



Office of Civilian Radioactive Waste Management

QA: QA

## **PROCEDURE**

### **CONTROL OF MEASURING AND TEST EQUIPMENT**

**LP-12.1Q-BSC**

**Revision 0 ICN 1**

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Date

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### **1.0 PURPOSE**

This procedure establishes the responsibilities and process for the identification, calibration, control, storage, and maintenance of measuring and test equipment (M&TE).

### **2.0 APPLICABILITY**

This procedure applies to individuals within Affected Organizations, including Bechtel SAIC Company, LLC (BSC), the national laboratories, the U.S. Geological Survey (USGS), and direct-support contractors, who control, calibrate, maintain, or use M&TE (including calibration standards and equipment that contains software or programmable hardware).

This procedure applies to the control of M&TE subject to *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, and shall be used by all Affected Organizations to document and resolve conditions resulting from the identification, listing, calibration, storage, use, out-of-calibration/tolerance conditions, loss, and removal from service of M&TE. This procedure also may be used for activities not subject to the controls of the QARD. M&TE software that is developed or modified by the Affected Organization shall be controlled in accordance with LP-SI.11Q-BSC, *Software Management*.

This procedure does not apply to standard commercial equipment (e.g., rulers, tape measures, levels, and other commercial equipment) that provides adequate accuracy for the intended work, unless those devices are specifically identified as requiring calibration by the Affected Organization within controlled implementing documents, or where there are no specified, required tolerances or accuracies.

All equipment calibrated on or after the effective date of this procedure shall meet the requirements of this version of the procedure.

### **3.0 OTHER DOCUMENTS NEEDED/REFERENCES**

- *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P
- AP-16.1Q, *Condition Reporting and Resolution*
- AP-17.1Q, *Records Management*
- LP-6.3Q-BSC, *Document Control*
- LP-SI.11Q-BSC, *Software Management*
- LP-SIII.11Q-BSC, *Scientific Notebooks*
- QA-PRO-1042, *Supplier Evaluation and Qualified Supplier List (QSL) Maintenance*
- QA-PRO-1071, *Acceptance of Items & Services*

### **4.0 RESPONSIBILITIES**

- 4.1 The BSC Post-Closure Activities Deputy Manager is responsible for the preparation, change, and approval of this procedure.

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4.2 The following organizations or positions are responsible for activities identified in Section 5.0 of this procedure:

- a. Responsible Manager
- b. Principal Investigator (PI)
- c. Engineering Test Lead
- d. Affected Organization M&TE Custodian
- e. Responsible Individual

## 5.0 PROCESS

Acronyms and Abbreviations used in this procedure are defined in Attachment 1, Acronyms and Abbreviations. Terms used in this procedure are defined in Attachment 2, Definitions.

### Process Outline

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### 5.1 IDENTIFICATION AND LISTING OF M&TE

Responsible  
Manager, PI, or  
Engineering Test  
Lead

- [1] **Select** the appropriate M&TE for use based upon anticipated measurement range capabilities and environmental considerations under which the equipment will be expected to perform.
- [2] **Ensure** that M&TE is uniquely identified by tag, sticker, marking, or other means that permit traceability to its calibration documentation (refer also to Step 5.3 [7]).
- [3] **Ensure** that the M&TE Custodian is provided accurate and current information so that the M&TE list can be maintained as required in Step 5.1 [4].

Note: Additional information, which is only for the benefit of the Affected Organization M&TE Custodian, may be maintained on the M&TE list. The optional information is subject to correction whenever updates are received.

Affected  
Organization M&TE  
Custodian

- [4] **Maintain AND be** responsible for an up-to-date list of M&TE that shall include the following, as a minimum:
  - Unique identification of the M&TE.
  - Description or type of M&TE.
  - Date calibrated. This may be left blank if the M&TE has a special status, such as one-time-only use or a calibration frequency based on number of samples rather than a specific timeframe.
  - Recalibration due date or frequency of calibration or shelf life, as appropriate. This may be left blank if the M&TE has a special status, such as one-time-only use, non-retrievable, or a calibration frequency based on number of samples rather than a specific timeframe.
  - Required calibration tolerance or a reference to same, where applicable.
  - Description of limited calibration status, as applicable.
  - Indication of special status (e.g., one-time-only use, non-retrievable, or a calibration frequency based on number of samples rather than a specific timeframe).

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**5.2 ESTABLISHMENT OF STANDARDS**

Note: This subsection pertains to when calibrating M&TE internally.

