So You Want To Be A Lab Rat?

Foundations of Analytical Competency and Laboratory Accreditation

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ODEQ

STATE ENVIRONMENTAL LABORATORY

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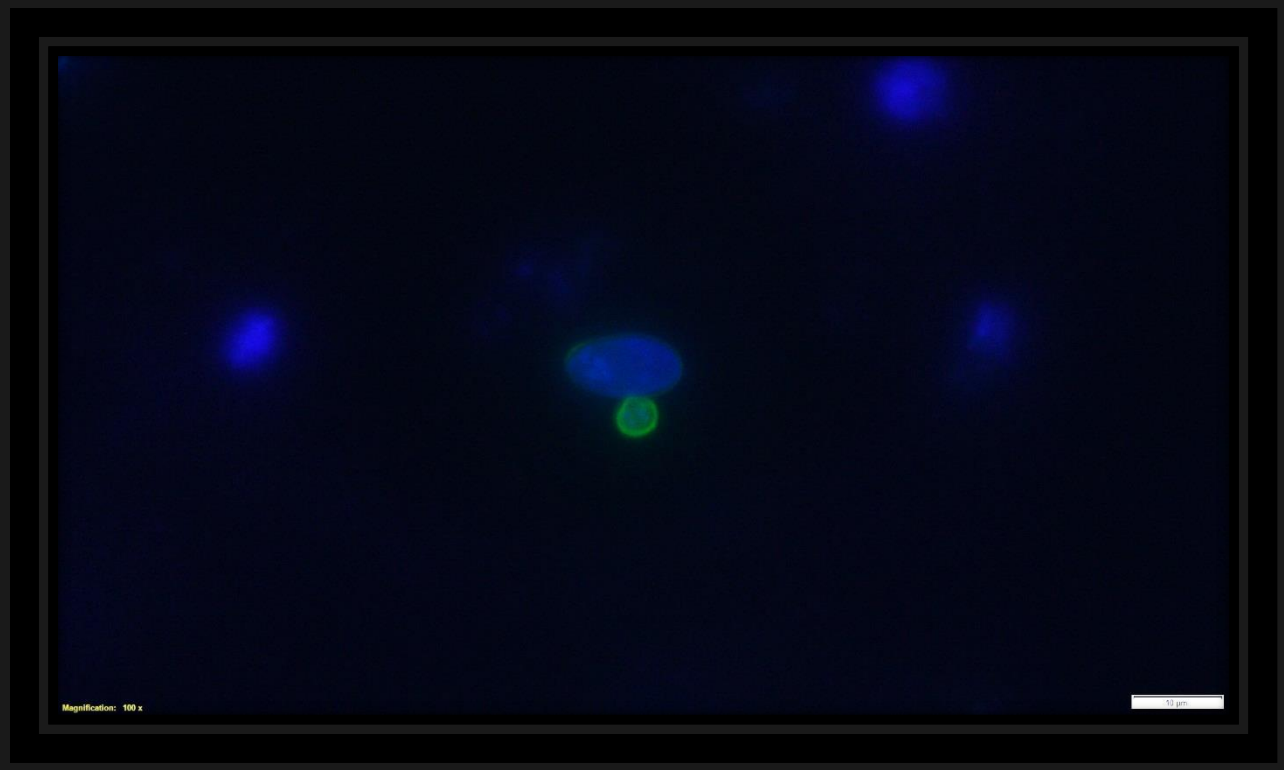
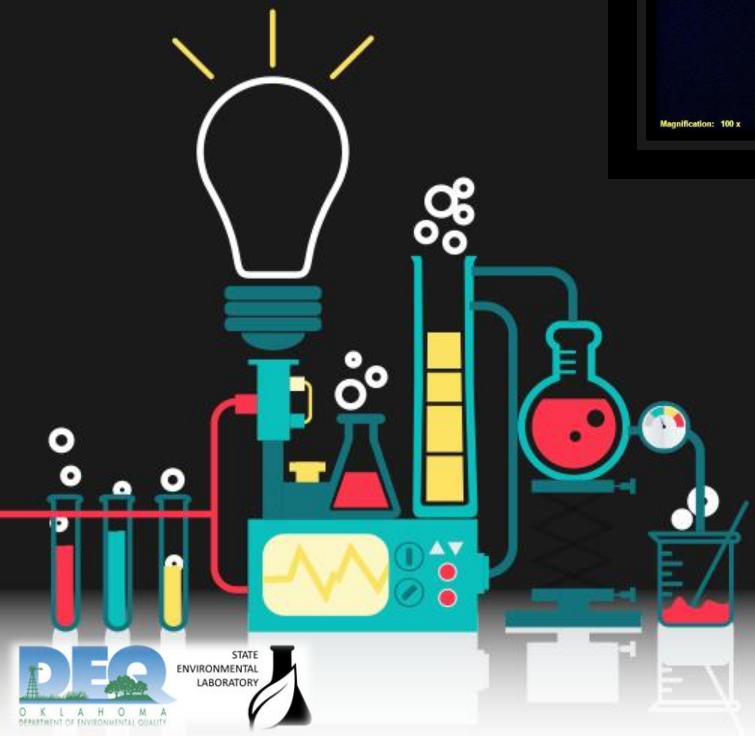
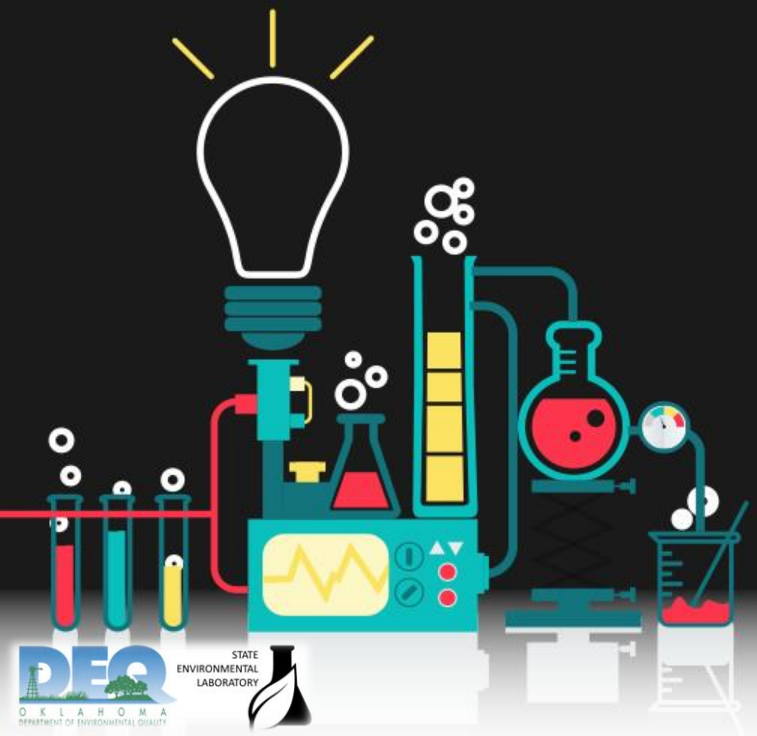




