A 17025:2005 Management System Made Simple

What to think about when reviewing the Management System

Structure of the Standard & HB 150

- Non-linear
  - Requirements are not mutually exclusive
- Holistic
  - This is a complete system, not just pieces and parts
  - Section 4 works with Section 5 and vice versa
- NVLAP Requirements: Section 3, Annex A, Annex B, Annex C and Annex D

Organization

- **Organizational Chart**
  - Communication pathways
  - Defines who is the lab and who is outside the lab
- **Who's in Charge?**
  - Top Management: Who is top management and what role does top management play?
- **Technical Manager/Quality Manager**
  - Does the Technical Manager need to understand Quality?
  - Does the Quality Manager need to have Technical expertise?

Management System

- Ownership
  - It's the lab's system and should speak to what the lab DOES and HOW it DOES it
- The tail shouldn't be wagging the dog
  - Reflect and support technical activities
  - Dynamic (aka: LIVING) system
  - Nothing is carved in stone but…
  - It should be a pretty solid system
- Holistic System
- To understand it, Read it, Speak it, Step back

Management System

- **Top down**
  - Management buy-in and commitment: Understanding the metrology/testing mission
- **Bottom up**
  - Staff commitment from metrologists/technicians to admins to shipping clerks
- **Integrity of the Management System during change**
  - Management shall lead the effort, audit (monitor) it, and make sure that the outcome meets the needs

Defined Document Structure

- Structure of Management System Documents must make sense to those who use it.
- Simple, Transparent: Document type titles should reflect their function
- Remember that the management system documents are a valuable training tool
- Bottom line: Do the management system documents meet the REQUIREMENTS of the standard, of the AB? (Read the book!)

Document Control

- **Defined document structure** – Master List
- **Revisions, Version, Issue**
  - Terms, Styles should be consistent!
- **Page Numbers**
  - X of Y
  - End of Section
  - End of Document
  - How does this work with electronic systems?
- **Pointers to supporting documents**
  - Standard Operating Procedures, Standard Administrative Procedures, Work Instructions…

What are Documents?

- NIST Handbook 150
- Management System Documents
  - Includes equipment manuals, test/calibration methods
- All standards listed or referenced on the scope of accreditation
- Other documents that are referenced such as GUM, ISO/IEC 17025, USA Code of Federal Regulations (CFR), etc.
- Document Control system may be a paper, electronic, or hybrid.

Document Changes

- Write-protection in electronic documents
- Handwritten Changes – Allowed? Reissue expediency (Integrity)
- Electronic changes – how indicated
- Review process and sign-off
- History of revisions
- Archival documents

Document Control

- References
  - References are part of the management system: How are they controlled? What is the Policy & Procedure?
  - Make sure list is current (internal audit & management review)
  - Historical documents clearly indicated
    - Is it historical OR is it required by regulation or contract?

Requests/Tenders/Contracts

- Incoming work: Communication
- Who receives, who reviews, who approves, who schedules?
- What happens if something goes awry?
  - Personnel, equipment issues (turnaround time)
- Records

Subcontracting

- Subcontracting occurs when:
  - Tests/measurements/calibrations that are on the scope of accreditation cannot be performed by the lab and are sent to a competent subcontractor
  - Some requested tests/measurements/calibrations do not appear on the scope and are sent to a competent subcontractor. Client is informed and agrees.
- Subcontracted results are clearly identified on the certificate/report
- Subcontracting may not be the basis of demonstrating competency during an assessment (i.e. what is on the scope must be demonstrated by the lab --- not the subcontractor)

Subcontracting

- List of approved subcontractors
  - HOW were they approved?
    - Who, what, when and accreditation status
- Records of customer notification and approval
- If subcontracting is not done, the QM should state so clearly
- Does the P.O. to the subcontractor state that the work to be performed is accredited work (if applicable)?