**Responsible  
Manager, PI, or  
Engineering Test  
Lead**

- [1] **Obtain** M&TE calibration standards having traceability to nationally recognized standards (e.g., standards from the National Institute of Standards and Technology).
- [2] **IF** no nationally recognized standards or physical constants exist,  
  
**THEN document** the basis for calibration on Attachment 3, M&TE Justification, or in a scientific notebook developed in accordance with LP-SIII.11Q-BSC that includes, as a minimum, the information required by the M&TE Justification form.
- [3] **Ensure** that standards have an accuracy greater than the required accuracy of the M&TE to be calibrated, except where indicated in the following steps:
  - a. **Use** standards with an accuracy equal to that of the M&TE if use of these standards can be shown to adequately meet the requirements and if standards with a greater accuracy do not exist or are unavailable.
  - b. **Document** the justification on the M&TE Justification form or in a scientific notebook that includes, as a minimum, the information required by the M&TE Justification form by explaining why the accuracy is limited and why the accuracy is adequate for the M&TE's intended use.
- [4] **Ensure** that the calibration standards are maintained in accordance with the requirements for all M&TE.
- [5] **Submit** the M&TE Justification form (if used) to the Records Coordinator for submittal to the Records Processing Center (RPC) in accordance with Section 6.0.
- [6] **IF** the M&TE Justification form was not used,  
  
**THEN ensure** that the scientific notebook is submitted to the RPC in accordance with LP-SIII.11Q-BSC.

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**5.3 CALIBRATION OF M&TE****Responsible  
Manager, PI, or  
Engineering Test  
Lead**

- [1] **Ensure** that M&TE is calibrated, adjusted, and maintained, as appropriate, at established intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards either by a calibration service supplier or by a Responsible Individual.
- [2] **Ensure** that calibration documentation includes the following:
- The unique identification of the M&TE calibrated.
  - Date calibrated.
  - Calibration data.
  - Recalibration due date or calibration interval/frequency.
  - Identification of the procedure (including revision level) used to calibrate the M&TE.
  - Identification of and traceability to the calibration standards used for the calibration.
  - Results of the calibration and statement of acceptability.
  - As-found condition of the M&TE, as appropriate.
  - Specified range and tolerances and whether the M&TE met those tolerances.
  - Personnel performing calibrations.
  - Reference to M&TE OCR number, if generated as a result of calibration. For M&TE calibrated by a calibration service supplier, this reference can be made on the Acceptance Report for Calibration Services (Form QA-PRO-1071.6) which is completed in accordance with QA-PRO-1071. For calibration services procured by USGS, the reference may be made on the appropriate USGS procurement acceptance documentation, performed in accordance with approved USGS procurement procedures.

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Note: Steps 5.3 [3] through [5] are not always applicable or followed in the order listed. Individual activities within these steps are required when a step is deemed applicable by the Responsible Manager and/or PI.

[3] **Ensure** the following when M&TE is calibrated internally:

- a. Procedures are developed and maintained for the calibration of M&TE in accordance with Section 5.2 of the QARD, or the calibration process is documented in a scientific notebook developed and maintained in accordance with LP-SIII.11Q-BSC.
- b. Calibration procedures or process documentation address the following requirements for the equipment to be calibrated:
  - Identification of standards to be used
  - Detailed description of calibration method
  - Identification of tolerances and range of use
  - Requirement that items in Step 5.3 [2] be addressed in calibration documentation.

[4] **Ensure** that pertinent information from equipment vendor manuals is incorporated into the applicable document (i.e., calibration procedure or scientific notebook), or that the manuals are controlled per LP-6.3Q-BSC.

[5] **Ensure** the following when M&TE is calibrated by a service supplier:

- a. Procurement of calibration supplier services is performed in accordance with applicable procurement procedures, including acceptance, in accordance with QA-PRO-1071. For calibration services procured by the USGS, the procurement is performed and accepted in accordance with approved USGS procurement procedures.
- b. The supplier is listed on the Office of Civilian Radioactive Waste Management Qualified Supplier List database. The National Institute of Standards and Technology is not subject to audits and surveys. All other calibration service suppliers are subject to audits or surveys in accordance with QA-PRO-1042.
- c. Supplier documentation meets the requirements of Step 5.3 [2] and is submitted to the RPC in accordance with the applicable procedure.

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Responsible  
Individual

[6] Ensure the following when internally calibrating M&TE:

- a. The M&TE is calibrated as specified by an approved procedure for that M&TE or as described in a scientific notebook.
- b. The calibration is documented in accordance with the approved calibration procedure or calibration process documented in a scientific notebook, and the documentation is submitted to the Records Coordinator for submittal to the RPC in accordance with the approved calibration procedure or LP-SIII.11Q-BSC.

