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LLNL Program for Calibration of Critical Measuring and Test Equipment

Recommended for approval by the ES&H Working Group

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New document or new requirements

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- New document
 Major requirement change

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LLNL Program for Calibration of Critical Measuring and Test Equipment

1.0 Introduction

The LLNL Program for Calibration of Critical Measuring and Test Equipment (herein referred to as the LLNL Calibration Program) implements LLNL's Calibration Policy for Measuring and Test Equipment (Rev. 2). That policy states that:

"The Laboratory is responsible for assuring the accuracy of test and experimental data that are used in reports and publications, specifications, acceptance testing, or in furnishing a product. The Associate Directors are responsible for the establishment, maintenance, and oversight of measurement standards and practices within their programs and organizations."

This document contains the requirements for the development and implementation of a directorate-specific measuring and test equipment (M&TE) calibration program within the context of the LLNL Quality Assurance Program.

1.1 Purpose

The purpose of the LLNL Calibration Program is to assure accuracy in measurements by establishing a set of Laboratory-wide requirements to ensure that:

- M&TE is identified, controlled, and calibrated.
- M&TE is calibrated at the appropriate frequency by procedures with traceable standards.
- The critical parameters for M&TE are specified and documented.
- Out-of-tolerance M&TE is
 - Removed from service.
 - Evaluated in a timely manner to determine the impact on previous output and current operability.
 - Repaired, recalibrated, discarded, or destroyed (as appropriate).

1.2 Scope

This document is applicable to LLNL organizations involved with:

- Use and control of critical M&TE.
- Procurement of critical M&TE.
- Performance of calibration services.
- Procurement of M&TE calibration services.

1.3 Inclusion in the LLNL Calibration Program

The LLNL Calibration Program shall apply to critical M&TE used for the determination or certification of measurements meeting any of the following criteria:

- The measurement accuracy of the M&TE is critical to the
 - Validity of programmatic results.
 - Monitoring or controlling of safe conditions to identify hazards to personnel or the environment. (The Hazards Control Department shall calibrate handheld instruments used for monitoring employee health and safety.)
- The M&TE is used
 - For the accountability of nuclear material.
 - To determine acceptability of the physical, mechanical, electrical, radiological, and chemical characteristics of equipment credited in safety basis documentation.
- The M&TE is used as secondary and transfer standards to calibrate other M&TE.
- The M&TE is used for acceptance testing of quality-significant items.

Noncritical M&TE may be calibrated by a directorate but not included in the LLNL Calibration Program. Devices not ordinarily calibrated (e.g., rulers, tape measures, resistance temperature detectors, and levels) are not included in the program if the devices provide adequate accuracy.

Hereafter the term M&TE refers to *critical* M&TE. M&TE not covered by the above definitions need not meet the requirements of this document.

The Corrective Action Plan responding to the NNSA/OAK Annual ES&H Assessment for 2001 specifies the implementation schedule for the LLNL Calibration Program.

2.0 Directorate Calibration Plans

Directorates with critical M&TE shall implement the LLNL Calibration Program through a Directorate Calibration Plan (DCP) and procedures. The DCP, and procedures as appropriate, shall identify critical instruments and address the controls listed below. The DCP may be a stand-alone document or included in the Directorate Quality Assurance Program (DQAP).

2.1 Identification of Critical Measurement and Test Equipment

The Associate Director shall designate in the DCP the individual (or individuals) responsible for establishing and maintaining an inventory list of critical M&TE in the LLNL Calibration Program. The directorate shall establish either one list for the directorate, or multiple lists at organizational sublevels. If multiple lists are maintained, the directorate shall designate an individual who will maintain record copies of each list. The list shall contain, as a minimum, a description or the name of the M&TE, a unique identifier such as a serial number or control number, the name of the M&TE owner, and the M&TE location. Other information, such as frequency of calibration and calibration expiration date, is useful data for an inventory list and should be considered for inclusion.

Directorates that do not have critical M&TE shall document this fact in lieu of a DCP with concurrence from the Associate Director or designee.

See Appendix B for an example of an LLNL Calibration Program Inventory List.

2.2 Calibration Procedures

Procedures based on manufacturer's manuals or other reference materials shall control the calibration and use of critical M&TE. Procedures shall be developed as described in Document 3.4, "Preparation of Work Procedures," in the *ES&H Manual*.

