

PROCEDURE FOR CONTROL OF MEASURING AND TEST EQUIPMENT

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## PROCEDURE FOR CONTROL OF MEASURING AND TEST EQUIPMENT

### 1.0 PURPOSE

The purpose of this quality administrative procedure (QP) is to establish a control system to identify and calibrate measuring and test equipment (hereafter referred to as instruments or M&TE) used for the Los Alamos National Laboratory (LANL) Yucca Mountain Project (YMP or Project). Implementation of this procedure ensures that M&TE used in activities affecting quality is properly identified and calibrated at appropriate intervals to maintain accuracy within specified limits.

### 2.0 SCOPE

This procedure applies to all M&TE (instruments) used in quality assurance (QA) Level I or II activities by LANL personnel in YMP investigations.

Control of operator-calibrated instruments is addressed in QP-12.2. Except where specified, this procedure does not apply to such operator-calibrated M&TE.

Calibration and control measures are not required for rulers, tape measures, levels, and other such devices if normal commercial-grade instruments or equipment provide adequate accuracy.

### 3.0 REFERENCES

LANL-YMP-Quality Assurance Program Plan (QAPP), Section 12.  
TWS-QAS-QP-2.1, Procedure for Personnel Selection, Indoctrination, and Qualification.  
TWS-QAS-QP-02.2, Procedure for Personnel Training.  
TWS-QAS-QP-03.5, Procedure for Documenting Scientific Investigations.  
TWS-QAS-QP-12.2, Procedure for Control of Operator-Calibrated Instruments.  
TWS-QAS-QP-13.1, Procedure for Handling, Storage, and Shipping.  
TWS-QAS-QP-15.1, Procedure for Nonconformances.  
TWS-QAS-QP-17.1, Procedure for the LANL Group Resident File.

### 4.0 DEFINITIONS

#### 4.1 Calibrate

To calibrate means to check, adjust, or systematically standardize the output of a measuring or test instrument.

#### 4.2 Calibration Certificate

A calibration certificate, provided by the National Institute of Standards and Technology [NIST, formerly the National Bureau of Standards (NBS)], the instrument's supplier organization, or a service organization, attests to the accuracy of a calibration and specifies the period of validity for the calibration.

#### 4.3 Calibration File

The calibration group or service organization maintains a calibration file for each instrument it calibrates. This file documents the equipment used in

calibrating that instrument and maintains the traceability of each piece of equipment to the NIST, other nationally recognized standards, and/or physical constants.

#### 4.4 Calibration Group

The calibration group referred to here is the LANL Standards and Calibration Group, which provides NIST-traceable calibration to other LANL groups and maintains the documentation for traceability.

#### 4.5 Calibration Label

All instruments covered by this procedure and QP-12.2 are identified with a calibration label. Examples are shown in Attachment 1.

#### 4.6 Calibration Standard

A calibration standard has a known, valid, documented relationship to the NIST or another nationally recognized standard or physical constant. The standard must have equal or better accuracy than that required of the instrument. However, the principal investigator (PI) may approve a standard with the same accuracy as that of the instrument if this standard is adequate for a specific application. The PI documents the basis for accepting this standard in a memo to the group Resident File, in a DP, or in an entry in the laboratory notebook.

#### 4.7 Controlled Calibration

Controlled calibration is performed according to written procedures and to standards that are traceable to nationally recognized standards or natural physical constants. Calibration performed by the calibration group, external service organization, or instrument operator is controlled calibration. Where no recognized standards exist, the calibrator documents the basis for calibration. These calibration procedures are described in written procedures, operator's manuals, or other standard reference documents.

#### 4.8 M&TE Calibration Record

The M&TE Calibration Record (Attachment 2) provides the following information:

- a record of the unique identification and calibration requirements of each individual instrument;
- the calibration procedure, accuracy, and range through which the instrument was calibrated; and
- the date of next scheduled calibration or the notation "operator calibrated."

For every instrument used in this program that requires calibration, an M&TE Calibration Record is completed and filed with the QAS.

#### **4.9 Service Organization**

A service organization is a group outside of LANL that can provide controlled calibration service using nationally recognized standards or physical constants and written procedures.

### **5.0 RESPONSIBILITIES**

#### **5.1 Principal Investigator**

The PI may delegate any designated function to another Project member by documenting such action in a memo to the group Resident File. The PI selects instruments for use on Project work, taking into consideration the type, range, accuracy, and tolerance required to accomplish the intended function. This selection is documented in DPs, laboratory notebooks, or log-books, as appropriate, following directions in QP-03.5.

The PI ensures that all appropriate instruments are calibrated before they are used for QA Level I or II Project work.

When the PI determines that specific instruments are exempt from control and calibration procedures described in this QP and QP-12.2, the PI documents the exemption in a DP, memo to the group Resident File, or entry in the laboratory notebook.

#### **5.2 Quality Assurance Support Group**

The QAS notifies the QAL of instruments due for calibration within the next month.

