NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2023-1062

July 2023

Subject: Information and Responsibilities of NIOSH Approval Holders for Nonconforming Respirator Investigations (NRIs)

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

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About NRIs

Since the 1980s, NIOSH has overseen Nonconforming Respirator Investigations (NRIs)—formerly known as a Certified Product Investigation Process (CPIP)—as part of its Respirator Approval Program post-market evaluations.

NRIs are conducted by the NIOSH Approval Holder when their NIOSH Approved® respirator does not conform to the requirements of Title 42, Code of Federal Regulations Part 84 (42 C.F.R. Part 84). NRIs are conducted to ensure workers' safety and health risks are minimized by investigating, analyzing, and resolving issues or nonconformances with NIOSH Approved respirators. NRIs are derived from Approval Holder obligations pursuant to 42 C.F.R. § 84.33(f)[1] and NIOSH has authority to act on nonconformances of NIOSH Approved respirators under 42 C.F.R. § 84.34.[2]

An NRI is intended to document findings of the Approval Holder's investigation into the root cause of the issue, provide a mechanism for NIOSH to review and agree to the Approval Holder's planned corrective actions to prevent recurrence of the nonconformance, and confirm the issue has been resolved for respirators that are in the field, in inventory, or slated for future production to maintain the NIOSH approval.

Approval Holders voluntarily cooperate with NIOSH throughout an NRI since this is an efficient and potentially less costly and time-consuming approach to address nonconformances involving a NIOSH Approved respirator. The process enables Approval Holders to provide NIOSH with planned corrective actions in order to maintain the approval.

[1] 42 C.F.R. § 83.33(f): Approval Holders must maintain or cause to be maintained the approved quality control sampling schedule and the acceptable quality level for each characteristic tested, and to assure that [the approved respirator] is manufactured according to the drawings and specifications upon which the certificate of approval is based.

[2] 42 C.F.R. § 84.34: Nonconformances such as misuse use of approval labels, misleading advertising, or failure to maintain the quality control requirements of the certificate of approval may provide cause for NIOSH to revoke a certificate of approval.

Examples of NRIs

Nonconformances that may result in an NRI include, but are not limited to:

- Performance or test failure identified during any NIOSH evaluation (such as a NIOSH product audit),
- Improper documentation or product labeling, such as products sold with an unapproved private label entity, or
- Misleading advertising by the Approval Holder, such as making false protection claims.

Initiation of NRIs

NRIs may be initiated by several sources, including (1) a respirator user or other entity informing NIOSH of a potential issue, failure, or nonconformance; (2) NIOSH recognizing issues based on testing findings, improper documentation, or identifying mislabeling/misleading advertising; or (3) the Approval Holder self-reporting the nonconformance to NIOSH.

Approval Holders should self-report[3] to NIOSH any nonconformance with a 42 C.F.R. Part 84 requirement affecting a respirator's performance, including those issues reported from customers in the field or found during an Approval Holder's internal audit. A respirator user or other entity informing NIOSH of a potential issue can reach out to PPEConcerns@cdc.gov. Using the information provided, NIOSH will determine if an NRI should be opened.

When NIOSH opens an NRI, NIOSH assigns a Task Number and sends an opening letter to the Approval Holder's primary contact on file with NIOSH. The opening letter provides a summary of the possible nonconformance being investigated, and the actions that an Approval Holder should take to maintain the respirator approval(s) as issued.

When an air-supplied respirator is the subject of an NRI, NIOSH may also inform and coordinate with the Safety Equipment Institute (SEI) and the Mine Safety and Health Administration (MSHA). [4]

Actions of the NIOSH Approval Holder

In the opening letter, NIOSH will provide a due date for the Approval Holder to respond to the following action items through a written response to the NIOSH investigator:

- Investigate and determine the reason(s) for the nonconformance.

[3] An Approval Holder may self-report by emailing the contacts at the end of this Conformity Assessment Letter.
[4] NIOSH may coordinate with SEI if a self-contained breathing apparatus (SCBA) is involved, and may coordinate with MSHA if a respirator worn in a mine or is MSHA-evaluated as intrinsically safe is involved.

- Determine how widespread the problem may be by identifying amount, part numbers, approval numbers, lot numbers, and manufacturing dates of affected components.
- Submit a complete report detailing the findings of the Approval Holder's investigation into the nonconformance, including any corrective actions proposed by the Approval Holder to address the problem.
- If a recall or stop sale is to be implemented, provide NIOSH with a copy of the Approval Holder's action plan prior to its implementation.
- If appropriate, prepare a user notice/safety bulletin to be distributed to all users of affected models and provide to NIOSH for review prior to distribution.

Although the root cause analysis, investigation, and corrective actions may not be completed within the initial requested response time, the Approval Holder should provide a timely response to each of NIOSH's questions, as well as timely updates to NIOSH regarding the full investigation if it extends past the due date. NIOSH may request that Approval Holders share documents (e.g., test reports) or photos as part of an NRI. NRIs may result in user notices, voluntary stop sales, recalls, retrofits, changes/improvements to the Approval Holder's quality control process or design through an application, or revocation of NIOSH approvals. **Note that NIOSH may request that the Approval Holder voluntarily stop sale of a nonconforming respirator if warranted.** NIOSH may also request that an Approval Holder prepare a user notice/safety bulletin. Alternatively, NIOSH may issue a Respiratory Protective Device (RPD)-Information notice if necessary for health and safety concerns.

When the Approval Holder prepares a user notice/safety bulletin, NIOSH requests that Approval Holders provide a draft notice to NIOSH for review and possible comment prior to posting on their website. After a notice is finalized and published on the Approval Holder's website, the Approval Holder should send NIOSH a hyperlink to this website so it can be posted on the NIOSH webpage Respirator User Notices Issued by Manufacturers. Once this hyperlink is posted, NIOSH will disseminate this information via its listserv.

Closure of NRIs

After NIOSH concludes that the Approval Holder effectively:

- identified the cause of the nonconformance,
- developed and implemented corrective actions to effectively resolve and prevent the nonconformance from recurring, and
- addressed field units, inventory units, and future production,

the NRI may be closed. A closing letter will be sent to the Approval Holder's primary contact. If the NRI has been resolved to NIOSH's satisfaction, the respirator approval may be maintained.

NIOSH NPPTL Contacts for Questions or to Report a Nonconformance

For NIOSH Approval Holders, contact:

Patrick Wiltanger, Team Leader of the Audits, Investigations, and Brand Protection Team; PWiltanger@cdc.gov

Lee Greenawald, Deputy Branch Chief of the Evaluation and Testing Branch; LGreenawald@cdc.gov

John Powers, Branch Chief of the Evaluation and Testing Branch; JPowers@cdc.gov

For non-NIOSH Approval Holders, such as respirator users, contact:

PPEConcerns@cdc.gov