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Workshop Excellence

Training for the Environmental Professional

Internal Audits and Annual Management Review

Practical Tools for Management

A Presentation by:

Jack Farrell, Analytical Excellence, Inc.

Welcome

- This is the third in our series of Quality Assurance and Accreditation topics
- Continue to explore topics for understanding the various
  - Management System elements
  - The TNI EL 2009 Standard
  - And suggestions on implementing them effectively
- Thank you for your support and participation

Introduction

- This is a partnership between Analytical Excellence, Inc. (AEX) and The NELAC Institute (TNI)
  - Primary Trainer: Jack Farrell – AEX
    - Workshop Development and Presenter
  - Host: Ilona Taunton – TNI Training Coordinator
    - Organization and Webex Administrator
  - Training Support: Patty Snyder – AEX
- Workshop Materials

Disclaimer & Confidentiality

- The materials presented in this workshop are for your use only.
  - You are free and encouraged to use them internally within your company or organization.
  - The materials are not for external use or distribution without written permission from AEX.
- If you have any questions, please contact Jack Farrell or Patty Snyder.
- Thank you for your consideration.

Continuous Improvement

- All of us continue to explore improvement, and these webinars can be elements of your
  - On-going training efforts for management, QA, supervisors and analysts, and
  - Continuous improvement and preventive action programs
- Your participation and feedback are a very important part of OUR continuous improvement processes.

Meeting Mechanics

Meeting Mechanics …

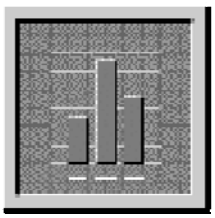
- All phone lines are muted when you join the call. There will be Q&A sections in this training. If you want to speak – click on the hand. The hand will come up next to your name, and this alerts the trainer you want to speak. Your phone will be un-muted (red x is removed) when it is your turn to speak.

Meeting Mechanics …

- Use the feedback button if you want to alert the trainer that the subject matter is going too fast or too slow.
- You can also type your questions or comments into the dialogue box, and the instructor will try to answer your questions or present your comments.

Meeting Mechanics …

- The trainer will have poll questions during the webinar to test your knowledge of the material and gain some feedback and opinions. You will see the poll pop up … answer the questions … and then submit your responses. The result summary will be presented and the answers reviewed.



Meeting Mechanics …

- When the webinar ends, a TNI Course Survey will pop up. You can select your answers, type responses and then click submit.

Learning Objectives

At the end of this session, you should…

- Gain awareness of the provisions for Internal Audits and Management Review contained in the 2009 TNI EL Standard.
- Gain an understanding of the benefits of conducting comprehensive and effective internal audits and annual management reviews for compliance as well as improvements to operations and quality.
- Understand the links between internal audits, management review, corrective action and continuous improvement.
- Gain a feel for some of the options for implementing these management system elements in your organization, small or large.
- Be able to set up and implement internal audits and management review programs for your organization.

AGENDA

- Definition and benefits of internal audits
- Requirements of the TNI Standard for internal audits
- Types of internal audits
- Considerations in conducting internal audits
- Documentation and reporting
- Conducting management reviews
- Linking internal audits and management review

Overview

- With everything going on –
  - Client issues/Regulatory requirements
  - Productivity demands
  - Personnel & training requirements
  - Quality & integrity concerns
  - Financial pressures

How do Managers, QA Professionals, technical supervisors and assessors keep it all straight!!

Elements of a Quality System

The Major Components of a Quality System

- Documented Procedures
- A Documented Training Program
- Document Control and Archiving
- Internal Auditing
- Management Review
- Management Policies and Procedures
- Corrective Actions
- Preventive Actions
- Ethics and Data Integrity
- Data Review and Reduction
- Effective Communication

Keeping Informed …

- Two of the most important management system tools for *real-time continued improvement*, *monitoring quality* and for information about *what is actually going on* in your operation are:
  - Internal Audits
  - Corrective Actions
- BUT…..only if the tools are <u>fully supported</u> and used in the manner that they were intended

Fact-finding –Monitoring - Continued Improvement

Define – Internal Audits

- What is an internal audit?
- What are the key components?
- Why audit?

So, what do you think?

Definition

What is an Audit?

