

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 1 of 9
Title: <b>Equipment Management</b>	Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018

**1. Policy**

Testing equipment and reference materials shall be performance checked and maintained in a way to ensure the accuracy, reliability, and traceability of testing results related to all official FAU casework.

**2. Scope**

The procedures outlined in this SOP apply to all equipment and reference materials used for the examination of casework.

**3. Definitions**

Testing Equipment: Testing equipment includes all equipment used during the examination of casework that results in a measurable outcome. Testing equipment includes, but is not limited to sliding/spreading calipers, osteometric boards, mandibulometer, tape measures, rulers, digital scales, microscopes, and digitizer (three-dimensional coordinate measurement machine/system).

Reference Materials: Anthropological analysis frequently requires the comparison of unknown case specimen(s) with known reference materials. Such items include, but are not limited to, osteological comparative materials and age casts (e.g., pubic symphysis aging casts). These items are not reference materials as defined by the International Vocabulary of Metrology and thus are not considered traceable reference materials.

Performance Check: An assessment of the performance of testing equipment relative to the test being performed. The types and nature of performance checks are discussed below.

Reference Standards: Reference standards refer to equipment used for performance checking testing equipment. Reference standards have been calibrated and are traceable to a National Institute of Standards and Technology (NIST) standard.

Calibration: Calibration is the process of determining the relationship between the readings obtained by a piece of measurement equipment and the applicable units of some defined system of measurement. The measuring item's readings are compared to the values of a measurement standard under controlled and specified conditions.

Traceability: An unbroken chain of comparisons to an approved or accepted standard with each metric comparison having stated measurement uncertainties.

Unique Identifying Number: Unique combinations of alpha-numerics assigned by the FAU to testing equipment, reference standards, and select reference materials that are

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 2 of 9
Title: <b>Equipment Management</b>	Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018

designed to facilitate tracking, documentation, and traceability of that item. A manufacturer's serial number may also serve as a unique identification number.

Measurement Uncertainty: The non-negative parameter characterizing the dispersion of the quantity values being attributed to the measurand. This parameter could be a standard deviation or half width of an interval having a stated level of confidence, or a confidence interval defined by statistical probability.

Measurand: Quantity intended to be measured.

#### 4. **Traceability and Measurement Uncertainty**

All FAU testing equipment is performance checked using calibrated reference standards that are traceable to National Institute of Standards and Technology (NIST) maintained standard that have stated Measurement Uncertainties (see section 6 Performance Checks). Measurements that fall within the FAU accepted parameters (see 6.2 Performance Check Metric Tolerances) should not affect the overall reported conclusions. As such, Measurement Uncertainty does not apply to FAU casework.

#### 5. **Testing Equipment and Reference Materials Management**

The FAU have suitable and adequate equipment to permit all activities to be carried out in a competent and safe manner. Testing equipment and reference materials are located in one of the secure Anthropology Laboratories within their designated storage areas. An approved list of FAU testing equipment suppliers is located on the Anthropology share drive.

5.1 **Access to and Use of Testing Equipment and Reference Materials:** FAU personnel, visiting scientists and interns have access and authorization to use testing equipment. Additionally, the FAU may give authorization to other individuals on a case-by-case basis.

- If testing equipment is removed from the FAU's direct control, the piece of equipment will be subject to a performance check upon its return and prior to use on casework (see section 6.1).

5.2 **Continued Suitability of Testing Equipment and Reference Materials:** The FAU ensures the continued suitability of equipment by completing performance checks (see section 6) and preventative maintenance (see section 7).

#### 6. **Performance Checks**

Testing equipment and reference materials that can influence a test result are required to be performance checked. A performance check shall entail the QA Specialist, or designee

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 3 of 9
Title: <b>Equipment Management</b>	Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018

comparing the measurements of the testing equipment to another instrument (reference standard) to ascertain if the measurements fall within an acceptable parameter (see 6.2).

