

EP-DIR-SOP-5006, Revision 0.0

Control of Measuring and Test Equipment

Effective Date: 06/11/07

Doris Quintana	Signature on File	06/11/07
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Procedure Owner

Signature

Date

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HISTORY OF REVISIONS

Revision Number	Issue Date	Action	Description
0.0	06/11/07	Revision to QP-5.2	Incorporate EP-DIR-QAP-0001 requirements; reformatted and renumbered. Supersedes QP-5.2, <i>Control of Measuring and Test Equipment</i> .

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1.0 PURPOSE AND SCOPE

The purpose of this procedure is to describe the requirements from ASME NQA-1-2000, Section 800, and EP-DIR-QAP-1001, *Quality Assurance Plan for the Environmental Programs Directorate*, and describe the process the Los Alamos National Laboratory (LANL or Laboratory) Environmental Programs (EP) Directorate uses to identify, maintain, and manage Measuring and Test Equipment (M&TE). This procedure does not provide instructions on how to calibrate M&TE, but the process used to obtain calibration services.

This procedure applies to all EP Directorate and subcontracted personnel conducting work for the EP Directorate. EP Directorate personnel deployed to other organizations will meet the requirements of the organization's Control of Measuring and Test Equipment Program.

2.0 BACKGROUND AND PRECAUTIONS

2.1 Background

Selection of measuring and test equipment (M&TE) for use within the EP Directorate is based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements. M&TE is calibrated at prescribed time periods or usage and whenever the accuracy of the equipment is suspect.

Inspections and acceptance testing of sampling, measurement, and analytical instrumentation (or other measurement systems) and their components are performed as required to confirm their capability for the intended use of the items as specified by the design. When acceptance criteria are not met, deficiencies are resolved and re-inspections performed, as necessary, prior to their use.

Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

M&TE, including that used for process monitoring or data collection within the EP Directorate, is sent to the LANL Standards and Calibration Laboratory for calibration under LANL's calibration program or calibrated at each use by the user under the specific procedure used for performing work. The EP Directorate uses the LANL Operational Support Tool OST308-00-00, Laboratory Calibration Program, to calibrate and control M&TE; however, this OST does not incorporate all of the requirements of the EP Directorate. Thus, this procedure contains the information describing the missing requirements to ensure compliance by the EP Directorate to ASME NQA-1-2000.

2.2 Precautions

Calibration of M&TE must be against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration must be documented.

3.0 EQUIPMENT AND TOOLS

None.

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4.0 STEP-BY-STEP PROCESS DESCRIPTION

4.1 General Requirements

M&TE Coordinator 1. Request calibration services from the LANL Standards and Calibration Laboratory and include all applicable requirements of ASME NQA-1-2000 or those specified within this procedure.

OR

Calibrate the item at each use employing the specific procedure used for performing the work or the manufacturer's instructions.

2. Develop a listing of available M&TE that contains the following information:

- Make, model, and serial number of the M&TE;
- Unique identifier of the M&TE;
- Date of calibration;
- Date of next calibration;
- Identification or reference to the required accuracy;
- Methods of calibration; and
- Frequency of calibration.

4.2 M&TE Management

M&TE Coordinator 1. Complete Section 1 of the M&TE Report (see Attachment 1) by assigning a unique identifier for the M&TE, and provide a description of the equipment, its location, capacity, range, and the tolerance required.

2. Assign an identification number for each item that is periodically calibrated, regardless of the calibrator, using one of the following:

- the serial number of the item,
- an optional file number assigned by the Standards and Calibration Laboratory, or
- other unique identification.

3. On Line 6 of Attachment 1, define the method and interval calibration for each device based on the following:

- Type of equipment;
- Stability characteristics;
- Required accuracy;
- Intended use; and
- Other conditions affecting capability.

4. On Line 7 of Attachment 1, define any special storage and handling requirements that are necessary to maintain the accuracy of the device.

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M&TE
Coordinator
(Continued)

5. For M&TE calibrated at each use, enter "at each use" on Line 6, and enter "N/A" with initial and date on Lines 19 and 21 to document these sections are not applicable.
6. Ensure standards are traceable to nationally recognized standards, and enter "N/A" on Line 9.
7. If a physical constant (i.e., standard) does not exist, document the basis for calibration on Line 9.
8. If the calibration standard has a higher accuracy than the M&TE being calibrated, enter "N/A" on Line 10.