- **Audit - Merriam-Webster Online Dictionary - 2004**
  "A formal examination of an organization's or individual's accounts or financial situation; a methodical examination and review"
- **Internal - Merriam-Webster definition**
  "Of, relating to, or occurring within the confines of an organized structure (as a club, company, or state)"
- **External - Merriam-Webster definition**
  "Of, relating to, or connected with the outside or an outer part; situated outside, apart, or beyond; arising or acting from outside"

- **US EPA Quality Assurance Division (QAD)**
  "Audit: a systematic evaluation to determine the conformance to quantitative *and qualitative* specifications of some operational function or activity."

What is an Internal Audit?

- An attempt to determine the competency and compliance of the laboratory
- A determination of how well you comply with the standards, methods, management systems and customer requirements
- A determination of how well your team knows the job and follows the management system

An opportunity to "find" things before someone outside your organization finds them.

Internal Auditing

- An incredibly important and cost effective tool for continued improvement and communications.
- It assesses performance against the requirements.
- It gathers and evaluates a variety of:
  - Facts & information
  - Exceptions & trends
  - Symptoms & gaps

Benefits of Internal Auditing

- It allows managers and analysts to understand what is going on – *at any given time and over time*
- It provides an opportunity for communication
- It provides a clear mechanism for improving systems, practices and procedures – *less rework – saves money*
- It provides a discipline and a focus for gap analysis
- It documents exceptions, gaps and mistakes
- It benchmarks performance against requirements
- It focuses the efforts of continuous improvements

Don't Waste the Effort

If the only reason that you are conducting an internal audit is to meet accreditation requirements, you are wasting a whole lot of time, energy, money and good information.

A mechanism to increase productivity, Quality and service to customers.

TNI Accreditation Requirements

2009 TNI EL Standard

- Not all participants are NELAP laboratories
- State accreditation programs contain various components of the TNI Standard provisions
- These provisions provide an excellent GUIDE for establishing and implementing CUSTOMIZED tools for effective management

2009 TNI EL Standard Volume 1 Module 2

- The TNI Standard primarily discusses internal audits in the following sections:
  - 4.1.7.1 - Responsibility and Authority
  - 4.13.1.1 - Control of Records
  - 4.14 - Description of Internal Audit Requirements and Actions (4.14.1 – 4.14.5)
- Requirements are pretty much the same as the 2003 NELAC Standard with a strengthened emphasis on corrective action and follow up!!

Authority and Responsibility

Volume 1 Module 2 Section 4.1.7.1

- The laboratory's quality manager and/or his/her designee shall
  - **arrange for or conduct internal audits,**
  - **notify laboratory management of deficiencies in the quality system, and**
  - **monitor corrective actions.**

2009 EL Standard
Volume 1 Module 2 Section 4.14

- **Internal Audits**
  - *4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard.*
  - *The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities.*

2009 EL Standard
Volume 1 Module 2 Section 4.14

- **Internal Audits (4.14.1 cont.)**
  - *It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.*
  - *Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.*

2009 EL Standard
Volume 1 Module 2 Section 4.14

- **Internal Audits**
  - *4.14.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.*
  - *4.14.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.*
  - *4.14.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.*

2009 EL Standard
Volume 1 Module 2 Section 4.14

- **Internal Audits**
  - 4.14.5 Additional Items
    - a) 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.
    - b) The laboratory management shall ensure that these actions are discharged within the agreed time frame.
    - c) The Internal audit schedule shall be completed annually.

2009 EL Standard
Volume 1 Module 2 Section 4.13

- **Control of Records**
  - *4.13.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.*

Types of Audits

Types of Internal Audits

- Internal Audits are multifaceted mechanisms for information gathering related to performance against requirements or standards
- Sometimes audits or assessment activities are combined at least partially to accomplish task objectives
- *For example,* combine "test method review with SOP review with analyst competency/training" in the "process demonstration"

It is entirely up to management how they decide to combine tasks for resource utilization and practicality

Types of Internal Audits

- There are a variety of types of information that can be gathered during Internal Audit activities
  - Performance Evaluation samples (*also PT samples)*
  - Data (*package and source data*)
  - **Systems and policies**
  - **Records and documentation**
  - **Technical and procedural *(knowledge and experience)***
  - Audits for cause (*complaints, severe non compliance, etc)*

Performance Evaluation Samples

- PE or PT samples can be folded into the internal audit process, giving valuable information, especially if
  - Submitted double blind
  - Test reporting as well as analytical test
  - Real world samples and contents
  - Test customer service and satisfaction procedures
  - Used as indicators of where to focus internal audit efforts
- Drawback: Costly and hard to assure double blind

