

	QM-006 Management Systems	Forensic Anthropology
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**RELEASED UNDER THE AUTHORITY OF THE
FIRST DEPUTY CHIEF MEDICAL EXAMINER**

1. Policy

The Forensic Anthropology Unit (FAU) maintains a management system which is capable of achieving the consistent fulfillment of the requirements of ISO/IEC 17020 International Standards and ANAB AR 3120 Standards in accordance with their “Option A” requirements.

2. Scope

The policies and procedures in this quality management document apply to all FAU personnel.

3. This management system shall address the following:

- Management System Documentation (QM-006: section 4).
- Control of Documents (QM-006: section 5).
- Control of Records (QM-006: section 6).
- Management Review (QM-006: section 7).
- Complaints and Appeals (QM-005).
- Internal Audit (QM-007).
- Corrective Actions (QM-008).
- Preventive Actions (QM-009).

4. Management System Documentation

4.1 The Forensic Anthropology Director (Director) is the top management of the Forensic Anthropology Unit. The Director is committed to establishing, documenting, and maintaining the policies and objectives for fulfillment of ISO/IEC 17020 and ANAB AR 3120 Standards. The Director oversees all FAU personnel to ensure the policies and objectives of the International Standards are acknowledged and implemented.

4.2 The Director provides evidence of his or her commitment to the development and implementation of this management system and the monitoring of activities for compliance with ISO/IEC 1720 and ANAB AR 3120 by implementing annual internal audits, annual management system reviews, preventive actions, corrective actions, and compliance with the quality assurance program.

4.3 The Director shall appoint the unit’s Quality Assurance (QA) Specialist who, irrespective of other duties, has the responsibility and authority to:

- a) Ensure that processes and procedures of the management system are established, implemented, and maintained;

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b) Report to top management on the performance of the management system and any need for improvement.

4.4 The FAU maintains an electronic folder that lists and specifies the documents maintained by the FAU and where, within those documents, are located the policies and procedures that fulfill the requirements of ISO/IEC 17020 and ANAB AR 3120 Standards.

4.5 The FAU personnel have access to all management system documentation and any related information that is applicable to their responsibilities.

5. Control of Documents

5.1 The FAU maintains control of all documents (internal and external) related to the quality system and fulfillment of the ISO/IEC 17020 and ANAB AR 3120 Standards.

5.2 This section describes the procedures for how internal controlled documents are created, accessed, revised, and archived.

a) **Creating Controlled Quality Documents:** Controlled quality documents (e.g., SOPs, Quality Management policy and procedure documents, and controlled forms) are initially created by the FAU's QA Specialist or designee. Quality documents shall be reviewed by all members of the FAU. All comments and suggestions shall be considered before issuing a finalized version.

The FAU may choose to upload controlled quality documents to the OCME managed Ideagen Quality Management (Ideagen) compliance software. Once a document has been uploaded to Ideagen, the document will be assigned a Ideagen document ID and any future changes to the document shall be recorded in the Ideagen system.

b) **Access to Documents:** FAU personnel can access controlled quality documents on the Anthropology network drive and/or on Ideagen. Additionally, a hardcopy of the current versions of documents should be maintained by the QA Specialist and readily available.

c) **Document Review:** Documents shall be reviewed at least annually during internal audits by the QA Specialist or designee. Changes can be made to a document during other times of the year if a change is warranted and the change cannot wait until the annual document review.

d) **Revising Documents:** For controlled quality documents uploaded to Ideagen, revisions to documents shall be recorded within the Ideagen system. All revisions to a document are viewable in the "History" tab under document properties.

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For controlled quality documents not uploaded to Ideagen, all changes to documents are recorded on the “List of FAU Controlled Documents” spreadsheet. The following information shall be recorded for all controlled quality documents not uploaded to Ideagen:

- FAU document control # (e.g., ANTH-001)
- Effective date
- Current revision number
- Dates of revision
- Brief description of revision.

Revisions to controlled documents will remain accessible for comment in Ideagen for 30 days or until reviewed by all FAU personnel, whichever comes first.

- e) **Archiving Documents:** Previous versions of revised quality documents, now considered obsolete, shall be removed from circulation (electronic and hardcopy).

For quality documents not uploaded to Ideagen, an electronic copy of the obsolete version is retained in the appropriate archive folder on the Anthropology network drive and will be saved with an “archived” watermark. Obsolete versions shall be retained following archival designation for at least the current accreditation cycle.

