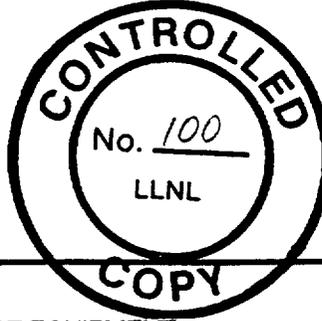


University of California



JCCA MOUNTAIN PROJECT
Quality Procedures



No.: 033-YMP-QP 12.0

Revision: 3

Effective Date: 8/24/92

Page: 1 of 12

Subject:

CONTROL OF MEASURING AND TEST EQUIPMENT

AUTHOR:

D. Wolfe

Training Required: Yes No

Comment:
Management & Technical personnel
Only. Also QA.

Approved by: W. d. Selame 8/14/92
Yucca Mountain Project Leader Date

Approved by: Dean Wolfe 8/14/92
YMP Quality Assurance Manager Date

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12.0.1 PURPOSE

This procedure provides for the control and calibration of Measuring and Test Equipment (M&TE) used for Lawrence Livermore National Laboratory (LLNL) Yucca Mountain Project (YMP) activities. This procedure is mandatory for quality-affecting activities. It is optional for other activities." |

12.0.2 SCOPE

This procedure is applicable to M&TE components or systems used to calibrate, measure, gage, test, or inspect: to control/acquire data for verification or conformance to a requirement, or to establish characteristics/values not previously known. This procedure does not apply to rulers, tape measurements, levels, and other such devices.

12.0.3 RESPONSIBILITIES AND AUTHORITIES

The Project Leader (PL) or designee is responsible for administration of the M&TE control and calibration support program. The identity of the designee is made by memo to the calibration coordinator and is part of the Quality Assurance Record.

The Calibration Coordinator is responsible for maintenance and periodic issuance of a Master Status List of M&TE acceptable for use on YMP; for issuance of recall notices; and for overall coordination with, technical staff, calibration laboratories, management, and QA.

The Technical Area Leader is responsible for necessary direction on the attachment of labels or tags, and the selection of the unique identifiers (that will be recorded on M&TE, on calibration records, on the activity/test records, and on the M&TE Master Status List). The TAL must approve statements-of-justification-for-use of standards with uncertainty >25% of M&TE tolerance and Technical Implementing Procedures (TIP's).

The Principal Investigator or Task Leader assigned the activity is responsible for the specification and selection of M&TE, for specification of calibration frequency and accuracy, for preparing necessary technical implementing procedures, for precluding the use of M&TE with out-of-calibration status, for impact assessment when equipment is determined to be outside of calibration tolerances, for preparing Nonconformance Reports, if necessary, after impact assessment, and for recording M&TE identifiers on equipment and in record documentation.

When the calibration certificate is returned with the calibrated instrument, it is the responsibility of the Principal Investigator to sign the bottom of the certificate as verification that his specifications have been met. The calibration certificate is sent to the Calibration Coordinator, who then adds that

12.0.4 PROCEDURE

Control: The M&TE Master Status Listing identifies the M&TE authorized for use on the YMP. Readiness Reviews will reference equipment from this list. The Calibration Coordinator will enter M&TE on the Master Status Listing upon receipt of the required calibration records. The Master Status Listing will be issued periodically by the Calibration Coordinator and the corresponding data base will be continuously revised/maintained for daily use and reference.

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YMP Calibrate Before Use (Orange) This instrument must be calibrated before and after use.

Out-of-calibration tolerance: If M&TE is reported to the Calibration Coordinator by a calibration laboratory to be out of calibration-tolerance, the Coordinator reports the out of tolerance to the Task Leader and equipment user by memo. The Task Leader (or designee) prepares an Out-of-Tolerance Report (OOTR) for disposition of activities impacted. See Exhibit B for sample. The Task Leader (or designee) evaluates if the out-of-tolerance condition(s) adversely affect(s) any YMP activities. If activities are not affected, the Task Leader will provide explanation and forward the signed report to the Calibration Coordinator. If YMP activities are adversely affected a Nonconformance Report will be prepared by the Task Leader (or designee). Nonconformances may be prepared by technical, management, or QA staff in accordance with QP 15.0.

