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**SANDIA NATIONAL LABORATORIES
QUALITY ASSURANCE PROGRAM
for the
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

QAP 12-1

MEASURING and TEST EQUIPMENT

Revision 1

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1.0 Purpose and Scope

1.1 Purpose

This procedure specifies the actions necessary to control the use and calibration of Measuring and Test Equipment (M&TE) used in Sandia National Laboratories (SNL) Office of Science and Technology and International (OSTI) Program activities. Implementation of these actions will ensure that equipment used for measuring or data collection during inspection, testing, or scientific investigation is controlled, calibrated and maintained, so that the measurements and data collected are reliable and accurate.

Acronyms and definitions for terms used in this procedure may be found in the OSTI Glossary

1.2 Scope

This procedure applies to M&TE used to monitor, measure, test, and collect data for the SNL OSTI Program. All personnel who use M&TE while working on OSTI activities shall follow the requirements of this procedure.

This QAP encompasses use, care, and maintenance of M&TE, as well as calibrations ranging from those performed by commercial calibration sources to checks performed in-house by user organizations.

Calibrations, and the labeling requirements stated here, are not required for rulers, tape measures, levels, and other such devices that are not intended for making precision measurements.

Notes:

1. Except for the non-precision devices described directly above, only M&TE that is calibrated will be used for data collection in any OSTI project or activity when then data collected is not used for indication only or for an operational check on other devices.
2. For any M&TE that is intentionally not calibrated (other than the non-precision devices described above), the user shall clearly label it as to its status, e.g., "Not calibrated - indication only", "Out-of-service", or "Out-of-tolerance - do not use". Nonconformance reports shall be initiated for noncompliant equipment as required by the process for nonconformance in QAP 16-1, Corrective Action.
3. Certain M&TE devices, such as laboratory scales and pH meters, can be checked at their location and time of use for operability and proper calibration, by use of check standards, which are readily available at that location. For these items, the user shall check the required accuracy of the item prior to the first time it is used, and then prior to each use (as a minimum, within the same day) against a calibrated physical standard or standard chemical(s). The user shall ensure that check standards used for this purpose provide adequate assurance and accuracy. Physical check standards shall be themselves calibrated in an established calibration system. Chemical standards shall be procured, certified by the provider, stored, and used in a way that ensures their integrity. The requirements of Section 2.2 below also apply.

2.0 Implementation Actions

2.1 Calibration Planning

2.1.1 Calibration Source Selection

The responsible Principal Investigator (PI) or individual delegated to establish calibration for an instrument shall identify an appropriate source of calibration from the OCRWM Qualified Suppliers' List.

Auditing for qualification shall be done by OQA in accordance with the SNL OSTI QAPP. This is to assure that the organization is technically capable of the performing the activity and has sufficient QA program to address problems and provide appropriate documentation.

2.1.2 Calibration Service Provider Actions and Responsibilities

Calibration Service Providers shall perform calibrations in accordance with user instructions, and OSTI requirements, e.g., contract or internal SNL agreement, and determine if the M&TE is operational, and in-tolerance. If the item is found to be out of tolerance, the Calibration Services Provider shall note this on the calibration report and annotate both the pre-calibration ("as-found") and post-calibration ("as-left") readings on the calibration report. If it is not possible to bring the instrument into calibration this shall be indicated on the calibration report. If the M&TE is found inoperative or out-of-tolerance and cannot be adjusted into tolerance, the Calibration Services Provider shall return the device to the user, with a calibration report that clearly reports the inoperative or out-of-tolerance condition. The user shall tag the device to clearly indicate its out-of-tolerance, out-of-service condition.

When an external calibration service is used, users shall ensure that proper calibration services for the item have been established. M&TE users shall ensure that the procurement document contains the following requirements:

- Calibration Service Providers shall use a recall system to notify M&TE users of the approaching expiration of the calibration interval for M&TE items.
- Calibration Service Providers shall assign a calibration interval (a time interval since last calibration) for each M&TE item, based on the type of equipment, its stability characteristics, required accuracy, intended use, and other considerations which will provide a high probability that the items will remain in-tolerance throughout the interval. The system for setting those intervals must be systematically applied to the M&TE items, shall have stated reliability goals, and shall include a method of verifying that those reliability goals are attained (reliability, in this requirement, is defined as the probability of the device remaining in-tolerance throughout its calibration interval). A calibration interval is not needed for M&TE intended for one-time-use, or for items which are regularly monitored through the use of check standards in a documented measurement assurance process.
- Calibration standards used by Calibration Service Providers shall have greater accuracy than the M&TE being calibrated, except as follows. If calibration standards with greater accuracy than required of the M&TE being calibrated do not exist or are unavailable, calibration standards with accuracy equal to the required M&TE accuracy may be used, if they can be shown to be adequate for the intended use of the M&TE. The basis for

acceptance of this “equal-accuracy” condition must be documented by the user and approved by the SNL OSTI QA Lead or delegate.