### **6.0 PROCEDURE**

#### **6.1 Performance of Calibrations**

Instruments are calibrated by LANL's Standards and Calibration Group, by a service organization, or by the operator. Calibrations by operators are addressed in QP-12.2. Individuals who perform calibrations are properly trained and certified following QP-02.1 and QP-02.2 or the service organization's procedures and use written procedures and appropriate calibration standards. Individuals document their calibrations and the standards used.

#### **6.2 Calibration Interval**

The PI determines the appropriate calibration interval for instruments, taking into consideration

- type of equipment,
- manufacturer's recommendation,
- government and industry codes and standards,
- frequency and conditions of use,
- stability, and
- required accuracy and precision.

The PI specifies the calibration interval on the M&TE Calibration Record for each instrument. When a service organization performs calibrations, the service organization specifies the calibration interval. Unless the PI determines otherwise, balances are calibrated annually and reference weights, every two years. The PI may have an instrument calibrated after a shorter interval and may shorten the regular calibration interval, if needed.

### 6.3 Calibration Procedure

#### 6.3.1 Initiating a Calibration

The PI initially fills in the first section of the M&TE Calibration Record (Attachment 2) for each instrument used in his/her Project work. For subsequent calibrations, the QAS can fill in this section of the record. The PI documents the following information:

- group and location where the instrument is kept,
- instrument description,
- capacity and tolerance as specified by the manufacturer,
- unique instrument identification (property number or other), and
- calibration interval.

The PI gives this record to the calibration group or service organization performing the calibration and sends a copy to the QAS to show that the instrument is used for Project work.

#### 6.3.2 Performing the Calibration

The PI may hand carry the instrument or have it packed and shipped to a service organization for calibration, or the individual who performs the calibration may calibrate the instrument where it is used, depending upon the circumstance. If handling and shipping are required, the PI makes arrangements necessary to prevent damage in transit, following considerations in QP-13.1.

An individual in the calibration group or service organization calibrates the instrument. This calibrator fills in the information required in the lower part of the M&TE Calibration Record, including

- reference number, including revision number, of the calibration procedure used;
- range through which the instrument was calibrated;
- accuracy before and after calibration (to determine whether the instrument is out of tolerance);
- identification number of the calibration file where the traceability to NIST or other standards is documented;
- name, date, location, and telephone number of the calibrator;
- date of next calibration;
- date by which the instrument should be returned for calibration, as applicable; and
- any comments, such as inability to calibrate the instrument within the manufacturer's specified tolerance.

The calibrator returns the record and the instrument, if applicable, to the PI. The PI places a copy of the calibration record and a calibration certificate, if any, in the group Resident File and sends the originals to the QAS as Project records.

#### 6.4 Labeling the Calibrated Instrument

The calibrator or the PI places a label (examples are shown in Attachment 1), tag, or other documentation on or with the instrument, indicating the next calibration date and traceability to the calibration data or indicating that the instrument is calibrated by the operator.

#### 6.5 Recalibration

After an instrument is in the system, the QAS initiates the updated M&TE Calibration Record and sends it to the QAL as notification that recalibration will be due within the next month. The QAL and PI arrange for recalibration (Section 6.3.2) and labeling, (Section 6.4).

#### 6.6 Instruments Not In Calibration

The PI or QAL affixes the tag "DO NOT USE FOR YMP" to any instruments that are beyond the calibration interval, are out of calibration, or cannot be calibrated within the tolerance listed. Any instrument that is consistently out of calibration must be repaired or replaced. The PI informs the QAS by memo of any instrument that is removed from service and places a copy of the memo in the group Resident File.

#### 6.7 Instruments Out of Tolerance

The PI compares the instrument's tolerance as stated by the manufacturer with the accuracy measured by the calibrator before adjustment and noted on the M&TE Calibration Record. If that accuracy is not within the stated tolerance, the PI evaluates the validity of information obtained from that instrument since the expiration of the previous calibration and documents the conclusions in an entry in the laboratory notebook or a memo to the group Resident File. If invalid or indeterminate information has been submitted to another organization (has crossed interface boundaries), a nonconformance report (NCR) must be written following QP-15.1. If invalid or indeterminate information has been submitted to other LANL Project personnel, the PI notifies these individuals.

#### 6.8 Handling and Storage

To maintain accuracy, measuring and test equipment is handled and stored using good scientific and engineering judgment, following manufacturer's recommendations or a specific procedure, if the PI so directs. The PI documents any specific procedure in a memo to the group Resident File and explains the procedure to the users of the instrument.

## **7.0 QUALITY ASSURANCE REQUIREMENTS**

### **7.1 Calibration Records**

A calibration record for each instrument is initiated and maintained by the PI and QAS on the M&TE Calibration Record form and includes the following kinds of information.

General information about the instrument includes

- instrument description,
- capacity and tolerance specified by the manufacturer,
- instrument identification number,
- group and location where the instrument is kept, and
- calibration interval.

