FORENSIC BIOLOGY
ADMINISTRATIVE MANUAL

Approving Authority: Timothy D. Kupferschmid, Laboratory Director

Table of Contents

Staff Roles and Responsibilities

GUIDING PRINCIPLES AND SCOPE

Staff roles and responsibilities within the Department of Forensic Biology are defined and organized so that the services provided by the Department can be conducted to a high standard of professionalism, efficiency, and accuracy.

This document describes the responsibilities, authorities, and interrelationships of Forensic Biology staff.

ORGANIZATIONAL STRUCTURE

The Director of the Department of Forensic Biology is a member of the Executive Staff of the Office of Chief Medical Examiner (OCME) and reports directly to the head of the agency, the Chief Medical Examiner. See the OCME Organizational Chart. Some support services, such as Human Resources and Finance, are provided to the Department of Forensic Biology by other departments within the OCME

The Department of Forensic Biology is a single operational unit organized into various teams by primary case type worked, e.g., property crimes, or by primary operational responsibility, e.g., quality assurance. The Forensic Biology Organizational Chart shows the structure.

ROLES AND RESPONSIBILITIES

Director

The Director is responsible for the overall scientific, quality, and administrative operations of the Department of Forensic Biology. The Director may perform administrative and technical reviews on selected cases. The Director prepares productivity, statistical reports, and audit reports, as required by Chief Medical Examiner and/or City, State, or Federal agencies. The Director may perform scientific analyses, train subordinates, testify in court, monitor testimony of subordinates, and prepare annual reviews of subordinates. The Director establishes guiding principles for the operation of the Department.

Deputy Directors

Deputy Directors assume the responsibilities of the Director in the Director's absence. Deputy Directors supervise Assistant Directors and work with them to achieve Department goals. Deputy Directors may assist the Director to develop guiding principles for the operation of the Department, perform scientific analyses, perform technical reviews of cases, review proficiency tests performed by Assistant Directors or others, train subordinates, testify in court, monitor testimony of subordinates, prepare annual reviews of subordinates, and complete miscellaneous projects as assigned by the Director.

Assistant Directors

Each Assistant Director leads an operational team within the Department. They manage the work of the team in order to achieve Departmental goals; supervise one or more Criminalist IV's and their subordinates; perform technical reviews of cases supervised by and/or worked on by subordinates; assist with the training of new hires or promoted staff, police investigators, or attorneys; represent the Department of Forensic Biology in meetings with other NYC law enforcement and/or criminal justice agencies; communicate with stakeholder agencies regarding testing requests and results; and triage evidence. In the absence of the Director and Deputy Directors, a designated Assistant Director will be assigned the responsibility for overseeing the administrative operation of the Department of Forensic Biology. An Assistant Director may perform scientific analyses on casework and testify in court. Assistant Directors prepare annual performance evaluations of subordinate personnel.

LIMS Administrator

The Forensic Biology LIMS Administrator is responsible for the implementation, maintenance and future development of the laboratory's LIMS program. The LIMS Administrator acts as a liaison between Forensic Biology and the OCME Information Technology department in all aspects pertaining to LIMS and other computer applications.

Technical Leaders

Technical Leaders are accountable for the technical operations of the laboratory. The Department has two DNA Technical Leaders (one for nuclear DNA operations and one for mitochondrial DNA operations) and one Serology Technical Leader. Each DNA technical leader has the authorities and responsibilities described in the FBI DNA Quality Assurance Standards. For specific information, see the DNA TECHNICAL LEADERS document in the Forensic Biology Administrative Manual.

CODIS Custodian/Supervisor

The CODIS Custodian/Supervisor is equivalent to the "Casework CODIS Administrator" position described in the "Quality Assurance Standards for Forensic DNA Typing Laboratories" and as such is the system administrator of the laboratory's CODIS network. For a specific list of duties and responsibilities see the Forensic Biology CODIS Manual.

Quality Assurance Manager

The Quality Assurance Manager is responsible for the overall implementation and maintenance of those aspects of the Department of Forensic Biology management system related to quality. The responsibilities are varied and meet ASCLD/LAB requirements and the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories. The Quality Assurance Manager supervises the Quality Assurance Unit, which is responsible for conducting numerous quality control activities within the Department.