Purchasing supplies and services

- Policy/Procedure for services and supplies that affect the quality of tests and/or calibrations
  - Metrological Traceability
- Inspection/evaluation/verification prior to use
  - Fit for purpose
  - Comply with applicable/specified requirements
  - Appropriate level to support calibrations/tests

Purchasing supplies and services

- **Purchasing documents**
  - Description of supply/service
  - Technical review/approval record
- **Evaluation of suppliers**
  - Accreditation status
    - Scope
    - Uncertainties (see Annex B)
    - MRA Partners

      or
  - Record of supplier audit (B.2.4)
- **Verify accreditation status and scope**

Seeking Customer Feedback

- Actively sought
  - Surveys after the service
    - Paper
    - Web-based
- Positive and Negative
- Analyze feedback
- Management review

Complaints

- **Policy and Procedure**
- **Who is complaining?**
  - Customer
  - AB
  - Management
  - Technical Staff
  - Regulator
- **Records of all complaints received, investigation of and corrective actions taken.**
- **Corrective /preventive actions with root cause analysis (first)**

Control of nonconforming work

- **Policy/procedure**
  - Who is responsible for
    - Initiating work
    - Halting work
    - Notifying customers if necessary
    - Recalling work
    - Resuming work
- **Initiate corrective action to prevent recurrence**
- **Evaluate impact**
- **Maintain records**

Corrective action

- Policy
  - Appropriate authorities
  - Sources of identification
- Procedure
  - In the beginning: A cause analysis
    - Why did it happen?
    - Don't just treat symptoms

Preventive Action

- Identify needed improvements and potential sources of nonconformities
- Nonconformities can be technical or within laboratory's management system
- Complaint records source for ideas – look for connection

Preventive Action is Proactive

Corrective/Preventive Action

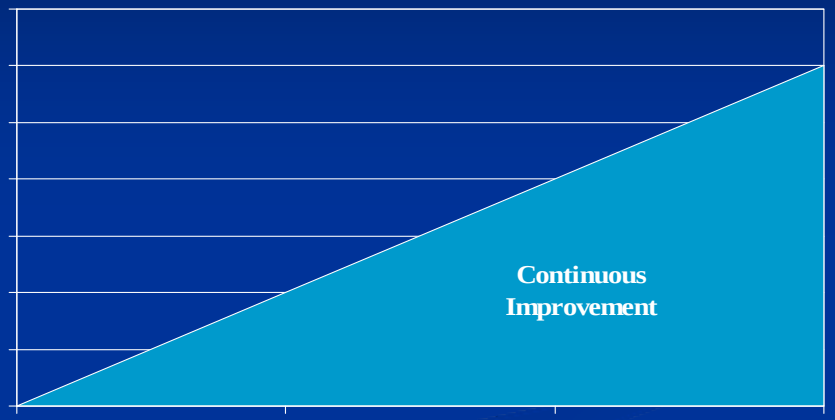
- Laboratory must develop procedures for preventive actions
  - Include initiation of preventive actions
  - Also include application of controls to ensure actions are effective – do nonconformaties recur?

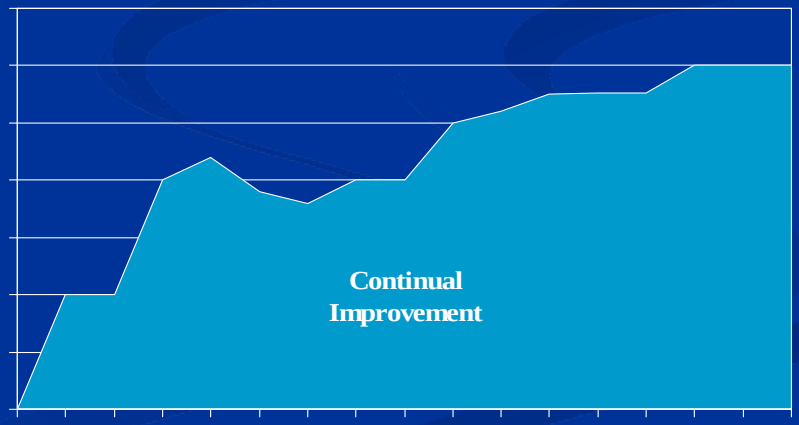
Control of Records

- **Quality records**: Internal audits, management reviews, corrective actions, preventive actions, complaints
- **Technical records**:
  - Sufficient information to repeat calibration/test
  - Identify factors that affect uncertainty
- Record at time made, linked to task
- Corrections: still see original, change must be signed
  - Equivalent for electronic records
- Question: What is an original observation?

IMPROVEMENT

- Continual vs. Continuous
- The danger of status quo
- Is the concept of continual improvement woven into the entire system – what's the evidence?





