Public Workshop

Getting ready for the NEW California Accreditation Program

Presenters
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Slide 1

Introductions and Objectives

- Introductions
- Agenda
- Objectives

Slide 2

Agenda Day 1: Start 9 AM

- Outline
- Overview Of The 2016 TNI Standard
- How Do I Prepare?
- How Do I Begin Implementation?
- Policies/Procedures/Other Details
- Assessments – Logistics And Preparation
- Questions And Answers

Slide 3

Agenda Day 1

Timing

9:00	Start	
10:30	Break	10 minutes
12 to 1	Lunch	1 hour
2:30	Break	10 minutes
4:30	Q&A	30 minutes
5:00	End	

Slide 4

Objectives

- Introduce the 2016 TNI Environmental Laboratory (2016 TNI EL) standard requirements
- Review the information that a laboratory must have available
- Review how to prepare and implement the materials
- Getting ready for the assessment
- Present what to expect during the assessment

Slide 5

Overview 2016 Environmental Laboratory (EL) TNI

- Accreditation Requirements
  - Consensus standard
- Input from anyone
  - No one group dominates
- Used as a requirement in 13 states
  - Two more expected within next 12 months
- A recognized standard for ensuring the production of known and documented quality data

Slide 6

Volume 1: Laboratory Requirements

EL-V1M#-2016

Module 1 - Proficiency Testing
Module 2 - Quality Systems:
- General Requirements

Module 3 - Asbestos Testing
Module 4 - Chemical Testing
Module 5 - Microbiological Testing
Module 6 - Radiochemical Testing
Module 7 - Toxicity Testing

Volume 1 Module 2

- 1.0 Introduction, Scope and Applicability
- 2.0 Normative References
- 3.0 Terms and Definition
- 4.0 Management Requirements
- 5.0 Technical Requirements
- 6.0 Bibliography

Laboratories follow their SOP!

Contents (V1M2) & Purpose

- 4.1 Organization
- 4.2 Management
- 4.3 Document Control
- 4.4 Review Requests, Tenders, Contract
- 4.5 Subcontracting
- 4.6 Purchasing
- 4.7 Service to Client
- 4.8 Complaints
- 4.9 Control of Nonconforming Work
- 4.10 Improvement
- 4.11 Corrective Action
- 4.12 Preventative Action
- 4.13 Control of Records
- 4.14 Internal Audit
- 4.15 Management Review
- 4.16 Data Integrity Investigation

Internal communication between staff and management

External communication clients, suppliers

Changes to laboratory operations

Management information to plan future
Proof of implementation

Contents (V1M2) & Purpose

- 5.1 General
- 5.2 Personnel
- 5.3 Accommodations and Environmental Conditions
- 5.4 Environmental Methods and Validation
- 5.5 Calibration Requirements
- 5.6 Measurement Traceability
- 5.7 Sampling
- 5.8 Handling of Samples and Test Items
- 5.9 Quality Assurance for Environmental Testing
- 5.10 Reporting the Results

Personnel

Facilities

Running the method

Samples

Quality Control

Reports

The Order = Roadmap = Plan

- Each lab will need to determine the order for completing the requirements
- Same labs will start with the quality manual and the operational procedures in Module 2
- Other labs will start with the methods and ensure they are implementing the applicable Modules 3-7

How Do I Prepare?

- 1. Read the Standard
  - Volume 1 and Applicable Modules
- 2. Develop a Plan
  - Preparing and Writing Documents
- 3.Follow the Plan
  - Monitor the Plan to stay on Track
- 4. Implement
  - Perform the processes as documented
  - Verify implementation
- 5. Get Accredited

1. Read the Standard

- Read Volume 1 – All Managers & QA Manager!
  - Determine which modules are applicable
- Read and understand the terms used in the standard
- Read the mandated methods
  - Review the terms in the methods with the terms in TNI standard Volume 1

Which Modules?

- What tests are on your scope of accreditation?
  - Don't waste time!!!
  - Only read the applicable Modules
- Microbiology Methods Module 5
- Chemistry Methods Module 4
  - Currently being revised
- Whole Effluent Toxicity Methods Module 7
- Radiochemistry Methods Module 6
- Asbestos Methods Module 3

What Do The Terms Mean

- Important information in the Definitions
  - Module 2 Section 3
    - Approximately 70 Definitions
  - Quality system matrix
  - Batch
  - Procedure
  - Quality Manual
  - Many others…..
- Any questions on any of the terms?

