FORENSIC BIOLOGY
ADMINISTRATIVE MANUAL

Approving Authority: Timothy D. Kupferschmid, Laboratory Director

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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 reports directly to the Chief of Laboratories. 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 Production Teams and supporting teams. Production Teams consist of casework analysts. Teams that provide supporting services include the Training Team, Research and Development Team and the Quality Assurance/ Quality Control Team. The Forensic Biology Organizational Chart reflects this 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 the Chief of Laboratories, the 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.

Assistant Technical Leaders

Where necessary, Assistant Technical Leaders will be appointed to assist the DNA Technical Leader. Under the DNA Technical Leader's direction, an Assistant Technical Leader may be assigned additional duties (e.g., coordination of training, reviewing validations, organization of records, etc.). In addition, an Assistant Technical Leader may assist in solving technical problems involving analytical methods under the approval of the DNA Technical Leader.

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 testsin 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 perform testing and/or review of DNA extraction, DNA quantitation, STR analysis, 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. They may perform testing and/or review of DNA extraction, DNA quantitation, and STR analysis as well as train new Criminalists, take proficiency tests as required by regulating and accrediting bodies, prepare written scientific reports which reflect testing, and testify 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 for bench work in the laboratory and, after appropriate training, may examine rape kits and other 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
February 2, 2015 – Added duties and responsibilities of Assistant Technical Leader position.
August 14, 2015 – Removed verbiage pertaining to the old Rotation System and added in the Chief of Laboratories position.

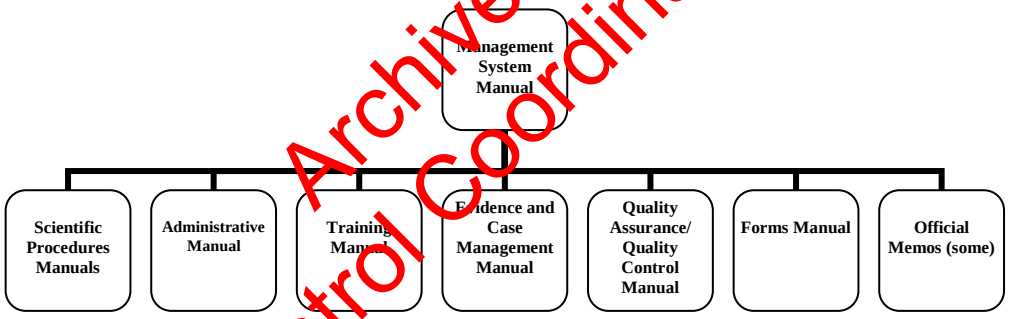
Document Control

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, LIMS Process 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 LIMS Manager** has the responsibility and authority for approval of the LIMS Process 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

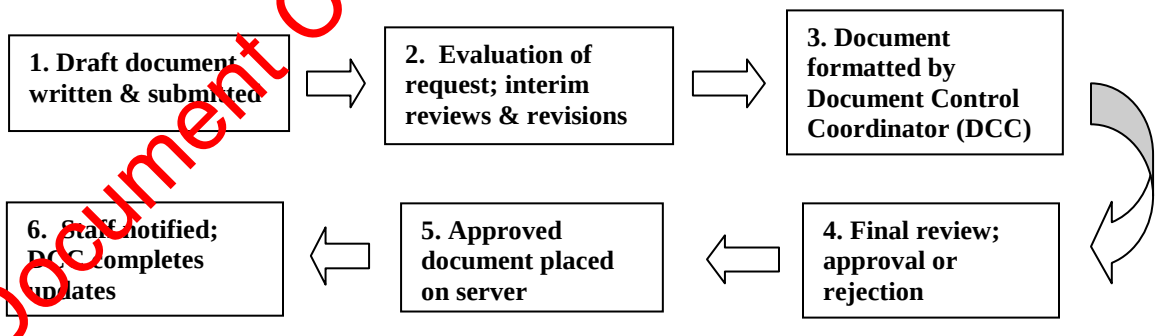
1. All management system documents generated by the laboratory are marked with:

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 document and form revisions are submitted to the Quality Assurance Manager.
- 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

- The QAM reviews requests for new and revised documents and forms.
- Feedback should be sought from knowledgeable staff members who would be affected by the requirements of the document.
- 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. The document Revision History should be updated as applicable.

