

Quality System Assessment and Records FY15 (927PP22) – Site Audits

Objective

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



Applicable Standards

- 42 CFR 84.33, labeling
- 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

Milestones FY15

- Base 5-year audit support contract under way
 - Eleven tasks begun (FY2014 funds)
 - Eight completed, three ongoing
 - New tasks (FY2015 funds) being prepared for bid
- Initiate work to define process and parameters for pre-approval site qualification visits

Outputs

- Site Audits 3Q, FY2014: 0 opened, 9 closed
- Site Audits 4Q, FY2014: 26 opened, 18 closed
- Site Audits 1Q, FY2015: 25 opened, 21 closed
- Site Audits 2Q, FY2015: 3 opened, 3 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 Feb 2015