2. Develop a Plan

- How do you plan for change?
- What is in the plan?
- What things need to be planned
- Details to plan
- A PLAN=ROADMAP=the ORDER
- Remember – you know your system best!!

Assistance

- Find tools to help – don't spend large dollars!
  - Distribute tools to the assigned staff
  - What help is available when I'm stuck
    - TNI website (free - additional areas free to members)
    - Email others (free)
    - TNI Committee members (free)

What is in the Plan

- Set target dates for drafts (Be realistic)
  - For each document in the system
  - Update (Revise) or Write the document
- Assign personnel to input to the documents
  - Input = write, update, review
    - Different or the same person?
  - Documents = Quality Manual, SOPs, Forms
- Set target dates for completion

What Things Need to be Planned

- Document timeline for the following:
  - Decide the structure of the organization
    - Technical manager
    - Quality manager
    - Other Personnel
  - Develop or update the Quality Manual
  - Reconcile current practices to new accreditation standard
    - This is part of planning if needed

What Things Need to be Planned

- Document timeline for the following:
  - Develop or update the administration and technical procedures
  - Implementation of procedures
    - Training personnel
    - Demonstration of capability (administrative and technical)
    - Perform and review on-going quality control
    - Reporting results

What Things Need to be Planned

- Document timeline for the following:
  - Implementation of procedures
    - Internal audit (within 12 months)
    - Management review (within 12 months)
    - Update timeline How often depends on resources
      - Monthly/weekly/timeframe
    - Update procedures as needed

Details to Plan

- After everyone working at the lab reads the standard
- Review and Update QM
- Follow TNI V1M2 4.2
  - Shall contain: 4.2.8.3 items a to i
  - Shall contain or reference: 4.2.8.4 a to r
- How do I decide if the item is in the quality manual or SOP?

Details to Plan

- Plan for a glossary for the QM
  - See V1M2 Section 3 and relevant modules
  - Incorporate method and regulatory program definitions
    - For example: LCS and LFB and lab term is blank spike
    - All the same – the lab does not need to change its term
    - The glossary in the QM shows that these terms are equivalent

Details to Plan

- Assign personnel doing work to update SOPs and review SOPs.
  - Do they accurately describe what is being done in your lab?
  - If not how do you change the SOP or provide input?

Details to Plan

- Terminology matters in your documents
  - Your SOP should follow the terminology
  - Every word matters in the standard
    - Shall, should, may
    - Shall include (a document)
    - Shall ensure (not a document)

  Example
  - The procedure shall ensure (V1M2 4.1.5 b and c)
  - The procedure shall include (V1M2 4.2.8.3.h, 4.11.6)

Details to Plan

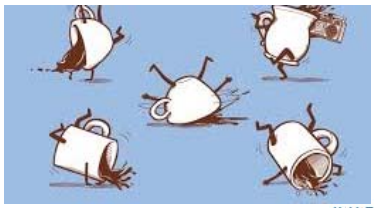
- Review and update technical SOPs
- Review and update administrative SOPs
  - Plan for writing an SOP on SOPs
- Training for everyone
  - Ethics
  - SOPs
- Who will train?
- When will the training take place?
- How will the training be documented?

Details to Plan

- Determine and update Forms, logbooks, etc.
  - What records are needed for each SOP
  - How will the records be maintained?
    - Electronic, Forms, logbook or a combination
  - Review V1M2 Section 4.13
    - Do you have a place for recording all the information?
    - Do you have a format for each record? (e.g.; form)

Break (10 minutes)

10 minutes



3. Follow the Plan

- Are some items done together
- Due dates may be adjusted
  - Resource limitation
  - Order of completion changes
- Some items completed before others
  - For example:
    - Must have document to write SOPs before writing SOPs and quality manual

The Order = Plan = Roadmap

A. Document Control Process
B. Quality Manual
C. SOPs For All Activities
D. Forms, Logbooks, All Records

Records versus Documents

- Records and Documents are not the same and not managed the same
- Documents are procedures that state how to create records (e.g. data, etc.)

