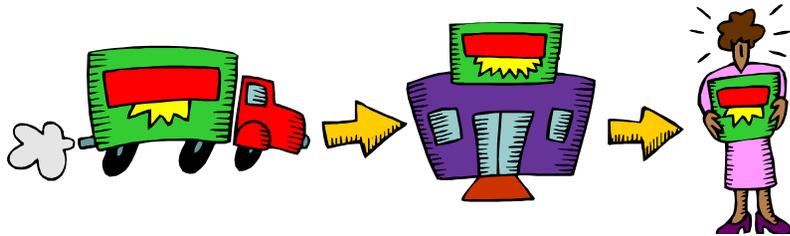


Quality System Assessment and Records FY15 (927PP22-1) Product Audits

Objective

Ensure manufacturer compliance to NIOSH-approved quality system plans and respirator performance requirements



Applicable Standards

- 42 CFR 84.40-43, Subpart E – Quality Control
- 42 CFR 84.65(e), Subpart G – General Construction and Performance Requirements

Key Partners

- All Approval Holders

Stakeholders

- Respirator manufacturers
- Respirator users

Project Scope

- Perform post-market surveillance product audits of NIOSH-approved respirators for post certification evaluation
- Review and evaluate proposed resolutions and corrective actions from approval holders to ensure conformance to the criteria listed in 42 CFR, Part 84

Milestones

- Perform product audits (on-going)
- Projected 40 product audits for FY-15

Outputs

- Product Audits FY2013 : 74 tested 74 passed
- Product Audits FY2014: 36 tested 32 passed 4 failed
- Product Audits FY2015: 19 tested 17 passed 2 failed

Outcomes

- Approval holder respiratory products continue to meet or exceed the criteria on which the approval was based.
- Approval Holders assure quality and reliability of respirators.
- Workers have stronger assurance of respirator reliability

Updated: 20 Feb 2015