Criminalist, Level IV

The responsibilities of Criminalist IV's are described in the Civil Service specifications for that title and in the Tasks and Standards documents. Generally, a Criminalist IV may supervise one or more Criminalist III's, II's, and/or I's, perform scientific analyses on evidence submitted to the laboratory, perform technical reviews of cases, prepare scientific reports, prepare annual performance evaluations as requested by OCME management, communicate with stakeholder agencies regarding testing requests and results, triage evidence, participate in the training of subordinates, testify in court, take proficiency tests as required by regulating and accrediting bodies, work on designated projects, and supervise analytical rotations in the laboratory.

Criminalist, Level III

The responsibilities of Criminalist III's are described in the Civil Service specifications for that title and in the Tasks and Standards documents. Generally, Criminalist III's may supervise Criminalist II's and/or Criminalist I's. Criminalist III's may also supervise and/or work in rotations: DNA extraction, DNA quantitation, P30 ELISA, STR analysis and review, perform scientific analyses on evidence submitted to the laboratory, prepare written scientific reports, perform technical reviews of simple cases, perform administrative reviews on DNA cases, train new Laboratory Associates and Criminalists, take proficiency tests as required by regulating and accrediting bodies, and testify to results. In the absence of a Criminalist IV, a Criminalist III may assume those responsibilities on an interim basis.

Criminalist, Level II

The responsibilities of Criminalist II's are described in the Civil Service specifications for that title. Generally, Criminalist II's are responsible for the daily examination and scientific work performed on evidence in casework, working in rotations, training new Criminalists, taking proficiency tests as required by regulating and accrediting bodies, preparing written scientific reports which reflect testing, and testifying to results. These scientists are examiner/analysts as defined by the FBI Quality Assurance Standards.

Criminalist, Level IA & IB

The responsibilities of Criminalist I's are described in the Civil Service specifications for that title. Generally, Criminalist I's are responsible to work in rotations in the laboratory and, after appropriate training, may examine rape kits and other small items of evidence, prepare written scientific reports on "negative" serology cases, and may testify in court, if required by an Assistant District Attorney. Criminalist I's who are performing casework must take proficiency tests as required by regulating and accrediting bodies. These scientists are DNA technicians as defined by the FBI Quality Assurance Standards.

City Research Scientist

The responsibilities of City Research Scientists are described in the Civil Service specifications for that title and in the Tasks and Standards documents. City Research Scientists conduct research and develop new scientific methods for the Department of Forensic Biology. Some City Research Scientists may be trained in DNA analysis, and those levels that are tasked to supervise may do so for other City Research Scientists or those in the Criminalist title. Generally, for those trained in DNA analysis, the responsibilities of a City Research Scientist, Level IV-A or Level IV-B are equivalent to the responsibilities of a Criminalist, Level IV; the responsibilities of a City Research Scientist, Level III are equivalent to the responsibilities of a Criminalist, Level III; the responsibilities of a City Research Scientist, Level II are equivalent to the responsibilities of a Criminalist, Level II; and the responsibilities of a City Research Scientist, Level I are equivalent to the responsibilities of a Criminalist, Level IA & IB.

Training Coordinator

The Training Coordinator is responsible for the scheduling and training of all scientists in the laboratory. The Training Coordinator reports to an Assistant Director. The Training Coordinator is responsible for maintaining training records and ensuring that the Department meets NYS and accreditation standards.

Forensic Biology Health and Safety Coordinator

The NYC Office of Chief Medical Examiner (OCME), Health and Safety Unit has an Agency-appointed Safety Officer for the Department of Forensic Biology. The Department of Forensic Biology appoints a Health and Safety Coordinator to assist with safety and compliance efforts in the laboratory, as necessary. The duties of the Safety Coordinator include, but are not limited to:

- Assisting the Agency-appointed Safety Officer in developing and implementing appropriate laboratory safety policies, practices, and procedures.
- Conducting an annual review of the Safety-related Manuals to ensure that all documents are up-to-date and to inform the Agency-appointed Safety Officer of any suggested revisions.
- Ensuring that the OCME Health and Safety Manuals (including the OCME Bloodborne Pathogen Exposure Control Plan, OCME Chemical Hygiene Plan, and the OCME Respiratory Protection Plan) is readily accessible to all employees, either as a paper copy, electronic copy online, or by other applicable means.
- Communicating to Forensic Biology staff any relevant safety information or concerns.
- Inspecting laboratories for compliance with the OCME Health and Safety Manuals.

- Assisting Laboratory Supervisors with maintaining laboratory compliance.
- Acting as a liaison to the Health and Safety Unit by assisting with laboratory safety inspections, coordinating safety training, and maintaining overall lab compliance, including hazardous waste management.

