

Implementation of ELAP's Internal Management System

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Expert Review Panel Meeting
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Implementation Process

- **Select**
- Analyze and Develop
- Implement
- Continuous Improvement

Select a Management System

- ELAP needed a Management System built around performance criteria
- We selected the 2009 TNI Standard, Volume 2
- Now what.....
 - Analyze our program and develop the system

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Developed a Management System

- Began by reviewing critical operational processes within our program
- Customized Standard Operating Procedures
- Created a Quality Assurance Manual

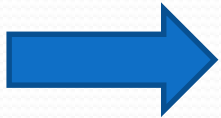
Quality Assurance Manual

- Gives an overview of the program, defines staff roles and responsibilities, documents standard operating procedures, and identifies the metrics for assessing performance
- Included in the Manual are sections on:
 - Document Control
 - Accreditation Workflow Process
 - Internal Audits
 - Preventative and Corrective Actions

Clearly Defined Staff Roles

- The QAM lists each staff position and specifically the duties they are required to perform
- We included a functional org chart that names current staff and their responsibilities
- Staff now understand what is expected of them

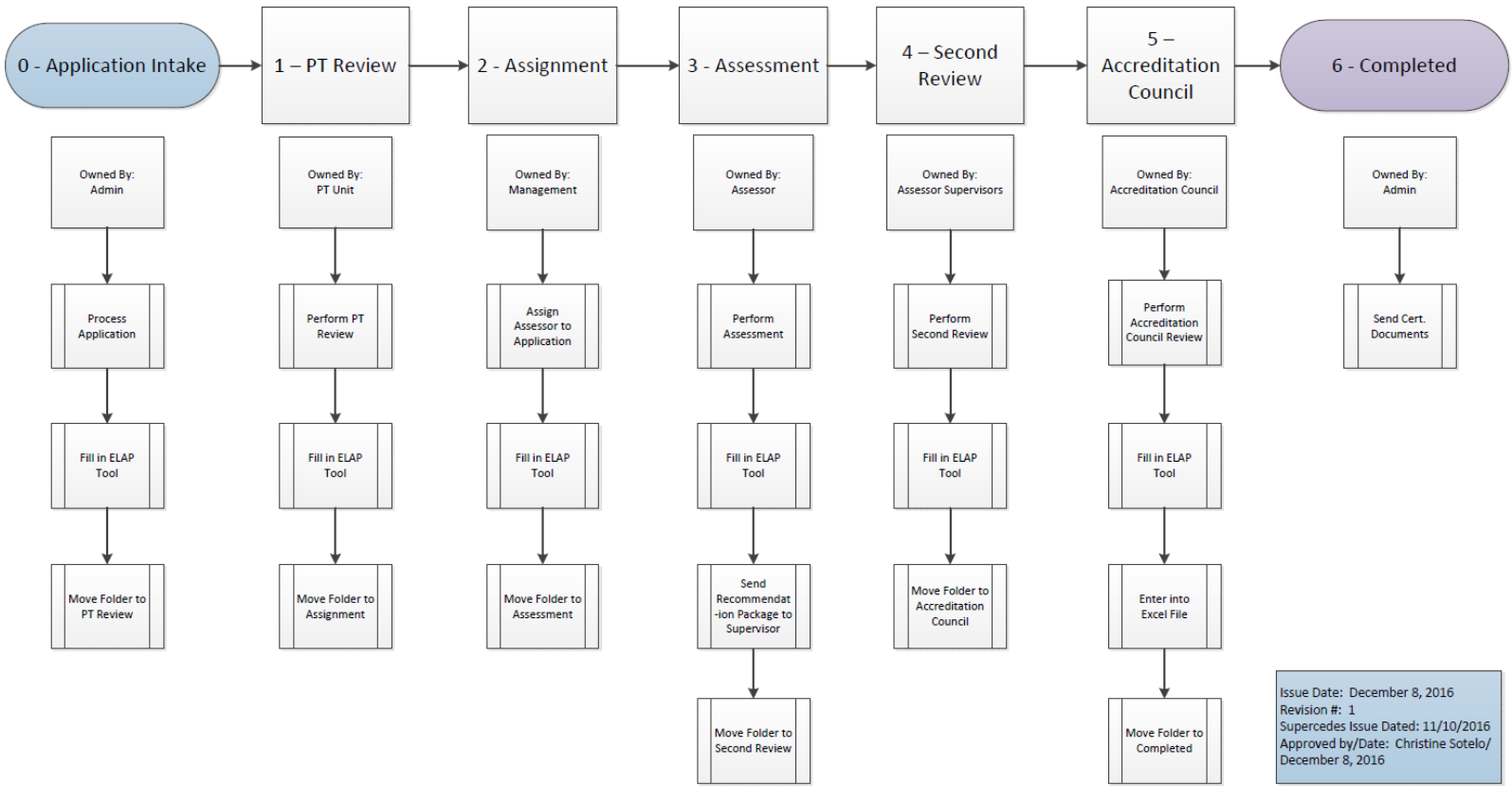
QAM - Staff Roles Page



Position	Role/Responsibilities
	<p>defined activities on behalf of top management.</p> <ul style="list-style-type: none"> - Member of the Executive Management Team of the SWRCB, Division of Drinking Water.
Quality Assurance Officer	<ul style="list-style-type: none"> - Implements and manages the QMS by maintaining documentation and ensures quality control and assurance.
Staff (Administrative and Technical, including On-Site Assessment)	<ul style="list-style-type: none"> - All staff must be familiar with this QAM and whenever revisions are made, will be requested to review it.
U.S. EPA Safe Drinking Water Act Laboratory Certification Officers for Chemistry, Radiochemistry, and Microbiology including Cryptosporidium and Giardia	<ul style="list-style-type: none"> - Certified by U.S. EPA to conduct on-site assessment of drinking water laboratories to meet requirements of the U.S. EPA Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition, including Supplement 1 and 2.

