

<b>CONTROL OF MEASURING AND TEST EQUIPMENT</b>	Identifier: PRD-5083		
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Quality Assurance	Program Requirements Document	For Additional Info: <a href="http://EDMS">http://EDMS</a>	Effective Date: 09/18/13

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\*The current revision can be verified on EDMS.

## 1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for controlling *measuring and test equipment* (M&TE; see def.).

## 2. APPLICABILITY

This PRD applies to company organizations that use or calibrate M&TE for determining *acceptance* (see def.) of *items* (see def.) and activities, process monitoring, or *data* (see def.) collection. The *calibration* (see def.) program applies to all calibration activities encompassed by Department of Energy (DOE) Order 414.1D, “Quality Assurance,” and 10 Code of Federal Regulations (CFR) 830, Subpart A, “Quality Assurance Requirements”..”

Measuring and test equipment shall be traceable to its application and use.

Calibration and control measures are not applicable for rulers, tape measures, levels, and other such coarse measurement devices that provide adequate accuracy as received from the manufacturer.

## 3. RESPONSIBILITIES

### 3.1 Organizations

Organizations using, calibrating, and maintaining M&TE, or procuring or requesting calibration services, are responsible for implementing the requirements of this document as they apply to their functions.

### 3.2 Senior Management

Senior management is responsible for ensuring that the calibration program and laboratory management staff has the authority and sufficient resources to discharge their duties.

## 4. REQUIREMENTS

### 4.1 Companywide Application

The requirements identified in this subsection meet the requirements in “Quality Assurance Requirements for Nuclear Facility Application,” American Society of Mechanical Engineers (ASME) NQA-1-2008 with Addenda through NQA-1a-2009, DOE O 414.1D, and the other standards listed in FWD-7, “Foreword.” These requirements apply to the entire company as defined by FWD-7.

#### 4.1.1 Basic

4.1.1.1 M&TE requiring calibration will include instruments or equipment used for *testing* (see def.), *inspection* (see def.), calibration of other instruments, process *verification* (see def.), or data collection for purposes of determining compliance with customer requirements.

4.1.1.2 Tools, gages, instruments, and M&TE used for *activities affecting quality* (see def.) will be controlled, calibrated at specific intervals, adjusted, and maintained to required accuracy limits.

#### 4.1.2 Selection

4.1.2.1 Selection of measuring and test equipment shall be based on the type, range, accuracy, and tolerance needed to accomplish the required measurements for determining conformance to specified requirements.

#### 4.1.3 Calibration

4.1.3.1 Measuring and test equipment shall be calibrated, at prescribed times or intervals and whenever the accuracy of the measuring and test equipment is suspect.

4.1.3.2 Calibration shall be against and traceable to certified equipment or *reference standards* (see def.) having known valid relationships to nationally recognized *standards* (see def.), or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no such standards exist, the basis for calibration shall be defined.

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4.1.3.3 Updates to software contained in measuring and test equipment that affect calibration shall require recalibration of the equipment prior to use.

**4.1.4 Reference Standards**

4.1.4.1 *Reference standards* (see def.) shall have a minimum accuracy four times greater than that of the measuring and test equipment being calibrated to ensure that the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be technically justified in an Engineering Design File (EDF) prepared and approved by Engineering and Quality Assurance that ensures that the equipment being calibrated will be within required tolerance. The basis of acceptance shall be approved by the responsible management. The level of management authorized to perform this function shall be identified.

**4.1.5 Control**

4.1.5.1 Calibration *procedures* (see def.) shall identify or reference required accuracy and shall define methods and frequency of checking accuracy.

4.1.5.2 The calibration method and interval of calibration shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance.

4.1.5.3 Measuring and test equipment, which is overdue for calibration or found to be out-of-calibration, shall be tagged and/or segregated, or removed from service, and not used until it has been recalibrated.

4.1.5.4 Measuring or test equipment consistently found to be out-of-calibration shall be repaired or replaced.

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**4.1.6 Corrective Action**

4.1.6.1 When measuring and test equipment is lost, damaged, or found to be out-of-calibration, the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested shall be evaluated. This evaluation shall be from at least the last acceptable calibration of the M&TE. The evaluation and resulting actions shall be commensurate with the significance of the condition. This evaluation shall be documented.

**4.1.7 Handling and Storage**

4.1.7.1 Measuring and test equipment shall be properly handled and stored to maintain accuracy.

**4.1.8 Environmental Controls**

4.1.8.1 Measuring and test equipment shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

**4.1.9 Precalibration Checks**

4.1.9.1 Measuring and test equipment and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

**4.1.10 Status Indication**

4.1.10.1 Measuring and test equipment shall be suitably marked, tagged, labeled, or otherwise identified (such as, in a calibration log) to indicate calibration status and establish *traceability* (see def.) to calibration records.

**4.1.11 Reports and Certificates**

4.1.11.1 Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

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- 4.1.11.2 Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

#### **4.2 Specific Requirements for DOE/RW-0333P, Quality Assurance Requirements and Description, Applications**

This subsection contains additional requirements from the Quality Assurance Requirements and Description (DOE/RW-0333P) that are specific to spent nuclear fuel and high level waste activities, as defined in FWD 7.

##### **4.2.1 Measuring and Test Equipment Documentation**

- 4.2.1.1 M&TE calibration documentation shall include the following information:
- A. Identification of the measuring or test equipment calibrated
  - B. Traceability to the calibration standard used for calibration
  - C. Calibration data
  - D. Identification of the individual performing the calibration
  - E. Identification of the date of calibration and the recalibration due date or interval, as appropriate
  - F. Results of the calibration and statement of acceptability
  - G. Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE, including evaluation results and repeated inspections or tests, as appropriate
  - H. Identification of the implementing document (including revision level) used in performing the calibration.

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4.2.1.2 Embedded *software* (see def.) developed or modified by the user shall be controlled in accordance with PRD-5092, “Software Quality Assurance.”

4.2.1.2.1 Data acquisition and control applications integral to operation, maintenance, or calibration of scientific investigation testing apparatus shall be verified or validated, and documented, in conjunction with the controlling test plan(s) and in conjunction with the M&TE or test hardware as an operating unit.

4.2.1.3 For M&TE used in one-time applications, the calibration shall be done both before and after use.

4.2.1.4 The use of M&TE shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify all M&TE use since the last calibration.

## 5. RECORDS

All records generated by this document that are designated in implementing documents as *quality assurance records* (see def.) will be controlled in accordance with PRD-5088, “Quality Assurance Records.”

## 6. DEFINITIONS

Refer to LST-199, “Quality Assurance Program Requirements Document Definitions,” for definitions of the following terms:

*acceptance*

*activities affecting quality*

*calibration*

*data*

*inspection*

*item*

*measuring and test equipment*

*procedure*

*quality assurance records*

*reference standard*

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*software**standards**testing**traceability (calibration)**verification***7. REFERENCES**

10 CFR 830, Subpart A, “Quality Assurance Requirements,” *Code of Federal Regulations*, Office of the Federal Register

ASME NQA-1-2008 with Addenda through NQA-1a-2009, “Quality Assurance Requirements for Nuclear Facility Applications,” American Society of Mechanical Engineers

DOE Order 414.1D, “Quality Assurance”

DOE/RW-0333P, *Quality Assurance Requirements and Description*, Rev. 20, Office of Civilian Radioactive Waste Management

FWD-7, “Foreword”

LST-199, “Quality Assurance Program Requirements Document Definitions”

PRD-5088, “Quality Assurance Records”

PRD-5092, “Software Quality Assurance”