Routine PT Samples

- Semiannual or annual PT samples can provide a wealth of valuable information on performance
  - Point management in the direction of potential non conformances
  - Look for information on failures/corrective action
  - More importantly, look for trends with the passing parameters – *warning levels, related analyses, etc.*
  - *Misses and near misses are much more important than passing results*

Data Audits

- A whole brave new world of very valuable information
- One of the best auditing tools available
  - Evaluates process and results
  - Focuses on the product to the client
  - Can evaluate the entire pedigree of the test
- Suggest monthly or at least quarterly "cradle to grave" review *(this takes time and effort)*
- *Data audits are very time and resource intensive*

Data Audits

- Data Audits can be simple or complex
  - Client packages (lab reports)
  - Support information and records
  - Raw source data including electronics
- *Tip from Experience*
  - *PT data packages are great tools for audit*
  - *Secondary Technical Reviews are great ways to target areas for audit*
  - *Best chance to spot inappropriate or improper behaviors*
- Fewer audits and more in-depth
- Integrate the various types of audits together

Systems & Policies

- A higher level review – good overall indicator
- Usually need records, documentation or data auditing to verify implementation or lack of
- Can help determine isolated or global areas of concern
- Can trigger additional more in-depth and specific audits
- Combine with Source Data review to get a complete picture – *"Data First"*

Systems & Policies

- Evaluates management system interactions in the generation of product
- Most popular audit focus for accreditation programs – major emphasis
- Some examples
  - Training & proficiency
  - Communication channels
  - Document control
  - Organization structures, conflicts & QA commitment

Records & Documentation

- Ascertains compliance with support or background activities
- Central tool for verification of implementation
- Can be standalone or support to other audit functions
- Can be superficial or very detailed
- Some examples
  - Calibration standards preparation logs
  - Support equipment

Technical & Procedural

- Commonly referred to as "Process Demonstration or Bench Audits"
- Evaluates
  - "Methods to SOPs to Performance"
  - Consistency of product generation
  - Compliance with internal and external requirements
- Most, unfortunately, are done superficially due to time and experience constraints

Take your time and talk with analysts

Technical & Procedural

- Contains the most analyst interaction
- Can also help assess management policies and culture
  - Ethical awareness and values
  - Communication and culture
  - Management and organization priorities
  - Technical competence and depth
- Often used to fill gaps from other audit tasks

Technical & Procedural

- Great mechanism to spot opportunities for improvement
  - Productivity and streamlining
  - QC and calibration irregularities and failures
  - Training opportunities
- Some examples of areas audited
  - Method 8260B bench review
  - Standards preparation
  - Sample preparation
  - Data review and reduction
  - Sample receiving, log-in, acceptance and storage
  - Microbiology techniques and aseptic techniques

Audits for Cause

- Usually a very specific focus
  - Particular analysts
  - Departments
  - Procedure or process
- Can be very, very detailed
- Many times associated with inappropriate practices but not always
- There is usually higher tension and less openness
- You are not an investigator – that is a completely different focus and approach altogether

Considerations in Conducting Effective Internal Audits

Conducting Internal Audits

- Be practical – Don't commit to something you can't do
  - Can always find deficiencies
  - Assessors will review internal audit reports
  - Audit reports with no findings are suspicious
- Whenever the events dictate the need for information gathering
  - Don't hesitate to go and look!
  - Don't be afraid of finding something
  - Don't just look for deficiencies

Conducting Internal Audits

- Look for secondary advantages/opportunities
  - Preventive actions – spot trends, leads
  - Case study examples – good and bad
  - Productivity and streamlining opportunities
  - Training opportunities
- If the audit results surface few or no findings
  - Then you are really, really good
  - Not looking hard enough
  - Don't care

Conducting Internal Audits

- Duration (*pick what works best for your needs)*
  - Can last from several hours to weeks
  - Can be on-going *(real value and maximum results)*
  - Can be broken down into "bite-sized" chunks over time
- Resource intensity
  - TNI assessment 3-6 man-days
    - Annually 5-14 man-days
    - Quarterly 4-5 man-days
    - Monthly 1 man-day
- Management defines a predetermined schedule

Conducting Internal Audits

- Encompass the entire laboratory operation at least annually
- Shall address **ALL** elements of the management system
  - All Quality Systems SOPs
  - All Test Method SOPs
  - All Administrative SOPs
- Commonly missed areas
  - Quality Assurance function
  - Corrective Action effectiveness
  - Project Management/customer service
  - Software validation
  - Electronic and paper records archiving
  - Safety and disposal