Administrative Supervisor(s)

Administrative Supervisors are in charge of the administrative support functions of the Department. Administrative Supervisors supervise a team of administrative professionals and ensures the proper handling of phone coverage; administrative review of casework files and distribution of reports; generation of certified copies of casework files for attorneys; and maintenance of casework files in archive, timecard and payroll handling. Administrative Supervisors may also oversee the management of all Departmental procurement matters and Departmental human resource functions including recruitment, retention, employee relations, and performance evaluations.

Administrative Staff

Administrative staff assists in the proper handling of phone coverage; administrative review of casework files and distribution of reports; generation of certified copies of casework files for attorneys; and maintenance of casework files.

Evidence and Property Control Specialists

The EPCS staff is responsible for creating Forensic Biology cases for evidence that has been submitted to the OCME Evidence Unit. They evaluate the submitted evidence and its associated administrative documentation; create the initial “Schedule of Analysis”; and follow-up with the submitting agency for additional information as needed.

Revision History:

February 9, 2010 – Initial version of procedure.
May 20, 2010 – Added the Role and Responsibility of the Forensic Biology Health and Safety Coordinator.
February 2, 2012 – Added the City Research Scientist role; updated the titles and roles of LIMS Administrator (formerly IT Manager) and Administrative Supervisor (formerly Administrative Manager).
October 29, 2013 – Role of the Administrative Supervisor revised to allow for multiple administrative supervisors; Role of Technical Leader revised to include Serology Technical Leader; Role of Quality Assurance Manager revised to eliminate its joint function as the Serology Technical Leader and the Nuclear DNA Technical Leader

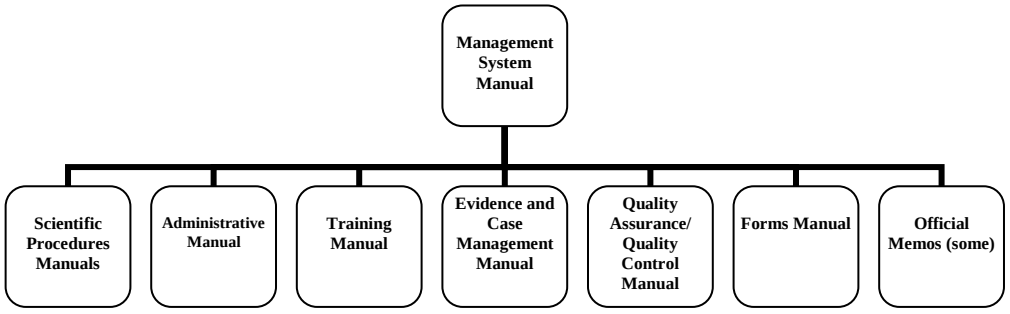
Document Control

I. Guiding Principles and Scope

The Department of Forensic Biology controls all documents that comprise its management system in order to ensure that invalid and/or obsolete documents are not used. This procedure describes how controlled documents are created, revised, distributed, and archived.

II. General Structure of Management System Documents

A. Internal Documents. The internal documents that comprise the management system are structured as follows:



- **Management System Manual:** The Management System Manual is the top tier document in the management system. It provides an overall guide to the management/quality system of the Department of Forensic Biology. It contains references to other management system documents that have more detailed information. In terms of Standard 4.2.2 of ISO 17025:2005, this is our "quality manual."

- **Scientific Procedures Manuals:** These manuals contain current procedures pertaining to the analytical testing of biological specimens. The manuals are: Serology Manual, STR Analysis Manual, Mitochondrial DNA Analysis Manual, and CODIS Manual.

- **Administrative Manual:** This manual contains procedures with laboratory-wide application pertaining to laboratory planning, organization, and documentation.

- **Quality Assurance/Quality Control Manual:** This manual contains procedures pertaining to the Department's quality assurance and quality control activities, for example, proficiency testing, reagent preparation and performance testing, validation, and equipment calibration and maintenance programs.

- **Evidence and Case Management Manual:** This manual contains procedures related to (1) evidence intake, distribution, and return; and (2) case handling, including evidence examination guidelines; handling, evaluation, and troubleshooting of cases which are in progress; report writing and reviews.

- **Training Manual:** The Training Manual details in-house training in the Department.

- **Forms Manual:** Forms are used to record information. Their use is specified in various procedures. Most official forms are compiled in the Forms Manual; however, forms used by the Quality Assurance team may be in an appendix in the Quality Assurance/Quality Control Manual.