Selection and specification of M&TE: M&TE will be selected for use and compatibility with requirements of individual activities, measurements, tests, or experiments. Selection of M&TE is addressed by the Principal Investigator or Task Leader in test plans, activity plans, technical procedures, or scientific notebooks. Handling and storage of M&TE is performed in accordance with manufacturer's instructions, Calibration Laboratory procedures, or instructions provided by PIs and TLs in applicable plans, procedures, or scientific notebooks. Principal Investigators and Task Leaders will specify the type, range, and accuracy in activity plans and procedures.

Trend Analysis: Calibration Records are used in Trend analysis to assess performance of instruments. Trend analysis may be requested by QA, a calibration laboratory, or YMP participant wishing to obtain historical data on calibration. Reasons for such data include, but are not limited to, setting of appropriate calibration intervals, the need to evaluate risks of requesting Calibration Waivers, decisions concerning replacement of equipment, and the identification of problem equipment. Requests for trend analysis are initiated by memo to the Calibration Coordinator.

User Calibration: Calibration of devices and systems performed by users are documented in the following manner.

- a. For devices and systems calibrated on a calendar basis (weekly, monthly, etc.), the calibration is documented and submitted to the Calibration Coordinator. The calibration document includes:
 - The unique M&TE identifier;
 - The name and organization of the person performing the calibration;
 - The date of the calibration;
 - The as-found condition with out-of-tolerance data identified or highlighted;
 - The as-left condition;
 - Identification of the standard(s) used;
 - Verification of calibration interval, if applicable;
 - The number and revision of the procedure used;
 - The Nonconformance Report number, if applicable.
- b. For devices and systems calibrated before each use, or periodically during use, calibrations are documented in the scientific notebook. The information to be recorded is the same as that specified in the previous paragraph.

Waiver of Calibration Interval: The Technical Area Leader may authorize the extension of a calibration interval using a M&TE Waiver Notice (Exhibit C) for technically justifiable cause. The TAL may authorize extension of a calibration interval at his discretion but should seek historical and technical justification for each extension that minimize the risk that instruments will be out-of-calibration tolerance at the expiration of waiver. This action may be taken in lieu of removing the M&TE from the

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Master Status List upon expiration of the calibration interval. The TAL approved waiver notice shall be sent to the Calibration Coordinator and the Calibration Laboratory that normally receives the instrument for periodic recalibration. The instrument shall be tagged with a Calibration Waiver Tag (see Exhibit D) until waiver expiration and recalibration of the instrument. Both the M&TE Waiver Notice and Calibration Waiver Tag shall indicate the expiration date of the waiver. The waiver tag shall be placed on or near the instrument or as appropriate for the experimental environment.

12.0.5 QUALITY ASSURANCE RECORDS

Quality Assurance records generated by this procedure are collected, stored, and maintained in accordance with procedure 033-YMP-QP 17.0, "Quality Assurance Records".

Calibration records are processed by technical staff and the calibration laboratories to the Calibration Coordinator. The Calibration Coordinator will collect, store and maintain the QA records received for active files in a fire resistant container. When specific M&TE is no longer scheduled for calibration for use on YMP, and the calibration coordinator judges the file records to be inactive they are transferred to the Local Records Center for retention and storage as Lifetime QA Records. Each issue of the Master Status List is forwarded to the LRC for retention.