- Calibration Service Providers shall have written approved procedures specifying the method of calibration for each M&TE item.
- Calibration Service Providers shall control environmental factors such as temperature, humidity, vibration, or electromagnetic interference, to ensure the validity of the calibration; or they must isolate M&TE items from these sources of contamination.
- Reference Calibration Standards shall be traceable to nationally or internationally recognized standards or natural physical constants. If such standards or physical constants do not exist, the basis for calibration shall be documented in the calibration report provided to the user.
- Calibration Service Providers shall affix labels to M&TE items indicating the status of the item. For items that are in-tolerance, the label must include the date calibrated, the next calibration due date, and any limitations on the device.
- Calibration Service Providers including Sandia internal calibration service providers shall provide a report for each item calibrated. This report shall include the following information:
 - The unique identification of the M&TE item,
 - Identification of the calibration standard(s) used for the calibration,
 - Identification of the calibration procedure, including revision, used in performing the calibration,
 - Identification of the individual(s) performing the calibration,
 - Calibration data (as-found data and post-adjustment data, if applicable),
 - Any calibration action taken (e.g., adjusted, repaired),
 - Calibration date and next calibration due date (or calibration interval),
 - Statement of acceptability of the device for use,
 - If the device was found to be out-of-tolerance (regardless of whether it was adjusted into tolerance), a clear statement of that fact, for the user’s information.

Note: See records section of this procedure for records that may be maintained at the service provider’s location.

If a calibration provider is qualified except that it is not able to meet all of the requirements for a recall system, the OSTI project PI and QA staff may develop a process that meets the calibration recall requirements. This system shall provide the traceability from the instrument to the recognized standard and document calibration activity as described above.

Upon completion of calibration of an M&TE item, Calibration Services Providers shall affix a “calibration label” to the item that indicates that the item is operational and within tolerance(s). The calibration label shall contain the following information:

- Date calibrated,
- Calibration due date, and
- Identification of any limitations on the device.

Notes:

1. When it is impractical to apply a label directly to the M&TE item, the label may be affixed to the instrument container; or some other suitable means may be used to indicate the calibration status.
2. If the calibration service is provided by the SNL Measurements Standards Program (MSP), the SNL MSP shall prepare and file their record of the calibration, update the recall system for the M&TE item, and prepare and forward a calibration report, along with the M&TE, to the user. Calibration is initiated by completing calibration request forms that are part of the MSP system and submitting required information to the MSP.
3. If the calibration service is provided by a contracted Calibration Service, that Calibration Services Provider shall prepare a calibration certification report, as specified in section 2.3.3, and forward it, with the M&TE, to the user.

2.1.3 OSTI Actions and Responsibilities

Chemical standards used to standardize or calibrate analytical equipment are controlled and documented through QAP 13-1, Samples, Chemical Standards, and Chain-Of-Custody. At the initiation of calibration of M&TE, the PI or designated staff shall ensure that the M&TE has:

- A unique identification - serial number or unique identifier assigned by the user,
- Been entered into a calibration recall system (unless it is a calibrate-prior-to-use device, or one which will be destroyed/damaged in use and rendered incapable of being calibrated),
- Been submitted for calibration and the calibration cycle has been established,
- Been calibrated and calibration range and other calibration requirements have been met.

Use and documentation of M&TE includes:

- Submittal of instruments for calibration when:
 - Upon procuring new M&TE, if the item is not received with a current, valid calibration.
 - Upon receiving a calibration recall notice.
 - When the accuracy of M&TE is suspect.
 - Range or accuracy requires different calibration requirements.

For One-time-only-use M&TE the user shall obtain a calibration of the item both before and after the one-time use (except for M&TE destroyed-in-use, or otherwise rendered not capable of being calibrated).

2.2 Use and Documentation of Use of Calibrated Equipment

Prior to each use of M&TE, the user shall examine the calibration label for the item, and determine whether the calibration expiration date has passed or the device appears to exhibit any condition that could affect its operability or accuracy, e.g., damage, corrosion. If either of these conditions is noted, the device must not be used, and must be submitted for recalibration.

Upon return of M&TE from calibration, the user shall review the calibration report to determine if the item is within specified tolerance(s). If the item is not within tolerance(s) when returned an appropriate Corrective Action shall be initiated in accordance with QAP 16-1.