- **Official Memos:** Official memos are used within the Department to document the distribution of operational information to staff and operational agreements between the Department and its customers. Some memos convey guidelines for issues that do not fall under the Department's management system, e.g., dress codes. However, other memos may address issues that do have an operational impact and are considered to be controlled documents.

- **Master List:** The current revision status and distribution of all documents that are part of the management system, whether internal or external are recorded in various Master Lists. The table of contents for a procedures or forms manual is the "Master List" for the documents contained within the particular manual. A Master List of active memos is maintained, as is a separate Master List for external management system documents.

B. External Documents. *External documents* are also part of the management system documentation. These may include, but are not limited to, accreditation requirements, OCME and Department of Health and Mental Hygiene (DOHMH) policies and procedures, and instrument manuals. References to applicable controlled external documents are found in internal management system documents.

III. Responsibility and Authority for Document Control

- **The Laboratory Director and/or Deputy Directors** have the primary responsibility and authority for approval of the Management System Manual and all guiding principles and procedures that are under the Administrative Manual. The directors may also act as back-up approvers for all other documents; however, where DNA Technical Leader authorization is needed, the approval can be done only where the director is acting as the designated deputy Technical Leader in the absence of the primary DNA Technical Leader.

- **The Quality Assurance Manager (QAM)** has the primary responsibility and authority for implementation and maintenance of the document control system. The QAM is also the primary approver of all guiding principles and procedures that are under the Quality Assurance/Quality Control Manual, Evidence and Case Management Manual, and Serology Manual.

- **The Nuclear DNA Technical Leader** has the primary responsibility and authority for approval of procedures in the Protocols for Forensic STR Analysis Manual; is principal or co-approver of the proficiency testing program; and is principal or co-approver of the Nuclear DNA training program content in the Training Manual.

- **The Mitochondrial DNA Technical Leader** has the primary responsibility and authority for approval of procedures in the Mitochondrial DNA Analysis Manual; principal or co-approver of the proficiency testing program; and principal or co-approver of mitochondrial DNA training program content in the Training Manual.

- **The Training Manager** has the responsibility and authority for approval of the Training Manual.

- **The CODIS Manager** has the responsibility and authority for approval of the CODIS Manual.

- **The Document Control Coordinator (DCC)** works under the direction of the Quality Assurance Manager and has the primary responsibility and authority to ensure that: guiding principles and procedures are in the correct format, the most current approved internal management system documents are on the Forensic Biology server, the Master Lists of documents are accurate, and obsolete documents are suitably marked and archived.

- **Assistant Directors** have the authority and responsibility to propose new and revised

guiding principles and procedures and to provide expertise for the review of document proposals.

- **All Forensic Biology staff** has the authority and responsibility to propose new and revised management system documents.

I. DOCUMENT FORMAT

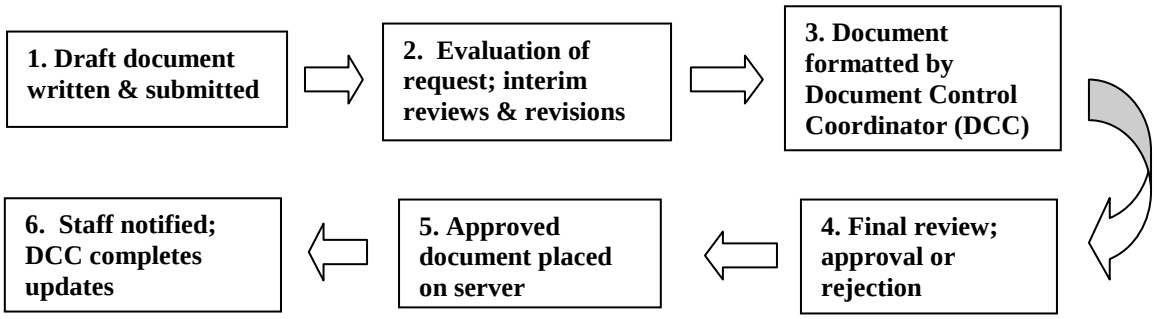
1. All management system documents generated by the laboratory are marked with:

i. Name or title of the document
ii. The name and/or title of the approving authority
iii. The effective date and/or date of approval
iv. Page numbering in an "page x of x" format

2. Stand-alone manuals (e.g., manuals that are not compilations of individually approved procedures) and individual procedures include a revision history.