What Do You Do Now?

A. Develop a document control process
  - Write procedure (SOP on SOPs)
  - See EPA guidance QA/G-6 (https://www.epa.gov/quality/guidance-preparing-standard-operating-procedures-epa-qag-6-march-2001)
  - Write or review existing SOPs and develop format to meet TNI requirements (see V1M2 4.3)

What Do You Do Now?

- Other SOPs may wait until quality manual is written
  - Defines terms and policies to be used in the lab
- Prepare for SOP writing by having staff write down how the test or operation is being done.
  - Start the process and then revise after quality manual approved

Follow Your Plan

B. Quality Manual

- Write or update your quality manual
  - To contain: V1M2 4.2.5, 4.2.8.3
  - To reference: V1M2 4.2.8.4
  - Assign one person to coordinate if more than one person providing input

Write Down - What and How

- Write down in the Quality Manual what you do and how you manage the laboratory process.
- Policy – Often unwritten but staff knows what's important.
  - Get the right numbers … fast ????

Follow Your Plan

C. SOPs For All Activities

- Write all Procedures or SOPs
  - How the process is done so it can be repeated by anyone who is trained.
  - Documented communication
  - Details sufficient to allow another to repeat the process
- Keep a list of all SOPs needed
- Master list of documents

Follow Your Plan

D. Forms, Logbooks, All Records

- Develop forms as defined in SOP
  - Record Data
  - Record other information as required by the TNI standard V1M2 4.13
  - Ensure traceability of
    - Samples
    - Results
    - Methods
    - Calibration and QC materials

Implement the Plan

- Monitor the timeline and adjust as needed
  - Don't allow the timeline to slip
- Management must allow time to update and communicate documents
- This can be done within one year and refined in second year

Implement the Plan

- When complete
- Continuous improvement is routine
  - Its not a struggle
  - Controlled change is the outcome!

B. Prepare the Quality Manual

- Demonstrate communication
  - Use TNI model manual (awaiting 2016)
  - Prepare documents
  - Ensure communication
- Develop policy statements required by the standard
- Develop procedures

Prepare the Quality Manual

- What you need
  - Policies (Next few slides)
- Procedures in manual or stand alone
  - Lab decides
  - How often do you expect to update the process?
  - Less frequent in Manual
    - Less to control/manage
  - More frequent changes in stand alone SOP
  - Make list of SOPs needed
    - `Document Control Master List

Quality Policy

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named). The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

- *a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;*
- *b) the management's statement of the laboratory's standard of service;*
- *c) the purpose of the management system related to quality;*
- *d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and*
- *e) the laboratory management's commitment to comply with this International Standard and to continually improve the effectiveness of the management system.*

Policies

4.1.5

- *c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;*
- *d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;*

4.2.8.4

- l) procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;
- m) policy for permitting departures from documented policies and procedures or from standard specifications;
- r) policy addressing the use of unique electronic signatures, where applicable

Policies

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

- *a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);*
- *b) the laboratory has the capability and resources to meet the requirements;*
- *c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).*

Policies

- *4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.*
- 4.8 *The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties.*
- 4.11.1 *The laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.*
- 4.14.5 The laboratory shall have a policy that specifies the time frame for notifying a client of events that cast doubt on the validity of the results

Policies

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, the customer is notified and work is recalled;

e) the responsibility for authorizing the resumption of work is defined.

Policies

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel.

Policies

5.8.6 Sample acceptance policy

a) proper, full, and complete documentation, which shall include sample identification, the location, date and time of collection, collector's name, preservation type, sample type and any special remarks concerning the sample;

b) proper sample labeling to include unique identification and a labeling system for the samples with requirements concerning the durability of the labels (water resistant) and the use of indelible ink;

c) use of appropriate sample containers;

d) adherence to specified holding times;

e) sufficient sample volume to perform the necessary tests;

f) procedures to be used when samples show signs of damage, contamination or inadequate preservation; and

g) qualification of any data that do not meet the above requirements.