When a piece of testing equipment or reference material is placed into circulation for use, an initial performance check shall be performed and documented. Additionally, the protocol for future performance checks and maintenance outlined in this SOP for each specific type of testing equipment or reference material shall be followed (see section 7, Testing Equipment and Reference Materials).

- 6. Types of Performance Checks:** Performance checks that are differentiated by time are described in detail below. Besides timing, the nature of performance checks can also vary. For example, a performance check may be a matter of record (e.g., the Quality Assurance (QA) Specialist officially documents the results of the performance check) or non-record (e.g., unscheduled performance check prior to each use).

6.1.1 The timing of performance checks required for each type of testing equipment and reference material is set by the FAU (see section 8, Testing Equipment and Reference Materials for more detail). The following section outlines the different types of performance checks.

- Initial-use Performance Check: All testing equipment and reference materials shall be performance checked prior to initial use to ensure they meet the requirements set by the FAU.
- Per-use Performance Check: Some testing equipment may need to be checked prior to each use. For example, before using the digitizer to take measurements the analyst should test the digitizer for accuracy by measuring two points on an FAU reference ruler.
- Periodic Performance Check: Performance checks conducted on a set interval (e.g., annual, semi-annual) are considered periodic. All testing equipment shall require periodic performance checks.
- Intermediate Performance Check: A supplementary (i.e., unscheduled) performance check to maintain confidence in the accuracy of a piece of testing equipment or a reference material. Intermediate performance checks are not required to be recorded and are considered independent from periodic performance checks.

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 4 of 9	
Title: <b>Equipment Management</b>		Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018	

6.2 **Performance Check Metric Tolerances:** The accepted tolerances for FAU testing equipment are as follows:

- Calipers =  $\pm 1$  millimeter
- Rulers =  $\pm 1$  millimeter
- Osteometric boards =  $\pm 1$  millimeter
- Digitizer =  $\pm 1$  millimeter
- Tape measures =  $\pm 10$  millimeters
- Microscopes =  $\pm 0.5$  millimeter
- Mandibulometer length =  $\pm 1$  millimeter
- Mandibulometer angle =  $\pm 1$  degree
- Digital scales =  $\pm 1$  gram

6.3 **Performance Check Kit:** The performance check kit is comprised of reference standards that are calibrated and traceable to NIST (National Institute of Standards and Technology) or International Systems of Units (SI). The reference standards in the FAU performance check kit includes, but is not limited to, rulers, stainless steel weights (100 gram and 50 gram), and a precision square. The performance check kit shall only be used for the purposes of performance checks.

Note: The FAU does not perform calibrations in-house. All reference standards are externally calibrated at ILAC approved labs.

6.3.1 The QA Specialist shall maintain a spreadsheet of all reference standards in the FAU performance check kit. The spreadsheet can be found on the Anthropology network drive. The following information shall be recorded:

- Type or name of equipment.
- Equipment serial number or unique identifying number.
- Date of calibration.
- Due date for replacement or re-calibration.
- Identity of individual or company performing calibration.

6.3.2 **Storage and Maintenance:** The performance check kit should be appropriately stored to avoid loss or damage to the reference standards. Additionally, the performance check kit shall be stored separately from the testing equipment in one of the secure anthropology laboratories.

6.3.4 **Reference Standards Certificates:** All certificates related to the traceability and calibration of reference standards are maintained in a designated file, and stored in one of the secure Anthropology lab spaces. The QA Specialist is responsible for maintaining calibration and traceability certificates for all reference standards, where applicable.

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 5 of 9	
Title: <b>Equipment Management</b>		Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018	

6.3.5 **Re-calibration:** Reference standards that require re-calibration (e.g., the stainless steel weights) shall be sent to an external ISO/IEC 17025 accredited lab (if possible) for re-calibration once every accreditation cycle or as needed. The period between re-calibration cycles may be shorter if the accuracy of the reference standard is under question.