[NOTE: The calibration standard used should have accuracy at least four (4) times greater than the device being calibrated.]
9. If standards with accuracy equal to the M&TE being calibrated must be used, and can be shown to be adequate for the requirements, document the basis for calibration acceptance on Line 10.
10. Enter the information into the M&TE Data Base.
11. Sign and date the signature block on Line 11 for initial entries or for subsequent changes to the information in Section 1.

[NOTE: This signature and date signify the information has been entered into the M&TE Data Base.]

4.3 Calibrate M&TE at the Set Frequency

M&TE
Coordinator

1. Coordinate the calibration with the Laboratory Standards and Calibration organization

OR

Perform the calibration per the appropriate procedure or manufacturer's instructions.
2. If the calibration is to be performed by an organization outside the Laboratory, initiate a Purchase Request in accordance with ISD 840-1.0, *Procurement Quality*.
3. Follow guidance in procedure ISD 840-1.0, *Procurement Quality*, to determine if the outside laboratory has been placed on the LANL Institutional Evaluated Suppliers List (IESL) for ML-1 and ML-2 M&TE.
4. Ship the M&TE to the Laboratory Standards and Calibration laboratory or the approved subcontractor laboratory.

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M&TE
Coordinator
(Continued)

5. Verify that the calibration is performed and that the calibrator completes Section II of the M&TE Report (see Attachment 1).
[NOTE: This information may be supplied on the M&TE Report on a separate document that is traceable to the M&TE Report.]
6. Complete Section III of the M&TE Report, as applicable, and sign and date Line 21.
7. If the M&TE accuracy was out of tolerance during calibration or if the M&TE could not be calibrated, go to Section 4.5 of this procedure.
8. Verify that a required calibration label (see Attachment 3) is placed on or adjacent to the M&TE.
[NOTE: The required labels are those necessary to indicate the status of periodically calibrated items. In this system, the word "certification" designates calibrations performed by the LANL Standards and Calibration Laboratory; "verification" refers to calibrations performed by the user or other calibrators.]
9. When a calibrator outside the EP Directorate supplies a label that contains the M&TE identification number and its calibration and expiration dates, accept this label as a substitute for a required label.
[NOTE: The optional labels in Attachment 4 indicate the status of M&TE that:
 - Are calibrated at the time of use;
 - Do not require calibration;
 - Are inactive; or
 - Have expired calibrations.]
10. Obtain calibration labels from the LANL Standards and Calibration Laboratory.
11. Verify that the M&TE Report is complete and that all items contain the applicable information, or that the information is attached.

12. Enter the information from the M&TE Report into the M&TE Data Base.

13. Transmit the M&TE Report to the Records Processing Facility (RPF) in accordance with procedure EP-DIR-SOP-4004, *Record Transmittal and Retrieval Process*.

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4.4 Calibration of M&TE that is "Calibrated at Each Use"

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|------------------|----|--|
| M&TE Coordinator | 1. | Place a label (see Attachment 3) on or with the M&TE that lists, as a minimum, the M&TE identifier as listed on the M&TE Report and the statement "This instrument is calibrated at each use." |
| M&TE User | 2. | Document the calibration and use of M&TE that is "calibrated at each use" in accordance with the SOP in which the instrument is used. |