Cryptosporidium & Giardia

STEP 1: RESEARCH



- Locate list of approved methodologies
- Determine certification/accreditation requirements
- Evaluate method performance criteria for best fit
- Establish specifications and vendors for raw materials
- Locate potential training opportunities
- Identify customer needs and other stakeholders
- Contact laboratories or individuals that have experience with the method
- Examine any legal or jurisdictional issues
- Identify any safety concerns

STEP 2: LAB CAPACITY ASSESSMENT

- Equipment & Instrumentation?
- Staffing?
- Expertise?
- Availability of Consumables?
- Workload?
- Infrastructure?
- Quality System implications?
- Impact on LIMS?

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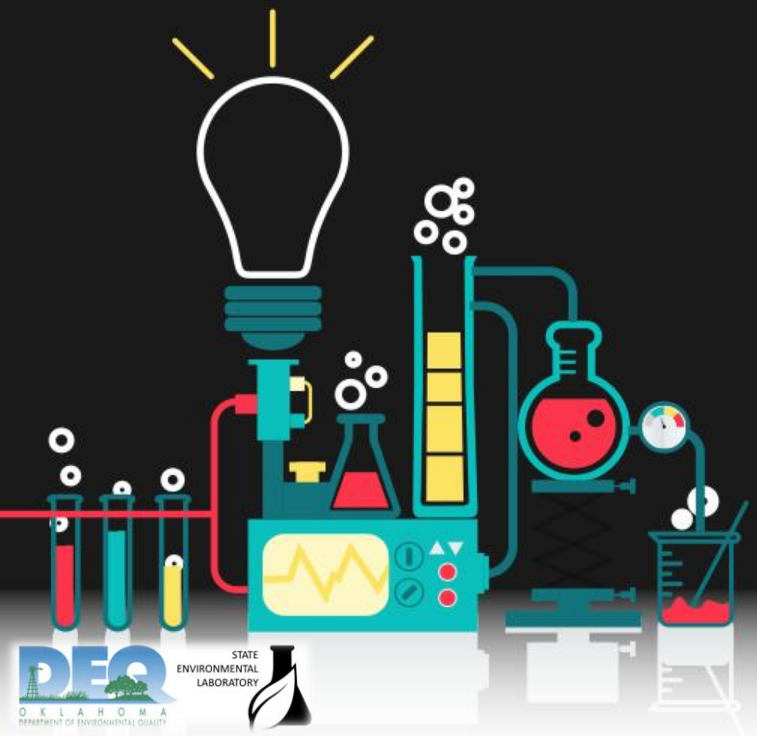
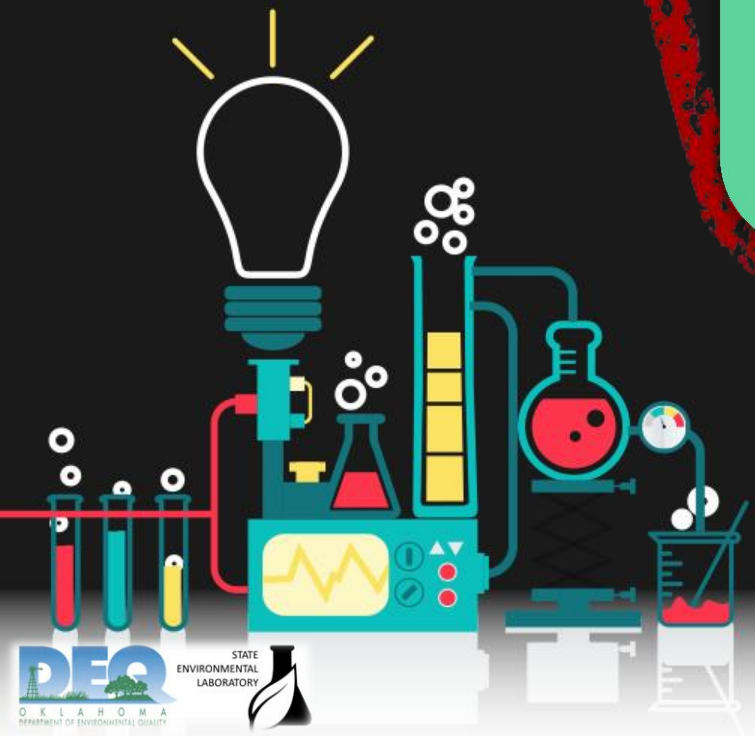
(Time & Cost Estimate)

