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EG&G - ROCKY FLATS PLANT
ENVIRONMENTAL MANAGEMENT

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**ROCKY FLATS PLANT
EMD ADMINISTRATION
PROCEDURES MANUAL**

CATEGORY 1

**Manual No.: 3-21000-ADM
Procedure No.: Table of Contents, Rev 3
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Organization: Environmental Management**

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ADMIN RECORD

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By George H. Setlock

Date 4/30/92

WFL 4/30/92 (LMP)

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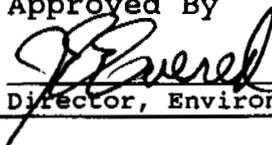
CONTROL OF MEASURING AND TEST EQUIPMENT

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TITLE:
CONTROL OF MEASURING
AND TEST EQUIPMENT

Approved By


Director, Environmental Management

4/8/92
Date

1.0 PURPOSE

This procedure describes the manner in which measuring and test equipment (M&TE) are controlled for quality.

M&TE are controlled in order to provide equipment and instrument performance within a known and acceptable range. Control of M&TE is achieved through calibrations, measurements, inspections, and testing.

2.0 SCOPE

This procedure applies to all equipment used to make quality affecting measurements or to calibrate devices used to make quality affecting measurements, as specified in the EMD operating procedures for that equipment.

M&TE may include such items as tools, gauges, instruments, equipment used to collect environmental data, and test and inspection equipment. Devices such as rulers, tape measures, levels, chronographs (e.g., wrist or pocket watches) may not require calibration or special controls if normal commercial practices provide adequate accuracy (e.g., traceability to the National Institute of Standards and Technology (NIST)).

3.0 DEFINITIONS

3.1 **Accuracy** - The closeness of a measured value to the true value or standard value; may be quantitatively expressed by the uncertainty about the expected value.

3.2 **Accuracy and operability checks** - Verification that the M&TE is operating within acceptable norms by checking its performance against a known source. Operability verifies that the instrument is functioning.

3.3 **Calibration** - The act of comparing M&TE against a known standard and either documenting the deviation from the standard or correcting to the standard.

3.4 **Inspection** - Checking against established standards and procedures.

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- 3.5 **Metrology Organization** - The RFP organization whose primary function involves measurement and includes performing calibrations.
- 3.6 **Precision** - The distribution of repeated measurements about the measurement mean.
- 3.7 **Quality Affecting Measurement** - Any measurement required to ensure protection of health, safety, and the environment, or to demonstrate regulatory compliance.
- 3.8 **Test** - A critical examination, observation, or evaluation for which acceptance criteria are known in advance.
- 3.9 **Uncertainty** - An estimate of the range of values about the measured value in which the true value is believed to exist (e.g., variance). Typically includes errors/deviations related to both accuracy and precision.

4.0 RESPONSIBILITIES

- 4.1 The EM Division Managers, or their designees, are responsible for developing control procedures which identify M&TE items, schedule calibration, specify methods employed for evaluations, training of personnel, and acceptance criteria. The responsible EM Division Manager is responsible for the control and maintenance of any standards possessed by their organizations.
- 4.2 The EM Quality Assurance Program Manager (QAPM) is responsible for assuring that applicable quality specifications, instructions, and procedures are contained in the procedures for control and calibration of M&TE.
- 4.3 The Project Manager is responsible for:
 - 4.3.1 Identifying required M&TE in work plans.
 - 4.3.2 Ensuring that field personnel have received documented training in the use of the M&TE required for the completion of their tasks.
 - 4.3.3 Ensuring that appropriate and calibrated M&TE are available to the personnel completing activities within their area of responsibility.

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- 4.4 The M&TE user is responsible for the following:
- 4.4.1 Using certified standards and equipment.
 - 4.4.2 Notifying the responsible manager of out-of-tolerance or discrepancy conditions.

5.0 PROCEDURES

5.1 Identification of M&TE

NOTE

The QAPM may provide assistance to identify applicable standards for M&TE calibration, maintenance, and accuracy and operability checks. Steps 5.1.1 to 5.1.3 may be completed in any order.

- 5.1.1 The Project Manager shall provide a list to the Division Manager of all M&TE required to complete the activities within their area of responsibility. This list is typically found in the work plan and called the M&TE List.
- 5.1.2 The Project Manager shall identify the applicable standards for calibration of the equipment identified in Step 5.1.1 and include them on the M&TE List.
- 5.1.3 The Project Manager shall identify the required maintenance and accuracy and operability tests required for use of the equipment identified in Step 5.1.1 and include these requirements on the M&TE List.
- 5.1.4 The Project Manager shall identify the acceptable accuracy and precision for the M&TE based on documented requirements, and shall include these requirements on the M&TE List. This list is typically included in the work plan.
- 5.1.5 The Division Manager shall complete the tasks in Steps 5.1.1 to 5.1.3 for all activities within the Manager's area of responsibility when the activity is not covered by a Project Manager.

