

9.0 Standards, Equipment, and Associated Apparatus

- 9.1 Laboratory standards, equipment, and associated apparatus are maintained suitable for the correct performance of tests and are maintained in accordance with the laboratory procedures (see Appendix H, AP No. 13), equipment maintenance and operational manuals, and this quality manual. The equipment, standards and associated apparatus are protected from dirt, dust, corrosion, and other causes of deterioration. The technical manager investigates any equipment or standards that are suspected in contributing to out-of-control conditions (see Appendix G, Standards List, and Appendix F, Equipment List). Records of corrective actions for discrepancies are maintained in the laboratory (see Section 13 Records, and Appendix O, Forms). Procedures for safe handling, transport, storage, use and planned maintenance of test equipment to ensure proper functioning are maintained in the laboratory (see Appendix H, AP No. 14).
- 9.2 Maintenance and calibration records for equipment and standards include the following as appropriate (see Section 13, Records, and Appendix O, Forms):
- 9.2.1 Item name and manufacturer; model, serial, and other identification numbers;
 - 9.2.2 Date and condition of receipt, date placed in service, and current location;
 - 9.2.3 History of calibration, maintenance, malfunction, modification, and repair;
 - 9.2.4 Calibration status, recertification date and maintenance plan, where appropriate;
 - 9.2.5 Identification of any software affecting the calibration and quality assurance of the program;
 - 9.2.6 Copy of manufacturer's instructions, where available;
 - 9.2.7 Verification that equipment complies with specifications;
 - 9.2.8 Verification of equipment used which is outside the control of the laboratory.

9.3 Operation and Maintenance

9.3.1 Equipment and Associated Apparatus

9.3.1.1 Laboratory equipment is properly maintained in accordance with procedures for calibration, verification, and maintenance (see Appendix H, AP No. 14). These procedures are located in the laboratory files.

9.3.1.2 Equipment used by the laboratory staff are handled and maintained in accordance with Appendix H, AP No. 14. The equipment is maintained so that it operates according to the manufacturer's specifications for device evaluations. The following activities are conducted to ensure that the equipment operates according to manufacturers specifications:

- a. maintenance and service of the equipment by trained technicians,
- b. operation by laboratory staff that have been trained,
- c. protection from factors that may affect the operation, such as drafts, dirt, dust, and extreme temperatures, and
- d. when not operating correctly, labeling the equipment with an out-of-service tag, removing the equipment from service, and whenever possible storing it in the laboratory storage room (see Appendix D) returning it to service only when its satisfactory performance has been verified.

9.3.1.3 The laboratory examines any previous tests that might have been affected by the equipment that was taken out of service (see Appendix H, AP No. 18, Procedure for Control of Nonconforming Work, and AP No. 14).

9.3.1.4 Operation manuals and instructions for proper maintenance of equipment are available and located in the laboratory files (See QM Section 13 Records for location of the files in the laboratory).

9.3.1.5 Newly installed equipment and software programs are tested to verify that they perform satisfactorily before they are placed into

service. Documentation of this verification is maintained in the laboratory (see Section 13 Records and Appendix O, Forms). The laboratory maintains procedures for testing newly installed equipment (see Appendix H, AP No. 14).

- 9.3.1.6 Equipment is used only when it is in a safe and reliable condition and only by personnel who have been appropriately trained and are qualified. Safe and reliable conditions include:
- a. Stable support for equipment,
 - b. Use of electrical outlets in accordance with equipment specifications, and
 - c. loading equipment in accordance with equipment specifications.
- 9.3.1.7 Use of equipment outside the laboratory's control is verified prior to use to ensure that it meets the same requirements of the laboratory quality system (see Appendix H, AP No. 14).
- 9.3.1.8 All equipment having an affect on the test is calibrated and is labelled, coded or otherwise identified to indicate the status of calibration, including date calibrated and recalibration due date (see Appendix H, AP No. 14).
- 9.3.1.9 The laboratory uses and maintains procedures for the intermediate checks of equipment calibration status when needed (see Appendix H, AP No.14).
- 9.3.1.10 The laboratory follows procedures to ensure that correction factors that arise from the calibration of equipment are correctly updated, including updates to any computer software data (see Appendix H, AP No.14).
- 9.3.1.11 The laboratory ensures that test equipment is safeguarded from adjustments that can cause invalid test results (See Appendix H, AP No. 14).

- 9.3.2 Standards (See Section 10, Measurement Traceability and Calibration)

- 9.3.2.1 To maintain integrity of the standards, all maintenance operations are performed according to documented procedures (see Appendix H, AP No. 13). The laboratory standards are:
- a. selected for use according to the level of precision, accuracy, and uncertainty required;
 - b. limited in access and use to trained and authorized laboratory staff only; and
 - c. handled and safely stored according to good laboratory practices.

[NOTE: Appendix H AP No. 13 should define how Section 9.3.2.1 a through c above are met or define your laboratory activities for maintaining the integrity of your standards]

- 9.3.2.2 All standards having an affect on the test, are calibrated by an accredited or recognized laboratory with traceability to a national laboratory, and calibration reports are maintained in the laboratory files.

[NOTE: In section 9.3.2.2, identify the calibration of your laboratory standards and how the calibration results are traceable to a national or recognized laboratory, e.g., “The laboratory standards of mass and volume are tested by our state metrology laboratory. The State metrology laboratory maintains a measurement traceability certificate from NIST WMD recognizing that the laboratories measurements are traceable to NIST (see Appendix H, AP No. 4 and Appendix R).]”