

NYC – OFFICE OF CHIEF MEDICAL EXAMINER		Page:
Forensic Anthropology – Quality Manual		1 of 5
Title: Management Systems	Control No. QM-006	Revision: 2
Approved by: Forensic Anthropology Director	Effective Date: 15 October 2018	

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 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. 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 the International Standards by implementing annual internal audits, annual management 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;
- b) Report to top management on the performance of the management system and any needs for improvement.

NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual		Page: 2 of 5
Title: Management Systems	Control No. QM-006	Revision: 2
Approved by: Forensic Anthropology Director		Effective Date: 15 October 2018

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 Standard.

4.5 All FAU personnel have access to all parts of the 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 International Standard.

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

- a) Controlled Quality Documents 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.

Note: All draft versions of Quality Documents shall be clearly marked as a draft.

- b) 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.

- c) Changes to documents are identified by three methods:

1. A spreadsheet named “List of FAU Controlled Documents” is maintained, which lists all FAU controlled documents, their document control # (e.g., ANTH-001), effective date, current revision number, dates of revisions, and brief description of the revisions.
2. The FAU SOPs and Quality Manual documents contain a revision section at the end of each document. This section records the revision number, revision date, and description of the revision(s).
3. The previous versions of revised document(s), now considered obsolete, shall be removed from circulation and a copy is retained in the archive folder on the Anthropology network drive. Obsolete versions of Quality Documents shall be retained for at least one accreditation cycle.

NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual	Page: 3 of 5	
	Control No. QM-006	Revision: 2
Title: Management Systems		
Approved by: Forensic Anthropology Director	Effective Date: 15 October 2018	

- d) All FAU personnel have access to the Anthropology network drive which stores all the Quality Documents including, but not limited to, the Quality Manual, SOPs, official forms, and various logs.
- e) Hand written documents, e.g. completed analytical forms, sketches, and logs shall be legible. The person(s) performing the technical and administrative reviews on these documents shall inspect them to ensure they are legible and contain the unique case number.
- f) Documents received from other departments of the NYC OCME or another agency shall be appropriately identified and shall not be distributed by FAU personnel to anyone outside the unit.
- g) When a document becomes “obsolete,” an electronic copy shall be watermarked “Archived” and retained on the Anthropology network drive in a folder titled “Archive.” Obsolete versions shall be retained for at least five years following archival designation. All members of the FAU shall be notified to discontinue the use and delete/destroy all electronic and hard-copies of the “obsolete” document(s).

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 International Standards ISO/IEC 17020.

Quality Records: Quality records refer to all records related to the fulfillment of this International Standard. 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 are marked (either handwritten or printed) with the unique case number for identification. **Quality records** are identified by the appropriate information located in the Header and/or Footer of the document. Information included on Quality records includes, but is not limited to: the document title, document control number, revision number, and effective date.

NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual		Page: 4 of 5
Title: Management Systems	Control No. QM-006	Revision: 2
Approved by: Forensic Anthropology Director		Effective Date: 15 October 2018

b) Indexing

Technical records are indexed by their assigned unique case numbers. **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 work spaces. Finalized technical records are filed or otherwise stored within designated anthropology laboratories or offices, the Anthropology network, 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 lab or office spaces.

d) Record Access, Retrieval, and Protection

Access to department records is restricted to those individuals with approved access to the areas 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 with approved access. The department's network is backed-up by the NYC Department of Information Technology and Telecommunications (DOITT) to ensure the availability of data.

e) Record Retention

The Forensic Anthropology Unit follows the New York City Charter which prohibits the destruction of any record without consent from the New York City Department of Records and Informational Services (DORIS), Corporation Counsel, and the Office of Chief Medical Examiner.

f) Disposal

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.

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.

NYC – OFFICE OF CHIEF MEDICAL EXAMINER Forensic Anthropology – Quality Manual		Page: 5 of 5
Title: Management Systems	Control No. QM-006	Revision: 2
Approved by: Forensic Anthropology Director		Effective Date: 15 October 2018

7.2 The management system review should be conducted annually in March and will review the management system 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 Copies of each year’s management review shall be retained, electronically, for at least ten years following the review.

7.4 Review Inputs

The input to the management 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.
- 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.

7.5 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.

8. Revision History

REV.	DATE	SUMMARY OF CHANGES
0	30 January 2018	New document.
1	21 May 2018	5.2.g – added a comment that obsolete documents shall be watermarked as “Archived.” Punctuation changes throughout the document. Changed first REV. to 0 instead of 1.
2	15 October 2018	7.2- added a statement that management reviews will be conducted annually in March.