1. Policy

Internal audits shall be conducted to verify that operations fulfill the requirements of the ISO/IEC 17020 International Standards.

2. Scope

This quality manual document applies to all FAU personnel who are involved in the internal audit process.

3. Definitions

Audits: An audit is an inspection used to evaluate or verify any activity related to quality assurance. Audits, which may be internal or external, are conducted with the aim of providing the laboratory with an evaluation of performance against existing standards.

Nonconformity: Nonconformity is a nonfulfillment of a requirement.

Preventive Action: A preventive action is an action taken as a proactive measure in order to identify potential nonconformities and opportunities for improvement.

Corrective Action: An action to remediate the cause of a confirmed nonconformity.

4. Internal Audit Procedure

The FAU shall conduct internal audits covering all aspects of the quality system in a planned and systematic manner to verify that the management system and inspection activities continue to comply with the requirements of the Laboratory Quality System and the ISO/IEC 17020 International Standards.

All FAU policies and procedures outlined in the Standard Operating Procedures (SOPs) and Quality documents shall be audited at least once every 12 months. The annual internal audit will typically occur during the month of January, unless circumstances dictate otherwise. Various areas that may require auditing include, but are not limited to, document control, evidence management and security, equipment management, and case file records.

4.1 **Scheduling the Audits:** The Quality Assurance (QA) Specialist is responsible for preparing an annual schedule for the audits. The schedule will identify the topic(s) and approximate dates of the audits. This schedule is used as a guide and may be changed at the discretion of the QA Specialist.

4.2 **Audit Preparation:** The OCME Quality Director, QA Specialist or designee shall manage the audit process. The QA Specialist may select additional auditors when assistance is needed. Audits shall be conducted by personnel who have the requisite

knowledge of the auditing process, the requirements of ISO/IEC 17020 International standard, and when necessary, sufficient knowledge of anthropological inspection activities.

The QA Specialist shall prepare a checklist. The audit checklist outlines the SOP requirements being reviewed for compliance. The checklist should be organized such that it will prompt the auditor(s) to observe operations, review necessary records, and interview personnel when necessary to make sure all requirements for the particular SOP under review are being met. The auditor(s) shall review records and interview personnel, and also observe operations, conditions, and facilities, when appropriate. The auditors shall also review the effectiveness of quality control measures. The audit checklist shall be used to document the audit process.

4.3 **Reporting the Audit**

4.3.1 For every audit conducted, the auditor will provide an audit report of the results to all appropriate members of the FAU. Any preventive actions and/or nonconformities which may or may not result in an official corrective action shall be documented in a clear and concise manner in the audit report.

4.3.2 If an audit report identifies potential nonconformities, a Preventive Action Request shall be included for each of the potential nonconformities with the audit report (see QM-009: Preventive Action). If an audit report identifies nonconformities that require corrective action, a Corrective Action Request shall be included for each corrective action (see QM-008: Nonconformity and Corrective Action).

4.4 **Responding to an Audit Report**: All members of the FAU shall acknowledge that they have received and reviewed the audit report, including any preventive or corrective action requests, by signing and dating the report and returning the original report to the QA Specialist.

4.5 **Tracking the Response to Preventive and Corrective Actions**: The QA Specialist is responsible for tracking all preventive and/or corrective action requests issued during an internal audit. Once a preventive/corrective action request has been addressed the QA Specialist may decide to conduct an additional audit to validate the effectiveness of the preventive and/or corrective action(s). If an audit is required, the appropriate members of the FAU shall be notified in advance and the audit shall be conducted in a timely manner.

4.6 **Closing out the Audit:** After preventive and/or corrective action(s) have been successfully addressed, copy(s) of the closed out Preventive/Corrective Action Request(s) shall be disseminated to all members of the FAU. An audit can be closed out once all the

preventive and corrective action requests have been successfully completed and approved by the QA Specialist or Forensic Anthropology Director. The QA specialist shall send a notification that the audit is closed.

4.8 **Internal Audit Records**: The following records shall be created and retained for at least the current accreditation cycle, unless otherwise stated:

- Annual audit schedule
- Completed audit checklists
- Completed audit reports and any associated responses
- Preventive Action Request and associated responses
- Corrective Action Request and associated responses
- Audit closure notification.

5. External Audit

An external audit of the OCME FAU shall be performed by the ISO/IEC 17020 accreditation body once every accreditation cycle (i.e., once every three years).

6. References

International Standards ISO/IEC 17020: 2012 (E) Conformity assessment - Requirements for the operating of various types of bodies performing inspection, 2nd edition, International Standards Organization (ISO)/International Electrotechnical Commission (IEC), 2012.

7. Revision History

REV.	DATE	SUMMARY OF CHANGES
0	1 February 2018	New document.
1	21 August 2018	Section 4: Included a statement indicating January as the month the annual internal audits will be conducted, unless circumstances dictate otherwise. Section 4.2: Included OCME Quality Director as someone that can lead the internal audit. Also, changed the wording for who can conduct an internal audit.