2.3 Calibration Frequency

The M&TE owner shall establish an initial designation of calibration frequency based on factors such as manufacturer's recommendations, nationally recognized standards, M&TE type and stability, frequency of use, accuracy, and reliability. The M&TE owner may adjust the calibration frequency according to trend analysis or review of previous calibration results, inherent stability, purpose of use, and accuracy required. This decision shall be documented.

2.4 Calibration Program Label

The M&TE owner shall affix to all M&TE included in the LLNL Calibration Program an LLNL Calibration Program label (a special yellow identification sticker that is one-half inch in diameter, available from the Engineering Assurance Office). This requirement does not apply to consumables and small devices. The M&TE owner shall include justification for not affixing a label to a class or set of critical M&TE in the calibration procedure.

Instruments in the LLNL Calibration Program shall display two labels, the yellow program identification label (see Figure 1) and a calibration record label (see Section 3.5). Only critical M&TE meeting the criteria in Section 1.3 shall display the LLNL Calibration Program label.



**Figure 1. LLNL Calibration Program Label
(larger than actual size)**

Directorates may calibrate noncritical M&TE and attach a label indicating calibration information, but such labels do not indicate inclusion in the LLNL Calibration Program. The label shall be distinguishable from the LLNL Calibration Program label.

2.5 Recalibration

The M&TE owner shall recalibrate critical M&TE on or before the scheduled recalibration date. If unable to recalibrate by the scheduled recalibration date, the M&TE owner shall remove the critical M&TE from service.

Recalibration shall be performed when the M&TE has been subjected to maintenance or repair that causes an adjustment to, or replacement of, active components within the device or system. M&TE that exhibits evidence of damage that could affect its accuracy shall be removed from service pending recalibration or disposal.

A calibration check is recommended, when the M&TE is being removed from service as Critical M&TE. The M&TE owner should contact users to determine if the measurements made by the equipment are of sufficient importance as to require a calibration check prior to removal from service.

In the case of equipment that is being removed from service due to equipment failure, the M&TE owner shall contact users to determine if the measurements made by the equipment are of sufficient importance as to require repair and recalibration of the equipment prior to excessing the equipment.

Depending on the operations of a directorate or facility, some M&TE included in the LLNL Calibration Program may be used only intermittently (i.e., may have long periods of disuse). When such M&TE exceeds its calibration period while not being used, the M&TE owner shall remove the M&TE from service and recalibrate it prior to its next use.

2.6 Out-of-Tolerance Measuring and Test Equipment

The calibration procedures shall indicate the action to be taken if M&TE is found to be out-of-tolerance. The M&TE owner shall ensure that the condition is documented and evaluated for impact on the process or item affected.

The M&TE user shall determine the impact of the out-of-tolerance conditions on values measured by the M&TE in question since the last valid calibration.

2.7 Removal from the LLNL Calibration Program

All calibrated M&TE to be inactivated or retired is required to have a Closing Calibration. The Closing Calibration is used to validate all measurements since its last calibration. The M&TE shall be removed from the LLNL Calibration Program by:

- Removing the LLNL Calibration Program label.
- Deleting the M&TE from the inventory list.

After M&TE is removed from the LLNL Calibration Program, the records for that M&TE shall be archived as specified in the DCP.

2.8 Assessments

The DCP shall describe the assessment of the directorate calibration program. The Directorate Self-Assessment Plan shall reflect the requirements of the DCP.

2.9 Recordkeeping

The calibrating organization shall retain and archive calibration documentation. The directorate shall designate in the DCP an individual (or individuals) responsible for collecting, retaining, and archiving historical records.

The DCP shall describe the period of time to retain calibration records. This time frame shall be consistent with the application of the instrument and the LLNL records retention schedule, available at the following website:

<http://www-r.llnl.gov/ibis/records/index.html>

This historical information can be used to justify changing the calibration interval or to support later inquiries about measurements.

3.0 LLNL Organizations Performing Calibration Services

3.1 Written Procedures and Parameters

An organization calibrating M&TE that is included in the LLNL Calibration Program shall use written calibration procedures. M&TE manufacturers' current manuals may be used as the calibration procedures. Document 3.4 in the *ES&H Manual* describes the preparation of work procedures.

Calibration procedures shall establish calibration ranges and tolerances appropriate for the equipment use (e.g., according to the applicable standards, technical requirements, manufacturing specifications, or design documents). Based on this information, the

calibrating organization shall select the proper types, ranges, and uncertainties of the standards required to perform calibrations.

