1. Policy

Internal audits shall be conducted to verify that operations fulfill the requirements of the ISO/IEC 17020 International Standards and ANAB AR 3120 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 FAU Laboratory Quality System, the ISO/IEC 17020 International Standards and ANAB AR 3120 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 require auditing include, but are not limited to, document control, evidence management and security, equipment management, case file records, and results of previous audits.

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 Standards and ANAB AR 3120 Standards, and when necessary, sufficient knowledge of anthropological inspection activities.

The QA Specialist should use an assessment checklist that covers the ISO/IEC 17020 standards and ANAB AR 3120 requirements. The checklist is used as a guide to prompt the auditor(s) to observe operations, review necessary records, and interview personnel when necessary to make sure all applicable requirements are addressed. The auditor(s) shall review records and interview personnel, and 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 identified (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 findings in the audit report by signing and dating the original report.

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. Any actions resulting from the internal audit shall be conducted in a timely and appropriate manner. 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:** An audit can be closed out once the internal audit report has been reviewed and signed by all the FAU staff, and all preventive and corrective action requests have been completed. The QA specialist shall send a notification that the audit is closed.

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

- Completed audit checklists and associated notes
- 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 ANAB once every accreditation cycle and will cover all the Standards in ISO/IEC 17020:2012 and ANAB AR 3120.

6. References

AR 3120: 2023, ANAB Accreditation Requirements Forensic Inspection.

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.