Conducting Internal Audits

- Management defines a predetermined schedule
  - Annual is a frequency, not a schedule
  - Schedules can change
  - Set the schedule each year – learn from experience
- Schedules can be simple or complex
  - Define what works for you
  - Don't keep putting it off – *too many samples*
  - Time needed is always underestimated
- Train and use other resources

Conducting Internal Audits

- Management defines a predetermined schedule
  - Set one or two days a month
  - Pick the same week each month
  - Alternatively, pick one entire week each quarter.
- External regulatory or client audits are good, but do not substitute for an effective internal audit program.
- Don't wait for the external audit to be scheduled to meet your compliance needs.

Conducting Internal Audits

- A simple schedule *(well, maybe not that simple)*
  - Microbiology* — January
  - Wet Chemistry* — February - March
  - Metals* — April
  - Quality System elements (QA, purchasing, archiving, subcontract, client/contracts) — May - June
  - Organics* — July - September
  - Corrective/Preventive Action — Continuous
  - QAM, QA, mgmt. policies — October

*includes SOP review, each test method

XYZ Laboratory
Annual Audit Schedule for 2007

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Organization	X											
Quality System	X											
Document Control		X										
Contracts			X									
Subcontracting			X									
Purchasing			X									
Service to Client			X									
Complaints			X									
Non-conformance		X										
Corrective Action		X										
Preventive Action		X										
Record Control				X								
Internal Audits				X								
Management Review				X								
Personnel					X							
Accomm/Environment						X						
Test Methods/Validation							X					
Equipment						X						
Traceability								X				
Sample Handing									X			
Quality of Results										X		
Reporting											X	
Calibert 24	X											
BOD (5210C)		X										
COD (52200)		X										
TOC (5310C)			X									
IC (300.0)				X								
VOA (624, 8260B)					X							
SVOA (625, 8270C)						X						
Turbidity (180.1)	X											
Alkalinity (310.2)	X											
Hardness (SM 2340B)	X											
Ammonia (350.1)		X										
TKN (351.2)							X					
Metals (6010, 200.7)								X				
Phosphate (365.1)									X			
Nitrate/Nitrite (353.2)										X		
Assessor	SAS	JKM	JKM	STM[2]	RFJ[1]	SAS	SAS	RFJ[1]	STM[2]	SAS	SAS	STM[2]

Footnotes:

[1] QAO for Northwest Laboratories
[2] Consultant

Conducting Internal Audits

- Who conducts these audits (Whomever!)
  - Independent & qualified *(to the extent practical)*
  - Trained
  - Does not have to be management
  - Can be internal or external personnel
- Quality Manager is not required to conduct audit
- Audit personnel should be independent of operations
  - Exchange Quality Managers for audits
  - Use technical personnel from another section of lab
  - Use consultants
  - If auditing own activities, have report reviewed for objectivity

Conducting Internal Audits

- ***If you found it one place, there is a #%$! good chance it is occurring in some other part(s) of your operations***
  - Error corrections
  - Training gaps
  - Missing section in SOPs (deviations/details)
  - Traceability
  - Calibration
  - Sample preparation steps

Conducting Internal Audits

- These are planned activities (usually)
- Can be simple or complex
- Use previous internal and external audit results
- Use Standard Operating Procedures
  - A detailed document describing how audits will be conducted, when, type and by whom
  - Established documentation procedures, reporting and follow-up
  - They are still a guide – build in some flexibility
- Liberally use checklists… but only as a tool

Conducting Internal Audits

- Checklists
  - Checklists are a great tool, but only a tool
  - Tailored to audit objectives
  - Usually developed before auditing
  - Can be tailored to spot repeat deficiencies
  - Can be tailored to fill gaps from document review
  - Cautions:
    - Don't get tunnel vision
    - Keep an open mind
    - Follow the trail or threads

Conducting Internal Audits

- Asking Questions and Interviewing
  - Getting information through interviewing is an art, not a science
  - Your task is to get information, not who to blame
  - Try to make it easy and friendly – TAKE YOUR TIME!
  - Back off if it gets intense; go on to something else or someplace else
  - Ask open ended questions; you want the interviewee to talk, not just say "yes" or "no"
  - Make sure that you are clear, ask questions a different way
  - Couple records or data with interviews

Conducting Internal Audits

- Follow-up audits shall verify and record the implementation and effectiveness of corrective action taken
  - Use Corrective Action process already in place
  - Document with Corrective Action form (CAF)
  - Use follow-up audit for monitoring of effectiveness
- This is one of the areas that is commonly found lacking
- More emphasis in the TNI Standard