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 in an archived folder 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.
May 1, 2015 – Updated procedure to reflect current practices.
December 24, 2015 – Added LIMS Process Manual to the listing of Scientific Procedures Manuals and added the LIMS Manager as the approving authority of this 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, validation studies, 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 Technical records that are in-progress are maintained in the LIMS. All Departmental records are filed or otherwise stored in designated areas within the DNA Building, the Forensic Biology network, or the LIMS 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 or approved access to the LIMS. Access to the LIMS is granted to all Department of Forensic Biology members. The Director of the Department of Forensic Biology may grant limited access to the LIMS to non-Forensic Biology personnel as deemed necessary for support of Department of Forensic Biology activities.

- Most hard-copy case files are stored in the OCME Records department.
- Electronic case files are stored in the LIMS.
- 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.
- Electronic quality records that have any degree of confidentiality (such as non-conforming work forms) are stored on the Forensic Biology Network in a secure manner accessible to Quality Assurance personnel only.
- Electronic quality records that are not of a confidential nature are stored on the Forensic Biology Network in an appropriately designated folder.
- 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, or in LIMS, 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 Department of Forensic Biology 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 the 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.

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.
May 1, 2015 – Addition of validation studies as a type of Quality Record retained by the Department.
December 24, 2015 - Updated section D to include storage of Forensic Biology documents and case files in electronic format.
April 15, 2016- Specified in general terms that the Department of Forensic Biology will follow the NYC Charter per record retention.

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. 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 December 31.

    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. The written report will be disseminated to the Department's managers either electronically (via email) or in hardcopy. The DNA Technical Leaders and Quality Manager will schedule a 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. In lieu of a meeting, the written report may be discussed by the Department's managers via email. The review of the report by Department's managers should take place within one month of management's receipt of the report.

5. 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.

6. 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.
May 1, 2015 – Updated procedure to reflect current practices.

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.

DNA TECHNICAL LEADER		
EFFECTIVE DATE 09-01-2014	APPROVING AUTHORITY LABORATORY DIRECTOR	PAGE 24 OF 51

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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) or the presentment agency (New York City Law Department/Corporation Counsel) may submit a form request which can be obtained from either the Legal Department or the Forensic Biology Administrative Team. All such requests shall be submitted electronically to: DNACertFileReq@ocme.nyc.gov. Requests should not be faxed.

Defense attorneys may submit a written request for certified copies of Forensic Biology casefiles or reports. That written request must be made on law firm letterhead and must state the name of the case, the party the attorney represents, the court in which the case is pending, the indictment/case number, the Forensic Biology case number, and a telephone number for the requesting attorney. That written request may be made either by mail or by email and must be approved by the Legal Department. Once the request is approved and the records are ready for distribution, the Administrative Unit will provide the records to the Legal Department for review. Only once Legal has reviewed and approved the production of the documents will they be provided to the defense attorney.

If the reports/case files relate to a homicide, OCME will NOT release any records absent a so-ordered judicial subpoena or absent the express written consent of the prosecutor.

As an alternative to a written request, defense counsel may submit a so-ordered judicial subpoena for certified copies of reports/case files. All subpoenas must be directed to the Legal Department for approval. As with written requests, Legal must review all documents prepared pursuant to a defense subpoena prior to distribution.

> 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 written request or judicial subpoena duces tecum is incorporated into the associated DNA case record.

The Administrative Team fulfills all requests for certified DNA case records.

Production of a certified copy of a DNA case record takes a minimum of ten (10) business days.

Certified copies of DNA case records will not be mailed to the requesting prosecutor; they must be picked up by a messenger or representative of the prosecutor's office.

All certified copies of DNA case records fulfilled in accordance with a judicial subpoena duces tecum will be mailed by the OCME Legal Department to the Court which issued the subpoena.

All inquiries concerning the status of a request for a certified copy of a DNA case record shall be directed to the Administrative Team at 212-323-1200.

All requests that a request for a certified copy of a DNA case record be rushed or expedited shall be directed to the Administrative Team at 212-323-1200.

B. Other Discovery Requests

All requests for documents beyond the DNA case record will be handled/coordinated by the Legal Department.