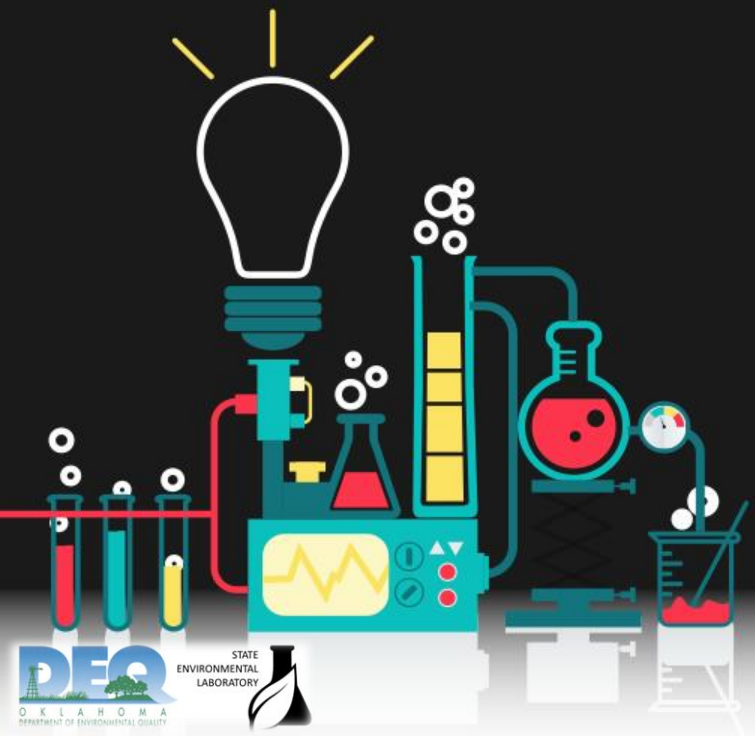


STEP 3: SECURE AUTHORIZATION AND FUNDING

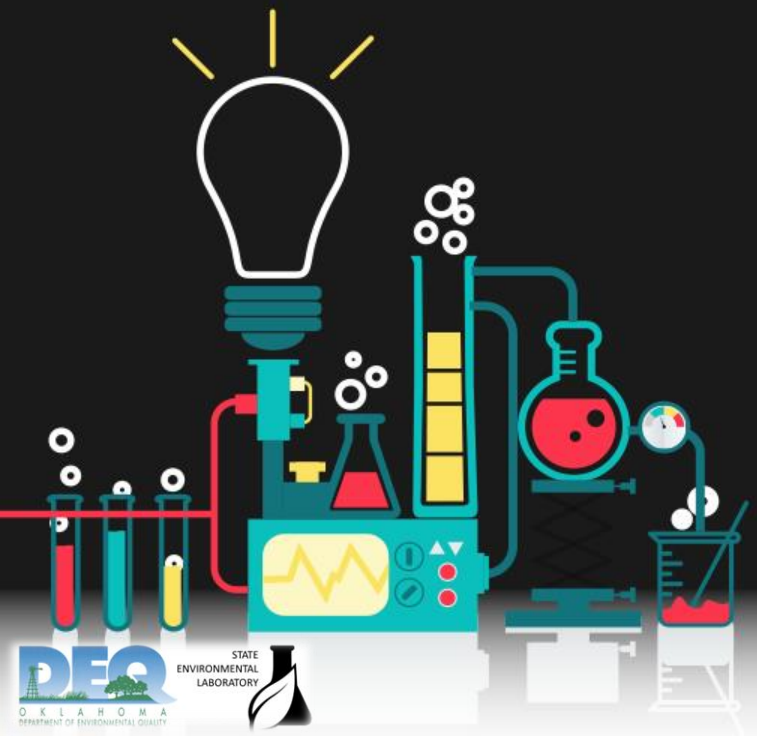


STEP 4: RESOURCE AND RAW MATERIAL ACQUISITION

- Instrumentation & Equipment
- Standard Reference Material
- Consumables
- Training
- Infrastructure
- Procurement Challenges