6.3.6 **Replacement of Reference Standards:** Most of the reference standards used by the FAU are inexpensive and shall be replaced rather than re-calibrated, when needed. All certificates for calibration and traceability for the new ruler shall replace the older rulers' certificates. Additionally, a new Unique Identifying Number shall be assigned to the new reference standard (e.g., ANTH-001: Evidence Security and Management). All documentation related to replaced reference standards (i.e., certificates and unique identification numbers) shall be appropriately up-dated.

6.4 **Performance Check Records:** All initial and periodic performance checks shall be recorded on a Performance Check Log sheet. Any electronic documentation shall be saved on the Anthropology network drive. The following information shall be recorded:

- Type or name of equipment.
- Equipment serial number or unique identifying number.
- Date of performance check.
- Identity of individual performing the performance check.
- Results of performance check.
- Reference standard used for performance check, including unique identifying number, if applicable.
- Additional notes about performance check, when appropriate.

## 7. **Maintenance**

The QA Specialist is responsible for completing scheduled preventive maintenance for appropriate testing equipment. The QA Specialist should be notified of unscheduled maintenance needs for malfunctioning or damaged items. The QA is responsible for contacting the appropriate service providers (when applicable) and completing all necessary documentation associated with maintenance.

7.1 **Preventive Maintenance:** Preventive maintenance shall be performed on the appropriate testing equipment, according to a set schedule based either on the manufacturer's recommendations or on the FAU's predetermined schedule. The QA Specialist is responsible for maintaining a database of all testing equipment that requires preventive maintenance. At a minimum, the following information should be recorded:

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER</b>		Page:
<b>Forensic Anthropology – Quality Manual</b>		6 of 9
Title: <b>Equipment Management</b>	Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018

- Serial number or Unique Identifying Number.
- Type or name of testing equipment.
- Frequency of preventive maintenance.

7.1.2 **External Vendors:** If maintenance is performed by an external vendor the FAU will maintain a copy of the maintenance records provided by the vendor (hardcopy or electronic).

7.1.3 **Health and Safety Equipment:** Certain health and safety equipment (e.g., fume hoods) shall undergo annual maintenance to make sure they are functioning properly and safely.

7.1.4 **Computer Software:** The FAU should periodically check for major updates of computer software programs that are used during anthropological analyses (e.g., Fordisc).

7.2 **Corrective Maintenance:** When any testing equipment or reference materials fail to meet the performance check requirements, it shall be taken out of service and labeled appropriately to avoid inadvertent use. Only after the item(s) has been properly calibrated and passes a performance check may it be returned to service. Any completed corrective maintenance shall be recorded in the appropriate maintenance records.

7.2.1 **Defective Equipment:** The QA Specialist will review all FAU casework that used defective equipment since the last performance check. Casework will be reviewed to determine if the defective equipment impacted the test results, and if so, the appropriate corrective action will be taken.

7.2.2 **Replacement of Laboratory Equipment and Reference Materials:** For testing equipment and reference materials that can be replaced, rather than undergo corrective maintenance, the equipment shall be removed from circulation and disposed of in an appropriate manner.

7.2.3 **Computer Software:** Any issues with computer software programs shall be referred to the OCME IT department or appropriate external vendor for support or replacement.

## 8. Testing Equipment and Reference Materials

All testing equipment and reference materials shall be stored in such a manner to prevent loss or damage.

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 7 of 9
Title: <b>Equipment Management</b>	Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018

## 8.1 Testing Equipment

Calipers: Calipers are subject to annual performance check by the QA Specialist, wherein a NIST certified ruler is used to check the measurements.

Mandibulometer: The mandibulometer is performance checked by the QA Specialist once a year using the same process as described for calipers for length measurements and via a precision square for the angle measurement component.

Osteometric Board: The osteometric boards are performance checked annually by the QA Specialist using the same process as the calipers.

Tape Measures: Tape measures are performance checked by the QA Specialist annually. If a tape measure fails to pass a performance check or is damaged it shall be replaced with an appropriate tape measure.

Rulers: Rulers used in testing are subject to a one time “initial-use” recorded metric performance check by the QA Specialist prior to being released for general use. Rulers do not need periodic maintenance and/or performance checks. If damaged or otherwise rendered unserviceable, the rulers should be disposed of and new ones ordered.