Items that will be produced only upon proper service (CPLR 2307) of a so-ordered judicial subpoena include, but are not limited to:

Electronic raw data files
Validation studies

Items that will be produced upon written request from an attorney on law firm letterhead stating the case caption, the Forensic Biology case number, the party whom the attorney represents, and attorney contact information include, but are not limited to:

Archived OCME protocols
Analyst c.v.

All other requests will be evaluated by the Legal Department to determine whether a subpoena is required for production.

IN GENERAL:

Protocols
Department of Forensic Biology protocols may be found online on the OCME's public website: www.nyc.gov/ocme under the tab "Forensic Biology", under the tab "Technical Manuals".

Any other requests for protocols, please contact the Legal Department.

C. Attorney Request to be Present for Testing

An attorney and/or their technical expert may request to be present for evidence viewing, evidence examination, and/or DNA testing. The Department of Forensic Biology permits an attorney and/or technical expert to be present within a Forensic Biology laboratory to observe the entire process or selected portions of DNA analysis (e.g., an attorney may request to be present only for evidence examination or an expert may solely ask to observe the swabbing of items of crime scene evidence).

All requests from attorneys to be present for testing must be brought to the attention of the OCME Legal Department.

1. The attorney must submit a written request to the OCME Legal Department at least one week in advance of the proposed observation date.

2. If evidence or exemplar examination has already commenced prior to receipt of the attorney's written request, Forensic Biology testing will **not** cease unless a Court Order directs the Department of Forensic Biology to do so.

3. The attorney's written request must include the following identifying information:

   a. The case caption (i.e., People v. John Smith, Indictment #1234/12)
   b. The name of the presiding Judge;
   c. The name of the attorney and/or expert who wishes to observe;
   d. The items of evidence [and NYPD voucher number if known] which the attorney or expert believes were submitted to the OCME for DNA analysis.

4. In accordance with Department of Forensic Biology protocol, no one is permitted to enter a DNA laboratory without first submitting a DNA sample. Therefore, the attorney and/or expert must complete and sign a Non OCME Employee DNA SAMPLE CONSENT FORM and provide a DNA sample to the Department of Forensic Biology prior to entering the laboratory.

5. A criminalist within the Department of Forensic Biology will collect an oral swab from the attorney and/or expert.

6. A record of the DNA profile(s) generated will be placed into LDIS.

7. The original consent form shall be maintained by the Forensic Biology Exemplar Group; a copy of the consent form shall be incorporated into the associated DNA case record(s).

8. The OCME will only permit an attorney or expert(s) to be present for observation during normal business hours: Monday to Friday, 9am to 5pm.

9. The attorney and/or expert will be escorted by an OCME Department of Forensic Biology personnel at all times.

10. The attorney and/or expert must gown up to OCME specifications prior to entering a laboratory. An attorney or expert who does not follow the OCME gowning specifications will not be permitted to enter the laboratory.

11. The attorney and/or expert may bring paper and pen into the laboratory.

12. The attorney and/or expert are prohibited from bringing cameras, cell phones or tape recording devices into the laboratory.

13. The attorney and/or expert are prohibited from photocopying any OCME documents.

14. The attorney and/or expert may not remove anything from the OCME Department of Forensic Biology laboratories or facility.

15. The attorney and/or expert will not be given a tour of the OCME DNA Facility. This is not an occasion or opportunity for the attorney and/or expert to question or quiz a criminalist about the testing process or technology or equipment utilized. If an attorney and/or expert wish to speak with the assigned criminalist in advance of trial concerning case-specific DNA testing and results, the attorney and/or expert may return to the OCME DNA Building at a later designated time to speak with the criminalist in person.

D. Request for evidence to be sent to a laboratory for testing

An attorney may request that case or exemplar evidence be sent to a laboratory for testing.

All requests for evidence to be sent to a laboratory for testing must be brought to the attention of the OCME Legal Department.

The Department of Forensic Biology may only forward case evidence or exemplars to a laboratory accredited by the New York State Department of Health (unless a Court Order dictates otherwise).

A list of the private laboratories accredited by New York State Department of Health can be found at http://www.wadsworth.org/labcert/clep/CategoryPermitLinks/CategoryListing.htm under the section "Forensic Identity."

The Technical Leader of the Department of Forensic Biology can also provide a list to any attorney of the private laboratories accredited by NYS DOH.

If the Department of Forensic Biology still possesses the case evidence, the OCME requires a Court Order to effectuate transfer to another laboratory.

