

Quality System Assessment and Records FY17 (927PP22) – Site Audits – Vance Kochenderfer

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 FY17

- Base 5-year audit support contract under way, expires 4Q
 - Twelve tasks awarded with FY2016 funds
 - Five completed, others in process w/ completion anticipated by August 1
 - New tasks (FY2017 funds) being prepared for bid
- New base contract to be awarded 4QFY2017 or 1QFY2018

Outputs

- Site Audits 3Q, FY2016: 19 opened, 13 closed
- Site Audits 4Q, FY2016: 34 opened, 19 closed
- Site Audits 1Q, FY2017: 0 opened, 10 closed
- Site Audits 2Q, FY2017: 6 opened, 13 closed

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: 26 Apr 2017