Documents uploaded to Ideagen are rarely deleted. If a document is no longer in use, then the document can be “retired” in Ideagen, meaning it is removed from the visible document tree and placed in a retired folder. Retired documents are still searchable in Ideagen.

All members of the FAU shall be notified to discontinue the use of “obsolete” document(s).

- 5.3 **External Documents:** Documents of external origin, such as reference books/articles and equipment manuals are maintained as either hard copies and stored in one of the secure Anthropology Labs/offices and/or as electronic copies on the Anthropology network Drive.

6. Control of Records

- 6.1 The following section outlines the procedures for the identification, storage, protection, retrieval, retention time, and disposition of FAU’s records related to the fulfillment of ISO/IEC 17020 and ANAB AR 3120 Standards.

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Quality Records: Quality records refer to all records related to the fulfillment of ISO/IEC 17020 and ANAB AR 3120. Quality records include, but are not limited to audit reports, management system reviews, equipment maintenance and performance check records, proficiency test records, preventive/corrective actions, and archived manuals.

Technical Records: Technical records are defined as analytical and administrative documentation as part of individual case files. These include but are not limited to analytical notes, written reports, computer data files, and photographs.

a) Identification

Technical records: Technical records are marked (either handwritten or printed) with the unique case number for identification.

Quality records: Quality records are identified by their descriptive title which will be in the Header/Footer of the document or prominently displayed near the top of the document, and in their saved electronic document name.

b) Indexing

Technical records: Technical records are indexed by their assigned unique case numbers.

Quality records: Quality records are indexed according to the type of record (i.e., audit reports, management system reviews) and by the date the record was created.

c) Record Storage

Technical Records: In-progress technical records are maintained with the assigned analyst or reviewer at their respective workspaces. Finalized technical records are filed or otherwise stored within designated secure anthropology laboratories or offices, the Anthropology network drive, and uploaded to CMS (when applicable) after all necessary reviews are complete.

Quality Records: Electronic quality records are stored on the Anthropology network drive, in appropriately named folders. Hardcopy quality records are stored in one of the secure Anthropology labs or office spaces.

d) Record Access, Retrieval, and Protection

Access to department records is restricted to those individuals with approved access to the anthropology laboratories in building 520 where the FAU records are stored. Electronic records saved on the secure Anthropology network drive are accessible only to select OCME personnel and FAU interns, visiting scientists, and external researchers with approved access. The department's network is backed-up by the NYC Department

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of Information Technology and Telecommunications (DOITT) to ensure the availability of data.

e) Record Retention

Technical Records: The FAU follows the New York City Charter which prohibits the destruction of any record relating to official casework (i.e., technical records) without consent from the New York City Department of Records and Informational Services (DORIS), Corporation Counsel, and the Office of Chief Medical Examiner.

Quality Records: Hardcopies of FAU Quality records shall be retained for at least the current accreditation cycle. Electronic versions of FAU Quality records will be retained indefinitely on the anthropology network drive.

f) Disposal

Technical Records: In the unlikely event that the destruction of records becomes necessary, the OCME Legal Department will be consulted first, and will act as a liaison with DORIS and the Corporation Counsel.

Quality Records: At the end of an accreditation cycle, the QA Specialist can dispose of hardcopy versions of Quality system documents such as Internal audit reports, performance check logs, management system review reports. All Quality documents shall be backed up on the anthropology network drive prior to disposal of hard copy versions.

7. Management Review

7.1 The FAU's top management has established procedures to review its management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review will evaluate the unit's policies and objectives related to the fulfillment of ISO/IEC 17020 and ANAB AR 3120.

7.2 The management system review shall be conducted annually and will evaluate the management system records for the prior year. If the review process is broken up into segments, the entire review shall be completed within a 12-month time frame.

7.3 Review Inputs

The input to the management system review shall include information related to the following:

- a) The results of internal and external audits.
- b) Feedback from clients and interested parties related to the fulfillment of this International Standard.
- c) The status of preventive and corrective actions.

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- d) Any follow-up actions from previous management reviews.
- e) The fulfillment of objectives.
- f) Changes that could affect the management system.
- g) Appeals and complaints.
- h) Impartiality risk identification.
- i) Adequacy of current personnel and equipment resources.
- j) Projected workloads.
- k) The need for training of both new and existing staff.
- l) Effectiveness of systems established to ensure adequate competence of the personnel.

7.4 **Review Outputs:**

The output from the management system review includes decisions and actions related to:

- a) Improvements of the effectiveness of the management system and its processes.
- b) Improvement of the FAU related to the fulfillment of this International Standard.
- c) Personnel and equipment resource needs.