Procedure for Equipment Calibration and Maintenance

1.0 Purpose – This procedure specifies the schedule and requirements for calibration, performance verification, and maintenance of State Crime Laboratory testing instruments and equipment.

2.0 Scope – This procedure applies to the critical laboratory equipment used by the Laboratory and employees that use critical laboratory equipment.

3.0 Definitions

- **Calibration** – Adjustment or standardization of the accuracy of a measuring instrument, usually by comparison with a certified reference or standard.
- **Certified Reference Material (CRM)** – A reference material whose property values are certified by a technically valid procedure and accompanied by or traceable to a certificate or documentation issued by a certifying organization.
- **Critical Laboratory Equipment** – Analytical instrumentation and equipment affecting the accuracy or precision of a test method.
- **Performance Verification** – The confirmation of the reliability of a previously validated method(s) or equipment.
- **Quality Control Checks** – Periodic confirmation of the reliability of equipment, instrumentation, and/or reagents.
- **Reference Standard** – Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
- **Traceability** – The linking of measurement standards and/or measuring instruments to relevant national or international standards through an unbroken chain of comparisons.

4.0 Procedure

4.1 General Equipment Requirements

4.1.1 The Forensic Scientist Manager or designee shall maintain an equipment inventory of critical equipment that shall include the following information:

- Item, including software and version.
- Manufacturer and model.
- Serial number or other unique identification.
- Location.

4.1.2 All equipment in the equipment inventory system shall be identified uniquely (e.g., DOJ bar code number).

4.1.3 All equipment shall be maintained in good operating order and according to manufacturer and/or Section maintenance requirements.

4.1.4 All critical equipment shall be calibrated or verified before use.

4.2 Equipment Calibration and Verification

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4.2.1 Forensic Scientist Managers/Supervisors shall include procedures for calibration and/or performance verification of new equipment in Section technical procedures. The procedure shall include specifications for the calibration laboratory, specified requirements for the calibration, and the interval of calibration.

4.2.2 Calibration procedures shall be appropriate for the intended use of the equipment and shall provide criteria for determining if calibration is satisfactory.

4.2.3 Reference Standards and Reference Materials

4.2.3.1 Whenever possible, reference standards and reference materials traceable to SI units (International System of Units) shall be used.

4.2.3.2 Reference standards shall be calibrated by an accredited organization or vendor that can provide proof of traceability. These typically would include, but not be limited to, ISO/IEC 17025-certified companies. Reference standards shall be calibrated before and after any adjustment. The reference standards shall be used for performance checks only.

4.2.3.3 In order to maintain confidence in the calibration status, intermediate performance checks shall be performed on reference standards as provided in the Section technical procedures. Any extension to the established intermediate check interval must be based on empirical data and evaluation of risk. The extension approval shall be documented according to the Procedure for Authorizing Deviations.

4.2.3.4 Certified reference materials used to establish or maintain measurement traceability shall be supplied by a vendor that is:

- A National Metrology Institute that is a signatory to the BIPM-CIPM Mutual Recognition Arrangement with the certified reference material listed in the BIPM key comparison database,
- A service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILA Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation, or
- An accredited reference material producer that is accredited to ISO/IEC 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement with a scope of accreditation covering the certified reference material.

4.2.3.5 In situations where a supplier of certified reference materials that meets the above criteria is not available, the Section shall confirm competence measurement capability, and measure traceability for the supplier and product being purchased. Records of the confirmation shall be maintained by the Section.

4.2.3.6 Reference standards and reference materials shall be handled only by employees authorized by the Forensic Scientist Manager/Supervisor and shall be stored to prevent contamination and/or deterioration. All reference standards, certified reference

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materials, or reference materials used for calibration shall be uniquely identified. A certificate of traceability, if applicable, shall be retained to ensure traceability.

4.2.4 Calibration Interval

4.2.4.1 Calibration or performance check intervals for each instrument requiring calibration shall be established. Manufacturer operating manuals shall be consulted to determine the correct calibration interval. Any extension to the established calibration interval must be based on empirical data and evaluation of risk. The extension approval shall be documented according to the Procedure for Authorizing Deviations.

4.2.4.1.1 Equipment used infrequently, such that the manufacturers' recommendations cannot be followed, shall have calibration verified prior to use.

4.2.4.2 Equipment which requires calibration shall not be used if satisfactory calibration cannot be achieved or the calibration date has passed.

4.2.4.3 Equipment shall be calibration or performance checked in the following situations:

- New equipment prior to being used in testing
- Anytime a piece of equipment leaves the control of the Laboratory
- After a power shut down, whether deliberate or otherwise
- Following service or other substantial maintenance.

4.2.5 Calibrations by an Outside Vendor

4.2.5.1 When available, Sections shall utilize competent external calibration services that can demonstrate measurement capability and traceability for equipment.

