



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



Being Creative



- Change is an interesting process, especially when you have to pull in individuals from outside the laboratory sections
 - Information Technology
 - Procurement
 - Business Office
 - Facilities




Information Technology



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



Procurement



- 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



Business



Office

- 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

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| <ul style="list-style-type: none"> ■ Much of the processes took more time than expected ■ How to explain ISO to non-Lab staff <ul style="list-style-type: none"> ■ Especially while trying to learn it as well ■ New partnerships <ul style="list-style-type: none"> ■ Working and learning about processes never had to consider before | <ul style="list-style-type: none"> ■ Moving forward <ul style="list-style-type: none"> ■ Some areas we reached out to have taken to the new requirements <ul style="list-style-type: none"> ■ 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 |
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Questions?



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