Specific calibration information includes

- reference number, including revision number, of the calibration procedure used;
- range through which the instrument was calibrated;
- accuracy before and after calibration (to determine whether the instrument is out of tolerance);
- identification number of the calibration file where the traceability to NIST or other standards is documented;
- name, date, location, and telephone number of the calibrator;
- date of next calibration;
- date by which the instrument should be returned for calibration, as applicable; and
- any comments, such as inability to calibrate the instrument within the manufacturer's specified tolerance.

The M&TE Calibration Record is sent to the QAS, and a copy is maintained in the group Resident File. If a calibration certificate (e.g., from the calibration group) is returned to the PI without the M&TE Calibration Record, the PI sends the certificate to the QAS. The QAS transfers the appropriate information to the M&TE Calibration Record and attaches the Record to the copy of the calibration certificate in the QAS file.

### **7.2 Labels**

All instruments covered by this procedure and QP-12.2 are labeled with one of the following designations or a functional equivalent:

- SCHEDULED CALIBRATION
- CERTIFIED CALIBRATION
- OPERATOR CALIBRATED

See Attachment 1 for examples of labels.

### **7.3 Transfer of Records Package to the Records Processing Center**

The records package for M&TE consists of the following for each calibrated instrument, including those addressed in QP-12.2:

- a completed M&TE Calibration Record,
- a calibration certificate if provided by the calibration group or supplier, and
- any correspondence on instruments removed from use.

During the first quarter of each year, the QAS duplicates all calibration records collected during the previous year and submits the duplicate copies as a records package to the Records Processing Center.

#### **8.0 ACCEPTANCE/REJECTION CRITERIA**

Completion of the M&TE Calibration Records and the appropriate tags and labels on instruments demonstrates satisfactory performance of this procedure.

#### **9.0 ATTACHMENTS**

**Attachment 1: Examples of Calibration Labels**  
**Attachment 2: M&TE Calibration Record**



EXAMPLES OF CALIBRATION LABELS

**SCHEDULED CALIBRATION**  
For QA Work

Ident. \_\_\_\_\_  
Date Calibrated \_\_\_\_\_  
Recalibration Due \_\_\_\_\_  
Procedure No. \_\_\_\_\_  
Calibrator \_\_\_\_\_  
QA-CL-20

For QA Work

Ident. \_\_\_\_\_  
**OPERATOR TO CALIBRATE**  
Procedure No. \_\_\_\_\_  
QA-CL-21

EXAMPLE

**Los Alamos**  
STANDARDS LABORATORY  
MS-C

FILE NO. \_\_\_\_\_  
ORDER NO. \_\_\_\_\_  
OFFICE \_\_\_\_\_  
BY \_\_\_\_\_

**CERTIFIED**  
TRACEABLE TO  
NATIONAL STANDARDS

**CERTIFICATION LIMITED**  
TRACEABLE TO NATIONAL STANDARDS

FILE NO. \_\_\_\_\_ ORDER NO. \_\_\_\_\_  
OFFICE \_\_\_\_\_ BY \_\_\_\_\_

**Los Alamos** STANDARDS LABORATORY  
MS-C

**CERTIFIED**  
TRACEABLE TO NATIONAL STANDARDS

FILE NO. \_\_\_\_\_ ORDER NO. \_\_\_\_\_  
OFFICE \_\_\_\_\_ BY \_\_\_\_\_

**Los Alamos** STANDARDS LABORATORY  
MS-C

LOS ALAMOS NATIONAL LABORATORY  
YUCCA MOUNTAIN PROJECT

M&TE CALIBRATION RECORD

(PI or QAS COMPLETES)

GROUP \_\_\_\_\_ LOCATION \_\_\_\_\_

INSTRUMENT / ITEM DESCRIPTION \_\_\_\_\_

CAPACITY \_\_\_\_\_ TOLERANCE \_\_\_\_\_

INSTRUMENT / ITEM ID NUMBER \_\_\_\_\_

DATE CALIBRATION EXPIRES \_\_\_\_\_ CALIBRATION INTERVAL \_\_\_\_\_

(CALIBRATOR COMPLETES)

CALIBRATION PROCEDURE NUMBER \_\_\_\_\_

RANGE OF CALIBRATION \_\_\_\_\_

ACCURACY BEFORE CALIBRATION \_\_\_\_\_

AFTER CALIBRATION \_\_\_\_\_

CALIBRATION FILE ID NUMBER \_\_\_\_\_

CALIBRATED BY \_\_\_\_\_ DATE \_\_\_\_\_

GROUP / LOCATION \_\_\_\_\_ TELEPHONE \_\_\_\_\_

DATE NEXT CALIBRATION DUE \_\_\_\_\_

RETURN (AS APPLICABLE) FOR CALIBRATION BY \_\_\_\_\_

COMMENTS: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

EXAMPLE  
CONTACT THE QAS TO  
OBTAIN ORIGINAL FOR  
YOUR USE