Lab Accreditation: My Story

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Our perspective of a Quality System Standard - AT THE TIME

- “kicking and screaming”
- Already doing QC – just more paperwork
- Already had SOPs – just more paper work
- Already had had a QA Manual – just more paperwork
- What is the extra benefit here? – doing more paperwork?

- First Inspection January 2001
  - Commercial Lab
  - Satellite Location of larger full service lab (Mostly Wet Chem and Microbiology)
  - Used the 1999 standard
  - 150+ findings
  - Very Daunting
    - Reformat SOPs
    - Add SOPs for other activities
    - Internal procedures implemented

- Lots of time writing documents
- Discovered that we were not getting enough detail in our documentation
- Day to day did not change
  - Already using blanks, spikes, and dups
  - Already doing PTs 2x per year
  - Methods already had required QC

The standard dictated the documentation.

Cost vs Benefit

- Lots of time up front ….. helps in the day to day
- Documentation was tough and time consuming to establish……tracking is very easy
- Then, no real help out there…….. Now lots of professional organizations willing to share and help.

Cost vs Benefit

- Additional cost of supplies…….less reruns and more ways to document. Data may still be useable.
- Additional cost of QC…… accountability to client and data users. Customer service
- Additional time devoted to QA/QC will impact productivity……..If you don't have time to do it right when will you have time to do it over?

Next assessment?

- < 10 findings
- SOPs and other documents in place
- Became easier over time.
- Always easier to follow a system rather than invent one.

Buy-in?

- In Florida, a must to stay in business.
- The parent lab was accredited over multiple states so helped with consistency
- Level playing field
- Clear lines between FDEP and FDOH
  - Very common to get contradictory info from these groups
  - FDEP data users
  - FDOH lab oversight

My experience and recommendation

- Early standards were not a true consensus std.
- Labs did not have a real voice
- Had an over zealous QA manager in the private sector, so decided to get involved and educate myself
- Be your own advocate
- There is no extra credit for complicated systems. Use the KISS method.

Next Phase of my journey

- Moved to utility lab in 2007.
- Had inspections but still multiple findings due lack of clarity in the requirements and lack of buy in from staff.
- Implemented some streamlining
  - Better compliance (fewer findings)
  - Better buy-in from staff
  - Being involved in the process helped me to get access

Most difficult portion (in both locations):

- Establishing the documentation
- Coming up with the forms
- Getting staff buy-in

Another experience

- Had to terminate an analyst
- Having a quality system in place help with:
  - Corrective Action
  - Communicating with State agencies
  - Having a bit of a safety net

A Quality System does not ensure nothing goes wrong. It tells you what do when it does. And it helps to prevent it from happening in the future.

Questions ?

Thank you

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