Documentation and Reporting

Documentation & Reporting

- *Of course we did it….oh, a few months ago*
- *I meant to do it before you got here…but….*
- *There is no formal report…we discussed at a meeting*
- *Results were communicated via email to supervisors*
- *The supervisor was there, they know what to do*
- *I haven't had time to finish…and write the report*
- *There were no real findings…everything is good*
- *We did not need a corrective action form, we fixed it right there*
- *The State is not coming in for a year or so…we have time*

Documentation & Reporting

- If it isn't documented, it did not happen!!
- Internal Audit reports vary by nature of the type of information gathering
- Reports must be clear, concise and contain sufficient information for reader to understand the issue and concern
- Reports should, where appropriate, cite requirements and standards, refer to laboratory documents records, or data reports
- Objective evidence should be collected as appropriate for clarity and documentation

Documentation & Reporting

Records of audits shall be maintained, and lab must ensure actions are taken within time frame specified in Quality Manual or SOPs.

Documentation & Reporting

- Reports
  - Don't write War and Peace
  - Keep the reports simple and useful
  - Function over form – ***Content is most is most important***
  - Excel and word tables work great – *running list/Sharepoint*
- One reporting option
  - What you looked at (short narrative)
  - What you found – finding and observations
  - Categorize and prioritize – not all findings are equal
  - Citations and references *(Regulatory, QAM, test method, SOP)*
  - Link to corrective action forms

Systemic vs. Random Events

- Re-occurring deficiencies
  - Show that your corrective action process doesn't work
  - Could be an indication that management is not serious about Quality
  - Could be an indication that the QA function and Quality System are in failure
  - Upset accreditation assessors
  - Can be grounds for lifting approvals
- Differentiating between
  - Random findings and observations
  - Handling systemic findings – patterns of behavior

Documentation & Reporting

- Findings establish the *what, who, how, what happened and sometimes why*
- *Don't stop with the minimum*
- Internal Audit findings manifest themselves in
  - Deficiencies
  - Observations
  - Recommendations
- Findings can be prioritized in different ways based on severity
  - Critical
  - Major
  - Minor

Documentation & Reporting

Internal Audit findings manifest themselves in

- Deficiencies
  - Practice, behavior or omission that does not meet or comply with Standards or Requirements
  - The Acid Test: "It must be able to be expressed in the words of the Standard, method or QAM"
  - Must be clear, concise and focused *(This can be hard)*
  - Look at the "Management System Components"
  - Must be addressed in corrective action plan

Documentation & Reporting

Deficiencies can be prioritized in different ways based on severity – a subjective determination

- Critical
  - Repeat or reoccurring deficiencies
  - Immediately impacts directly on current data quality
  - Needs immediate attention
  - Usually an operation deficiency or omission
  - Improper or inappropriate practice a given!
  - Examples – Dropping calibration points
    Not analyzing method blanks per batch

Documentation & Reporting

Deficiencies can be prioritized in different ways based on severity – a subjective determination

- Major
  - Necessary operational changes or significant technical issues
  - Needs attention in the short term
  - Examples – Not adhering to calibration or QC limit
    Not digesting blanks and QC
    Not following key method steps

Documentation & Reporting

Deficiencies can be prioritized in different ways based on severity – a subjective determination

- Minor
  - Everything else
  - Formal documentation updates
  - Example – updating training files (training occurred)
    Formally revising SOPs

Priority of finding differs by assessors and can be open to discussion

Documentation & Reporting

Internal Audit findings manifest themselves in

- Observations
  - Practices, behaviors or omissions identified
  - Not necessarily standards or requirements based
  - Optional but noteworthy
  - Positive and negative observations
  - Items that you want to point out and keep on the radar screen
- Annual Management Review topics

Documentation & Reporting

Internal Audit findings manifest themselves in

- Recommendations
  - Opinion, suggestion, helpful hint
  - Laboratory discretion on how to address
  - Usually a good idea
- Biggest opportunity for continued improvement and cost savings
- Annual Management Review or other real time mechanisms

Common Findings

- Practices that do not conform to SOPs
- Training records out of date
- Internal audits not performed at proper frequency
- Exceptions not properly documented
- Not following up on corrective actions
- Strike-outs and obliterating data entries
- Running too many QC samples
- Running small batches of samples – *holding times*
- Documentation - Documentation - Documentation

