

NIOSH Conformity Assessment Letter to Manufacturers

**NIOSH CA 2022-1041R1
July 2022**

Subject: Effective Immediately – NIOSH fraud and fraudulent statements policy and new information about using NIOSH marks

This notice and NIOSH CA 2022-1040 supersede NIOSH CA 2022-1041 and NIOSH CA 2021-1032



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

Subject: Effective Immediately – NIOSH fraud and fraudulent statements policy and new information about using NIOSH marks

This notice and NIOSH CA 2022-1040 supersede NIOSH CA 2022-1041 and NIOSH CA 2021-1032

This NIOSH Fraud and Fraudulent Statements Policy was first included in the February 2021 Conformity Assessment Letter to Manufacturers (NIOSH CA 2021-1032). That notice also offered prioritization guidance and is now superseded by this notice – NIOSH CA 2022-1041R1 (fraud and fraudulent statements) – and NIOSH CA 2022-1040 (February 2022 prioritization guidance).

The fraud and fraudulent statements information has been updated to include information for NIOSH approval holders that the marks N95, N99, N100, P95, P100, R95, the NIOSH stylized logo with and without text, and the term “NIOSH Approved” have been registered as certification marks.

NIOSH RESPIRATOR APPROVAL PROGRAM CERTIFICATION MARKS

The marks N95, N99, N100, P95, P100, R95, the NIOSH stylized logo with and without text, and the term “NIOSH Approved” have been registered with the U.S. Patent and Trademark Office (USPTO) as certification marks. NIOSH, as the certifying federal entity for the Respirator Approval Program, owns the certification marks, meaning that NIOSH controls who can use the marks. Accordingly, NIOSH allows approval holders to use these certification marks only if their respirators meet NIOSH’s regulatory standards set forth in 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 (as opposed to a trademark registration), these marks are now registered with the USPTO as federal registrations as well as in various foreign countries and are therefore subject to additional protections under the Lanham Act, 15 U.S.C. §§ 1051 et seq., and foreign trademark laws. Thus, any misuse of the aforementioned marks on products released to the market, *including respirators that have failed to satisfy NIOSH’s regulatory requirements or have not received NIOSH approval*, is a direct violation of applicable trademark law and NIOSH may pursue action as necessary.

FRAUD AND FRAUDULENT STATEMENTS

If the NIOSH Respirator Approval Program determines, at any time, that an applicant¹ or a third party acting on behalf of the applicant 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 manufacturers' code, respirator approval number, or NIOSH title or logo; or
- misrepresenting or misusing certification marks including the term "NIOSH Approved" and the NIOSH particulate protections N95, N99, N100, P95, P100, and R95;

the NIOSH Respirator Approval Program **will discontinue the processing of any current application for a certificate of approval from the applicant** for the duration of the HHS COVID-19 public health emergency declaration first issued on January 31, 2020² and **will not process any new application for a certificate of approval from the applicant** for that same time period.

Information concerning suspected fraud related to the NIOSH Respirator Approval Program will be reported to the Department of Health and Human Services 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 is 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 ongoing, heightened concerns over fraud and misrepresentation, NIOSH will not respond to emails that lack recognizable company domains. Examples include emails that look like 3894876@hotmail.net, cv2009@vip.126.com, or 3273865@qq.com. NIOSH will only respond to inquiries concerning an approval application or request from an email address recognizably associated with a legitimate business or stakeholder.

¹ "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.

² See <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx> for the most current *Renewal of the Determination that a Public Health Emergency Exists Nationwide as the Result of the Continued Consequences of Coronavirus Disease 2019 (COVID-19) Pandemic*.

Revision (R)	Date	Reason for Revision
1.0	19 July 2022	NIOSH revised this notice to include the registration of the R95 certification mark.