

# NMI Peer Review Process

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# NMI Peer Review (Assessment)

- Outline
  - Purpose
  - NMI cooperative planning
  - Pre-Assessment documentation
  - Pre-Assessment meeting
  - On-site assessment
  - Report of Findings
  - Post Assessment review of corrective actions

# Process & Scope of the On-Site Peer Review

- ISO 19011: *Guidelines for Quality and/or environmental management systems auditing.*
- Protocol for the peer review followed CIPM 2007-25
- On-site visit to assess the laboratories implementation of their quality system and the technical requirements of ISO/IEC 17025.

# NMI Cooperative Planning

- Who to contact when you receive request
  - Group Leader
  - NIST Quality Manager
- AIK vs. Reimbursable
  - AIK means that the NMI pays for your travel during your travel
    - You can't take any money (e.g., food, taxi)
  - Reimbursable means you never worry about touching money
    - NIST pays for your travel on Group Funds
    - NIST sends the bill to the NMI and the money goes back to the Group

# NMI Cooperative Planning

- Travel Arrangements
  - Make sure your travel is to your satisfaction
    - Reimbursable makes this part easier
- Determine who is the lead assessor and make contact
- Determine the number of assessors on the “team”
- Accreditation Body run assessment means that rules/forms will be provided

# Pre-Assessment Documentation

- Items to request from the NMI / Lead Assessor in English (unless you can read the native language)
  - Standard operating procedures
  - Supporting publications
  - Staff qualifications
  - Uncertainty budgets
  - Traceability information
  - Software validation
  - Check standard results
  - Equipment list
  - Internal audits
  - Previous peer assessment findings and corrective actions
  - Complaint log
  - Key Comparison results
  - CMCs (KCDB and pending)

# Pre-Assessment Meeting

- If possible, review documentation with another NIST expert
- Review documentation with the NIST Quality Manager
  - Assessment template from NIST QM
- Determine and document areas of concern and any non-conformities
- Compare CMCs with that of NIST
- Compare CMCs with similar NMIs

# On-site Assessment

- Opening meeting
- Make sure there is a sign-in sheet
  - lead assessor should do this, but may not
- Tour the facilities
- Plan on a ½ day to 2 days per area / laboratory
  - You will be on their schedule
  - Language differences will slow the process
- Always make sure they understand each finding you will report
- Take time each night to write up your findings
- Closing meeting
  - No surprises should occur

# Section 5 focus areas

## 5.3 Environmental

- Range of acceptability
- Records and traceability
- Out of compliance action

## 5.4 Test and calibration methods

- Realization methods
- Handling and storage
- Analysis of results
- Up-to-date instructions

### 5.4.5 Method validation

- Control charts / Check Standards
- Analysis of measurement that substantiate uncertainty claims
- Laboratory comparisons
- Use of a traceable artifact

### 5.4.6 Uncertainty

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

### 5.4.7 Control of data

- Data integrity (e.g. cross-check analysis)
- Software validation

## 5.5 Equipment

- Equipment list
- Proper identification
- Calibration or Certification status and intervals
- Validation interval

## 5.6 Measurement traceability

- Annex B
- Documented path of measurements and uncertainties

### 5.6.3 Reference standards and materials (e.g. SRMs)

- Intermediate checks

## 5.9 Assuring quality of calibration results

- Statistical process control (e.g. control charts, redundant data, graph of results)
- Check standards
- Proficiency tests / Comparisons
- Redundant measurements
- Correlation plots

### 5.10.2 Reporting Results

- Required Report information

### 5.10.7 Electronic transmission of Report

# Report of Findings

- Assessment template
- Critical non-conformity
  - Show stopper
  - Impacts CMCs
- Minor non-conformity
  - Does not impact the acceptance of the QS in SIM
  - Other RMO viewpoints may differ on this type
- Comment
  - Does not need a fix
- Recommendation
  - Something for the NMI to consider

# Reporting a Finding

- Using the Assessment Template
- Reference to ISO/IEC 17025
- Make sure you identify the
  - Level of Concern
  - Finding in clear English
  - Reference the section from ISO/IEC 17025
    - E.g., 5.4.7 Control of Data
  - Evidence given

# Assessment Template

Number	Non-Conformity	Level of Concern	Relevant reference of ISO: 17025	Evidence / Comments
3	Section 5.4.5 needs to be thoroughly implemented i.e. control charts to validate calibrations, in every area that has CMCs (at a minimum). In SPRT and fixed-point calibrations freezing and melting plateaus to show process control are necessary.	Minor (*)	5.4.5	There are charts for the calibrations for each fixed point performed at XXXX and for each SPRT but they need to be reworked and updated.

# Post Assessment Review of Corrective Actions

Number	Cause Analysis	Corrective Action	Estimated date of Implementation	Status
3	Charts of three of the SPRTs have been done for triple point of water (TPW) with the registered available data. Other charts have to be done for the other SPRTs. We haven't enough time to finish yet.	To register new freezing and melting plateaus, to update freezing and melting plateaus for each fixed point cell	02/14/2014	On course

# Outcome of a SIM NMI Peer Assessment (Peer Review)

- Narrative summary of the Peer Assessment
  - Include a statement about CMC capabilities – is there confidence in their ability to provide the CMC's
- The laboratory has 18 months to take actions and make corrections prior to SIM quality system task force review.
- Quality System is approved!