M&TE calibration shall be traceable to one or more of the following standards:

- U.S. national measurement standards maintained by the National Institute of Standards and Technology (NIST) or the U.S. Naval Observatory.
- Fundamental or natural physical constants with values assigned or accepted by NIST.
- Other countries' national measurement standards, as approved by NIST, that are correlated with the U.S. national standards.
- Accepted industry standards or (if none exist) consensus measurement standards.
- A defined and documented basis for calibration if no nationally recognized standards exist.
- Standards of the DOE Primary Standards Laboratory.

3.2 Qualifications and Training

Individuals performing calibration services shall have the appropriate training and be qualified to perform assigned tasks. The calibrating organization shall maintain a record of training and qualifications.

3.3 Out-of-Tolerance Measuring and Test Equipment

When as-found readings for M&TE exceed the calibration tolerance, and the M&TE may have been used in this state, the calibrating organization shall notify the M&TE owner of the out-of-tolerance condition. Notification is not required if the owner has indicated that he or she is aware of the out-of-tolerance condition and has not used the out-of-tolerance M&TE for critical measurements.

3.4 Calibration Software

The calibrating organization shall verify and control computer software used to calibrate M&TE.

3.5 Calibration Record Label

The individual performing the calibration shall prepare a calibration record label and affix the label to the M&TE after calibration. The calibration record label is in addition to the LLNL Calibration Program Label (see Section 2.4).

The calibration record label indicates the date of calibration, the date of the next scheduled calibration, and the initials of the individual performing the calibration.

Figure 2 shows examples of different calibration record labels used at LLNL. If the label cannot be directly affixed because of space or other considerations, the label shall be affixed near the M&TE if practical.

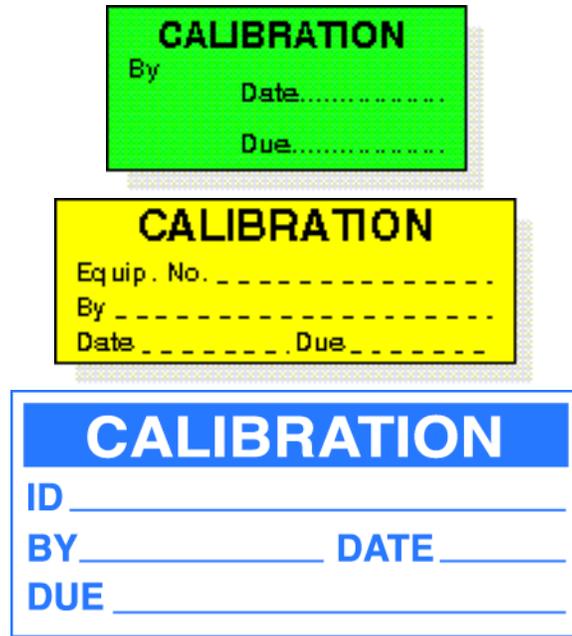


Figure 2. Examples of Calibration Record Labels.

3.6 Records

The calibration supplier shall maintain records that contain sufficient information to permit recalibration. See Appendix C for a list of required records.

The supplier shall maintain clear documented procedures on the retention (including duration) and safeguarding of records. Records shall be kept for the period specified in the supplier’s quality manual.

4.0 Procurement of External Calibration Services

External Calibration Services are controlled items or services and as such may not be procured with a government credit card or check request, or be reimbursed from a personal credit card expenditure. Calibration services may only be procured from suppliers who have blanket agreements established (by release) or by a properly reviewed and approved requisition. The Procurement and Material Department shall only place a requisition for calibration services with companies on the approved list.

4.1 Procured Calibration Services

When calibration services are to be procured from a supplier, the supplier is required to meet one or more of the following:

- International Organization for Standards (ISO) 10012-1, "Quality Assurance Requirements for Measuring Equipment," Part I: Metrological Confirmation System for Measuring Equipment.
- ISO Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories."
- American National Standards Institute (ANSI)/National Conference of Standards Laboratories (NCSL) Z-540-1, "Calibration Laboratories and Measuring and Test Equipment-General Requirements."
- A specific standard identified and documented in the DCP.

The Procurement and Materiel Department shall maintain a list of previously approved suppliers qualified to appropriate standards and make this list available to personnel requesting calibration services. Currently this list can be accessed at:

<http://www-r.llnl.gov/pm/trr/html/controlitem.html>

Suppliers shall be placed on the approved list only after passing a supplier survey conducted by a qualified individual or after being accredited to ISO 10012-1, ISO Guide 25, or ANSI Z-540-1 by an ISO-recognized accrediting body (e.g., the National Voluntary Laboratory Accreditation Program or the American Association for Laboratory Accreditation).