Finalize the Quality Manual

- Who must review and approve the manual
  - Issued by top management
  - Defined by lab
  - Usually function that provides resources
- In most labs
  - Quality manger and the Technical Manager
  - Person providing the resources

Follow Your Plan

- Complete the steps developed in the plan
- Use Excel, whiteboard or other to track progress
- Show actual completion date with planned completion date.
  - Shows how well you plan
  - You are demonstrating preventive action (V1M2 4.12)

Lunch

60 minutes for lunch!
Be back promptly at 1:00 PM

C. Prepare SOPs

- Management/administrative SOPs
  - Contents of SOP not defined by standard
  - Lab must define the format and content
- Technical SOPs
  - Contents defined by standard
  - Lab must Write SOPs, OR
  - Use reference method with options used in the lab

Procedures Needed

- Procedure: A specified way to carry out an activity or process. Procedures can be documented or not.
- PT handling procedures (V1M1 4.2)
- Procedure of confidential information (V1M2 4.1.5.c) may combine with data integrity (V1M2 5.2.7)
- Procedure to remain impartial (V1M2 4.1.5.d)
- Must implement all procedures (V1M2 4.2.2.d)

Procedures Needed

- Procedures that define personnel adequately experienced to perform duties (V1M2 4.2.8.4.q) and define requirements for technical manager (5.2)
- Procedure used to generate test data (V1M2 4.2.8.5.a)
- Procedure to control all documents (V1M2 4.3)
- Procedure for review of work (V1M2 4.4)
- Procedure for purchasing (V1M2 4.6)

Procedures Needed

- May combine into one procedure
  - Procedure for complaints (V1M2 4.8)
  - Procedure for non-conforming work (V1M2 4.9)
  - Procedure for corrective action (V1M2 4.11)
  - Procedure for preventive action (V1M2 4.12)
- Procedure for internal audits (V1M2 4.14)
- Procedure for management review (V1M2 4.15)
- Procedure for training needs (V1M2 5.2.2)
- Data integrity procedure (V1M2 5.2.7)

Procedures Needed

- Method SOPs (V1M2 5.4)
- Uncertainty procedure (V1M2 5.4.6.2)
- Data protection electronic (V1M2 5.4.7.2)
- Traceability procedure (V1M2 5.6)
- Sampling procedures (V1M2 5.7)
- Sample handling procedure (V1M2 5.8)
- Quality Control procedure (V1M2 5.9)

Organization

- Define Roles and Responsibilities
  - Organization chart (web or in QA manual)
  - Interrelationship to other parts of the organization (not within lab structure)
- Management
- Organization
  - Job descriptions

Management

- Define technical manager
- Define quality manager
  - See responsibilities in standard
  - May also be the technical manager (limited staff)
  - May be from another lab (shared resources)
- Define who is top management
  - Performs management review
- Define process for communication

Organization

- Job descriptions
  - Human Resources – job listing
  - Specific to work done in lab – not general
  - Don't forget reporting, sample receiving, purchasing and sales or client interaction staff.
    - Everyone has clients
    - Who sends you samples to test? Engineering, operations, internal clients or external clients

Data Integrity

Detecting Improper Practices

https://www.epa.gov/quality/training-courses-quality-assurance-and-quality-control-activities#detectlab

Technical SOP

- Contents of technical SOPs
  - States the lab's process for performing the method
- Support equipment
  - In Quality Manual or Stand Alone SOP
- Based on reference method requirements
- QC requirements in standard and reference methods
  - Module 3 to 7 includes QC requirements

Technical SOP Contents

- identification of the method;
- applicable matrix or matrices;
- limits of detection and quantitation;
- scope and application, including parameters to be analyzed;
- summary of the method;
- definitions;
- interferences;
- safety – may refer to other procedure or chemical hygiene plan

Technical SOP Contents

- equipment and supplies;
- reagents and standards;
- sample collection, preservation, shipment and storage;
- quality control;
- calibration and standardization;
- procedure;
- data analysis and calculations;
- method performance;

Technical SOP Contents

- data assessment and acceptance criteria for quality control measures;
- corrective actions for out-of-control data;
- contingencies for handling out-of-control or unacceptable data;
- waste management – may refer to another SOP
- references;
- any tables, diagrams, flowcharts and validation data

Technical SOP Document

- Communicates what is allowed by the laboratory to produce test data.
- Helps to reduce the risk of data integrity problems creeping into lab
- Produces repeatable data since everyone does the method using the same process.