4.2.5.2 When external calibrations are performed, service providers that demonstrate competence, measurement capability, and traceability shall be used. When possible, providers accredited to ISO/IEC 17025 with the calibration to be performed listed in the scope of accreditation or a National Metrology Institute that is a signatory to the BIPM-CIPM Mutual Recognition Arrangement with the calibration to be performed listed in Appendix C of the BIPM key comparison database shall be used. Copies of the provider's accreditation documentation shall be maintained by the section.

4.2.5.3 In situations where a supplier of external calibrations that meets the above criteria is not available, the Section shall confirm competence measurement capability, and measure traceability for the service provider. Records of the confirmation shall be maintained by the Section.

4.2.6 Internal Calibrations

When necessary (e.g., no external calibration is available), Sections may perform internal calibrations of instrumentation. These calibrations shall establish traceability by a means of an unbroken chain of calibrations or comparisons linking the calibration standards to the relevant primary standards of the SI units of measurement. Calibration methods must be validated and

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include an evaluation for the measurement uncertainty. Calibrations may be performed only by authorized personnel.

4.2.7 Laboratory equipment requiring calibration shall be labeled or coded to indicate the calibration status, including the date when last calibrated and the due date for recalibration (or expiration criteria for when recalibration is due).

4.3 Calibration Records

4.3.1 Calibration records shall be maintained and associated with the unique identifier of each piece of equipment. These records shall include:

- Identity of the item of equipment and software.
- Name of manufacturer.
- Serial number or unique identifier.
- Date of calibration.
- Current location.
- Manufacturer's instructions or a reference to location.
- Reference standard, certified reference material or reference material used for calibration.
- Copies of all reports, results of calibration, and/or certificates of calibration.
- Maintenance plan and due date for the next calibration.
- Identity of the individual performing calibration.

4.3.2 Calibration certificates from external providers shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

4.3.3 The Section document control custodian shall maintain the original calibration records provided by the vendor and a copy of the relevant records shall be readily available.

4.4 Equipment Maintenance

4.4.1 Equipment shall be maintained as specified in the technical procedure.

4.4.2 Critical equipment shall have documented procedures for the maintenance process. Maintenance procedures and frequencies, either in the form of vendors' manuals or in-house procedures, shall be available for each piece of equipment. The operating and maintenance manuals shall be readily available to the operator. In the absence of manufacturer's instructions, instructions shall be provided in the technical procedure.

4.4.3 Preventative maintenance procedures (other than basic cleaning) for each equipment item shall be developed by each Section unless already described elsewhere (e.g., the equipment manual) and shall be performed according to a regular, predetermined schedule. Preventive maintenance shall be documented in the maintenance records.

4.5 Maintenance Records

4.5.1 Maintenance records shall be maintained and shall include:

- Type of equipment.

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- Equipment serial number or unique identifier.
- Date of maintenance.
- Adjustments or repairs made.
- Identity of the individual performing maintenance.

4.5.2 If maintenance is performed by an outside vendor on a lab-wide basis (e.g., microscope maintenance), the Forensic Scientist Manager or designee shall retain the original maintenance records provided by the vendor.

4.5.3 When a piece of equipment is retired from service, maintenance and repair records shall be incorporated into the Section archives by the Forensic Scientist Manager or designee.

4.6 Out of Service Equipment

4.6.1 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated and/or clearly labeled (Out of Service – Do Not Use) to prevent use until repaired and shown by calibration or test to perform correctly.

4.6.2 Prior to returning a piece of equipment to use (out of service for any reason - e.g., maintenance, malfunction, leaving the direct control of the Laboratory), correct operation shall be demonstrated by calibration or performance verification. Laboratory personnel shall examine the effect(s), if any, of a malfunction on analysis results and implement the Procedure for Corrective Action as required.

4.6.3 An exception may be made if the equipment failure is not directly related to its analytical function, such as a problem with peripheral equipment.

4.7 Quality Control Checks - Quality control checks may be carried out at appropriate intervals to verify that equipment is functioning as expected. The procedures for quality control checks shall be included in the technical procedure for which the equipment is being used. Any extension to the established quality control check interval must be based on empirical data and evaluation of risk. The extension approval shall be documented according to the Procedure for Authorizing Deviations.

4.8 Correction Factors - Where calibrations give rise to a set of correction factors, the Section shall ensure that software is updated with these correction factors.

4.9 Safeguards - The Forensic Scientist Manager/Supervisor shall designate the personnel (Equipment Monitor) responsible for equipment calibration and maintenance (including outside vendors used for these services).

5.0 Records

- Listing of critical equipment requiring calibration and/or maintenance
- List of authorized equipment service providers
- Calibration, maintenance and verification records
- Service and repair records
- Certificates of traceability for reference standards

6.0 Attachments – N/A

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Revision History		
Effective Date	Version Number	Reason
05/01/2020	10	2.0 – clarified scope 4.2 – consolidated calibrations requirements and records, added evaluation of risks for extensions of intervals 4.2.3.4 – added ISO/IEC 17025 accredited vendor.

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