II. CREATION, REVISION, AND APPROVAL OF MANUALS, PROCEDURES AND FORMS

The process for creating new or revised manuals, procedures, and forms is:



Step 1. Draft document written & submitted

- All documents except for forms are submitted to the Quality Assurance Manager
- Forms are submitted to the chair of the Forms Committee
- The top portion of a "Request for Document Creation/Change" form is completed and submitted with the draft document.
- For ease of document creation, the preferred format for a draft document is an electronic "Word" file.
  - Staff should request an unprotected electronic copy of the document(s) they wish to revise from the Quality Assurance Manager or Document Control Coordinator.
  - "Track changes" should be active for document revisions so that the proposed changes are apparent to a reviewer.

Step 2. Evaluation of Request; Interim reviews & revisions

- Feedback should be sought from knowledgeable staff members who would be affected by the requirements of the document.
- The Forms Committee evaluates requests for new and revised forms.
- Based on the feedback obtained, the Quality Assurance Manager may recommend at this stage that the document change/creation request be rejected.
  - The recommendation is discussed with the Approver.
  - If the Approver agrees with the recommendation, the "Approval" section of the "Request for Document Creation/Change" is completed as per Step 4.
  - If the Approver feels that the request has merit, the document continues through the approval process.
  - Performance checks must be conducted for forms containing macros, and the documentation provided to the Quality Assurance Manager.

Step 3. Document formatted by Document Control Coordinator

- Formatting includes ensuring that the document has the correct header and footer layout.

Step 4. Final review; approval or rejection

- The Approver completes the "Approval" section on the "Request for Document Creation/Change" and forwards the form to the Quality Assurance team for filing.
  - If the proposed document is not approved, the requestor is notified of the reason(s) for the rejection.
- If approved, the Quality Assurance Manager or their designee enters the "Effective Date" and the identity of the Approver (either by name or title) into the new or revised document.

Step 5. Approved document placed on server

- The Document Control Coordinator or designee places the new or revised document on the Department server.
  - The documents on the server are the official "controlled copies" for internally generated management system documents.
  - The documents on the server are protected against unauthorized changes by creating a protected template version of the original document.

Step 6. Staff notified; Document Control Coordinator completes updates

- The Document Control Coordinator or designee performs the following tasks:
  - Updates the Table of Contents or other applicable "Master List"
  - Archives out-of-date documents, as applicable
    1) Archived documents are marked with "Archived" (or equivalent), the date archived and the identity (by position or name/initials) of the archiver.
    2) Electronic copies of archived internal management system documents are retained indefinitely.
    3) Access to archived documents is restricted to the Quality Assurance Manager, Document Control Coordinator, Director and Deputy Directors.
    4) Requests by staff for copies of archived documents must be submitted in writing to the Quality Assurance Manager.
  - Files the completed "Request for Document Creation/Change" and a copy of the draft document (from Step 1)
- Staff discards printed copies of obsolete versions of documents.

Note: Interim revisions to controlled documents are not allowed**.**

III. OFFICIAL MEMOS

Official memos are used within the Department to document the distribution of operational information to staff and operational agreements between the Department and its customers. Memos fall under the Department's document control system only when the content impacts testing or the management system. This procedure describes the parameters by which official memos are created and archived.

The authority and responsibility to issue official memos is restricted to managers (assistant directors, deputy directors, and director).

1. Official memos are prepared on Department letterhead and must identify the author and date of issue.
2. Official memos are protected against unauthorized changes, retained on the Department server, and grouped in folders by year of distribution.
3. A memo that is out-of-date is marked "archived" (or equivalent) and with the date archived and the identity (by name or position) of the individual who is archiving the document.
    a. The memo is retained in its original location on the server and the file name is modified to include the word "archived".
    b. Electronic copies of archived memos are retained indefinitely.

IV. PERIODIC DOCUMENT REVIEW

1. The Quality Assurance Manager creates a document review schedule to ensure that all documents that form part of the management system are reviewed at least once during a calendar year.

2. The schedule lists the documents, the staff responsible for review, and the proposed date(s) by which the review is to be completed.

3. The staff member responsible for the review of a document is the approving authority. For example, the review of technical DNA procedures is assigned to the appropriate DNA Technical Leader.

4. The approving authority may designate other reviewers, but retains the ultimate responsibility for ensuring that the document is current and correct, or is revised as needed.

5. Each assigned reviewer notifies the Quality Assurance Manager in writing when their assigned reviews are complete. The notification includes the results of the review for each assigned document, that is, whether: (1) revisions are needed, (2) the document is satisfactory, or (3) the document is no longer needed.