STEP 5: METHOD DEVELOPMENT



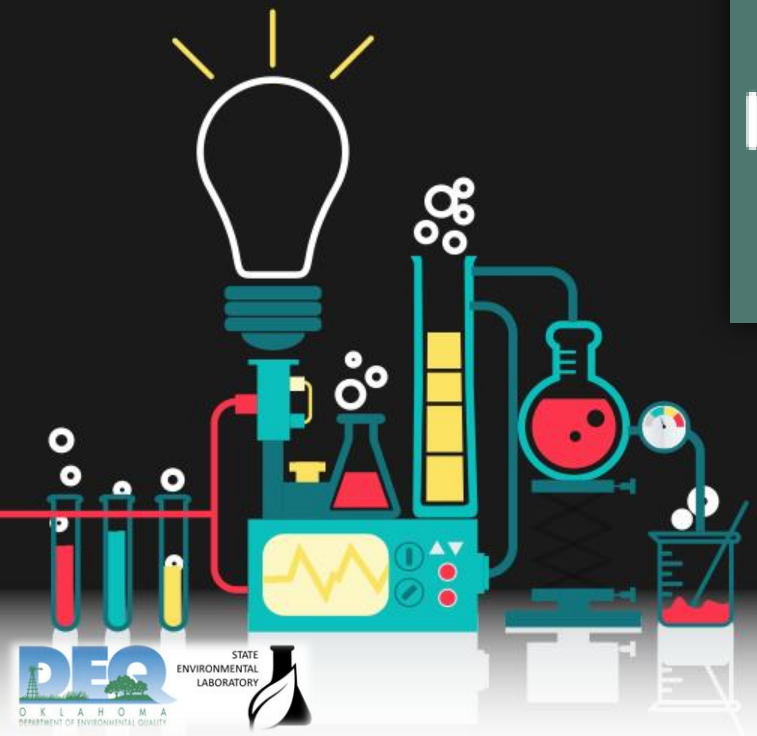
- Validate instrumentation/equipment
- Ensure traceability of all materials
- Define data quality objectives for the method
  - Analytes of interest
  - Detection & quantitation limits
  - Type, concentration, and frequency of QC samples
- Training
- Contingencies
- Experimentation with documentation
- More experimentation with documentation
- Even more experimentation with documentation
- Draft SOPs with supporting documents

STEP 6: METHOD VALIDATION

- Identity
- Specificity
- Sensitivity
- Range
- Reproducibility
- Robustness
- Finalize the Standard Operating Procedures
- Establish Fee

