NYE COUNTY NUCLEAR WASTE REPOSITORY PROJECT OFFICE

QUALITY ADMINISTRATIVE PROCEDURE

TITLE: **Control of Measuring and Test Equipment**	REVISION: **2** DATE: **3-31-04** PAGE: **1 of 8**
PROCEDURE NUMBER: **QAP-12.1**	SUPERSEDES: **Revision 1, 1-28-02**
APPROVAL 4-5-04 Project Manager Date	CONCURRENCE 3/31/04 On-Site Geotechnical Representative Date 3/28/04 Quality Assurance Officer Date

1.0 PURPOSE

This quality administrative procedure (QAP) describes Nye County Nuclear Waste Repository Project Office (NWRPO) requirements and responsibilities for ensuring that only calibrated or standardized measuring and test equipment (M&TE) is used during technical activities and that calibration or standardization is performed in a timely and appropriate manner.

2.0 APPLICABILITY

This QAP applies to the control, calibration, standardization, and maintenance of M&TE used for quality-affecting activities of NWRPO technical programs. Commercial measurement devices (e.g., rulers, tape measures, levels, or similar devices) are not covered by the controls of this QAP.

3.0 DEFINITIONS

3.1 ***Calibration***—the method of comparing a measuring device with a standard or instrument of known accuracy to detect, correlate, report, or eliminate any variation in the accuracy of the item being compared.

3.2 ***Measuring and test equipment***—devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data.

3.3 ***Periodic/special calibration***—calibration performed periodically by NWRPO personnel, a commercial calibration laboratory, or the manufacturer that requires special training, equipment, and/or standards to perform.

3.4 ***Prior to use calibration***—required, routine calibration conducted before using M&TE at a job site.

3.5 ***Quality administrative procedure***—a procedure developed to implement the quality assurance (QA) requirements described in the QA Program Plan (QAPP).

3.6 ***Quality Assurance Program Plan***—the controlled plan that outlines the NWRPO QA requirements, which are based principally on the applicable portions of the requirements set forth by the U.S. Nuclear Regulatory Commission and the American National Standards Institute for nuclear power plants, as adapted for a nuclear waste repository.

3.7 ***Standard***—the highest available measurement of accuracy in a calibration system that establishes the basic accuracy values for that system.

3.8 ***Standardization***—the method of comparing the output of M&TE measuring a substance or quantity with the output from an instrument known to be in calibration measuring the same substance or quantity.

4.0 RESPONSIBILITIES

4.1 Project Manager

The Project Manager (PM) or designee is responsible for approving this QAP.

4.2 Quality Assurance Officer

The QA Officer (QAO) is responsible for verifying that the NWRPO M&TE calibration/standardization program is conducted in accordance with QA requirements. The QAO shall assess the effectiveness of the program through surveillances and audits.

4.3 On-Site Geotechnical Representative

The On-Site Geotechnical Representative (OSGR) is responsible for supervising the NWRPO M&TE calibration/standardization program.

4.4 Principal Investigator

The Principal Investigator (PI) or designee is responsible for activities requiring the use of M&TE and shall identify appropriate M&TE in QA plans and procedures, ensure that equipment users are qualified and trained, and supervise equipment users on the job site.

4.5 Equipment Custodian

The equipment custodian is responsible for entering calibration/standardization data into the M&TE tracking database, keeping calibration/standardization stickers up to date, and submitting an electronic copy of the database to the NWRPO QA records center (QARC) semi-annually. The custodian is also responsible for coordinating calibrations conducted by outside laboratories or manufacturers and in-house periodic/special calibration.

4.6 Equipment User

The equipment user is responsible for using M&TE in accordance with applicable QA plans or procedures and verifying that calibration or standardization status is current. The user is also responsible for calibrating M&TE that requires prior-to-use or NWRPO in-house periodic/special calibration and recording the results.

5.0 PROCESS

5.1 Equipment Selection

The PI or designee shall select M&TE from existing NWRPO inventory, request the procurement of new M&TE, or require NWRPO contractors to use specific M&TE based on the accuracy, precision, and calibration or standardization requirements in the governing QA plan or procedure for the data collection activity to be performed. The M&TE shall be appropriate for its intended use and available in sufficient quantities and condition to generate and, as required, process data in a reliable and documentable manner.

Acceptance criteria for new NWRPO or contractor-used M&TE shall be defined either by inspection, certificate of conformance, source verification, or post-installation testing to verify that the M&TE performs as designed. For new M&TE, acceptance criteria are also described in QAP-7.1, *Procurement of Items and Services*.

In cases where the manufacturer calibrates new M&TE, the PI or designee shall obtain all available calibration or standardization documentation from the manufacturer or contractor supplying the M&TE. The calibration/standardization documentation for M&TE shall include a record of measurements made under laboratory or factory conditions.

5.2 Equipment Calibration and Standardization

5.2.1 Documentation

Upon receipt of, and before using, new M&TE, the PI or designee shall do the following:

- Determine whether the M&TE requires prior-to-use or periodic/special calibration or standardization.
- Determine the frequency of the calibration or standardization.
- Identify the standard(s) to be used.
- Determine special environmental conditions, if any.
- If manufacturer calibration/standardization data are supplied with the new M&TE, verify that the data are consistent with the requirements specified in applicable QA plans and procedures.
- Transmit the above information, along with operating manuals, to the equipment custodian.

The equipment custodian shall enter all calibration/standardization information into the NWRPO M&TE tracking database and store copies of all available documents and manuals concerning the calibration, standardization, and/or operation of the MT&E.

