INSPECTION PROCEDURE 78160

CONTROL OF MEASURING AND TEST EQUIPMENT (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: MC 2300

78160-01 INSPECTION OBJECTIVES

01.01 To determine if tools, gauges, instruments, and other measuring and testing devices are properly controlled and maintained, to ensure total accuracy.

78160-02 INSPECTION REQUIREMENTS

02.01 Calibration and Control Program. To determine if adequate measures are established to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted, at specific periods, to maintain accuracy within necessary limits.

02.02 Calibration of Equipment. To determine if equipment is being maintained in accordance with the calibration program.

02.03 Out-of-Calibration or Lost Equipment. To determine if provisions are established for out-of-calibration or lost equipment.

78160-03 INSPECTION GUIDANCE

General Guidance

This inspection procedure applies to the implementation of the U. S. Department of Energy's (DOE's) quality assurance (QA) program during the design and construction of a geologic repository at Yucca Mountain. The DOE QA program is described in the QARD, DOE/RW-0333P. This inspection procedure applies to Systems, Structures, and Components (SSCs) important to safety; to design, characterization, and construction of barriers important to waste isolation; and to related activities described in the Safety Analysis Report.

Selection of areas for evaluation during inspections shall be based on the risk significance of the SSCs, related activities, and past performance. The scope of inspections should also consider the cumulative effect of failures related to low-risk-significant SSCs,regarding their potential effects on overall system performance and reliability.

Specific Guidance

03.01 Calibration and Control Program. Verify that a program is established for this use, including calibration and control, of measuring and test equipment for activities affecting quality. Program documentation should adequately describe the scope of the program and the types of equipment to be controlled. Responsibility for review and concurrence of implementing procedures should be described, including responsible organizations. Responsibility for equipment calibration should be identified, including identification of responsible management authorized to approve the basis for acceptable calibration of specific equipment. Responsibilities of the QA organization and other organizations should be adequately described for establishing, implementing, and ensuring the effectiveness of the calibration program.

Verify that the calibration program requires measuring and test equipment, including equipment that contains software or programmable hardware, to be calibrated, adjusted, and maintained, as a unit, at prescribed intervals, or before use, against reference calibration standards having traceability to National recognized standards. If no Nationally recognized standards or physical constants exist, the basis for calibration shall be required to be documented. Verify that calibration of the equipment is against standards that have an accuracy of at least 4 times the required accuracy of the equipment being calibrated or, when this is not possible, that have an accuracy that assures that the equipment being calibrated will be within required tolerances.

Verify that procedures are established for the control of measuring and test equipment, including instruments, tools, gauges, fixtures, reference and transfer standards and nondestructive equipment used in the measuring, inspection and monitoring of SSCs. Calibrations and controls are not required for rulers, tape measures, levels and other normally commercial equipment that provide adequate accuracy. Review the procedures to verify that sufficient detail is provided for the calibration (including technique and frequency), maintenance, and control of the equipment. Verify that procedures define the method and interval of calibration of each device, based on the type of equipment, stability characteristics, required accuracy, intended use, degree of use, and conditions affecting measurement control. For measuring and test equipment used in one-time-only applications, the calibration shall be done both before and after use.

Procedures should establish criteria for selecting proper measuring and test equipment, for use in processes, inspections, and tests that: (1) are of the type appropriate for measuring specified characteristics of items being processed, inspected, or tested; and (2) have sufficient range, accuracy, and tolerance to determine conformance to specified requirements.

Verify that measuring and test equipment software developed or modified by the user shall be controlled in accordance with Supplement I, “Software,” of the QARD and that updates to software that affect calibration require recalibration of the equipment prior to use.

03.02 Calibration of Equipment. Select several items of equipment controlled under the measuring and test equipment program and verify that the equipment is labeled or tagged or “otherwise controlled,” to indicate the due date or interval of the next calibration. Verify that the controls and calibration frequency are consistent with procedural or program requirements for the control of the equipment.