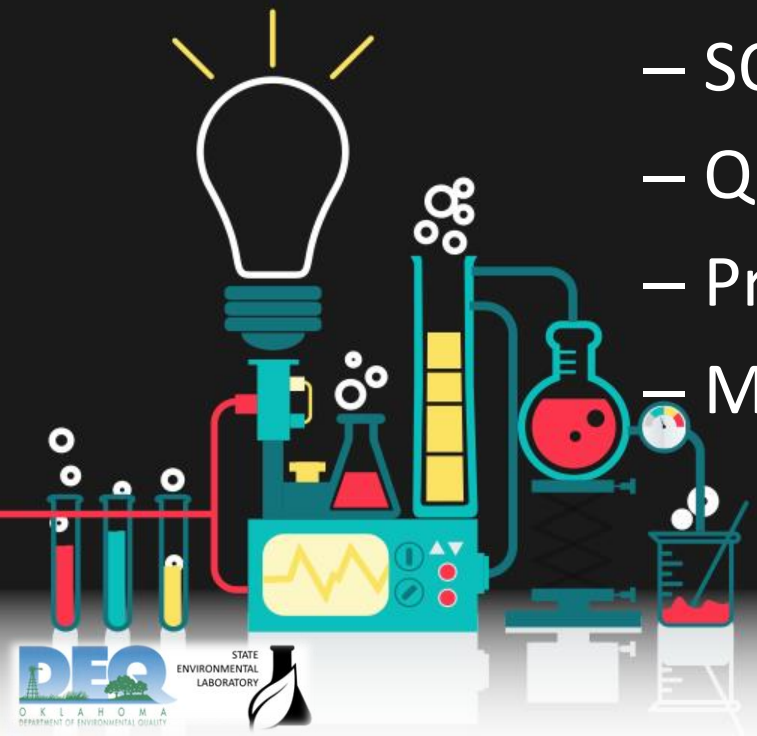
STEP 7: ANALYTICAL COMPETENCY

- SOP
- Instrument Calibration
- n
- Training Logs
  - Ethics
  - Safety

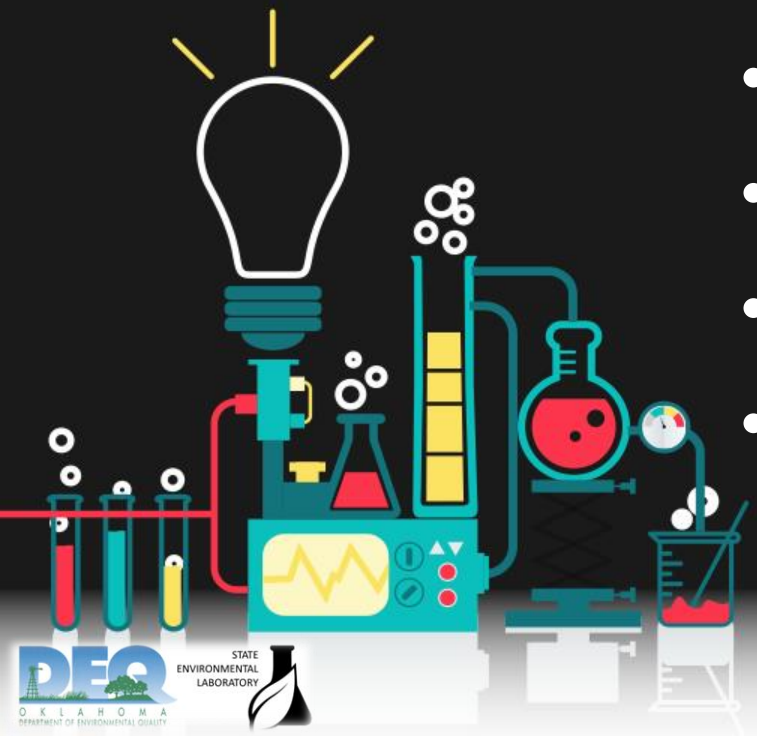


Step 8: Certification/Accreditation

- Application to Accrediting Authority
  - Quality Manual
  - Personnel Qualifications
  - Analytical Competency
  - SOP's
  - QC Control Charts
  - Proficiency Testing History
  - Maintenance Records

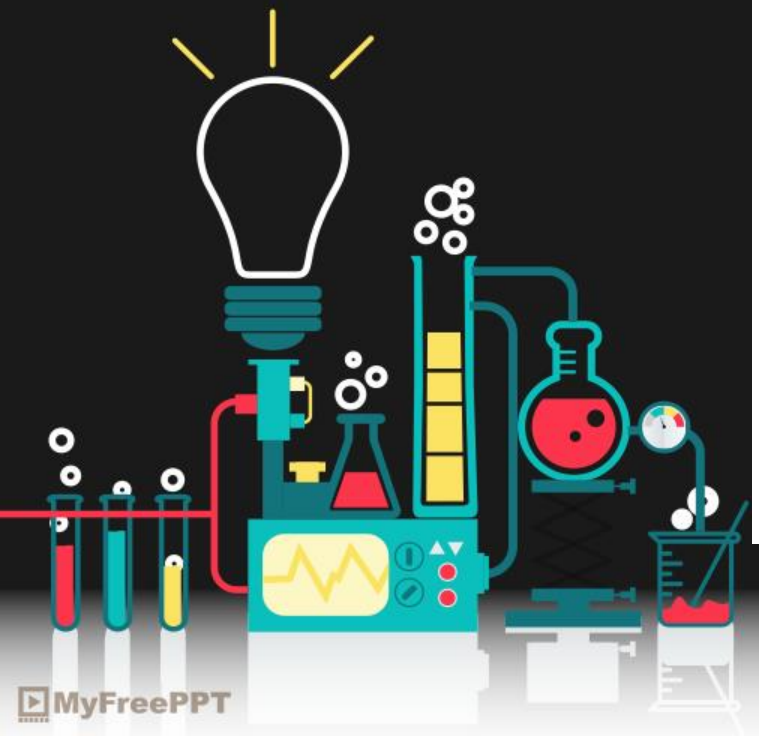


STEP 9: ON SITE AUDIT



- Document Review
- Process Assessments
  - Analytical
  - Operational
  - Data Management
- Analyst interviews
- Practical Bench Audits
- Safety Protocols
- Records Management
- *Findings & Recommendations*
  - *Corrective Actions*

