PPE CASE Notes

Personal Protective Equipment Conformity Assessment Studies and Evaluations Notes

Common Site Audit Nonconformance: Lack of Internal Audit Procedures and Documentation

NIOSH approves respirators in accordance with 42 Code of Federal Regulations Part 84 (42 C.F.R. Part 84). An acceptable quality control plan (QCP)—a subset of the larger quality management system (QMS)— is an important part of an approval holder being granted and maintaining a NIOSH approval. After the approval is granted, NIOSH conducts various respirator post-market conformity evaluations, such as site audits, to ensure respirators continue to be manufactured to the approval holder's accepted QCP on file with NIOSH and their larger QMS. During site audits, NIOSH identifies and informs the approval holder of any nonconformances found (i.e., instances where a requirement is not met) with the QCP or other aspects of the QMS. Nonconformances discovered during a site audit require the approval holder to take corrective action.

NIOSH upholds **internal audit requirements** for approval holders per 42 CFR §84.41 (a)(7) related to maintaining internal audit schedules and records, qualifying internal auditors, and the scope of the internal audit program. The internal audit program must cover the entire QMS, including the accepted QCP. **NIOSH finds many instances where approval holders do not meet these internal audit requirements in accordance with their QMS and the requirements in 42 C.F.R. Part 84.**

Approval holders should refer to NIOSH CA 2019-1019 for assistance with internal audit requirements and pay particular attention to non-conformances NIOSH commonly observes by being sure to establish (1) an audit schedule, (2) procedures for training auditors, and (3) procedures for maintaining audit documentation.

NONCONFORMANCES IDENTIFIED DURING SITE AUDITS

Approval holders frequently do not

- Demonstrate that all areas of their QMS are subject to internal audits.
- Establish or follow their internal audit schedule—for example failing to perform a section of the internal audit or reschedule an audit when needed.
- Put procedures in place to determine how internal auditors are qualified.
- Provide adequate or any internal audit documentation, including what was audited, by whom, internal auditor training records, or detail on nonconformances found.

BEST PRACTICE REMINDERS ON INTERNAL AUDITS FOR APPROVAL HOLDERS

- Refer to NIOSH CA 2019-1019 for guidance on NIOSH requirements for QCPs and internal audits.
- Consider a systematic approach of reviewing internal procedures/processes to ensure all aspects of the QMS—including the accepted QCP requirements and sections of applicable quality standards (e.g., 42 C.F.R. 84 and ISO 17025)—are audited.
- Establish and follow an internal audit schedule as documented in the accepted QCP.
- Consider how management practices can prioritize internal audits and be scheduled to minimize conflicts with other activities and responsibilities.
- Establish a process to effectively qualify internal auditors—for example through internal or external training, such as ISO 1900: 2018 *Guidelines for Auditing Management Systems*—and to ensure the auditors understand the internal audit requirements specified in 42 C.F.R. Part 84. Document the training records for the internal auditor.
- Ensure proper internal audits documentation and records are maintained. This includes identifying the internal auditor or auditors, the date of the audit, the scope of the audit, records of questions asked and evidence provided, and detail on nonconformances.

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