

# DOM05 – Procedures for Instrument Checks and Maintenance

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## 1. Background

- 1.1. These procedures establish calibration and maintenance requirements to ensure the accuracy and reliability of instrumental results. These procedures conform to the requirements of the Agency, government regulations, accreditation standards, and the applicable supplemental standards.

## 2. Definitions

- 2.1. For the purposes of this document, the following terms shall have the designated meanings:

**DFS:** Department of Forensic Sciences

**DOM:** Departmental Operations Manual

**FSL:** Forensic Science Laboratory

**SOP:** Standard Operating Procedure

## 3. Scope

- 3.1. These calibration and maintenance procedures apply to the instrumentation and equipment that have an impact on any testing performed in the DFS.

## 4. Responsibilities

- 4.1. The **Manager/Supervisor** or designee will:
  - 4.1.1. Ensure a list of instruments and equipment requiring calibration and/or maintenance is maintained.
  - 4.1.2. Ensure procedures for calibrations and maintenance are maintained.

- 4.1.3. Ensure instruments and equipment are calibrated and/or maintenance is performed within the required intervals.
- 4.1.4. Ensure calibration and maintenance records are complete, current, and retained.

## 5. Procedures

### 5.1. Calibration

- 5.1.1. The Manager/Supervisor or designee will ensure each unit maintains a record of instruments and equipment that require calibration. This record will include, at a minimum: the identity of the item of equipment and its software; the manufacturer's name, type identification, and serial number or other unique identification; checks that equipment complies with the specification; current location, where appropriate; the manufacturer's instructions, if available, or reference to their location; dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; the maintenance plan, where appropriate, and maintenance carried out to date; any damage, malfunction, modification or repair to the equipment. In addition to these records, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.
- 5.1.2. Instruments or equipment that require calibration will not be used for casework if satisfactory calibration cannot be achieved or the calibration due date has passed. These instruments shall be removed from service and the date of removal from service, signature of removing member and reason why instrument was removed will be documented.
- 5.1.3. Calibration procedures must also be satisfactorily completed on any applicable instrument/equipment that goes outside the control of the DFS prior to its return to service.

### 5.2. Calibration Procedures

- 5.2.1. Instruments and/or equipment requiring calibration should have documented procedures for performing calibrations. Calibration procedures may be included in the SOP in which the instrument/equipment is used or may be written as a stand-alone SOP for calibration in accordance with the requirements set forth in *DOM02 – Procedures for Document Control*. These procedures will reflect current calibration requirements based on the use of the instrument or item of equipment and will be readily available to appropriate unit personnel. All

calibrations will be performed in accordance with the appropriate calibration procedures. If these procedures are performed by external sources, casework units will verify the calibration was completed. Calibration records will be maintained.

### 5.3. Calibration Interval

- 5.3.1. The calibration interval will be documented for each instrument requiring calibration. Manufacturers' operating guidelines should be consulted to determine the correct calibration interval. However, instruments used infrequently, such that recommendations by the manufacturer cannot be followed, will be calibrated or have their calibration verified prior to use. New instruments and equipment, or instruments and equipment that have undergone repair or maintenance that affect calibration, will be calibrated or have their calibration verified before being used in casework. The Manager/Supervisor or designee will ensure appropriate actions are taken to comply with calibration intervals.

### 5.4. Maintenance

- 5.4.1. Instruments and equipment will be properly maintained. The Manager/Supervisor or designee will ensure a record of the unit's instruments and equipment that require maintenance is maintained. This record will include, at a minimum: the identity of the item of equipment and its software; the manufacturer's name, type identification, and serial number or other unique identification; checks that equipment complies with the specification; current location, where appropriate; the manufacturer's instructions, if available, or reference to their location; dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration; the maintenance plan, where appropriate, and maintenance carried out to date; any damage, malfunction, modification or repair to the equipment. Instruments and/or equipment having a direct effect on the quality of the examination or evidence process will have documented procedures for the maintenance activities. Maintenance procedures may be written as a stand-alone maintenance SOP in accordance with *DOM02 – Procedures for Document Control*, incorporated into the appropriate technical SOP, or may be manufacturer-supplied procedures for maintenance. These procedures will reflect current maintenance requirements and will be readily available to appropriate unit personnel. Maintenance records will be maintained.
- 5.4.2. Where applicable, and in order to ensure proper functioning and prevent contamination, the laboratory shall handle, store, transport, use, and conduct planned maintenance of all measuring equipment according to the manufacturer's recommendations and instructions.

## 5.5. Preventive Maintenance

- 5.5.1. Preventive maintenance will be performed according to a regular, predetermined schedule, based on manufacturer's recommendations (as available and relevant), historical observations of problems, operating experience, and how often the instrument or equipment is used. Preventive maintenance will be documented in the maintenance records.

## 5.6. Corrective Maintenance

- 5.6.1. When an instrument cannot be properly calibrated, fails to meet the performance characteristics established for the procedures, or produces suspect results, the instrument will be taken out of service and labeled to prevent inadvertent use until corrective maintenance is performed. Only when it is shown by calibration or a performance check to operate correctly can the instrument be returned to service. Any corrective maintenance will be documented in the maintenance records.

## 5.7. Performance Checks

- 5.7.1. In instances where calibration is not required or appropriate, performance checks will be carried out at appropriate intervals to verify the equipment or instrument is functioning as expected. Performance check procedures may be included in the SOP in which the instrument/equipment is used or may be written as a stand-alone SOP for performance checks, in accordance with the requirements set forth in *DOM02 – Procedures for Document Control*. These procedures will reflect current performance requirements based on the use of the instrument/equipment and will be readily available to appropriate unit personnel. If an instrument can be affected by a power interruption, unit personnel will check the performance after such an interruption.
- 5.7.2. Performance checks must also be satisfactorily completed on any applicable instrument/equipment that goes outside the control of the DFS prior to its return to service.

## 5.8. Malfunctioning Equipment

- 5.8.1. 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 will be isolated to prevent its use or clearly labeled as being out of service. The equipment will remain in this state until necessary repairs have been made and shown by calibration or test to perform correctly. Units will determine the effect of the malfunction, if any, on test results and implement nonconforming actions when necessary. Any equipment that is required to be sent off site for repairs will be properly packaged according to the requests of the

vendor conducting the repairs or according to the manufacturer's instructions.

#### 5.9. Equipment Security

- 5.9.1. Test equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test results. Such safeguarding will be conducted by placing passwords, where applicable, on equipment/software and security of the laboratory areas. Only authorized and appropriately trained individuals are permitted to handle or use laboratory equipment or software.

### **6. Documentation**

- 6.1. The following records will be generated and permanently retained:

- 6.1.1. Listing of instruments requiring calibration and/or maintenance.
- 6.1.2. Calibration and Maintenance records.
- 6.1.3. Certificates of traceability for reference standards.

### **7. References**

- 7.1. ISO/IEC 17025:2005 – General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland.
- 7.2. ANAB Supplemental Requirements for Forensic Testing, ANSI-ASQ National Accreditation Board, Milwaukee, WI, (current revision).
- 7.3. Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, (current revision).
- 7.4. Division-specific Quality Assurance Manuals, (current revisions).