NYC – OFFICE OF CHIEF MEDICAL EXAMINER	Page:	
Forensic Anthropology – Quality Manual	1 of 4	
Title: Internal Audits	Control No.	Revision:
	QM-007	4
Approved by: Forensic Anthropology Director	Effective Date:	12 April 2023

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. **vope**

The cality matual document applies to all FAU personnel who are involved in the internal audit soci

3. Denniti s

Audits. An aud a inspection used to evaluate or verify any activity related to quality assurance. Aud s, which is the internal or external, are conducted with the aim of providing the latest with an expluation of performance against existing standards.

Nonconformity: Nonconformity is a nor sulfillment of a requirement.

<u>Preventive Action</u>: A preserve as an is an action taken as a proactive measure in order to identify potential nonconform sets a proportion of the prevention of the preventio

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

4. Internal Audit Procedure

The FAU shall conduct internal audits overing a daspects of the quality system in a planned and systematic manner to verify that the manager and system and inspection activities continue to comply with the requirement of the FAU Laboratory Quality System, the ISO/IEC 17020 International Standards and ANAP AR 31 2 Standards.

All FAU policies and procedures outlined in the Standar Operator Procedures (SOPs) and Quality documents shall be audited at least once every 12 months of annual internal audit will typically occur during the month of Jaharry, unless circum tances dictate otherwise. Various areas that require auditing include, but the not limited to, document control, evidence management and security, equipment is pagement, one 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

NYC – OFFICE OF CHIEF MEDICAL EXAMINER	Page:	
Forensic Anthropology – Quality Manual	2 of 4	
Title: Internal Audits	Control No. Revision:	
	QM-007	4
Approved by: Forensic Anthropology Director	Effective Date:	12 April 2023

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 A pecialist should use an assessment checklist that covers the ISO/IEC 17020 and ANAB AR 3120 requirements. The checklist is used as a guide to prompt the untor(s) to be be operations, review necessary records, and interview personnel wher necessary to take sure all applicable requirements are addressed. The auditor(s) shall review tecords and interview personnel, and observe operations, conditions, and facilities when appropriate. The auditors shall also review the effectiveness of quality control measure. The audit checklist shall be used to document the audit process.

4.3 Reporting the Ludit

- 4.3.1 For every aut t conducted, the arctitor will provide an audit report of the results to all appropriate members the FAU. Any preventive actions and/or nonconformities that makes may not result in an official corrective action shall be documented in a clear and carcise proper in the audit report.
- 4.3.2 If an audit report identifies prontial conformities, a Preventive Action Request shall be included for a m of the potental 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 (M-008: Nonconformity and Corrective Action).
- 4.4 **Responding to an Audit Report**: All members of the FALL and acknowledge that they have received and reviewed the findings in the audit report by arming and dating the original report.
- 4.5 Tracking the Response to Preventive and Corrective Actions: The QA Special st 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 timely and appropriate manner. Once a preventive/corrective action request has 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

NYC – OFFICE OF CHIEF MEDICAL EXAMINER	Page:	
Forensic Anthropology – Quality Manual	3 of 4	
Title: Internal Audits	Control No.	Revision:
	QM-007	4
Approved by: Forensic Anthropology Director	Effective Date:	12 April 2023

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 accreditation cycle, unless otherwise stated:
 - Commeted audit checklists and associated notes
 - Caple Laudit reports and any associated responses
 - ventive ction Request and associated responses
 - Con tive ction Request and associated responses
 - Aud crosure notification.

5. External Aud

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 Recomment Forensic Inspection.

International Standards ISO/IEC 17020 2012 (Paconformity assessment - Requirements for the operating of various types of bodies pacormin anspection, 2nd edition, International Standards Organization (ISQ) 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 inducting January as the Funth the annual internal audits will be conducted, a less circums ances dictate otherwise. Section 4.2: Included OCME Quality Direct, as someon that can lead the internal audit. Also, changed the wallier of who can conduct an internal audit.	
2	15 October 2018	4.5- Added a statement that any actions resulting from the	
		internal audit shall be conducted in a timely and appropriate	
		manner.	
3	1 March 2021	Edited clause 4.2 to indicate an assessment checklist for ISO/IEC	
		17020 and ANAB standards should be used for the internal audit.	
		Updated clause 4.4 by removing "including any preventive and	
		corrective action requests". This is redundant since reviewing the	

NYC – OFFICE OF CHIEF MEDICAL EXAMINER	Page:	
Forensic Anthropology – Quality Manual	4 of 4	
Title: Internal Audits	Control No. Revision:	
	QM-007	4
Approved by: Forensic Anthropology Director	Effective Date:	12 Aprıl 2023

	audit report implies reviewing any potential nonconformities or nonconformities. Deleted the first sentence in clause 4.6 and edited the statement to indicate that the audit is closed out when the report has been reviewed and signed by staff and the preventive/corrective action requests have been completed. Updated clause 4.8 by deleting the first bullet and added "and associated notes" to "Completed audit checklist".
April 202	In clause 4, last sentence of the second paragraph the word "may" was removed and "results from previous audit" was added. Added reference to ANAB AR3120 document. See number correction "4.8" was changed to "4.7". Updayd the language in clause 5.