6. The records of review are maintained by the Quality Assurance team.

7. Document revisions, if needed, are completed as per the process described in Section V.

V. RELEASE OF MANAGEMENT SYSTEM DOCUMENTS TO EXTERNAL PARTIES

1. Requests for the release of Department of Forensic Biology management system documents to parties external to the Department must be made in writing. If the external party is an attorney making a discovery request, refer to the ATTORNEY REQUESTS procedure.

2. The Quality Assurance Manager has the authority and responsibility to consider all such requests and may require documentation from the requestor with regard to their proposed use of the document(s).

3. The Quality Assurance Manager may consult with an OCME Legal Counsel.

4. Records of all requests and their dispositions are maintained by the Quality Assurance team.

Revision History:

February 9, 2010 – Initial version of procedure.

May 20, 2010 – Revised the Responsibility and Authority of the Director, Deputy Director(s), and the Quality Assurance Manager to specify the responsibility for the approval of the Management System Manual, Administrative Manual, Quality Assurance/Quality Control Manual, Evidence and Case Management Manual, and the Serology Manual.

Control of Records

GUIDING PRINCIPLES AND SCOPE

All Department of Forensic Biology quality and technical records will be legible and readily retrievable from storage.

This section will establish the procedures for the identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records.

PROCEDURE

Quality Records include, but are not limited to, audit reports, personnel qualifications, management system reviews, proficiency test records, archived manuals, court testimony monitoring records, quality incident review reports, preventative actions, and reagent and equipment performance verifications and maintenance.

Technical Records are defined as examination and administrative documentation as part of individual laboratory case files. These include, but are not limited to, written reports of analytical findings, interpretations, and conclusions formed from these findings; bench notes, worksheets, computer data files associated with electropherograms, printed electropherograms, etc. used to reach these conclusions.; records of phone conversations, court orders, and discovery requests.

A. Identification

Technical records are prepared whenever examinations are performed and are marked (either handwritten or computer printed) with a laboratory number for identification and association to a case record.

Quality records are identified by appropriate information on the records, such as a header with the title of the record.

B. Indexing

Technical records are indexed by the laboratory 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. Collection

Records are collected for filing and/or storage in a timeframe which varies according to the specific type of record. For example, electropherograms are collected with other records that are associated with the same laboratory number; calibration records are collected with other calibration records associated with the same equipment.

D. Maintenance – Filing, Storage, and Access to Records

All Departmental records are filed or otherwise stored in designated areas within the DNA Building after all necessary reviews are completed.

Access to Department records is restricted to those individuals with approved access to the secure areas of the building where records are stored.

- Most hard-copy case files are stored in the OCME Records department.
- Hard-copy quality records that have any degree of confidentiality (such as personnel qualifications and court testimony monitoring records) are stored in the Quality Assurance Unit and are accessible only to Quality Assurance personnel.
- Other hard-copy technical and quality records are stored appropriately with the person/unit responsible for the record, such as the OCME Records department, the Quality Assurance Unit, the Training Unit, or with the DNA Technical Leaders.

Electronic records saved on the Department's secure network are accessible only to Department of Forensic Biology personnel. The Department's network is backed-up by the NYC Department of Information Technology and Telecommunications (DOITT) to ensure the availability of data.

Records produced by the Department of Forensic Biology may be converted to another format should storage space become an issue (e.g., hard copies scanned and uploaded to a secure network). Alternatively, the New York City Department of Records and Informational Services (DORIS) can arrange for storage space of hard copy records for all New York City agencies. Should the services of DORIS be needed, the OCME Legal Department will be consulted and will act as the Department's liaison with DORIS.

E. Retention

The New York City Charter prohibits the destruction of any record without consent from the New York City Department of Records and Informational Services (DORIS) and the Corporation Counsel. Therefore, it is the practice of the Department of Forensic Biology to retain records indefinitely.

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.

Revision History:

February 9, 2010 – Initial version of procedure.

May 20, 2010 – Inserted section entitled "Retention" to clarify the Department's Record Retention Practice and moved the first paragraph of the "Disposal" section to "Retention."

July 16, 2012 – Revised Section D.3 to clarify where hard-copy records may be stored.

Management System Review

GUIDING PRINCIPLES AND SCOPE

Department of Forensic Biology management is committed to operating the Department within a management system that is appropriate to the scope of its activities and that meets the needs of the Department's customers and accrediting authorities. Management's participation in an annual review of the management system demonstrates this commitment and allows opportunities for improvement to be identified and acted upon.