Clear Accreditation Process

Laboratory Accreditation Work Flow Process



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Standard Operating Procedures (SOPs)

- Governing ELTAC
- Implementation of SCAP
- Document Control
- SOP Format
- Electronic Content Management
- Receiving and Processing Applications
- Assignment of Applications for Laboratory Certification
- Accreditation Council
- Generating and Sending Certification Documents
- Generating Certificate List for GIS Map
- Training for Laboratory Assessors
- Renewal PT Review
- Annual PT Review
- On-Site Assessment
- On-Site Assessment for Cryptosporidium
- Assessment through Off-site Data Review
- Reciprocity Certification
- Second Review
- Change of Ownership, Location, Personnel, Instrumentation
- Internal Audits
- Nonconformities and CAPA

SOP Format

- Each SOP defines:
 - Scope
 - Applicability and Limitations
 - Procedures
 - Results and Reports
 - Quality Control

Other Notable Activities

- We responded to your findings and are implementing each of these tasks
- These SOPs have a high impact on the overall success of the program:
 - Document Control
 - Records Management
 - Internal Audits
 - Addressing Nonconformities

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Implementation

- QAM distributed to staff in all offices
- Comprehensive training is scheduled in early March
- Supervisors are ensuring that staff have read the manual and are following SOPs

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Internal Audits

- Spot checks
- Annual internal audits
 - First one is scheduled for June 2017
- Performed by ELAP's Quality Assurance Officer
 - Using criteria for quality control in the SOPs
- Results of the audit will set the tone for our management review

CAPA

- We see our internal management system as a means to continually get better
 - Provides mechanism to identify and correct problems
 - Established procedures for responding to nonconformities
- We have already conducted 4 nonconformity investigations
 - Using 5-Why's for our root cause analysis

In Conclusion

- Sustainability

Questions