Suppliers approved by the Primary Standards Laboratory (PSL) of Sandia National Laboratory (SNL) in Albuquerque, New Mexico, or Department of Defense (DoD) Primary Laboratories, or on NNSA Nuclear Weapons (NW) Contractors' approved source lists: Commercial Calibration Laboratories (CCL's) and Designated Calibration Sources (DCS's) shall be acceptable for use.

Original equipment manufacturers or their qualified service suppliers who provide calibration certification with their equipment shall meet one or more of the consensus standards listed in this section.

4.2 Purchase Requisitions

Purchase requisitions for M&TE shall require the following documentation shipped together with the equipment:

- Copies of technical manuals, schematics, specifications, calibration procedures, parts lists, and troubleshooting guidelines.
- The original certificate of calibration and tolerance, and calibration data sheets. The certificate shall include the information specified in the standards listed above.

The M&TE owner shall control these documents as required by the DQAP or document control procedure.

4.3 Out-of-Tolerance Measuring and Test Equipment

External suppliers who find that readings for M&TE exceed the calibration tolerance, and that the M&TE may have been used in this state, shall notify the M&TE owner of the out-of-tolerance condition. Notification is not required if the owner has indicated that he or she is aware of the out-of-tolerance condition and has not used the out-of-tolerance M&TE for critical measurements.

4.4 Calibration Record Label

The individual performing the calibration shall prepare a calibration record label and affix the label to the M&TE after calibration. The calibration record label is in addition to the LLNL Calibration Program Label (see Section 2.4).

The calibration record label indicates the date of calibration, the date of the next scheduled calibration, and the initials of the individual performing the calibration. See Section 3.5 for examples of calibration record labels used at LLNL. If the label cannot be directly affixed because of space or other considerations, the label shall be affixed near the M&TE if practical.

4.5 Records

The calibration supplier shall provide records that contain sufficient information to permit repetition of the calibration. The M&TE owner shall maintain these records (see Section 2.9). See Appendix C for a list of required records.

The supplier shall maintain clear documented procedures on the retention (including duration) and safeguarding of records. Records shall be kept for the period specified in the supplier's quality manual or as required by the contract between the Laboratory and the supplier.

5.0 Responsibilities

5.1 Associate Directors

The Associate Director or designee is responsible for having a DCP prepared and approved, and assuring the plan is followed.

Associate Directors of directorates that perform calibration services shall implement an M&TE calibration program in accordance with the requirements specified in this document and their DQAP for equipment within the inclusion guidelines.

Directorates that do not have critical M&TE shall document this fact in lieu of a DCP with concurrence from the Associate Director or designee.

5.2 Procurement and Materiel Department

The Procurement and Materiel Department shall:

- Maintain a list of approved suppliers qualified to appropriate standards and make this list available to personnel requesting calibration services. P&MD may delegate responsibility for maintenance of the vendor list for specific instrument types to the organization responsible for calibrating those instrument types. LLNL SME for Calibration shall be the approval source for the approved supplier list.
- Procure calibrated services only from approved suppliers.

5.3 Owners of Critical Measuring and Test Equipment

The owner of critical M&TE shall:

- Identify M&TE to be included on the organization's formal list of critical M&TE.
- Ensure that M&TE is calibrated.
- Ensure that if M&TE is out-of-tolerance, the condition is documented and evaluated for impact on the process or item affected.
- Ensure that calibration records are specified, maintained, and archived.
- Affix a Calibration Program Label to the M&TE.
- Maintain records from suppliers.

5.4 LLNL Calibrating Organizations

The calibrating organization shall:

- Calibrate critical M&TE in accordance with approved procedures.
- Notify the M&TE owner if M&TE is out-of-tolerance.
- Verify and control computer software used to calibrate M&TE.
- Maintain records that contain sufficient information to permit repetition of the calibration, and procedures on the retention and safeguarding of these records.

- Select the proper types, ranges, and uncertainties of the standards required to perform calibrations based on applicable standards, technical requirements, manufacturing specifications, or design documents.
- Prepare and affix a calibration record label to M&TE after calibration.

5.5 Hazards Control Department

The Hazards Control Department shall calibrate handheld instruments used for monitoring employee health and safety.

5.6 Users of Critical Measuring and Test Equipment

Users of critical M&TE are responsible for assuring that their critical M&TE is within its current calibration cycle.

6.0 Work Smart Standards

Department of Energy Order (DOE O) 414.1A, *Quality Assurance, Attachment A, "Contractor Requirements Document,"* under criteria 5 (Work Processes) and criteria 8 (Performance/Inspection and Acceptance Testing).