If M&TE is lost, damaged beyond repair, or inadvertently destroyed, the validity of data obtained from use of that device since its last valid calibration shall be evaluated, and that evaluation documented.

Recording the Use of M&TE. Users shall document each use (date, device ID, data-collection activity) of M&TE in a use-log for the device or laboratory, the Scientific Notebook, or other suitable record, in a manner that will allow for easy retrieval. This will aid in the investigation and evaluation of the impact on data if M&TE is found out-of-tolerance during calibration or a user check. This documentation of each use shall be performed in addition to recording the actual data in a Scientific Notebook or on data sheets.

2.3 Temporary Extension of Calibration Due Date

If, during use of M&TE, it becomes necessary to temporarily extend the calibration due date for a limited period of time, such as for the completion of an experiment in progress, the user shall document the situation on a Nonconformance form and enter the information on the equipment/recall log and track the situation to disposition/resolution.

2.4 Control of M&TE

2.4.1 Environment

M&TE and calibration standards shall be used in environments that support the accuracy requirements of the equipment. Users shall monitor and record any environmental factors that might affect measurements, such as temperature, humidity, lighting, vibration, dust, cleanliness, electromagnetic interference, or other unique factors. When appropriate for accuracy purposes, correcting compensations shall be applied to the measurement results.

2.4.2 Storage, Operation, Handling, Transportation, and Maintenance

Users shall ensure that storage, operation, handling, transportation, and maintenance activities are performed in a manner that does not adversely affect the operation or calibration of the M&TE. The following considerations apply:

- Storage and use areas shall provide acceptable conditions of temperature, humidity, and other pertinent factors to preclude deterioration.
- Handling of equipment during transportation or use shall follow manufacturer's recommendations.
- Tamper-resistant seals shall be affixed to operator accessible controls or adjustments that, if moved, would invalidate the calibration of M&TE. M&TE found with damaged or broken seals shall be removed from service and submitted for recalibration.

The user is responsible for assuring that the calibration information is complete as described above and meets user needs and requirements consistent with any inspection requirements prior to putting the M&TE in service.

2.4.3 Retirement of M&TE

When equipment is no longer needed on the project, the equipment shall be removed from the recall system, tagged not-calibrated and properly stored, preferably with other non-calibrated equipment. Equipment no longer required by the project may be transferred to SNL Reapplications or other OSTI organizations.

2.5 M&TE Nonconformance

2.5.1 Identifying and Processing Nonconformance

The following conditions shall be identified, by the user of the M&TE, and resolved via the Nonconformance system specified in QAP 16-1.

- M&TE found to be out-of-tolerance during a calibration check, regardless of whether the device was or could be adjusted into tolerance.
- M&TE that produces results known to be in error.
- When M&TE Calibration or Accuracy is in question or the conditions listed below are noted, the user shall tag, segregate, or otherwise control the M&TE item to prevent its use until it has been calibrated:
 - The item has exceeded its calibration due date (see also section 2.2.5).
 - The accuracy of the item is suspect because of mishandling, misuse, or unusual results.
 - The item has broken calibration seals.
 - The item has been modified or repaired, had components replaced, or operating software updated.

The user shall ensure that the QA contact is notified in such cases, in a documented manner (e.g., memo, e-mail, copy of the calibration report).

These conditions shall result in the following QA actions:

- Immediate remedial action to tag, segregate, or otherwise control the device to prevent the further use of M&TE that could not be adjusted into tolerance during calibration,
- Investigative action to identify all of the uses of the subject M&TE item since its last calibration, including notification to any other users of the equipment, and to evaluate the impact of the out-of-tolerance condition with regard to the validity of previous inspection, test, or data-collection efforts, including the acceptability of items, data collected, processes monitored, or conclusions reached.

Note: If any M&TE is consistently found to be out-of-tolerance during calibration, the user shall have it replaced or repaired, unless a reduced calibration interval is expected to correct the situation.

3.0 Records

The following QA records, including corrections and changes thereto, generated as a result of implementing this QAP, shall be prepared and submitted to OCRWM and a copy to the SNL Records Center in accordance with QAP 17-1 (Records):

QA Record

- Record of M&TE use specified in Section 2.2.3 (use-log or Scientific Notebook)
- The calibration reports specified in Section 2.3.4
- Corrective Action Reports, if any, and associated documentation, specified in QAP 16-1

Note: Documents that may be maintained at the calibration provider's facility include:

- Calibration facility quality manuals
- Calibration procedures
- Calibration personnel qualification and training documents
- Recall system documentation
- Documentation of calibration standards traceability

4.0 Appendices

Not applicable – there are no appendices to this procedure