Note: The means of attachment of the M&TE Calibration Sticker (see Attachment 4, Example of M&TE Calibration Sticker and Out of Service Tag) shall not impair the function or accuracy of the equipment. If the device is too small to attach a calibration sticker, the sticker may be attached to the M&TE storage container as long as the container stays within proximity when the device is in use. Calibration stickers for calibrated M&TE that are not accessible for observation may be displayed in reasonable proximity to the device. M&TE that cannot be physically tagged and do not have containers may be referenced by their locations on grids, charts, or other documents.

M&TE that has been labeled, tagged, or otherwise suitably marked or documented to indicate due date or interval of the next calibration by a calibration service supplier does not need to be relabeled in accordance with Steps [7] and [8].

[7] IF the calibration documentation is acceptable,

THEN attach an M&TE Calibration Sticker to M&TE.

[8] Enter the following information on the M&TE Calibration Sticker:

- a. IF the M&TE is classified as one-time-only use, non-retrievable, or another special calibration status (e.g., the calibration frequency is based on number of samples rather than a timeframe),

THEN indicate the special status on the calibration label AND proceed to Step 5.3 [9].

- b. IF the calibration was performed by a calibration service supplier,

THEN enter the name of the supplier and the initials of the person attaching the calibration sticker in the "BY" space.



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c. **IF** the calibration was performed internally,

**THEN** enter the name or initials of the person performing the calibration in the "BY" space.

d. **Enter** the date calibrated. As a minimum, the calibration date should consist of month, day, and year.

e. **IF** the device will **NOT** be placed in long-term storage in accordance with Subsection 5.5,

**THEN** enter the due date for the next calibration (month, day, and year) if the device is placed in service.

f. **Enter** the unique identification number of the device.

Note: If a calibration sticker affixed by a calibration service supplier meets the requirements for a limited calibration sticker, then an internal sticker does not need to be generated and affixed to the M&TE.

[9] **IF** M&TE meets the definition of limited calibration,

**THEN** label the M&TE with an M&TE Limited Calibration Sticker (see Attachment 4 for an example) rather than with an M&TE Calibration Sticker.

The M&TE Limited Calibration Sticker is subject to all of the requirements imposed upon the use of the M&TE Calibration Sticker, identified in Steps 5.3 [7] and [8], in addition to the following:

- The sticker shall be labeled with the heading "limited calibration."
- The sticker shall be partially or entirely red, orange, or yellow.
- The sticker shall indicate either the calibration limitations or a specific reference to where this information can be found.

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Responsible  
Manager, PI, or  
Engineering Test  
Lead (where  
applicable)

[10] Ensure that M&TE is calibrated both before and after use for one-time-only applications of M&TE:

[11] Perform the following for nonretrievable applications of M&TE:

- a. Document on the M&TE Justification form the validity of data collected with M&TE that cannot be, or is not intended to be, retrieved for recalibration.
- b. Submit a copy of the M&TE Justification form to the Records Coordinator for submittal to the RPC in accordance with Section 6.0.

Responsible  
Individual

[12] Notify the M&TE Custodian of the M&TE calibration status after all calibration activities so that the M&TE list can be updated and maintained in accordance with Step 5.1 [4].

### 5.4 STORAGE OF M&TE

Responsible  
Individual

- [1] Ensure that M&TE, when placed in storage, are appropriately stored, handled, and protected to maintain accuracy and to reduce the likelihood of damage or loss.
- [2] Consider the manufacturer's recommendations regarding storage and handling.
- [3] Ensure that access to designated M&TE storage is adequately controlled. Methods may include locked cabinets, rooms, buildings, or other appropriate means.

### 5.5 LONG-TERM STORAGE OF CALIBRATED M&TE

Note: The following subsection describes the control of calibrated equipment that is ready for use and placed into long-term storage until activation of the calibration period. This process provides for a ready supply of calibrated spare units to minimize down-time in the event of equipment failure or expiration of calibration periods. The use of this section is optional.

Responsible  
Individual

- [1] Establish the technical justification for storing calibrated M&TE without activating the prescribed calibration period.

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[2] **Consider** the following during development of the justification:

- a. Environmental effects on electronic or mechanical components
- b. Previous maintenance history of the M&TE during normal calibration sequences (e.g., reliability, inherent stability, purpose of use)
- c. Special storage requirements such as temperature and humidity control
  - Special packaging requirements (e.g., sealed bags, use of desiccant, plugging of open ports)
  - Any deviations from manufacturers' recommendations and specifications.

[3] **Present** evidence to justify the maximum length of time the M&TE can be stored and still receive the full calibration period upon activation to the Responsible Manager and/or PI on the M&TE Justification form or in a scientific notebook that includes, as a minimum, the information required by the M&TE Justification form.