If case evidence has been returned to the custody of the New York Police Department, then the attorney must make all arrangements directly with the NYPD.

The Court Order must include the following identifying information:

1. The case caption (i.e., People v. John Smith, Indictment #1234/12) the name and address of the selected laboratory;
2. Acknowledgement that the selected laboratory is accredited by the New York State Department of Health;
3. A listing of the precise evidence which the OCME Department of Forensic Biology is directed to forward for testing.
4. A statement that the laboratory shall return to the OCME Department of Forensic Biology evidence "leftover" subsequent to its testing.

The Court Order must be sent to the OCME Legal Department for review.

The Order shall be incorporated into the associated DNA case record(s).

It is suggested that the assigned criminalist and/or supervisor speak with the attorney to come to a specific understanding as to 'how much' of each item of evidence will be sent by OCME to the laboratory to enable testing.

The OCME will not assume the cost of mailing evidence to the laboratory named in the Court Order. The selected laboratory must forward the Department of Forensic Biology a prepaid mailing label and any shipping material which the laboratory deems necessary.

The assigned criminalist and/or her/his supervisor will locate the requested evidence and will be responsible for sending to the laboratory named in the Court Order.

E. Request for Testimony / Case Conferences

As a general practice, the Office of Chief Medical Examiner does not require a personal appearance subpoena in order to secure the court appearance of any OCME employee.

A criminalist may testify in all manner of proceedings (Grand Jury, criminal or civil trials, depositions) without the need for an attorney to send a personal appearance subpoena.

Typically, the criminalist who authored a case report testifies on behalf of that specific case. If the author of the report is not available for testimony, the Technical Reviewer of the case should testify in their stead. If neither the criminalist who authored the case report nor the Technical Reviewer of the case are available for testimony, any criminalist may testify to the reported results (specific to whether a DNA Interpreting Analyst is needed for testimony or not). The criminalist testifying is required to review the case record and complete the CASE RECORD REVIEW-PRIOR TO TESTIMONY form and place the form in the case file.

Attorneys should contact the criminalist directly in advance of grand jury or trial, to coordinate scheduling of testimony.

OCME requires that all attorneys who intend to call a criminalist as a witness at trial have a pre-trial conference with the assigned analyst. That conference may take place either in-person at OCME, or via telephone. The OCME Legal Department shall be informed of each pre-trial conference at least 24 hours in advance of the scheduled meeting. The criminalist will be notified directly if Legal will be in attendance at the conference.

In general, if an attorney wishes to speak with the assigned criminalist concerning reported case-specific DNA results, the attorney is welcome to do so. If the criminalist is a less experienced (less than two trial testimonies) criminalist, a Criminalist III or above **must** be present for the pre-trial conference. It is good practice to have a criminalist who has testified at trial on multiple occasions to be present during pre-trial meetings simply to ensure that the attorney understands clearly the information and opinions which are being given. Having a fellow criminalist present can be of value if the opposing attorney later files a motion or asks questions at trial which inaccurately describe the statements the assigned criminalist relayed during the pre-trial.

All meetings with attorneys – the date and names of all persons present – shall be documented in the case communication log of the Forensic Biology case record.

If an attorney or expert witness wishes to communicate via the telephone, the criminalist must document the conversation in the case communication log. No criminalist shall discuss results of DNA testing prior to completion of the technical review process.

If an attorney communicates with a criminalist via email, the criminalist must similarly document the communication in the case communication log of the DNA case record.

A criminalist shall not reveal the subject of conversation with one attorney to the opposing counsel involved in the same case.

F. Protective Orders

Courts may issue protective orders in conjunction with swab orders, which permit law enforcement to collect suspect exemplars for comparison to case evidence. A protective order issued by the court places restrictions on what OCME is permitted to do with the suspect's known DNA profile. Such orders may specify exactly which items of evidence within the evidence file may be compared with the suspect's known profile, or they may simply limit comparison of the known suspect DNA profile with the evidence tested in associated with that specific case. Often, these orders also direct OCME not to enter the suspect's known DNA profile, generated from the underlying swab order, into the local NYC DNA databank (LDIS).

The OCME requires a Court Order specifying the protection(s) to be afforded the DNA.

A telephone call informing the criminalist of a Court's directive or copy of court transcript or letter from a prosecutor or defense attorney is not sufficient.