10 CFR 830.122, under criteria 5 (Work Processes) and criteria 8 (Performance/Inspection and Acceptance Testing).

7.0 Resources for More Information

7.1 Contacts

See the ES&H Contact List.

7.2 Lessons Learned

For lessons learned applicable to M&TE, refer to the following Internet address:

http://www-r.llnl.gov/es_and_h/lessons/lessons.shtml

7.3 Other Sources

ANSI/NCSL Z540-1-1994, "Calibration Laboratories and Measuring and Test Equipment—General Requirements."

DOE Standard 1054-93, *Guideline to Good Practices for Control and Calibration of Measuring and Test Equipment*, 1993.

ISO Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories," 1990.

ISO 10012-1, "Quality Assurance Requirements for Measurement Equipment," Part I: Metrological Confirmation System for Measuring Equipment, 1992.

LLNL Calibration Policy for Measuring and Test Equipment (Rev. 2), January 21, 2003

LLNL QA Plan

Plant Engineering Maintenance and Operations Procedure 11001, "Control and Calibration of Measuring and Test Equipment," Rev. O, June 1994.

UC-DOE Contract W-7405-ENG-48, Appendix E, 1992.

Appendix A

Acronyms, Terms, and Definitions

Accuracy	Conformity to a certified or approved standard. A measure of closeness of agreement between a measured result and the true value.
Calibration	Calibration is defined as the set of operations that establishes, under specific conditions, the relationship between values indicated by a measuring instrument or measuring system and the corresponding standard or known values derived from the standard.
Certification	The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.
Critical M&TE	<p>Critical M&TE is M&TE that meets any of the following criteria:</p> <ul style="list-style-type: none"> • The measurement accuracy of the M&TE is critical to the validity of programmatic results; or monitoring or controlling of safe conditions to identify hazards to personnel or the environment. • The M&TE is used for the accountability of nuclear material; or to determine acceptability of the physical, mechanical, electrical, radiological, and chemical characteristics of equipment identified in safety basis documentation. • The M&TE is used as secondary and transfer standards to calibrate other M&TE. • The M&TE is used for acceptance testing of quality-significant items.
Critical M&TE owner	The designated individual who has custody of the critical M&TE.

Document	Recorded information that describes, defines, specifies, reports, certifies, requires, or provides data or results. This information can be in written, pictorial, photographic, or computer media form.
Item	An all-inclusive term used in place of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts, or data.
Measuring and test equipment (M&TE)	Includes devices or systems used to verify conformance to specified requirements or to acquire data for research or other purposes. See Critical M&TE.
Measurement standard	Devices, artifact, or other items used to calibrate M&TE or other measurement standards and provide traceability.
Range	The extent of variation of a measurement. The inclusive difference between the extreme values in any series of variable data.
Recalibration (recall) date	The expiration date for the previous calibration. Also called the recall date.
Record	A completed document or other media that provides objective evidence of an item or process. A document is not considered a record until it is complete and designated as a record or record copy.
Tolerance	The allowable deviation from a certified or approved standard.
Traceable	The property of the result of a measurement whereby it can be related to appropriate international or national measurement standards through an unbroken chain of comparisons.
Verification (of software)	Assurance that any computer program or software conforms to all specified requirements and will perform satisfactorily after being placed in service.

Appendix B

Example LLNL Calibration Program Inventory List

Instar ID#	Description	Location	Owner	Calibration Frequency
Xxx123	Widget	T123/R456	John Doe	Annual

Appendix C

Required Records for Calibration Suppliers¹

Calibration suppliers shall maintain records that include the following:

- Description and unique identification of equipment.
- Date on which each calibration was completed.
- Calibration results obtained before and after any adjustment and repair.
- Assigned calibration interval.
- Identification of the calibration procedure.
- Designated limits of permissible error.
- Source of the calibration used to obtain traceability.
- Relevant environmental conditions and a statement about any corrections thus necessary.
- Statement of the uncertainties involved in calibrating the equipment and of their cumulative effects where relevant.
- Details of any maintenance (e.g. servicing, adjustments, repairs, or modification) performed during the calibration process.
- Any limitations in use.
- Identification of persons responsible for ensuring the correctness of the recorded information.
- Unique identification (such as serial numbers) of any calibration certificates and other relevant documents concerned.

¹ ANSI/NCSS Z540-1-1994, section 13.2
ISO GUIDE 25, section 13.2
ISO 10012-1, section 4.8