**Responsible  
Manager, PI, or  
Engineering Test  
Lead**

[4] **IF** the justification is acceptable,  
**THEN** sign the form or scientific notebook entry to indicate approval.

[5] **Return** the documentation to the Responsible Individual.

**Responsible  
Individual**

[6] **IF** the justification was not approved,  
**THEN** return to Step 5.5 [1].

[7] **Ensure** that the justification is submitted to the Records Coordinator for submittal to the RPC in accordance with Section 6.0 if documented on the M&TE Justification form, or in accordance with LP-SIII.11Q-BSC if documented in a scientific notebook.

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Note: The calibration due date for stored M&TE is listed as the calibration date (month, day, and year) plus the maximum shelf life plus the established period between calibrations (calibration interval) (e.g., if the calibration date is 3/15/00 with a calibration frequency of one year and a maximum shelf life of three years, then the M&TE list calibration due date will show 3/15/04).

- [8] **Notify** the M&TE Custodian of the long-term storage status and calibration due date so that the M&TE list can be updated and maintained in accordance with Step 5.1 [4].

Note: A storage area may be a building, room, or storage cabinet that will provide physical and environmental protection.

Responsible  
Manager, PI, or  
Engineering Test  
Lead

- [9] **Provide** storage area(s) with controlled access. The area shall be locked when not attended.

Responsible  
Individual

- [10] **Place** the calibrated equipment in the designated storage area **AND** initiate Attachment 5, M&TE Calibrated Equipment Storage Datasheet.

- [11] **Complete** the datasheet when removing the M&TE from the storage area for placement into service.

- [12] **Submit** the completed M&TE Calibrated Equipment Storage Datasheet to the Records Coordinator for submittal to the RPC in accordance with Section 6.0.

- [13] **Do NOT** return M&TE removed from storage and placed into service back to storage without recalibration.

- [14] **Verify** the calibration status and performance of M&TE prior to use.

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Note: Due dates are determined by adding the calibration frequency period to the date that the equipment is removed from storage (e.g., if the date the M&TE was removed from storage is 3/15/00 and the calibration frequency is one year, then the calibration due date would be 3/15/01).

[15] **Annotate** the calibration due date (month, day, and year) on the calibration sticker.

[16] **Perform** a cursory check of the M&TE for damage that may be detrimental to its normal operation prior to placing it into service.

[17] **Notify** the M&TE Custodian of the activated calibration status so that the M&TE list can be updated and maintained in accordance with Step 5.1 [4].

### 5.6 USAGE OF M&TE

Responsible  
Manager, PI, or  
Engineering Test  
Lead

[1] **Ensure**, when M&TE is used, that Affected Organization personnel document the use so that if the M&TE's calibration validity comes under question, items, equipment, devices, data, or other M&TE checked with it can be identified, rechecked, or re-evaluated.

[2] **Document** the use of M&TE, including standards, on Attachment 6, M&TE Usage Log. Alternatively, use can be documented in a scientific notebook or by other means (e.g., documents generated by the calibration or operational check procedures) if all information required by Attachment 6 is included.

[3] **WHEN** its accuracy is suspect (i.e., conditions exist that could be expected to have changed the M&TE calibration, or the M&TE is sensitive to motion and the instrument has been moved),

**THEN** perform an operational check **OR** recalibrate the M&TE.

[4] **Document** the check and/or recalibration results in accordance with controlled implementing procedures or method documented in a scientific notebook.

[5] **Ensure** that M&TE is used within its calibrated capabilities.

[6] **IF** the M&TE is labeled with a Limited Calibration sticker,

**THEN** determine the appropriate limits prior to use.

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**5.7 OUT-OF-CALIBRATION CONDITIONS, INCLUDING LOSS OR DAMAGE TO M&TE****Affected  
Organization M&TE  
Custodian or  
Responsible  
Individual****[1] Control the issuance of M&TE OCR numbers by the following actions:**

- a. **Maintain** a log of the organization's issuance of M&TE OCRs.
- b. **Ensure** numbers conform to the following format: AAA-YYYY-NNN, where:
  - AAA (not limited to three characters) represents the initials of the organization's acronym or name.
  - YYYY represents the calendar year the M&TE OCR was initiated.
  - NNN represents a unique number, starting with 001 for the first report of the year and using sequential numbers thereafter.

**Responsible  
Individual****[2] Consider M&TE out of tolerance or out of calibration if any of these conditions exist, as applicable:**

- The calibration due date or interval has passed without recalibration when M&TE is in use.
- The M&TE produces results known to be in error.
- Software or programmable hardware for the M&TE has been upgraded and affects calibration.
- M&TE that has not been calibrated has been used to collect data or gauge performance.
- The M&TE has been subjected to recalibration procedures or periodic checks and found to be out of the allowed specification tolerances.
- M&TE is lost.
- M&TE is damaged.