Other Considerations

- Your approach and style are your own
- Use other qualified persons
- Audits should not be confrontational or judgmental *(fact finding, not assigning blame)*
- Real time tape recording is not recommended
- Collect objective evidence or supporting data as needed
- Make audits constructive training events

Objective – Comprehensive – Critical Analysis

Other Considerations

- Use the observations and recommendations to drive continued improvement and productivity
- Find patterns, trends - not just symptoms
- Focus on eliminating REPEAT FINDINGS!!!
- Use results to augment audits of other departments and functions
- Make audits positive and constructive
- Do not settle for less rigor to be nice
- This is the time to be critically honest

Objective – Comprehensive – Critical Analysis

Other Considerations

- Measure the Results
  - Yes, the number of findings is important *(but not the only measure or the most important)*
  - Trend as to type: QC, QA, method, training, records, etc.
  - Length of time deficiencies remains open
  - Number of re-occurring findings
  - Increase or decrease in re-work, complaints, questions, etc.
  - What you did not find or correct compared to external audits
  - $ saved or increase in samples processed without error
  - Increase in customer satisfaction

Annual Management Review

Management Review

- An integral part of any management system
- Management Review links all the components together
  - Management Policies and Procedures
  - Internal Audits
  - Corrective Action
  - Continuous Improvements
  - Customer Satisfaction

Management Review

- It is simpler than it is made out to be
- Do not need to build an elaborate bureaucracy
- The importance is often generalized and underestimated
- Can be likened to strategic planning or budgeting exercises
- Need a procedure with accountability
- Communications critical to success
- Must have records of management review activities
- Need an implementation plan with follow up
- Results can feed into corrective action activities and be the basis for preventive actions – *helps keep it all straight*

Management Review

- A management review generally has four components
  - Information gathering
  - Interactive meeting of key personnel
  - Action plan
    - What are you going to do about it
    - Who is responsible for making it happen
  - Implementation and follow up
- Schedule is up to you. Frequency is 12 months.

Management Review

- Management review is linked to a variety of provisions in the current TNI EL Standard
  - V1 M2 4.2.2 Quality Policy
  - V1 M2 4.10 Improvement
  - V1 M2 4.11.1 Corrective Action
  - V1 M2 4.13.1.1 Control of Records
  - V1 M2 4.15 Management Review

Management Review

(2009 TNI EL Standard V1 M2 4.15.1)

In accordance with a predetermined schedule and procedure, the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

Management Review

The review shall take account of:

- *the suitability of policies and procedures;*

  (can include technical and administrative SOP review, QAM review, management policies)

- *reports from managerial and supervisory personnel;*

  (encourage open frank feedback from supervisors and key managers)

- *the outcome of recent internal audits;*

  (where are the gaps, and were internal audit efforts effective and comprehensive)

Management Review

The review shall take account of:

- *corrective and preventive actions;*

  (did the actions eliminate the problem, and were they lasting solutions)
- *assessments by external bodies;*

  (were the regulatory assessment results different than internal audit results)
- *the results of interlaboratory comparisons or proficiency tests;*

  (trends, failures and improvement opportunities)

Management Review

The review shall take account of:

- *customer feedback;*

  (a big one – lots of information if approached correctly)
- *complaints;*

  (real opportunities for improvement and customer satisfaction)
- *recommendations for improvement;*
- *other relevant factors, such as quality control activities, resources, and staff training.*

Management Review

- It should be an analysis of what you did well and what needs attention
- Should be a formal process with an SOP
- Who should be involved in the meeting
  - It is up to you (somewhat)
  - Senior management and key staff
- Management review shall be conducted annually
  - All at one time
  - Monthly or quarterly

Closing Remarks

- Internal audits, management reviews, and corrective actions are interlinked for success
- Don't just do them for compliance purposes
- Adapt the procedures for your operation
- How you conduct the procedures is up to you – but… do them well!!!
- Don't need a bureaucracy – keep it simple
- Be critical and comprehensive – it is worth it!
- Take the time and effort to do them RIGHT

Closing Remarks

- Document, Document, Document
- Communicate, Communicate, Communicate
- Get everyone involved
  - Use other resources
  - Communicate results
  - Seek feedback and input
- Follow through, Follow through, etc.

Closing

- Remember

Prevention beats "Damage Control" every single time.

It just makes good business sense!

It can make Dollars and Cents!

Thank You

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Quality Systems

Compliance Mgmt.

Profitability

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