The OCME Legal Department must review and approve all Protective Orders.

The OCME Legal Department will email the assigned criminalist and their Assistant Director supervisor that a Protective Order exists for their assigned case and in what manner the Protective Order is directing the OCME in reference to the DNA profile of the defendant.

The assigned criminalist or her/his Assistant Director supervisor shall incorporate a copy of the Protective Order into the associated DNA case record(s) (in the LIMS case record(s) and in a hard copy of the case record(s) if one exists). The assigned criminalist or her/his Assistant Director supervisor shall make an entry in the case communication log (in the LIMS case record(s) and in a hard copy of the case record(s) if one exists) detailing the directive of the Protective order. Placing a copy of the email received from OCME legal Department into the communication log is sufficient.

The assigned criminalist and the technical reviewer of the case record(s) shall confirm that a protective order does or does not exist pertaining to a defendant's DNA sample by searching the PROTECTIVE ORDERS folder in the general FORENSIC BIOLOGYLOGY_MAIN folder. This search is to be performed in every case where no email from OCME legal Department exists in reference to that defendant or case record.

This search is to be performed before the report for that case record is finalized and distributed to external agencies.

G. Expungement Requests

An attorney may request that a suspect or defendant's known DNA profile be expunged from the local OCME DNA databank (LDIS).

Anyone inquiring as to expungement of a DNA profile **must** be referred to the OCME Legal Department.

The OCME Legal Department will advise the attorney that they may wish to ask for the following:

1. The defendant's known numeric DNA profile be expunged from OCME's local DNA database
2. The swabs collected from the defendant be destroyed
3. The associated DNA extracts be destroyed
4. The associated Forensic Biology S case file be destroyed

The OCME requires a Court Order. A letter of request is not sufficient.

Upon receipt of an Expungement Order, the OCME Legal Department will send an email, with the Expungement Order attached, to the assigned criminalist or her/his supervisor.

The assigned criminalist or her/his supervisor shall be responsible for ensuring the "terms" of the Expungement Order are honored.

H. Post Conviction DNA testing

The Office of Chief Medical Examiner will perform post-conviction DNA testing upon Court Order, or the written approval of the District Attorney's Office, or with the approval of the Legal Department and the Chief of Laboratories.

A defense attorney or defendant's written request for post-conviction testing is not sufficient.

The Court Order or written assent of the District Attorney's Office **must** be sent to the OCME Legal Department.

Any attorney involved in Post Conviction DNA testing is welcome to come to the OCME DNA building to speak with the assigned case criminalist to discuss case-specific testing. If the assigned criminalist is a Criminalist II or III, the criminalist's supervisor must be present for any post-conviction conference.

The Order or written assent from the District Attorney's Office shall be incorporated into the associated DNA case record(s).

I. Requests for Additional Testing

If a Prosecutor or Defense attorney requests additional testing, including statistical analysis not previously calculated for the case, the request will be reviewed by OCME Management and the Technical Lead team on a case by case basis. The request can be made through the case analyst. The requesting agency will be notified of the decision on whether or not testing will be conducted.

Revision History:
- February 9, 2010 – Initial version of procedure.
- April 30, 2012 – In consultation with the OCME Legal Department, substantial revisions were made to Sections A through C, and new Sections D through H were added.
- July 16, 2012 – Generalized terminology to allow for the electronic storage of information.
- May 5, 2014 – Sections were updated to reflect new practices.
- October 1, 2014 – Section F, Protective Orders was updated.
- May 1, 2015- Section E updated to reference when the CASE RECORD REVIEW-PRIOR TO TESTIMONY form is required.
- December 24, 2015 – Added Section I - Requests for Additional Testing
- April 1, 2016- revised procedure with the consultation of the OCME legal Team

Security

GUIDING PRINCIPLES AND SCOPE:

All Department of Forensic Biology laboratory activities are carried out at the OCME DNA Building at 421 East 26th Street. Access to areas of the building critical to the integrity of evidence and the quality of tests conducted by the Department is restricted. Security is provided at both a building level and a Department level. The Director of Forensic Biology determines the level of access into the Forensic Biology laboratory and office areas.

This document describes Forensic Biology building security procedures.

PROCEDURES:

A. OCME DNA Building Security

A. The OCME DNA Building is equipped with a security monitoring system. Cameras are situated throughout the inside of the building and at key locations outside the building. Cameras are monitored by OCME Security in the security command center located on the 3rd floor.