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5.1.6 The M&TE Lists shall be submitted to the responsible Division Manager (either directly or as part of the work plan) who examines them for adequacy and arranges for revisions as necessary.

5.1.7 The Division Manager shall handle the M&TE List as a QA record per 3-21000-ADM-17.01, Records Management.

5.1.8 The QAPM shall review the M&TE Lists against existing procedures and documents and resolve any discrepancies with the responsible Manager or the Metrology organization.

5.1.9 The QAPM and the Project Manager or Division Manager shall at any time, but at least quarterly, review the M&TE List, procurement, and the schedule for examination of M&TE. Previous examination findings and present or future workloads requiring M&TE shall be assessed in order to provide appropriate equipment that fulfills the acceptance criteria for any particular program.

5.2 Calibration Program

5.2.1 The responsible Division Manager shall establish a calibration and maintenance program for the items on the M&TE list for which they are responsible. This program shall include the following:

5.2.1.1 Labeling calibrated equipment with a uniquely numbered label indicating the date the calibration expires and initialed by the individual attaching the label. These labels can be obtained from the Responsible Division Manager or designee. The number of this label shall be noted on the calibration certificate. If this label is added after the calibration, the individual applying the label shall note its number, calibration

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expiration date, and date of application on the certificate and then sign the note. If the calibration label is applied by a vendor, the responsible Division Manager may elect to also affix a RFP label.

5.2.1.2 M&TE calibration certificates and maintenance records which includes the following information:

1. Instrument description and model number.
2. Instrument identification number (typically the serial number).
3. Identification of the traceable standard/source including the accuracy and precision (e.g., standard error at 95 percent confidence level), expiration date of its calibration, and the information identified in items 1 and 2 for the standard/source. For maintenance documentation, this identification is only required if a standard/source is used as part of the maintenance activity.
4. Description of the as-found conditions of the M&TE including accuracy and functional state. Also, formal requirements for notification (and including temporary hold point) if the as-found conditions exceed the tolerances on the M&TE List (see Step 5.1.4). Additional special tests may be needed to establish as found conditions

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for out-of-specification equipment, so calibration should only proceed after authorization from the QAPM.

5. The accuracy and uncertainty after calibration (i.e., the calibrated value) when calibration is performed.
6. Description of any maintenance activity performed. This shall include documentation of any parts replaced and justification for any replacement parts, that are not of the same make and model as the original part.
7. The environmental conditions under which the calibration was performed (e.g., temperature).
8. Special uses, limitations, status, or calibration/maintenance expiration date, when applicable.
9. Any supplementary data needed for accuracy and operability checks.
10. Location and date of installation at RFP, if any. Otherwise, indicate the fate of the M&TE (e.g., field survey instrument controlled by ...).
11. Date and time.
12. Name or initials of the individuals conducting the calibration or maintenance.

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- 5.2.1.3 Calibrations include at least 3 reasonably distributed points on each routinely used scale. Fewer points can be used if the linearity of the instrument is clearly established. At least one point of calibration is required on all scales used to make measurements. Typically the first time M&TE is calibrated the number of points are increased to establish the M&TE performance.
- 5.2.1.4 Separately calibrating portions of an instrument is acceptable if there is technical justification for assuming the calibration would apply to the instrument as a whole. However, calibration of the entire instrument in its functional configuration is preferred.
- 5.2.1.5 The calibration shall be consistent with the planned measurement and projected environments.
- 5.2.1.6 Calibrations, measurements, inspections, and testing shall be conducted at a frequency commensurate with equipment manufacturer's suggestions or occur either at the time of use or on a periodic basis as specified in operational procedures or work plans, whichever is more frequent, except as discussed in Step 5.2.1.7. These calibration intervals shall be conducted in such a manner as to minimize the occurrence of out-of-tolerance conditions.
- 5.2.1.7 Manufacturer's calibration intervals may be changed based on a documented technical evaluation.

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Such an evaluation could be based on the following considerations:

1. Historical data on M&TE's performance in the actual environment in which it is used.
2. The routine use of accuracy and operability checks.
3. The projected amount of use the M&TE has received and the environment in which it occurs.
4. Other technical considerations.

This evaluation shall have the concurrence of the responsible Division Manager, the QAPM, and the Metrology organization.

5.2.1.8 Calibration and maintenance shall be consistent with the standards, applicable guidance, and requirements identified in the M&TE List.

5.2.1.9 Traceable certified standards shall be employed when calibrating, measuring, inspecting, or testing equipment. These standards shall be documented for uncertainty, stability, range, and resolution, according to their intended use. These standards may be maintained by the Metrology Organization, the Responsible Division Manager, or subcontractor's calibration organization.

5.2.1.10 A procedure for identifying and documenting equipment that is out of compliance, damaged, expired,

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lost, or inappropriate for use shall be installed for the EM Department and be consistent with any Level 1 and 2 procedures.