Roadmap to Competency and Accreditation



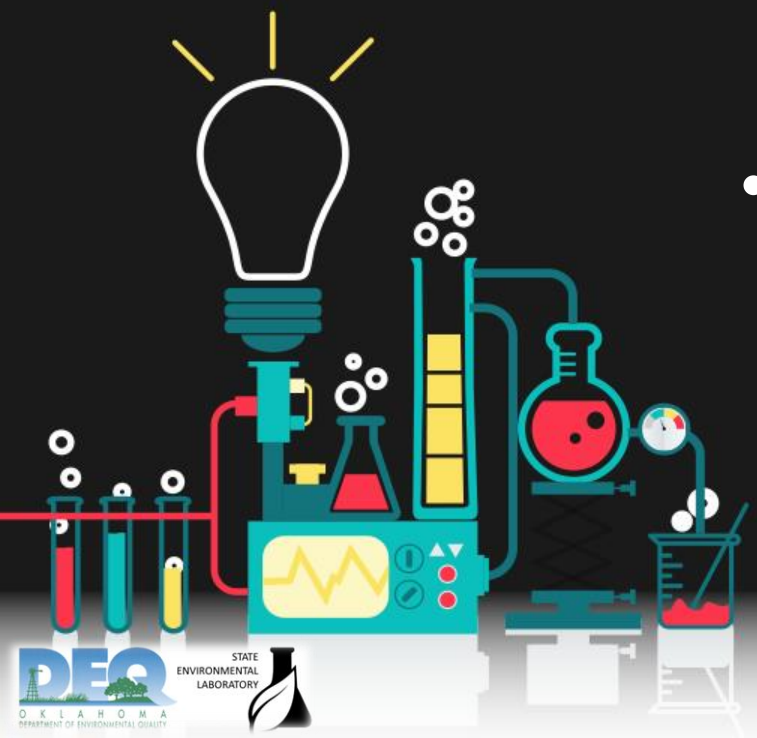
CRYPTOSPORIDIUM IMPLEMENTATION CHECKLIST

	Checklist Line Item	Length of Time to Accomplish	Accomplish by Date	Status (include date completed if complete)
X	Research method, determine to proceed with certification		Spring 2014	Completed ~ 3/19/14
X	Attain funding		Spring 2014	Completed ~ 5/29/14
X	Research equipment/supply/workspace needs and prices	2 months	Spring-Summer 2014	Completed
X	Order supplies, equipment, casement etc.	3 months	Spring-Summer 2014	Completed, need to order enough reagents/supplies to get through entire certification process
X	Research proficiency tests available for method		Spring 2014	Completed
X	Complete fee worksheet for test	1 month	Summer 2014	Completed 4/16/15
X	Order casement		Summer 2014	Completed
X	Install casement	1 month	Summer 2014	Completed 9/2014
X	Install dark room walls		Spring 2015	OCI installed 1/29/2015
I	Determine QS needs for LW	1 month	Winter 2014/Spring 2015	Waiting to add to LabWare until there is a better understanding of reporting requirements.
I	Choose an accrediting body		Winter 2014/Spring 2015	Have a list of ABs
X	Determine QS needs for Micro technical		Winter 2014/Spring 2015	In progress, implementing receipt logs, TNI / 2nd supplement requirements. Over 50 supporting documents completed as of 6/22/15
X	Research and secure hands-on analytical training		Winter 2014/Spring 2015	Training occurred in-house week of 3/16/15 and at EPA week of 3/23/15
X	Set up work areas, install equipment	2-3 months	Spring 2015	Completed week of 3/9/15. New casement being ordered.
X	Hands on analytical training (from an outside source)	1-2 weeks	Spring 2015	Completed 3/16-3/20/15
X	Hands on sampling training		Fall/Winter 2014	Completed 3/16-3/20/15
X	Write SOP		Winter 2014/Spring 2015	Draft Completed by JET/LRS. Working on instrument maintenance and other associated WIDS. SOP completed 6/22/15 by JEG/CRD
X	Add test/batch to LabWare for practice samples	2 weeks	Summer 2015	
X	Decide what supplies we will provide to our customers/collection details, Determine from what PWSs to attain samples for certification		Spring 2015	Meeting 1/30/15
X	Coordinate w/WQD for scheduling and compliance		Fall 2014	WG meeting 12/12/14. LT2 schedule here
I	Run samples required for certification		Summer 2015-Summer 2016	IDC Samples completed. Ongoing through process
I	Gather and review all data and determine trends/recoveries/etc. per matrix		Summer 2015-Summer 2016	Ongoing through process
I	Run PT samples required for certification	1 year	Fall 2015, then Spring 2016	Cryptosporidium Proficiency Testing Program | Wisconsin State Laboratory of Hygiene In process of enrolling for Fall PT event
	Develop LW V7 for TNI approved Crypto testing/reporting		Fall 2015	
	Develop fact sheet and flyers for advertising		Spring 2016	
	Audit/certification		Summer 2016	
	Begin testing		Fall/Winter 2016	