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[3] **Control** out-of-calibration M&TE (except lost M&TE) to prevent inadvertent use by doing one or more of the following, except when physically inaccessible or when the appropriate disposition action (such as calibration) has already been performed:

a. **Apply** an M&TE Out of Service tag (see Attachment 4) or other similar tag to the M&TE to indicate the out-of-calibration condition. Tags indicating an out-of-calibration condition shall include, as a minimum:

- Description of the M&TE
- Unique identifier of the M&TE
- Reason for applying the tag
- Dated signature of person tagging the M&TE.

b. **Segregate** the out-of-calibration M&TE by moving the M&TE to an area identified as "segregated" or "out-of-service."

Note: The Responsible Individual may skip Steps 5.7 [6] through 5.7 [11] and cross-out blocks 11 and 12 on the OCR when documenting M&TE considered out-of-calibration as a result of having been subjected to recalibration procedures and found to be out of the allowed specification tolerances but then brought back into specified tolerances as a result of the calibration process.

[4] **Document** the out-of-calibration conditions using Attachment 7, M&TE OCR, in accordance with the instructions provided immediately after tagging and/or segregating the affected M&TE or after discovering M&TE has been lost.

[5] **Obtain** an OCR number from the Affected Organization M&TE Custodian or Responsible Individual (see Step 5.7 [1]) **AND** print name, sign, **AND** date the M&TE OCR.

[6] **Submit** the M&TE OCR to one of the following:

- The appropriate PI in the scientific community
- The appropriate Responsible Manager in the Environmental Safety and Health group
- The appropriate Engineering Test Lead in the engineering discipline.

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Manager, PI, or  
Engineering Test  
Lead

[7] **Evaluate** the M&TE Disposition Recommendation for approval.

[8] **IF** unsatisfactory,

**THEN** return it to the Responsible Individual.

[9] **IF** satisfactory,

**THEN** print name, sign, **AND** date the M&TE OCR.

[10] **Return** the M&TE OCR to the Responsible Individual.

Responsible  
Individual

[11] **Complete** the M&TE disposition action(s) and provide the completion date on the M&TE OCR.

[12] **Notify** the Responsible Manager, PI, or Engineering Test Lead that the M&TE OCR is ready for impact evaluation.

Responsible  
Manager, PI, or  
Engineering Test  
Lead

[13] **Assign** an individual to complete the impact evaluation.

[14] **Ensure** that they are knowledgeable in the functional use of the M&TE and its relation to applicable items, samples, or data.

Responsible  
Individual

[15] **Evaluate** the impact to associated items, samples collected, or data collected as a result of using out-of-calibration, damaged, or lost M&TE.

[16] **IF** it is determined that there is an impact,

**THEN** document this on the M&TE OCR, immediately report the condition in accordance with AP-16.1Q, **AND** note the Condition Report (CR) number on the M&TE OCR.

[17] **IF** it is determined that there is no impact,

**THEN** document the justification for this decision on the M&TE OCR. This evaluation and justification shall be sufficiently supported by a logical, documented process to address applicable issues such as reviews of previously collected data, calibration history for the specific M&TE, statistical analysis and comparisons, and the operational status up to the point of the out-of-calibration condition.

[18] **Print** name, sign, **AND** date the M&TE OCR **AND** submit it to the appropriate Responsible Manager, PI, or Engineering Test Lead.



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Responsible  
Manager, PI, or  
Engineering Test  
Lead

[19] Review the M&TE OCR for approval and closure.

[20] IF unsatisfactory,

THEN return it to the Responsible Individual.

[21] IF satisfactory,

THEN print name, sign, AND date the M&TE OCR.

[22] Return the M&TE OCR to the Responsible Individual.

Responsible  
Individual

[23] Submit the completed M&TE OCR to the Records Coordinator for submittal to the RPC in accordance with Section 6.0.

[24] Notify the M&TE Custodian of the M&TE's disposition/calibration due date status so that the M&TE list can be updated and maintained in accordance with Step 5.1 [4].

[25] Remove M&TE from out-of-service area AND/OR remove out-of-service tags/labeling when the disposition action has been performed and the OCR has been completed.

[26] Repair OR replace M&TE that is consistently found to be out of calibration when recalibrated.

### 5.8 REMOVAL OF M&TE FROM SERVICE

Note: This subsection applies when M&TE is to be removed from service.

Responsible  
Individual

[1] IF the M&TE is operable and has been used since its last calibration,

THEN ensure that the M&TE is calibrated in accordance with Subsection 5.3.