B. OCME security staff is present 24 hours a day, 7 days a week. After normal business hours, on city holidays, and on weekends, security staffing consists of a security officer at the 3rd floor Security Command Center and a roving security officer.

C. The building has two entrances:
- Main entrance at the west end of the building
- Vehicular breezeway off 26th Street

D. Main Entrance Security
- Retractable vehicular bollards at the entrance exterior prevent unauthorized vehicular access to the plaza.
- The reception desk is staffed Monday through Friday during business hours.
- Employees gain access to the staff elevators and other parts of the building through turnstiles equipped with ID card readers.
- Visitors to the building must sign a guest logbook at the reception desk before being escorted throughout the building.

- Employees use an ID card reader on the non-revolving door to gain access to the building during non-business hours.
  - In case of difficulty with the card reader, employees should use the intercom to request assistance from the officer staffing the 3rd floor Security Command Center.
  - If no response is received from the Command Center within a few minutes, the employee should seek assistance from the OCME Officer at the vehicle access point.

E. Vehicular Breezeway Security
- A guard booth is situated at the entrance and is staffed by an OCME security officer from 7 AM to 7 PM Monday through Friday, excluding holidays.
- The security officer controls a gate which allows vehicular access.
- The security officer monitors access to the loading dock.

F. Interior Building Security
- Employee access to floors and rooms inside the building is controlled via ID card readers that have been programmed by OCME Security.

B. Laboratory Security

1. The offices and laboratories of the Department of Forensic Biology are accessible only to personnel authorized by the Laboratory Director.

2. The **Security Access Plan for Forensic Biology** outlines standard access permissions for various OCME employee groups.

3. All visitors, including OCME employees who are not permitted access to Department laboratories or offices via their ID card, must be escorted by a Forensic Biology employee.
   - All individuals who enter laboratories must provide a buccal swab sample for the quality control database.

4. Non-standard access for OCME employees and for individuals not covered by the Security Access Plan requires a written authorization from the Director or designee.

5. Evidence storage areas in the sub-basement and on the 5th floor are under the control of the Evidence Unit and are not accessible by Forensic Biology staff.

6. **Long-term records storage** areas are located on the 4th floor and are under the control of the OCME Records Department. Access is available to selected members of Forensic Biology as requested by the Director of Forensic Biology.

7. Guidelines have been created for Forensic Biology staff regarding visitors and guest tours of the OCME DNA building. See memo M2008-005.

SECURITY ACCESS PLAN FOR FORENSIC BIOLOGY

The **Security Access Plan for Forensic Biology** outlines standard access permissions for various OCME employee groups. Exceptions to or deviations from this Plan for OCME employees or permissions for other individuals or groups not covered by Plan requires a written authorization from the Forensic Biology Director or designee.

Definitions:

Unlimited Access: 24 hours a day, 7 days a week
Limited Access: 8 a.m. to 6 p.m. weekdays
Extended Limited Access: 6 a.m. to 8 p.m. Sunday through Saturday
No Access: Entry to offices/labs only with an escort who has authorized access

Group	Laboratories (4 to 8)	Office Areas (5, 7, 8, 11, 12)	Office Area (13)
FBio Crims, CRSs[1]	Unlimited, all but QA lab	Unlimited	Unlimited
QATeam, Managers	Unlimited	Unlimited	Unlimited
FBio A-Team	No Access	Unlimited	Unlimited
FBio Interns	Limited access to lab(s) needed for project; defined by memo per individual	Limited access to assigned office area; defined by memo per individual	Limited
Chief Medical Examiner, Chief of Staff, Assistant Commissioner Building Services	No Access	Unlimited	Unlimited
OCME Administration*	No Access	No Access	Limited
Forensic Investigations (Medicolegal Death Investigators, Family Outreach)	No Access	Unlimited 8 & 11	Limited
OCME Senior Staff**	No Access	No Access	Limited
SIU Criminalists	Limited, 5 & QA lab on 6	Limited	Limited
Legal (general)	No Access	No Access	Unlimited
Legal-FBio	No Access	Limited	Unlimited
OCME Health & Safety	Limited	Limited	Limited
OCME CIO and IT Desktop Support	No Access	Limited	Limited
OCME Security	Unlimited	Unlimited	Unlimited
OCME Fire and Safety Director	Unlimited	Unlimited	Unlimited
EU-Non-Supervisory	Unlimited 5	Unlimited 5	Unlimited
EU-Supervisors	Unlimited 5	Unlimited 5; Limited 11 & 12	Unlimited
Facilities-Engineers	Unlimited	Unlimited	Unlimited
Facilities-Maintenance	Limited	Limited	Limited
OCME Cleaners	Extended Limited	Extended Limited	Extended Limited
OCME Records	No Access	Limited	Limited