Review SOP

- Each lab must review and update SOPs to ensure they reflect the operation of the equipment and sample preparation.
- The amount of detail must be sufficient to allow a person to perform the operation and therefore reconstruct the results.
- For DW follow the reference method and only modify based on instrument operational requirements. Cannot demonstrate equivalency for DW program
- Wastewater, RCRA and others can demonstrate performance based on a reference method or clients needs.

Update SOPs

- SOPs revised – Update all SOPs
  - Ensure the documents meet the method and TNI standard
  - Do not write in the SOP what you're not doing
- All technical SOPs require review to ensure the Module requirements are defined in the SOP
  - Module 4 Chemistry
  - Module 5 Microbiology
- Review plan for implementation practice

Common Finding

- Most common assessor finding – 'The laboratory SOP does not accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.' (V1M2 4.2.8.5)

Break

10 minutes

4. Implement

- Perform the processes as documented
- Verify implementation
  - Records
  - Personnel performance
  - Equipment performance
  - Internal audit
  - Management review

Implementation

- Records
  - Demonstrate you are implementing a consistent operation
  - V1M2 Section 4.13 provides list
  - Demonstrate traceability
  - Demonstrate you do what you say you do

Implementation

- Personnel
  - Interviews demonstrate competency
  - Records indicate person(s) perform the process and produce acceptable work
  - Testing is more consistent between people
  - Data can be reproduced

Implementation

- Equipment
  - Operation demonstrates the lab has the capability
  - Maintenance of equipment
  - Traceability of data to instrument and process used to generate the data

Implementation

- Conduct internal audit (V1M2 4.14)
- You must do an audit to see if you are doing what you say you do.
- Once per year all activities must be audited by lab
  - State assessors do a sampling

Implementation

- If the audit is done correctly – you will not be surprised by the assessors findings
  - If you are surprised, your internal audit is not effective
- If your internal audit is objective you will fix the problems before the assessor arrives
  - Therefore the assessor will have limited or no findings

You're Ready for the Assessment

- ELAP Gap assessment
- The assessment process
  - What if there are findings?
- Getting Ready for the assessment

ELAP Gap Assessment

- Assessment is a Gap Analysis
- Gaps in the lab's system to be identified
  - Not following or using 2016 TNI EL standard
  - Gaps must be filled by implementation date
- NCs written during first year
  - When methods are not consistent with the reference method
  - When regulations are not followed (federal/state)

Assessment not an Audit

- Lab performs audit of its own system
- Assessor performs assessment to evaluate the operations of the lab.
- **Definitions:**
  - Assessment: The evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria (to the standards and requirements of laboratory accreditation).
  - Audit: A systematic and independent examination of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system to determine whether QA/QC and technical activities are being conducted as planned and whether these activities will effectively achieve quality objectives.
  - Accreditation: The process by which an agency or organization evaluates and recognizes a laboratory as meeting certain predetermined qualifications or standards, thereby accrediting the laboratory.

Assessment Process

- Preparation
  - Application
  - Proficiency testing (PT)
  - Quality manual
  - Test procedures (SOPs)
  - Personnel qualifications/Demonstration
  - Records and Documents ready
- Assessor assigned and documents sent to assessment team
  - Documents reviewed and outcome reported to lab
  - Prior to site visit or at opening meeting

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Assessment Process

- On-site assessment
  - Opening meeting
  - Interview staff
  - Observe staff performing tests, sample receiving and review and report results
  - Review records
    - Demonstrate records are complete
    - Following SOPs
  - Determine conformance to the requirements
  - Closing meeting
    - Present preliminary findings during the assessment and summarize at the closing meeting

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Assessment

- Assessor gathers evidence of conformance
  - If something is not met from the mandated method or requirements of the standard = non-conformance (NC)
  - NC based on standard not assessor's opinion
    - Ask where the requirement is found
    - Do not cause delay in assessment
  - Discussed at closing, but only respond to NC sent 30 days after assessment.
  - Demonstrate corrective action process for every NC
  - Submit to accrediting body (AB) for review
  - AB makes decision **not** assessor alone

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Only Failure If Your Reply Is Not Correct

- Review Non-conformances (if any)
  - Its okay to disagree with the assessors' findings
  - Be ready to defend what you have done based on the standard or mandated method
  - Have documentation – either records or procedures or both
    - If standard question, submit a standards interpretation request (SIR) to TNI
    - If method question, submit to the method publisher
  - Not based on "This is how we always did it. The previous auditor liked what we did."