[2] IF the M&TE is found to be out of calibration, lost, or damaged,

THEN generate an M&TE OCR in accordance with Subsection 5.7.

[3] Remove the M&TE from service AND remove all indications that the M&TE is in service and available for use.

[4] Notify the M&TE Custodian of the removal from service so that the M&TE list can be updated and maintained in accordance with Step 5.1 [4].

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### **6.0 RECORDS**

The records listed in Subsections 6.1 and 6.2 shall be collected and submitted to the RPC in accordance with AP-17.1Q as individual records or included in a records package, as specified.

LP-12.1Q-BSC is an administrative procedure. Calibration records are submitted to the RPC in accordance with the lower-tier calibration procedures/processes in which they are actually generated.

#### **6.1 QA RECORDS**

Submit as an Individual Record or a Records Package, as applicable:

- M&TE Justification form
- M&TE Calibrated Equipment Storage Datasheet
- M&TE OCR
- M&TE Usage Log

Submit in accordance with LP-SIII.11Q-BSC:

Scientific Notebook, if applicable to this procedure

#### **6.2 NON-QA LONG-TERM RECORDS**

Submit as an Individual Record or a Records Package, as applicable:

- M&TE Justification form
- M&TE Calibrated Equipment Storage Datasheet
- M&TE OCR
- M&TE Usage Log

#### **6.3 NON-QA SHORT-TERM RECORDS (THREE YEARS OR LESS RETENTION)**

None

### **7.0 ATTACHMENTS**

Forms attached to this procedure are controlled and distributed as full-size pages separate from this procedure and may be copied for use when implementing this procedure. The change history for this procedure is included as Attachment 8, Change History.

- 1 Acronyms and Abbreviations
- 2 Definitions
- 3 M&TE Justification (Form L121-1)
- 4 Example of M&TE Calibration Sticker and Out of Service Tag
- 5 M&TE Calibrated Equipment Storage Datasheet (Form L121-2)
- 6 M&TE Usage Log (Form L121-3)

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7 M&amp;TE OCR (Form L121-4)

8 Change History

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BSC	Bechtel SAIC Company, LLC
CR	Condition Report
M&TE	measuring and test equipment
OCR	Out of Calibration Report
PI	Principal Investigator
QA	quality assurance
QARD	Quality Assurance Requirements and Description
RPC	Records Processing Center
USGS	U.S. Geological Survey

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Attachment 2

### Definitions

**Accuracy**—The degree of agreement of the measurement with the true value of the quantity measured.

**Calibration**—The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or system and the corresponding standard or known values derived from the standard.

**Calibration Standard**—A material measure, measuring instrument, reference material, or system intended to define, realize, conserve, or reproduce a unit or one or more known values of a quantity to serve as a reference.

**Engineering Test Lead**—An individual responsible for the engineering testing activity. The Engineering Test Lead may be from design engineering, field engineering, startup, or another organization. For the purposes of this procedure, the Engineering Test Lead is considered equivalent to the PI.

**Limited Calibration**—M&TE that is calibrated to less than the full range, function, or manufacturer's accuracy specification.

**Measuring and Test Equipment (M&TE)**—Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements (QARD).

**Nonretrievable M&TE**—M&TE that is installed in situ and cannot be, or is not intended to be, retrieved for recalibration.

**One-Time-Only M&TE**—M&TE that falls under one of the following three types:

- 1) Instruments that require calibration prior to each use (e.g., pH meters or gas analyzers)
- 2) Instruments that take measurements or readings that cannot be taken any other time
- 3) Instruments used only once and not used again (i.e., instruments that will be used once and then removed from service or discarded).

**Operational Check**—An examination performed and documented to verify that M&TE is functioning and operating within specified tolerances. A check may be performed at any time prior to the calibration expiration date or whenever the reliability of the M&TE is suspect.

**Out of Calibration**—An all-inclusive term that identifies M&TE that has never been calibrated, has not been recalibrated within the required time period, has been subjected to recalibration procedures or periodic checks and found to be out of the allowed specification tolerances (i.e., out of tolerance), or has been damaged or found in a condition that has been determined to be suspect.

**Principal Investigator (PI)**—An individual who has the technical responsibility for the scientific work and/or conducts technical work.

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**Attachment 2****Definitions (Continued)**

***Repair***—The process of restoring an item to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement (QARD).

***Scrap/Reject***—The disposition that is authorized when the M&TE cannot be fixed and is considered unacceptable for its intended use.