*Includes: First Deputy Chief Medical Examiner, Deputy Commissioner Administration, Deputy Commissioner Operations
**Includes: Director and Assistant Directors-Forensic Toxicology, Agency Chief Contracting Officer, Public Affairs Director, Assistant Commissioner Finance, Budget Director, Assistant Commissioner Human Resources, Director-Human Resources, Director-Anthropology, Director-Special Operations/Investigations, Director-Histology, Director-Agency Wide Projects, Director-Small Purchases.

SECURITY		
EFFECTIVE DATE 12-24-15	APROVING AUTHORITY LABORATORY DIRECTOR	PAGE 40 OF 51

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Revision History:

February 9, 2010 – Initial version of procedure.
September 27, 2010 – Revised Guiding Principles and Scope section to properly reflect the contents of the procedure.
January 3, 2011 – Revised Security Access Plan to grant the OCME Fire and Safety Director and Facilities-Engineers unlimited access to all operational areas of the Department of Forensic Biology.
July 16, 2012 – Section A.5 modified to reflect changes in Security coverage of the garage entry (no longer 24/7).
May 1, 2015 – Security Access Plan for Forensic Biology chart was updated to include Forensic Investigations personnel.
December 15, 2015 – Added Extended Limited Access hours to Definitions and modified OCME Cleaners to have this access type.

Complaints

GUIDING PRINCIPLES AND SCOPE

Complaints can provide valuable information about problems with the management system or insight into potential improvements. Complaints have varying degrees of seriousness. The Department of Forensic Biology endeavors to respond to complaints to a degree commensurate with the magnitude and urgency of the complaint.

This procedure describes how the Department of Forensic Biology deals with complaints received from customers, other parties, and employees.

PROCEDURE

1. Complaints may be received verbally or in writing by any member of staff.

2. The recipient evaluates the complaint and directs it to an appropriate staff member for follow-up. For example:

   a. General concerns and complaints or those relating to a specific function of the laboratory, case acceptance criteria, or evidence and reporting policies should be directed to a Criminalist IV Supervisor, the Quality Assurance Manager (QAM), a Technical Leader, or a Manager.
   b. Evidence intake issues should be directed to a Sign-In specialist.
   c. Specific case issues or personnel performance issues should be directed to the supervisor of the scientist assigned to the case.
   d. External customer complaints (i.e. NYPD or DAO) should be directed to the Chief of Laboratories, the Director, a Deputy Director, an Assistant Director or the QA Manager.
   e. Internal customer complains (i.e. OCME staff) should be directed to the Chief of Laboratories, the Director, a Deputy Director, an Assistant Director, a supervisor or the QA Manager.

3. The staff member evaluates the complaint.

   a. As needed, the staff member contacts the complainant to discuss the specifics of the issue. If the staff member is able to resolve the issue during this discussion, and the issue was not related to non-compliance with the laboratory's management system, no further action is necessary.

i. Case related contacts are documented in the case communication log.

b. If the evaluation indicates that the complaint is due to a specific non-conformance with Forensic Biology guiding principles, procedures, or quality system, the staff member determines whether the CONTROL OF NON-CONFORMING WORK and/or QUALITY INCIDENT REVIEW procedures are applicable

i. The staff member may consult with the QAM and/or an appropriate Technical Leader to assist in making the determination.

ii. To avoid duplication of effort, complaints investigated and documented as quality issues are not required to be investigated via the COMPLAINT FORM.

c. If the staff member is unable to resolve an issue, and the issue does not fall under the requirements for investigation as non-conforming work or a quality incident review, the issue rises to the level of a formal complaint.