Upon receipt of the M&TE from the PI, the equipment custodian shall attach green periodic/special or standardization stickers or a yellow prior-to-use sticker. All stickers shall display a unique identification number, the date of the last calibration/standardization, and the individual or company that conducted the calibration or standardization (Attachment 1). In addition, periodic/special and standardization stickers shall display the date of the next scheduled calibration or standardization. The date of the last calibration and the calibrator's name on prior-to-use stickers shall be printed in pencil or erasable ink to facilitate updating after calibration, which may occur several times in one day.

A new calibration sticker shall be attached each time calibration or standardization is performed on M&TE or when the operating status changes, as described in this QAP. The previous sticker shall be removed when a new one is attached, with the exception of prior-to-use stickers. Prior-to-use sticker information shall be erased and rewritten and the calibration shall be documented in the appropriate scientific notebook or form.

5.2.2 Out-of-Calibration Status

M&TE that cannot be brought into calibration shall be isolated and tagged to preclude its use until calibration can be achieved, and the equipment custodian shall enter the out-of-calibration status into the M&TE database. Out-of-calibration stickers are red and display the message "Do Not Use" (Attachment 1).

M&TE found to be out of calibration shall be documented and reported to all affected PIs and users for the evaluation of any data that may be impacted. The discoverer of out-of-calibration status shall report it to his/her supervisor and the QAO, as detailed in QAP-15.1, *Control of Nonconforming Items or Activities*.

If M&TE can be repaired and brought back into calibration without adverse effect on its measurements, the red sticker shall be removed, the M&TE put back into use, and the change in calibration status entered into the M&TE database.

5.2.3 In-House Calibration

The equipment user shall perform prior-to-use or periodic/special calibrations, using a standard traceable to the National Institute of Standards and Technology or a recognized international standard where possible. Calibration standards shall have a greater accuracy than the M&TE being calibrated, unless standards with the same accuracy are shown to be adequate. If no recognized standard exists, a laboratory or industry consensus standard shall be used. The equipment user shall document all relevant calibration or standardization information in the scientific notebook or form for that data-gathering activity.

The equipment user shall submit in-house periodic/special calibration information to the equipment custodian for entry into the M&TE database. Prior-to-use calibrations shall be documented in the appropriate scientific notebooks or forms.

The PI shall ensure that the equipment user is adequately trained to perform in-house periodic/special and prior-to-use calibrations. The OSGR shall ensure that the equipment custodian is adequately trained in the maintenance of M&TE records.

5.2.4 Other Calibration

The equipment custodian shall coordinate the periodic/special calibration of M&TE sent to outside organizations, maintain the documentation for these calibrations, and update the M&TE database with the calibration information, including the method used.

5.2.5 Equipment Standardization

The equipment user shall conduct and document M&TE standardizations and submit the documentation to the equipment custodian. The equipment custodian shall attach a green standardization sticker and enter the standardization information into the M&TE database.

Standardization procedures, which vary widely, shall be specified in the appropriate QA plan or procedure for the test to be performed. The standardization method shall be recorded in the documentation for that test and entered into the M&TE database by the equipment custodian.

5.3 Equipment Storage

M&TE not currently in use shall be handled and stored to maintain accuracy. M&TE shall be appropriately packaged, as prescribed by the manufacturer, and stored in a suitable environment that is not subject to frequent temperature, pressure, or moisture changes. Procedures required for the handling and storage of M&TE shall be referenced in the M&TE database.

5.4 Calibration and Standardization Verification

The QAO shall conduct audits or surveillances to verify that M&TE is calibrated and the appropriate documentation is maintained. Audits and surveillances shall be performed as described in QAP-18.1, *Audits and Surveillances*.

6.0 RECORDS

Documents generated by this QAP are QA records and shall be submitted to the QARC by the responsible individual in accordance with QAP-17.1, *Records Management*.

The QA records generated by this QAP include the following:

- The NWRPO M&TE database.
- Scientific notebooks and forms documenting in-house calibrations or standardizations.
- Documentation for calibrations performed by outside organizations.

The M&TE database shall be submitted semiannually to the QARC by the equipment custodian and shall include for each M&TE item, at a minimum, the following:

- NWRPO identification number.
- Model and serial numbers.
- M&TE description and location.
- Calibration or standardization type, standard, and frequency.
- Acceptable tolerance(s).
- Date of last calibration or standardization.
- Date of next calibration or standardization.
- Requirement for failed calibration.
- Special storage environmental condition(s).
- Required documentation.

Scientific notebooks and/or forms used to record details of in-house calibration shall be submitted to the QARC in accordance with QAP-3.2, *Documentation of Technical Investigations*. Documentation for calibration or standardization conducted by individuals

other than NWRPO personnel (e.g., the manufacturer) shall also be submitted to the QARC.

The equipment custodian shall store copies of all available documents and manuals relating to the calibration, standardization, and/or operation of M&TE.

7.0 References

QAP-3.2, *Documentation of Technical Investigations*.

QAP-7.1, *Procurement of Items and Services*.

QAP-15.1, *Control of Nonconforming Items or Activities*.

QAP-17.1, *Records Management*.

QAP-18.1, *Audits and Surveillances*.

QAPP, *Nye County Nuclear Waste Repository Project Office Quality Assurance Program Plan*.

8.0 Attachments

Attachment 1 Calibration Stickers

Attachment 1
Calibration Stickers