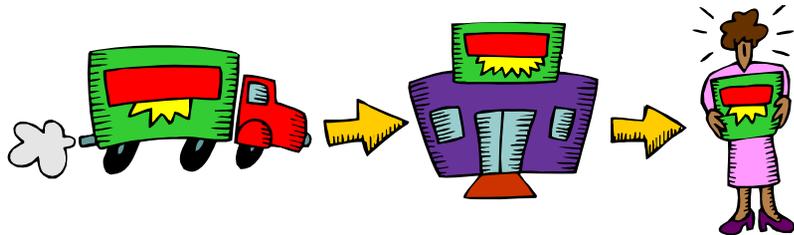


Quality System Assessment and Records FY13 (927PP22)

Objective

Ensure manufacturer compliance with quality system plans and respirator performance requirements.



Applicable Standards

- 42 CFR 84.33, labeling and 42 CFR 84.65(e), product audit
- 42 CFR 84.40-43, Subpart E – Quality Control

Key Partners

- All Approval Holders
- 2 Private sector auditing firms

Stakeholders

- Respirator manufacturers
- Respirator users

Project Scope

- Perform a site audit every 2 years for all Approval Holders
- Perform respirator product audits for post-certification and filtering facepiece shelf life study

Milestones FY13

- Simplified acquisition contracts (FY2012 funds) on-going (35 of 56 audits performed to date)
- Base 5-year audit support contract awarded
 - Task orders going out for bid (FY2013 funds)
- Perform product audits (on-going)

Outputs

- Product Audits FY2012: 126 tested, 10 failed
- Product Audits FY2013: 32 tested, 0 failed (to date)
- Site Audits FY2012: 47 opened, 50 closed
- Site Audits FY2013: 47 opened, 14 closed (to date)

Outcomes

- Approval Holder quality systems and products continue to meet standard, or approval revoked.
- Approval Holders assure quality and reliability of respirators.
- Workers have stronger assurance of respiratory functionality.

Updated: 4 Apr 2013