4.5 Out-of-Calibration M&TE

- | | | |
|------------------|-----|---|
| M&TE Coordinator | 1. | Ensure M&TE that is out of calibration is not used until it has been recalibrated.
[NOTE: M&TE that are calibrated at a set frequency are considered to be out-of-calibration under the following conditions: <ul style="list-style-type: none">• If the results are known to be in error• If the calibration due date has passed• If any condition exists that could have changed the M&TE's calibration (e.g., if movement of the M&TE could cause it to be out of calibration, and it has been moved).] |
| | 2. | Control the use of the M&TE by placing a tag, label, or other suitable marking to indicate the M&TE is out of calibration. |
| | 3. | Segregate, if possible, the M&TE in an area where it will not be inadvertently used. |
| | 4. | Verify that out-of-calibration M&TE are either calibrated or are removed from the EP Directorate M&TE program in accordance with Section 4.6 of this procedure. |
| | 5. | If the M&TE accuracy was out of tolerance before calibration, could not be calibrated within the specified tolerance, or was lost, and the M&TE was used to collect data governed by procedures since its last calibration, complete an M&TE Evaluation Report (see Attachment 2). |
| | 6. | If the out-of-tolerance condition did not affect data, attach the M&TE Evaluation Report to the M&TE Report. |
| | 7. | If the out-of-tolerance condition affected data, initiate a Nonconformance Report (NCR) in accordance with ISD 330-6, <i>Nonconformance Reporting</i> , and control the M&TE. |
| | 8. | Document the evaluation of the validity of the results. |
| | 9. | Attach the M&TE Evaluation Report and a copy of the NCR to the M&TE Report. |
| | 10. | Repair or replace M&TE that is consistently out of calibration (e.g., three failures within the calibration) is either repaired or replaced. |
| | 11. | For lost M&TE, remove it from the M&TE control system in accordance with Section 4.6 of this procedure. |

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|------------------------------------|-----|---|
| M&TE
Coordinator
(Continued) | 12. | Verify the information has been entered into the M&TE Data Base. |
| | 13. | Enter the information from the M&TE Report and its attachments into the M&TE Data Base. |

4.6 Removing M&TE from the M&TE Data Base

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|---------------------|----|--|
| M&TE
Coordinator | 1. | Calibrate the M&TE before removing it from the M&TE Data Base if the M&TE was used to collect data since its last calibration. |
| | 2. | Indicate in Section III of the M&TE Report that the M&TE was removed from service and the date removed, and complete Line 21. |
| | 3. | Enter the M&TE Report information into the data base and archive the record for future use. |

4.7 Storage of M&TE

- | | | |
|---------------------|----|--|
| M&TE
Coordinator | 1. | Verify the 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. | Control the access to M&TE storage.

[NOTE: Methods of control may include locked cabinets, rooms, buildings, or other appropriate means.] |

4.8 Use of M&TE

- | | | |
|-----------------------------|----|--|
| M&TE User's
Organization | 1. | Use only M&TE that is controlled by the M&TE Coordinator and entered into the M&TE Data Base. |
| | 2. | Obtain necessary M&TE from the M&TE Coordinator by completing the M&TE Usage Log (see Attachment 5). |
| | 3. | Immediately after use (within one (1) working day of completion of the task) or no later than the M&TE Coordinator's scheduled return date, the M&TE will be returned to the M&TE Coordinator.

[NOTE: The M&TE may be reissued following this procedure for an additional time period established by the M&TE Coordinator.] |
| | 4. | Upon return of M&TE, verify the M&TE Usage Log is correct and updated as necessary. |

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M&TE Coordinator	5.	Verify that the M&TE to be released has a current calibration and the M&TE Usage Log is complete.
	6.	Establish the scheduled return date, which will not exceed one week prior to the M&TE calibration due date.
	6.	Upon return of M&TE, update the M&TE Usage Log.
	7.	Review the M&TE Usage Log periodically (i.e., at least monthly) to ensure M&TE that has been released for use has been returned by its scheduled return date.
	8.	Contact the M&TE User to coordinate prompt return of delinquent M&TE.
	9.	Report to the M&TE User's management any M&TE that has not been returned by one week after the scheduled return date.

4.9 Records

M&TE Coordinator	1.	Submit the following records generated by this procedure to the Records Processing Facility: <ul style="list-style-type: none">• M&TE Report and attachments;• M&TE Evaluation Report; and• M&TE Usage Log
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5.0 PROCESS FLOW CHART

Flow chart is to be included at a later date.

6.0 ATTACHMENTS

Attachment 1: 5006-1 M&TE Report (1 page)

Attachment 2: 5006-2 M&TE Evaluation Report (1 page)

Attachment 3: 5006-3 M&TE Required Calibration Label Examples (1 page)

Attachment 4: 5006-4 M&TE Optional Calibration Label Examples (1 page)

Attachment 5: 5006-5 M&TE Usage Log (1 page)

[Using a CRYPTOCARD, click here to record "self-study" training to this procedure.](#)

If you do not possess a CRYPTOCARD or encounter problems, contact the ERSS training specialist.