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Attachment 3

**M&TE Justification**

**BSC**

**Measuring and Test Equipment Justification**

QA:

Page of

*Complete only applicable items.*

1. M&TE ID No.		2. M&TE Type	
3. Initiator Name	4. Date	5. Responsible Manager or Principal Investigator	
6. Justification			
<h1>EXAMPLE</h1>			
7. Approved By			
Responsible Manager or Principal Investigator: _____		Date: _____	
_____		_____	
Signature			

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**Attachment 3**

### **Instructions for M&TE Justification**

**Responsible Manager,  
PI, or Engineering Test  
Lead**

1. Enter the QA designation in the Title Block.
2. Enter the number of pages in the Title Block.
3. In Block 1, enter unique M&TE identification number. If the justification is for a particular type of M&TE and not for a specific device, enter "N/A" in this block.
4. In Block 2, enter type or description of M&TE.
5. In Block 3, print name of person initiating the justification form.
6. In Block 4, print date when justification form is initiated.
7. In Block 5, print name of Responsible Manager, PI, or Engineering Test Lead.
8. In Block 6, enter appropriate justification.

**Responsible Manager,  
PI, or Engineering Test  
Lead (after the  
justification has been  
reviewed and  
approved)**

9. In Block 7, print and sign name in the spaces provided.
10. In Block 7, print date in space provided.



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Attachment 4

**Example of M&TE Calibration Sticker and Out of Service Tag****M&TE Out of Service Tag**

Description: \_\_\_\_\_

\_\_\_\_\_

ID #: \_\_\_\_\_

☐ Calibration Required

☐ Damaged

☐ To Be Excessed

☐ Maintenance Required

Comments/Disposition: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

(Front)

**Out of  
Service**

(Back)

**M&TE Calibration Sticker**

CALIBRATION	
BY _____	DATE _____
NEXT CAL DUE _____	
INSTRUMENT # _____	

**M&TE Limited Calibration Sticker**

LIMITED CALIBRATION	
BY _____	DATE _____
NEXT CAL DUE _____	
INSTRUMENT # _____	
LIMITS _____	

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Attachment 5

**M&TE Calibrated Equipment Storage Datasheet**

**BSC**

**Measuring and Test Equipment Calibrated  
Equipment Storage Datasheet**

QA:

Page

of

*Complete only applicable items.*

Equipment Description		
Equipment Identification Number	Serial Number	
Date Calibrated	Maximum Storage Period	
Person Placing Equipment Into Storage (Printed Name)	Signature	Date Placed in Storage
Person Removing Equipment From Storage (Printed Name)	Signature	Date Removed From Storage
Comments:		
<h1>EXAMPLE</h1>		
Forward this form to the M&TE Custodian after removal of equipment from storage.		

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**Attachment 6**

## Measuring and Test Equipment Usage Log

QA: Page of

**Complete only applicable items.**

[illegible]

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Attachment 7

**M&TE OCR****BSC****Measuring and Test Equipment  
Out of Calibration Report**

QA:

Page 1 of

*Complete only applicable items.*

1. M&TE OCR No.		2. Organization	
3. Responsible Individual (Print)		4. Date	5. Responsible Manager, PI, or Eng. Test Lead (Print)
6. M&TE Description (manufacturer, name, model, etc.)			
7. <input type="checkbox"/> Q <input type="checkbox"/> Non-Q		8. M&TE Unique ID	9. Previous Calibration or In Service Date
10. Out of Calibration Condition Description (condition of equipment; location; function/use; job scope/activity [e.g., scientific notebook, procedure, etc.])  Check appropriate box: <input type="checkbox"/> Out of calibration <input type="checkbox"/> Lost <input type="checkbox"/> Damaged  <div style="text-align: center; font-size: 48pt; font-weight: bold; opacity: 0.5;">EXAMPLE</div> <input type="checkbox"/> Out of Service Tag Affixed			
11. M&TE Disposition Recommendation  Check appropriate box(es) <input type="checkbox"/> Calibrate <input type="checkbox"/> Repair <input type="checkbox"/> Scrap/Reject  Recommended Disposition by Responsible Individual: (Print/Sign) _____ Date: _____  Approval of Disposition by PI, Responsible Manager, or Engineering Test Lead: (Print/Sign) _____ Date: _____			
12. M&TE Disposition Action Completion Date: _____			
13. Condition Impact Evaluation <input type="checkbox"/> Item <input type="checkbox"/> Sample <input type="checkbox"/> Data  Performed by: (Print/Sign) _____ Date: _____  <input type="checkbox"/> CR   CR No. _____			
14. Final Approval and Closure by PI, Responsible Manager, or Engineering Test Lead: (Print/Sign) _____ Date: _____			

☐ Continuation Page  
(include OCR #)☐ Continuation Page  
(include OCR #)