Records include:

- Calibration (Results) Records
- Standards Certifications/Documentation
- Master Status List (Periodic issues)
- Waiver Notices
- M&TE Calibration Standards Exceptions (with statement of justification)
- Identification (Reference) of calibration procedure used TIPs or Manufacturer's Instructions/Specifications or other approved procedures

12.0.6 ATTACHED FORMS

- M&TE RECALL NOTICE (Exhibit A)
- OUT-OF-TOLERANCE REPORT (OOTR) (Exhibit B)
- M&TE WAIVER NOTICE (Exhibit C)
- CALIBRATION WAIVER TAG (Exhibit D)
- M&TE CALIBRATION STANDARDS EXCEPTIONS (Exhibit E)
- REQUEST TO ADD M&TE TO MASTER STATUS LIST (Exhibit F)
- M&TE STATUS CHANGE NOTICE (Exhibit G)

University of California		Lawrence Livermore National Laboratory	YUCCA MOUNTAIN PROJECT
M&TE RECALL NOTICE			
		Issue Date: _____	
User: _____			
Instrument Name: _____			
Manufacturer/Model #: _____			
Unique Identification #: _____			
Serial #: _____		Calibration will Expire: _____ (Date)	
Fill in Appropriate Blanks or Mark N/A:			
<input type="checkbox"/>	Submit to _____ by _____ (Laboratory/Contractor)		(Date)
----- OR -----			
<input type="checkbox"/>	Perform User Calibration by _____ (Date)		
Comments _____			
Signature _____		Date _____	
NOTE: M&TE is removed from the status list (not usable for YMP activities) If not calibrated within the required interval.			

YMP 048 Rev. 5

Out-of-Tolerance Report (OOTR)

M&TE Identification: _____

Out-of-tolerance values:

See attached calibration report

Does not adversely affect YMP activities

Explanation:

Does adversely affect YMP activities. A NCR will be written

Task Leader Approval _____
Date _____

YMP 073 Rev 0

OUT-OF-TOLERANCE REPORT
(OOTR)
Exhibit B

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YUCCA MOUNTAIN PROJECT

M&TE WAIVER NOTICE

Issue Date: _____

Item: _____

ID #: _____

Extension of Calibration Interval:

From: _____
(Date)

To: _____
(Date)

Justification/Technical Basis:

Recommended:

Approved:

(Task Leader) (Date)

(Technical Area Leader) (Date)

YMP 049 Rev 1

E

L

Calibration
Waiver

Expires ~~M~~ _____

Approved by _____



A

S

University of California  Lawrence Livermore National Laboratory		YUCCA MOUNTAIN PROJECT	
M&TE CALIBRATION STANDARDS EXCEPTIONS (traceability to NIST or accuracy)			
Item: _____ ID #: _____ Exception: <ul style="list-style-type: none"> <input type="checkbox"/> No NIST Standards Available <input type="checkbox"/> Standards Uncertainty > 25% of Required Tolerance <input type="checkbox"/> Other: _____ _____ 			
Justification/Technical Basis: 			
Recommended: _____ (Task Leader)		Approved: _____ (Technical Area Leader)	
_____ (Date)		_____ (Date)	

YMP 046 Rev 0

**REQUEST TO ADD M&TE
TO MASTER STATUS LIST**

EQUIPMENT NAME/DESCRIPTION _____

EQUIPMENT LOCATION _____

MANUFACTURER/MODEL _____

DOE/ASSET # (or serial #) _____

ACTIVITY NO. _____

USER/CONTACT NAME _____

BUILDING/ROOM _____

TELEPHONE _____

Attachments:

- CALIBRATION CERTIFICATE**
- TRACEBILITY STANDARD**
- PROCEDURE FOR CALIBRATION**

YMP 100 Rev. 0

University of California



Lawrence Livermore
National Laboratory

YUCCA MOUNTAIN PROJECT

M&TE STATUS CHANGE NOTICE

Issue Date: _____

Custodian: _____

Item: _____

ID #: _____

STATUS

NCR No. _____

Calibration Expired _____ (Date)

Removed from Master Status List _____ (Date)

Other (describe):

Submitted to Cal Lab

(Date) _____ (Signature)

Approved for Master Status List _____ (Date)

YMP 047 Rev 1

M&TE STATUS CHANGE NOTICE
Exhibit G