This document describes the procedure for the periodic review of the management system.

PROCEDURE

1. During the first half of each calendar year, the DNA Technical Leaders and Quality Manager evaluate/review the following management system activities covering the time period subsequent to the previous year's management system review.

    - Action items from the previous management review (if applicable)
    - The suitability of guiding principles and procedures;
    - The suitability of the management system manual and training manual;
    - Reports from managerial and supervisory personnel;
    - The outcome of internal audits;
    - Quality incident reviews
    - Preventive actions;
    - Assessments and/or audits by external bodies;
    - The results of inter-laboratory comparisons or proficiency tests;
    - Changes in the volume or type of work;
    - Customer feedback;
    - Complaints;
    - Recommendations for improvement;
    - The suitability of the quality principles statement and overall objectives;
    - Validation of analytical procedures;
    - Quality control activities, resources and staff training;
    - Safety program

2. The DNA Technical Leaders and Quality Manager may delegate portions of the evaluations/reviews to other staff.

3. The results of the evaluations/review are compiled into a written report by the DNA Technical Leaders and Quality Manager. The target date for completion of the report is June 30.

    a. The report should include critical assessments with respect to whether the information indicates that changes are needed in any aspect of the Department's management system:

4. A copy of the report signed by the Technical Leaders and Quality Manager is provided to all managers.

5. The DNA Technical Leaders and Quality Manager will schedule a "Management System Review" meeting of the Department's mangers to discuss the contents of the report and what its conclusions mean with respect to (a) the suitability and effectiveness of the management system and (b) whether changes or improvements are needed. The meeting should take place within one month of management's receipt of the report.

    a. An agenda for the meeting is prepared.
    b. Minutes of the meeting are kept.

6. When applicable, follow up actions are developed to address needed changes or improvements to the management system.

    a. The Director assigns the follow up actions to specific personnel and specifies the timelines for their progress.
    b. The progress of action items may be tracked during regularly scheduled management meetings and documented in the meeting minutes. The Quality Manager documents the completion of action items.

7. Documentation of Management System Reviews is treated as records, and is maintained in accordance to the CONTROL OF RECORDS procedure.

Note: Changes and improvements to the management system need not be limited to this annual review. Feedback from any of the activities listed in Step 1 may indicate the need for expedited changes or improvements to the management system.

Revision History:
February 9, 2010 – Initial version of procedure.

DNA Technical Leader

GUIDING PRINCIPLES AND SCOPE

The Department shall have experienced and qualified individuals serving as DNA Technical Leaders. While a single individual can serve as the DNA Technical Leader for all technologies in which the Department conducts DNA casework (Autosomal STR, Y-STR, and Mitochondrial DNA Testing), it is possible that more than one individual can be appointed to serve as a DNA Technical Leader for different technologies.

This section defines the job duties of a DNA Technical Leader and the education and experience required to be appointed as a DNA Technical Leader. This section also defines a contingency plan in case the position of the DNA Technical Leader has been suddenly vacated.

RESPONSIBILITIES

The DNA Technical Leader:

- Is accountable for the technical operations of the laboratory and is responsible for technical problem solving.
- Has the authority to initiate, suspend, and resume DNA analytical operations for the laboratory or an individual.
- Evaluates all DNA validation and methods, and oversees the training, quality assurance, and proficiency testing programs.
- Is responsible for reviewing the academic transcripts and training records for newly qualified analysts and approves their qualifications prior to their conducting independent casework analysis to ensure that they are in compliance with accreditation guidelines.
- Approves the technical specifications for outsourcing agreements.
- Conducts an annual review of the procedures of the laboratory.
- Serves as the Deputy DNA Technical Leader for the other technologies within the laboratory for which a permanent DNA Technical Leader has been appointed.

EDUCATION AND EXPERIENCE

The DNA Technical Leader shall have a minimum of a Master's degree in biology-, chemistry-, or forensic science-related area. He/She must have twelve (12) semester hours or equivalent credit hours, including at a minimum, one graduate level class registering three (3) or more

semester hours or equivalent credit hours, covering the subject areas of biochemistry, genetics, molecular biology, and statistics and/or population genetics.

The DNA Technical Leader must have at least three years of human-DNA experience as a qualified analyst of forensic samples. This experience must be obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters.