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ATTACHMENT 2: M&TE EVALUATION REPORT

5006-2

M&TE Evaluation Report

Records Use only



Section I.

M&TE Identifier:

M&TE Description:

The M&TE identified above:

- was out of tolerance.
- could not be calibrated.
- could not be located.

Was the device used to collect data?

- No, Complete Section III of this form.
- Yes, determine if the data collected were affected by the identified condition and document the results in Section II of this form.

Section II.

Evaluation:

a) Identify the data collected:

b) Identify the processes monitored:

c) Identify the notebooks reviewed:

Conclusion: The validity of results obtained with the M&TE or Standard and the acceptability of data collected since the last calibration have been evaluated as required, and is documented as follows:

- data is acceptable (complete Section III, below).
- data is unacceptable (initiate nonconformance report and complete Section III, below).

Nonconformance report number: _____

Section III.

The impact of the identified condition has been evaluated by an SME.

Print name and Title

Signature

Date

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ATTACHMENT 3: M&TE REQUIRED CALIBRATION LABELS

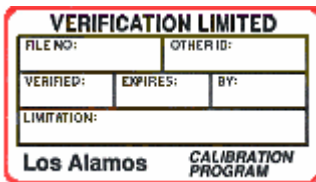
5006-3

M&TE Required Calibration Labels

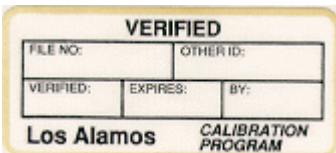
Records Use only



Certified (blue border). The item has been calibrated by the Standards and Calibration Laboratory and meets all applicable specifications (after adjustments, if any).



Verification Limited (red border). The item has been calibrated by the user or by a calibrator other than the Standards and Calibration Laboratory but does not meet all applicable specifications (after adjustments, if any); or, the item has been calibrated by the user or by a calibrator other than the Standards and Calibration Laboratory over a limited subset of its available functions, ranges, or attributes.



Verified (tan border). The item has been calibrated by the user or by a calibrator other than the Standards and Calibration Laboratory and meets all applicable specifications (after adjustments, if any).



Certification Limited (red border). The item has been calibrated by the Standards and Calibration Laboratory but does not meet all applicable specifications (after adjustments, if any); or, the item has been calibrated by the Standards and Calibration Laboratory over a limited subset of its available functions, ranges, or attributes.

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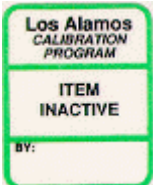



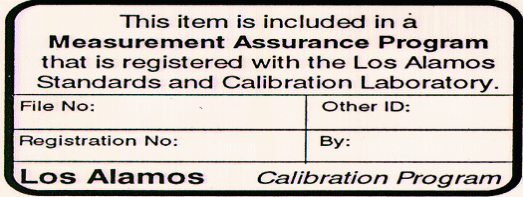
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ATTACHMENT 4: M&TE OPTIONAL CALIBRATION LABELS

<p>5006-4</p> <p>M&TE Optional Calibration Labels</p>	<p>Records Use only</p> 
	<p>Verify Before Use (orange border). The item must be calibrated by the user before quality-or safety-affecting activities are conducted.</p>
	<p>Item Inactive (green border). The item is intended for measurements but is not in use at the present time.</p>
	<p>Calibration Not Required (black border) The item is not relied on for measurement data. When necessary, output parameters of these items are monitored by calibrated equipment.</p>
	<p>Calibration Expired (black on red). The item has been previously calibrated and has exceeded its expiration</p>
	<p>Calibration Void If Seal Is Broken (black on silver). The item has externally accessible adjustments that, if disturbed, will invalidate the calibration. The label is attached so that any attempt to adjust the item will break the seal.</p>
	<p>Measurement Assurance Program (black border). The item is included in a formal measurement assurance program (a quality control program that calibrates an entire measurement system).</p>

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