- 5.2.1.11 The M&TE documentation discussed in Step 5.2.1.2 shall be reviewed during or after completion of the calibration or maintenance activity to assure that the as-found conditions are within specification. If the as-found conditions are outside acceptable specifications, a Nonconformance Report (see 3-21000-ADM-15.01, Control of Nonconforming Items and Activities) shall be generated to assess the impact and, when possible, qualify the data collected for "use as is". The intended actions to correct the problem shall also be stated.
- 5.2.1.12 The use of preventive maintenance shall be implemented to maintain continuously acceptable M&TE.
- 5.2.1.13 Records of equipment maintenance shall be documented. If the M&TE is not calibrated prior to use following maintenance, this must either be addressed in an existing procedure or the decision to not calibrate must be formally documented with QAPM concurrence.
- 5.2.1.14 A recall and notification system shall be established to assure the M&TE is appropriately maintained and calibrated.
- 5.2.1.15 The responsible manager should maintain a file or log of each piece of M&TE documenting its maintenance and calibration history for at least 36 months. Where accuracy and operability

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checks are performed, these data should also be included in this file.

5.2.1.16 Yearly reviews based on the date maintained per 5.2.2.13 and other sources shall be made to assess the M&TE's performance and reliability. M&TE with poor performance and reliability shall be replaced as soon as practicable.

5.3 Ensuring Conformance

- 5.3.1 Out-of-tolerance criteria shall be established to ensure that measurements made by M&TE and measurement standards that are found to be out-of-tolerance do not adversely affect quality. All out-of-tolerance conditions shall be documented on a label consistent with the operational procedures for the equipment or other equivalent methods.
- 5.3.2 If M&TE is not functioning or potentially malfunctioning, it shall be tagged to indicate that it is out of calibration and segregated where feasible until it can be repaired, if necessary, and recalibrated.
- 5.3.3 If the M&TE does not have a current calibration indicator, it is presumed to be out of calibration.
- 5.3.4 All documentation of control techniques shall be in accordance with procedure 3-21000-ADM-06.01, Document Control.
- 5.3.5 The QAPM shall arrange for QA inspections (per 3-21000-ADM-10.01, Inspection) of the M&TE program at least twice each year.
- 5.3.6 The QAPM shall arrange for a surveillance (per 3-21000-ADM-18.02, Surveillance) of the M&TE program at least once each year.

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5.3.8 The use of M&TE shall be addressed by procedures, which include the following:

1. Clear identification of the M&TE to be used.
2. A requirement for verification of the M&TE prior to usage.
3. Inclusion of any accuracy and operability checks.
4. Clear specification of the required accuracy of the measurement.
5. Specification of any applicable environmental limitations.
6. Documentation of the M&TE used (typically including serial number).

5.3.9 Approval from the RFP metrology organization should be solicited for purchase requisitions and purchase orders for M&TE services.

5.3.10 Calibration adjustments shall be sealed by the calibrating organization and the M&TE shall be presumed to be out of calibration if the seals are lost or broken.

5.4 Controls

5.4.1 Measurement standards should be approved by the Metrology organization and assigned an uncertainty factor and expiration date.

5.4.2 Storage and Transportation

5.4.2.1 Measurement standards and M&TE shall be stored, handled, and transported in a manner that shall not adversely affect the calibration or proper operation of the equipment.

5.4.2.2 All measurement standards and M&TE shall be tested prior to shipment

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to be tested for proper operation. Upon return, the equipment shall be retested.

5.4.2.3 Requests for new M&TE and disposal of old M&TE should be approved by the Metrology organization.

5.4.3 Procedures addressing the calibration of M&TE shall contain the following:

5.4.3.1 Precautions and limitations for the M&TE.

5.4.3.2 Identification of calibration standards to be used in the calibration.

5.4.3.3 Calibration instruction and documentation of performance.

5.4.3.4 Acceptance criteria for each range.

5.4.3.5 Verification review of the calibration documentation by a qualified individual who did not perform the calibration.

5.5 QA Records

5.5.1 A copy of all documentation prepared under this procedure shall be submitted to the EM Department records center per 3-21000-ADM-17.01, Records Management, by the individual who completes this record.

5.5.2 The records maintained by the responsible Division Manager are for field use and are not required to be complete or auditable.

5.5.3 Copies of maintenance and operations manuals for all instruments shall be submitted to the EM Department records center upon receipt of the M&TE. Copies of existing manuals for M&TE shall be submitted to the EM Department records center as soon as practicable.

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5.5.4 The Records Center should be notified to accumulate each year's records for each specific M&TE in a single records package. Records for several similar M&TE may be kept in the same package.

6.0 REFERENCES

1. Environmental Management Procedure 3-21000-ADM-17.01, Records Management.
2. Environmental Management Procedure 3-21000-ADM-06.01, Document Control.
3. Environmental Management Procedure 3-21000-ADM-10.01, Inspection
4. Environmental Management Procedure 3-21000-ADM-15.01, Control of Nonconforming Items and Activities
5. Environmental Management Procedure 3-21000-ADM-18.02, Surveillance

7.0 ATTACHMENTS

None