

# **NIOSH Conformity Assessment Letter to Manufacturers**

**NIOSH CA 2023-1056  
April 2023**

**Subject: NIOSH fraud and fraudulent statements policy and information  
about the NIOSH Respirator Approval Program certification marks**

**This notice supersedes NIOSH CA 2022-1041-R1.**



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

**Subject: NIOSH fraud and fraudulent statements policy and information about the NIOSH Respirator Approval Program certification marks**

The NIOSH Fraud and Fraudulent Statements Policy, published as a letter to manufacturers in July 2022 (NIOSH CA 2022-1041-R1), has been updated because the HHS COVID-19 public health emergency is no longer being renewed effective May 11, 2023. This notice provides updated information for NIOSH approval holders, applicants, and other interested parties about several NIOSH Respirator Approval Program certification marks that have been registered with the U.S. Patent and Trademark Office (USPTO).

**NIOSH RESPIRATOR APPROVAL PROGRAM CERTIFICATION MARKS**

NIOSH, on behalf of the Department of Health and Human Services (HHS), registered several certification marks with the USPTO that are specific to NIOSH Approved® respirators to help combat the sale of respirators that are counterfeit or are misrepresented as being approved by NIOSH. These registered certification marks currently include the NIOSH stylized logos with and without full text, NIOSH Approved®, and certification marks, such as N95® and P100®, that correspond to the approved respiratory protection levels for powered and non-powered air-purifying respirators (APRs). The registered certification marks can be found on the NIOSH [Post-market Evaluations Conducted by NIOSH](#) webpage under the section *Protecting End Users from Wearing Respirators Being Misrepresented as NIOSH Approved® Respirators*.

HHS is the owner of these certification marks and NIOSH, as the certifying federal entity for the Respirator Approval Program, is the custodian of these marks. This means that NIOSH administers and controls who can use these marks. Accordingly, the certification marks may only be used by approval holders in reference to respirators that NIOSH has approved under Title 42, Part 84, of the Code of Federal Regulations (42 C.F.R. Part 84).

While these marks have historically been protected under common law, they are now registered with the USPTO and are therefore subject to additional protections under the Lanham Act, 15 U.S.C. §§ 1051 *et seq.* In addition to being registered in the United States, N95 and NIOSH Approved are registered in several international jurisdictions. ***Any misuse of the aforementioned marks on products released to the market or associated with their packaging or marketing description, including (1) respirators that have failed to satisfy NIOSH's regulatory requirements or have not received NIOSH approval, and (2) any other type of face-worn products falsely claiming to be approved by NIOSH, is a direct violation of applicable trademark law and may be subject to enforcement action.***

## **FRAUD AND FRAUDULENT STATEMENTS**

If the NIOSH Respirator Approval Program determines, at any time, that an approval holder, applicant,<sup>1</sup> a third party acting on behalf of the applicant, or any other entity 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 manufacturer code, respirator approval number, or NIOSH title or logo; or
- Misrepresenting or misusing any NIOSH or Respirator Approval Program-associated certification marks,

this information may be reported to the HHS Office of the General Counsel (OGC) and the 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 may be *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 concerns over fraud and misrepresentation, NIOSH will not respond to emails that lack recognizable company domains. Examples include emails such as 3894876@hotmail.net, cv2009@vip.126.com, or 3273865@qq.com. NIOSH will only respond to inquiries about an approval application or request from an email address recognizably associated with a legitimate business or organization.

P100 is a certification mark of the U.S. Department of Health and Human Services (HHS) registered in the United States.

N95 and NIOSH Approved are certification marks of the U.S. Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.

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<sup>1</sup> "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.