Verify, with selected users of the equipment, that when the accuracy of the equipment is suspect, that a calibration check method is available for the user to verify acceptable performance of the equipment, or the equipment will be returned for recalibration.

Verify that the use of calibrated equipment is being documented. As appropriate, this documentation should include the process monitored, data collected, or items inspected or tested, since the last calibration.

Verify that the measuring and test equipment is being properly handled and stored to maintain accuracy, by touring areas where the equipment is used or stored.

Review the calibration records for the equipment. Verify the equipment is traceable, through some unique identifier, to the calibration test data. Verify that the equipment was calibrated against a standard having an accuracy of at least 4 times the required accuracy of the equipment. If the calibration standard did not meet this requirement, review the basis for acceptance of the calibration used and verify approval of the calibration process by responsible management, in accordance with the calibration program.

Verify that the calibration records for the equipment include documentation of the following:

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 measuring and test equipment, including evaluation results; and
h. Identification of the implementing document (including revision level) used in performing the calibration.

Select several standards used for calibration of equipment. Verify that the standards are traceable to nationally recognized standards. Where traceability to nationally recognized standards does not exist, review the documentation that justifies the use of the standard. Verify that standards are calibrated by calibration standards that have greater accuracy. Calibration standards that have the same accuracy as the standard being calibrated may be used if this level of accuracy can be demonstrated to be adequate for the requirements and provided that the basis of acceptance is documented and authorized by responsible management, consistent with procedural and calibration program requirements.

03.03 Out-of-Calibration or Lost Equipment. Verify that program requirements are established such that when measuring and test equipment is found to be out of calibration, measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration. For any inspections or tests on items determined to be suspect, the inspection or test shall be repeated.

Verify that the criteria for determining when equipment is out-of-calibration include: (1) the calibration due date, or interval passed without recalibration; and (2) the device producing results known to be in error.

Verify that controls are established for out-of-calibration equipment, to ensure the equipment is tagged, segregated, or otherwise controlled to prevent use until recalibrated. During tours of work areas and calibration labs, verify that equipment available for use is calibrated. For any equipment not in calibration, verify that controls have been implemented to prevent use.

Verify that requirements are established for equipment found out of calibration during recalibration, to validate the results obtained from using that equipment since its last valid calibration. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested, and shall be documented. Any equipment consistently found to be out of calibration during the recalibration process shall be repaired or replaced.

Verify that requirements are established for validating data when the measuring and test equipment is lost. This evaluation should include review of all data collected since the last calibration. The evaluation shall include the determination of acceptability for previously collected data, processes monitored, or items previously inspected or tested, and shall be documented.

Review selected calibration records and repair records to determine if any equipment was found out of calibration during the recalibration process, or had been lost, and review documentation generated to validate the data collected by the instrument.

78160-04 INSPECTION RESOURCES

An initial inspection of the program for the control of measuring and test equipment may be conducted approximately 1 year before submittal of an application. This inspection will consist of one inspector on site for 2 weeks. Preparations for the inspection and documentation of the inspection will consist of 2 weeks. Implementation of the first inspection is 4 inspector-weeks.

After the construction authorization is issued and construction starts, semiannual inspections of the program will be conducted by one inspector, for a total of 2 inspector-weeks per year.

Once construction is complete and the operating license is issued, an annual inspection will be conducted by one inspector, for a total of 1 inspector-week per year.

78160-05 REFERENCES

U.S Nuclear Regulatory Commission, NUREG-1804, “Yucca Mountain Review Plan,” Draft Revision 2.

U.S Code of Federal Regulations, 10 CFR Part 63, “Disposal of High-Level Radioactive Wastes in a Proposed Geologic Repository at Yucca Mountain, Nevada.”

U. S. Department of Energy “Quality Assurance Requirements and Descriptions (QARD),” DOE/RW-0333P, Latest revision accepted by NRC.

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