Internal Audits

- Performed periodically ◄DEFINED
  - Whole system or broken into segments (technical part of calibration or test methods must be included)
  - Trained/qualified personnel
    - How trained? External Vendor or In-house
    - How qualified? What evidence exists
- Laboratory must have written records of audits
- Audits carried out by a customer or assessments by NVLAP SHALL NOT be considered an internal audit

Management Reviews

- Pre-determined, documented schedule and inputs
- Involves Top Management reviewing
  - Continuing suitability of management system and Calibration activities
  - Used to introduce:
    - Changes
    - *Improvements*
  - Used for planning
    - Goals
    - Objectives
    - Action plans

Management Reviews

- Conducted **separately** from internal audits
- Documentation (agendas/reports) of reviews – addresses the 'laundry' list
- Beware the paper exercise – Look for METRICS
  - How is success being evaluated?

Personnel

- Challenge of Succession planning
  - Training, Training, Training
- Documentation of Qualifications
  - Continual training
  - Cross-training
  - Review
- Effectiveness of training
- Goals for further training (succession planning…)

Environment

- Documented appropriate environmental conditions
- Monitor/record
  - Metrological traceability of environmental monitors
- Stop work/resume work: Who is responsible?
- Cleanliness
- Access

Test & Calibration Methods

- Selection of methods
  - Needs of the customer
  - Appropriate
- International, national, regional
- Lab-developed
- Up-to-date instructions
- Inform the customer
  - Records

Method Validation

- **Control charts**
- **Analysis of measurement that substantiate uncertainty claims**
  - analysis of resultant data
  - comparison to other methods
  - interlaboratory comparisons
  - Use of a NIST-calibrated artifact
- Appropriate range and accuracy of values obtained

Uncertainty

- Completeness of uncertainty budget
- Source of component values (e.g. own measurement, manufacturer)
- Method and validation of uncertainty values

Data Control

- Policy/Procedures to verify data transfer
  - Systematic
- Data Integrity (cross-check analysis)
- Spreadsheets –
  - Are the cells really locked?
  - Who validated the calculations?
- Verify calculations

Equipment

- Equipment list (including associated control software and/or instrument firmware)
- Proper identification
- Location
- Instructions/manuals
- Calibration or certification status and intervals
- Validation
- Intermediate checks
- Safeguard against adjustments

Measurement Traceability

- Documented path of measurements and uncertainties
- Ref: NIST HB 150 Annex B

Detailed information in Presentation on Metrological Traceability

Reference Materials

- Program and Procedure for calibration of Reference standards
  - Only used for calibration to ensure integrity of value
- Metrological traceability to the SI where possible
- Intermediate checks to maintain confidence in values
- Transport and storage

Sampling

- Representative sample of the whole
- Plan and procedures for sampling
  - Available where the sampling is taking place
  - Based on appropriate statistical methods
- Records
  - relevant data
  - procedure
  - identification of the sampler
  - Other pertinent information (environment, location, etc.)

Handling of Test and Calibration Items

- Provisions to protect the integrity of test or calibration item and interests of the customer
- System for identifying and tracking the test or calibration item
- Examination upon receipt to assess the condition of the item and suitability for test or calibration
- Appropriate facilities to avoid deterioration or loss during storage, handling, and preparation

Assuring Quality of Results

- Statistical process control
- Check standards
- Proficiency tests
- Redundant measurements
- Correlation plots

Reporting Results

- Accurate
- Clear
- Unambiguous
- Objective
- In accordance with any specific instructions in the test or calibration method

Reports and Certificates

- Title
- Name & Address of lab where tests/calibrations performed
- Unique ID of report
- Name & Address of Customer
- ID of method used
- Unique ID of item tested/calibrated
- Date of Receipt where critical to results
- Date of test or calibration
- Reference to procedures, sampling plans used
- Test or Calibration results with units of measurement
- Name, function and signature or other ID of person(s) issuing report
- Statement that results relate only to tested/calibrated items where relevant.

Reports: Additional Information Where Appropriate/Needed

- Deviations from, additions to, exclusions from test method
- Specific test conditions
- Statement of compliance/non-compliance
- Statement of estimated uncertainty of measurement
- Opinions and interpretations
- Date of Sampling
- Unambiguous ID of Substance/Material/Product
- Location of sampling (Diagrams, photographs, sketches)
- Sampling plan and procedure used
- Environmental details when they affect results