Arizona’s Experience From The Field – ISO 17025

Background

- Arizona State Public Health Laboratory

- Grants to participate in the Food Emergency Response Network (FERN) as a CAP Lab
  - But did not receive the FDA ISO Grant

- The state delegates the MFRPS to the counties
Change is an interesting process, especially when you have to pull in individuals from outside the laboratory sections:

- Information Technology
- Procurement
- Business Office
- Facilities

Journeying with ITS

Explaining the need for a Quality Management System:

- Document Control System
  - Looped ITS in at the beginning
  - Originally encouraged to pursue outside vendor
    - After about a year, scope of work ready, changed direction
  - SharePoint Site
    - 15 months later finally in Production
  - ITS Staff capable – no resources, but wanted to keep in house
    - We ended up having to spend funds on a contractor to get completed
ISO 17025 Accreditation Body (AB)
- No one AB required and there are six viable ABs
  - Thus having to go out for bid on an AB
- Explaining to Procurement staff need and how accreditation worked – new process for all
  - Developing a scope of work
  - Including other agencies in the state that might need ISO
  - Reviewing the bids and figuring out costs

Lab Business Office (LBO) reports to the Agency Business Office (ABO) not the Lab Managers
- Loop in the top ABO staff in addition to LBO staff
- Presentation on ISO & Purchasing sections
- Multiple sessions explaining the need for procedures, reviews, and forms
  - How some agency forms will work & others will not
- Technical Reviews – how to incorporate?
Facilities

- Building Management
  - Equipment maintenance
    - Centrifuges
    - Refrigerators/Freezers/Incubators
    - Autoclaves
  - Environmental Controls
    - Maintain temperature & humidity
  - Explaining the need for procedures, reviews, and forms

Lessons Learned

- Much of the processes took more time than expected
- How to explain ISO to non-Lab staff
  - Especially while trying to learn it as well
- New partnerships
  - Working and learning about processes never had to consider before

- Moving forward
  - Some areas we reached out to have taken to the new requirements
    - Tying into improvement
    - Consulting with Lab about up & coming things that could impact us (not always related to ISO)
  - Some areas it is still a process of explaining
Questions?

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