DNA TECHNICAL LEADER CONTINGENCY PLAN

The Department currently has two (2) DNA Technical Leaders: one responsible for nuclear DNA technical operations (which includes autosomal DNA testing and Y-STR testing) and one responsible for mitochondrial DNA technical operations.

A DNA Technical Leader shall serve as the Deputy DNA Technical Leader for the other technologies within the laboratory for which a permanent DNA Technical Leader has been appointed. Therefore, if a permanent DNA Technical Leader is on leave and cannot be contacted for a matter requiring immediate attention, the other DNA Technical Leader may make decisions on his/her behalf. In the unlikely event that both DNA Technical Leaders cannot be contacted for an immediate matter, the Director shall have the authority to make decisions on their behalf.

If a DNA Technical Leader position becomes vacant, the remaining DNA Technical Leader within the Department may serve as the interim DNA Technical Leader. Within fourteen (14) calendar days of the vacancy, the Director or his/her designee shall appoint a qualified individual within the laboratory to assume the DNA Technical Leader position on a permanent basis.

The Director must ensure that the newly appointed DNA Technical Leader meets or exceeds the education and experience requirements in this document and the FBI's Quality Assurance Standards for Forensic STR Analysis.

REQUIREMENTS OF NEW DNA TECHNICAL LEADERS

A newly appointed permanent DNA Technical Leader must review all validation studies and methodologies currently used by the laboratory in their area of responsibility and must review and approve the qualifications of currently qualified analysts. Completion of these reviews must be documented no more than 90 calendar days after appointment.

(THIS PAGE INTENTIONALLY LEFT BLANK)

Revision History:

February 9, 2010 – Initial version of procedure.

December 29, 2011 – revised contingency plan to allow the remaining DNA Technical Leader to serve as the interim DNA Technical Leader when a position becomes vacant

July 16, 2012 – Minor grammar changes

Discrepancies in Interpreted Results

Legitimate differences of opinions or disputes concerning the interpretation of results may occur between the reporting analyst and the technical reviewer. If differences of opinion cannot be resolved by the reporting analyst and the technical reviewer, then the appropriate Technical Leader (nuclear DNA or mitochondrial DNA Technical Leader) will be the final arbiter. Although a resolution must be reached, the process must not force the reporting analyst or technical reviewer to change his/her results or opinions.

When the resolution process has been exhausted and agreement cannot be reached between the reporting analyst and the technical reviewer, a report will be issued to clearly indicate that the reviewer and original analyst could not come to an agreement. (As an example, where an association is the subject of the difference of opinion, a report may be issued with an "inconclusive" conclusion. Furthermore, the report will clearly indicate that the "inconclusive" conclusion is due to the reporting analyst and the technical reviewer's failure to reach an agreement.) In addition, full disclosure of the resolution process will be documented in the case record.

The Technical Leader reserves the right to re-assign any case for re-analysis. However, if that option is employed, full disclosure of the resolution process and the re-assignment of the case will be documented in the case record.

Revision History:
September 1, 2014 – Initial version of procedure.

Attorney Requests

GUIDING PRINCIPLES AND SCOPE:

This document describes the processes by which attorneys may receive documents, etc pertaining to work performed by the Department of Forensic Biology.

These procedures were established in consultation with the OCME Legal Department.

PROCEDURE:

The OCME Legal Department in general reviews all requests for records which are served upon the Office of Chief Medical Examiner.

A. Requests for Forensic Biology Case Records

An attorney who wishes to receive a certified copy of the Forensic Biology case and/or suspect records must submit a written request directly to the OCME Legal Department.

Prosecuting attorneys (e.g., District Attorney's Office, United States Attorney's Office, New York City Law Department/Corporation Counsel) may submit a subpoena or letter of request which must be signed by the prosecuting attorney. All requests shall be submitted electronically to: DNACertFileReq@ocme.nyc.gov This replaces entirely the historic practice of faxing a request for a certified copy of a DNA case file.
Defense attorneys must submit a judicial subpoena duces tecum. OCME requires the original; a copy is not sufficient.

> New York State Criminal Procedure Law states when a subpoena is directed to any department, bureau or agency of the state, it may only be issued on behalf of a defendant upon order of a court. CPL§ 610.20[3]; CPLR §2307

The request for a certified copy of a DNA case record must include the following identifying information:

1. The name of the decedent or complainant victim
2. The name of the defendant
3. The Forensic Biology case number
4. The case caption (i.e., People v. John Smith, Indictment #1234/12)
5. A contact telephone number for the requesting attorney