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Attachment 7

**M&TE OCR (Continued)**

**BSC**

**Measuring and Test Equipment  
Out of Calibration Report**

QA:  
Page of

Continuation Page

OCR No.: \_\_\_\_\_

**EXAMPLE**

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**Attachment 7****Instructions for M&TE OCR**

- Responsible Individual**
1. Title Block: Enter QA designation.
  2. Block 1: Enter unique M&TE OCR organization sequential tracking number obtained from the Affected Organization M&TE Custodian.
  3. Block 2: Enter the name of the organization generating the M&TE OCR.
  4. Block 3: Print Responsible Individual name.
  5. Block 4: Enter date the M&TE OCR was initiated.
  6. Block 5: Print name of Responsible Manager, PI, or Engineering Test Lead who is responsible for the care and maintenance of the M&TE identified as being out of calibration, damaged, or lost.
  7. Block 6: Enter the name of the M&TE (e.g., manufacturer and model) and any other appropriate identifying information, as applicable.
  8. Block 7: Check the appropriate box, identifying the M&TE as Q or Non-Q.
  9. Block 8: Enter the M&TE unique identification (e.g., serial number).
  10. Block 9: Enter previous calibration date or date when the M&TE was last put into service.
  11. Block 10: Describe in sufficient detail:
    - The present condition of the M&TE and check appropriate box: out of calibration, lost, or damaged. Indicate if the M&TE has already been brought back into specified tolerances as a result of a calibration process.
    - The location of the M&TE when identified as being out of calibration or damaged. If M&TE is lost, describe the last known location.
    - The function and use of the M&TE.
    - The job scope or activity (e.g., scientific notebook or procedure) for which the M&TE is used.

Provide any additional information necessary to describe the situation. Out-of-calibration conditions are defined in Step 5.7 [2].
  12. Block 10: Check box if Out of Service tag or other similar tag was affixed to out-of-calibration or damaged M&TE to identify that the equipment cannot be used.
  13. Block 10: Check the Continuation Page box if additional pages are required to provide a description of the M&TE.
  14. Block 11: Check the appropriate box(es) for the M&TE Disposition Recommendation (calibrate, repair, or scrap/reject).

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**Attachment 7****Instructions for M&TE OCR (Continued)**

15. Block 11: Print name, sign, and date.

**Responsible Manager,  
PI, or Engineering Test  
Lead**

16. Block 11: Evaluate the M&amp;TE Disposition Recommendation for approval. Print name, sign, and date.

Block 11 may be crossed-out when documenting M&TE considered out-of-calibration as a result of having been subjected to recalibration procedures and found to be out of the allowed specification tolerances but then brought back into specified tolerances as a result of the calibration process.

**Responsible Individual**

17. Block 12: Enter date of M&amp;TE Disposition Action Completion.

Block 12 may be crossed-out when documenting M&TE considered out-of-calibration as a result of having been subjected to recalibration procedures and found to be out of the allowed specification tolerances but then brought back into specified tolerances as a result of the calibration process.

18. Block 13: Describe in detail the condition impact evaluation and indicate whether or not the out-of-calibration, damaged, or lost condition of the M&amp;TE has impacted items, samples, and/or data by checking the appropriate box(es). If there is no impact, provide adequate justification for this decision and leave the item, sample, and data boxes unchecked.

19. Block 13: If there is an impact to items, samples, and/or data, check the CR box, process in accordance with AP-16.1Q, and note the CR number on the M&amp;TE OCR form.

20. Block 13: Check Continuation Page box if additional pages are required to provide the details of the impact evaluation.

21. Block 13: Print name, sign, and date. Present the M&amp;TE OCR form to the Responsible Manager, PI, or Engineering Test Lead.

**Responsible Manager,  
PI, or Engineering Test  
Lead**

22. Block 14: Evaluate M&amp;TE OCR form for completeness and adequacy. Print name, sign, and date.

23. Title Block: Provide final pagination.

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**Attachment 8****Change History**

<b><u>Revision Number</u></b>	<b><u>Interim Change No.</u></b>	<b><u>Effective Date</u></b>	<b><u>DESCRIPTION OF CHANGE</u></b>
0	1	10/31/2005	ICN to address physically inaccessible out-of-calibration measuring and test equipment, clarify labeling requirements for measuring and test equipment calibrated by a calibration service supplier, and other miscellaneous administrative and editorial changes. Close-out of the following Document Action Requests: D27570, D26190, D27610, D23650, D28253, and D26644. Resolve corrective action 6320-001.
0	0	02/04/2005	Initial issue. Supersedes AP-12.1Q, <i>Control of Measuring and Test Equipment</i> .