Digitizer: The digitizer is subject to an annual performance check by the QA Specialist, wherein a NIST certified ruler is used to check the accuracy of the digitizer’s measurements. In the same manner, the digitizer is subject to per-use performance checks when used to take measurements on casework.

Microscope: The FAU microscopes are maintained by the OCME’s Pathology Department through an annual contract service, which includes necessary cleaning and maintenance. The microscopes are subject to per-use performance checks when used to take photographs and/or make measurements. Prior to taking any microscopic photographs the digital scale should be compared to a one of the FAU’s reference rulers.

Digital Scales: All analytical scales are electronically self-adjusting. The analyst may electronically adjust the scale at any time following the instructions outlined in the user’s manual. The QA Specialist shall electronically adjust the scale and conduct a performance check using the appropriate standard weight annually (100 gram or 50 gram weight).

## 8.2 Reference Materials

Casts: Cast materials are subjected to an annual performance check to ensure that there is no visible damage.

<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 8 of 9
Title: <b>Equipment Management</b>	Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018

Photographic Scales: Photographic scales are subject only to the initial use performance check for general adequacy by the QA Specialist prior to general use. These materials do not need periodic maintenance or performance checks. If damaged or otherwise rendered unserviceable (e.g., stained, illegible, and/or presenting an unprofessional appearance), the items should be disposed of and new ones ordered.

Osteological Comparative Material: Osteological comparative material is subject to periodic performance check once per accreditation cycle. The performance check will entail visual inspection of storage bags and boxes for damage, worn labeling, or improper storage. The osteological comparative reference materials are grouped taxonomically and are not required to have unique identifying numbers.

## 9. Documentation

Performance checks, maintenance, and other records for testing equipment, reference materials, and performance check kit reference standards shall be properly maintained by the QA Specialist. The following records shall be maintained with the most up-to-date information:

- Inventory of testing equipment, reference materials, and performance check kit reference standards.
- Calibration, maintenance, and performance check records (refer to sections 6 and 7 for more detail).

## 10. References

ISO 17020:2012 *Requirements for the Operations of Various Types of Bodies Performing Inspection.*

JCGM 200:2012 *International vocabulary of metrology: basic and general concepts and associated terms (VIM).*

## 11. Revision History

REV.	DATE	SUMMARY OF CHANGES
0	1 February 2018	New document.
1	18 October 2018	<p><b>3.0:</b> Added definitions for Measurement uncertainty and Measurand.</p> <p>Created a new 4.0 Section: “<b>Traceability and Measurement Uncertainty</b>” – adjusted the clause numbering to account for this addition throughout the entire document</p> <p><b>5.0:</b> Added a statement that an approved list of FAU testing equipment suppliers is located on the Anthropology share drive.</p> <p><b>6.0:</b> Added the following statement: “A performance check</p>



<b>NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual</b>		Page: 9 of 9
Title: <b>Equipment Management</b>	Control No. QM-004	Revision: 1
Approved by: Forensic Anthropology Director		Effective Date: 18 October 2018

REV.	DATE	SUMMARY OF CHANGES
		<p>shall entail the QA Specialist, or designee comparing the measurements of the testing equipment to another instrument (reference standard) to ascertain if the measurements fall within an acceptable parameter (see 6.2).</p> <p><b>6.2:</b> Changed the clause to include specific accepted metric tolerances for all types of testing equipment.</p> <p><b>7.2.1:</b> Added a section: <b>Defective Equipment:</b> The QA Specialist will review all FAU casework that used defective equipment since the last performance check. Casework will be reviewed to determine if the defective equipment impacted the test results, and if so, the appropriate corrective action will be taken. <b>Replacement of Laboratory Equipment and Reference Materials and Computer Software</b> shifted down to 7.2.2 and 7.2.3, respectively.</p> <p>Changed section <b>10.</b> to references and made revision history section <b>11.</b></p>