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Only Failure If Your Reply Is Not Correct

- Handling Non-conformance
  - Written report from AB
  - Submit Root Cause and Corrective Action (CA) Plan
  - Lab has 30 days to submit (current 45 days)
  - AB has 30 days to review for acceptance or rejection
  - Lab has 30 days resubmit
  - AB has 30 days to accept/reject
- Accreditation granted, denied or revoked

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Before the Assessor Arrives

- Learn about the Standard
- Attend meetings (Local or National)
  - Join local lab meetings (Start one if non-available)
- Participate in meetings (teleconference)
  - Full member or associate member of committee(s)
  - Discussion groups in AWWA, WEF, AWMA, Others
- Join TNI
- Talk to Colleagues

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Getting Ready for the Assessment

- Internal Audit
  - Complete before your assessment
  - Staff interview – Preparation for assessor
- Corrective Action – Have records
  - Demonstrate implementation
- Preventive Action – Have plan
- Records – List of records
  - Example of review

Corrective Action (V1M2 4.11)

- Departures from procedures, administrative and technical, then non-conforming work is identified
- What went wrong?
  - QC failed on TSS 5 out of the last ten runs
- Determine root cause. One way- Ask why five times!
  - Oven temperature not read daily
  - Oven was not with 103-105^0 C- as read by another analyst during the time. Personnel were not familiar with all method requirements
  - Analyst wasn't trained
  - Person checking temperatures not familiar with criteria for TSS and no training on how to report criteria not met
  - Training on all aspects of the method not considered

Corrective Action (V1M2 4.11)

- Once identify root cause, determine corrective action
  - All personnel must be familiar with the temperature criteria or where to find it
  - Train personnel
  - Observe personnel
  - Written quiz on criteria required for various activities
  - Written quiz to ensure understanding of what to do when criteria are exceeded.
- Successful fix is not having the problem recur
  - Keep records of all steps
  - Process of communication with managements

Preventive Action (V1M2 4.12)

- How do you prevent corrective actions?
- When you want to add a test method, add equipment, review procedures due to a change in regulation
  - Plan
  - Do
  - Check
  - Act

Fundamental principles of management systems

Records (V1M2 4.13)

- Yes you must keep records for at least five (5) years
  - Longer if required by regulation or the client
- Use the standard as a checklist of all the records you must keep.
  - About 4 pages which list the records
  - Others mentioned in other sections
  - Search function record or records
- If you don't know why the record is needed - ASK

Management Review (4.15)

- The standard indicates what must be covered by the review.
- Management defined by lab
  - Makes plans for what needs improvements for the next year
  - Determines the areas needing the most improvements or changes
- Records of the review – tasks (findings not negative), due dates
- See if objectives are met

Objectives Measures

1. generate data of known and documented quality,
2. ensure the implementation of the management system,
3. continually improve the testing services,
4. meet the needs of its clients,
5. follow the 2016 TNI Environmental Laboratory standard,

1. accreditation (>95% conformance)
2. internal audit (no repeat findings
3. client feedback (improves score within year)
4. preventive action (met due dates on 90% of items)
5. data acceptable (<10% qualified) & internal audit (>95% conformance)

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Objectives Measures

6. provide timely data,
7. ensure staff and client communication,
8. ensure staff are familiar with and implement the policies and procedures

Other items being measured

6. turnaround time (< 10 days)
7. corrective action process (met due dates - 90% of items)
8. training/observation/DOC (all personal met training goals and successfully completed DOC)

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Generate Data

- Known and Documented Quality
- Its not Perfect – its Science
  - The defensibility
    - Show exactly how it was produced
    - No questions about how the result was generated
    - Do the test the same way as others in the lab
    - Consistency proven
    - Quality control tells the user how consistent the data is generated – Not if the number is right or wrong

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Questions

- Last Chance for Questions
- Thank you

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