Timeline


1
Research
5-30 days
2
Lab Capacity Assessment
15-60 days
3
Secure Funding and Authorization
5-30 days
4
Resource and Raw Material Acquisition
90-180 days
5
Method Development
15-60 days
6
Method Validation
15-60 days
7
Analytical Competency
30-240 days
8
Certification/ Accreditation
15-60 days
9
On-site Audit
90-120 days

AND THEN… MAINTENANCE OF LABORATORY ACCREDITATION (page 1)



- **Every 2 Years**
  - On site audit
- **Annually**
  - QAP
  - Internal Audits
  - SOP Revisions
  - Strategic Planning (PIPs)
  - Ethics Training
- **Every 6 Months**
  - Detection Limit Studies
  - PTs
  - EPA Compendium Update

MAINTENANCE OF LABORATORY ACCREDITATION

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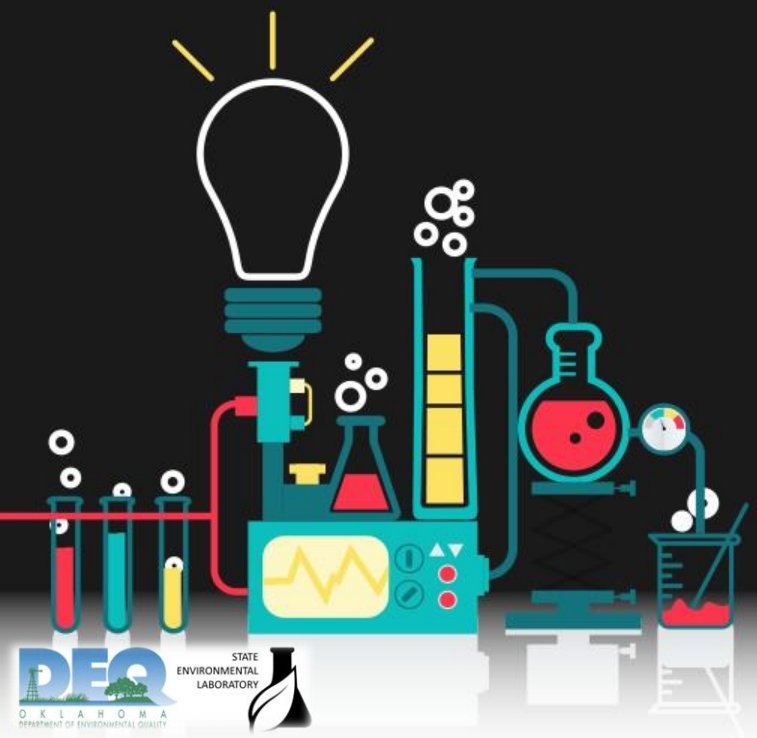

- **Monthly**
  - Trend Analysis
  - QA Performance Reporting
- **Daily**
  - Method Performance Verifications
  - QC Tracking and Charting
  - Equipment Verification
  - Instrument Maintenance
  - Data Management

Questions?

Contact Information

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