and Health (NIOSH) is providing this notice to consolidate and update information about the content and meaning of a NIOSH respirator approval.

NIOSH issues certificates for approvals for respiratory protective devices under the provisions of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR Part 84). NIOSH will issue approvals only for complete respirator assemblies or combination respirator assemblies (configurations) that meet the minimum requirements set forth in the regulation. Only the NIOSH approval holder is authorized to use the NIOSH approval label, and that holder is obligated to define proper use and maintenance procedures, maintain the production quality, and provide replacement parts in accordance with the approval. Only those maintainance procedures deemed appropriate and identified by the approval holder are viewed as acceptable in maintaining conformance of the respirator assembly.

NIOSH approval holders communicate NIOSH-approved configurations to the user community and other affected parties through NIOSH-approved labels and related user instructions. The labels and user instructions serve as notifications that the products listed are NIOSH-approved and document approved configurations, protections, and any pertinent cautions and limitations with regard to use.

The NIOSH approval labels list the major subassemblies (parts) that belong to the approved respirator configurations. If any major subassembly has user-replaceable components that are not listed on the approval labels, they must be identified (by part number) in the user instructions. The user instruction manuals are controlled documents that are maintained as part of the approval and listed on the approval label for most types of NIOSH-approved respirator assemblies.

A NIOSH approval applies only to the respirator as tested and the documents provided for NIOSH review and acceptance in accordance with 42 CFR Part 84, NIOSH Standard Application Procedures (listed below), and Letters to Interested Parties or Respirator Manufacturers. NIOSH has updated the Letter format is now providing information as Conformity Assessment Notices,

including Conformity Assessment Interpretation Notices, and Conformity Assessment Letters to Manufacturers.

2 AUTHORITY

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

3 BACKGROUND and SUPPLEMENTAL INFORMATION

Quality Assurance:
The respirator manufacturer's quality control plans are reviewed and must be determined to be satisfactory, in accordance with 42 CFR Part 84, to achieve and maintain the NIOSH approval (see §§ 84.33(f), 84.40, 84.41, 84.42, 84.43). The provisions include regular audits of the Approval Holder's products and manufacturing sites. A NIOSH approval applies only to the specific respirator that consists of the components included on the NIOSH approval label. The issuance of an approval number to a respirator manufacturer does not signify that every respirator built within that manufacturer's facility is also NIOSH-approved.

Performance Testing:
Complete and specific respirator assemblies or configurations are approved after the respirator has been evaluated in the laboratory and found to comply with all relevant performance requirements. Testing completed to achieve NIOSH approval is specific to the respirator type. This includes non-powered and powered air-purifying respirators, or atmosphere-supplying respirators such as self-contained breathing apparatus and supplied-air respirators, and the protections offered.

Certificate of Approval:
A NIOSH certificate for approval applies only to the respirator as tested, and additions or modifications that may affect the performance and design will void the approval. When NIOSH issues an approval, the approval package includes specific electronic files identifying the contents of the approval label or labels and the approved respirator assembly, including the user instructions. The approval labels and user instructions provided to the user serve as notification that the products listed are NIOSH-approved and document approved configurations, protections, and ensure appropriate communication of pertinent cautions and limitations with regard to use. They are part of the approved respirator configuration (see §§ 84.31, 84.33(a), 84.33(b)).

4 REFERENCES

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

Standard Application Procedure for the Approval of Air-Purifying Filtering Facepiece Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Closed-Circuit Escape Respirators Under 42 CFR Part 84, revised October 16, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Supplied-Air Respirators, Industrial Self-Contained Breathing Apparatus, and Combination Supplied-Air Respirators/Industrial Self-Contained Breathing Apparatus Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Powered Air-purifying Respirators and Chemical, Biological, Radiological and Nuclear Powered Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Air-purifying Respirators and Chemical, Biological, Radiological and Nuclear Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Self-Contained Breathing Apparatus, and Chemical, Biological, Radiological and Nuclear Self-Contained Breathing Apparatus Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2