4. Formal Complaint Process

a. The staff member conducting the initial follow-up of the complaint (the "Forensic Biology Reporter") completes Page 1 of the COMPLAINT FORM and submits the form to the QAM.

i. Written complaints are attached to the form.

b. The QAM, either independently or after discussion with the Director or designee, assigns someone to conduct additional investigation with respect to the validity of the complaint. The investigator can be the same as the "Forensic Biology Reporter". Page 2 of the COMPLAINT FORM is used to record the details of the investigation and the investigator's conclusion.

c. The investigator returns the form to the QAM for review.

i. If the QAM disagrees with the investigator's conclusion, he/she may request additional investigation or may change the "Investigation Status" on the form.

d. When the investigation is complete to the satisfaction of the QAM, the appropriate box on Page 3 is completed by the QAM to describe the corrective actions taken and/or follow-up with the complainant.

e. The form is provided to the Director for review and signature. The Director returns the form to the QAM.

f. The QAM assigns the complaint a unique identifier for documentation purposes and files the complaint as a Quality Record.

Revision History:
February 9, 2010 – Initial version of procedure.
July 16, 2012 – Minor terminology change: added "communication log" in Section 3.a.i.
April 15, 2016 – Updated to include where complaints should be directed, specified where complaints against the quality system should be addressed with a Control of Non-Conforming Work procedure, or QIR procedure, and reflected that a unique identifier will be assigned instead of a "complain number" to each complaint.

Purchasing Services and Supplies

GUIDING PRINCIPLES AND SCOPE:

Many of the services and supplies used by the Department of Forensic Biology have a direct impact on the quality of the testing conducted by the Department. Only services and supplies of the required quality will be used. Therefore, the Department's purchasing and performance verification procedures must ensure that all Department requirements are met.

This procedure describes how the Department (1) purchases, receives, and stores reagents and laboratory consumable materials relevant for the tests conducted; (2) verifies that these purchased supplies, reagents and consumable materials meet Department requirements; and (3) evaluates suppliers of critical consumables, supplies, and services which affect the quality of testing. Refer to the LIMS manual for Forensic Biology for specific procedures within the LIMS system.

PROCEDURE:

A. General Ordering Process

The Department purchasing process is guided by New York City Procurement Policy Board Rules.

1. Working within an approved budget, requisitions for purchase orders for services and supplies are entered by designated individuals from the Department into the OCME procurement software. These requisitions, including any technical specifications, are approved by the Director of Forensic Biology and/or the Director's designated proxy before they are processed for expenditure by the Office of Budget Administration and forwarded to the Purchasing Unit for action.
    a. Requisitions for purchase orders for services and supplies may be subject to City competitive bidding requirements.
2. After the external approval process is completed, the Department of Forensic Biology receives copies of the following, as applicable:
    a. Blanket purchase orders for a specific vendor, typically expiring at the end of the Fiscal Year.
    b. Contracts for one year or multiple years

B. Forensic Biology Process for Ordering Supplies, Reagents and Consumable Materials

1. Internal requests for supplies, reagents, and consumables are submitted to the Quality Assurance (QA) Unit, generally via:

   a. QA/QC Request Form, or
   b. E-mail

   QA Unit members may also self-initiate requests.

2. The requests describe the item(s) needed and quantity of each. The technical specifications are based upon the needs of the particular procedure and, where applicable, past ordering information.

3. A member of the QA unit determines whether the item(s) requested are in stock. Items in stock are delivered to the requesting staff member/Department unit.

4. When items are not in stock:

   a. The QA Unit enters items that need to be ordered into the "Pending Orders Sheet" on the Department server. These entries are reviewed by a QA Unit supervisor who verifies (1) the technical specifications of the items requested (2) whether a purchase order is in place for the item, and if so (3) whether the purchase order has sufficient funds to purchase the requested items. The supervisor approves entries by placing their initials into the worksheet. The supervisor then enters the information into the QA "Orders and Receiving Database" on the Department server.
   b. Forensic Biology procurement staff has the primary responsibility for placing orders; however, assistance may be provided by members of the QA Team.
   c. Orders for ABI products with a valid, blanket purchase order are placed using a suitable mechanism such as the internet or telephone.
      i. Detailed specifications for products not previously ordered (e.g., item description, catalog number, etc.) should be supplied by the original requestor.
      ii. A copy of the order is maintained.
      iii. The order date and any additional information regarding the order are entered into the Orders and Receiving Database. Order information is also entered into an "accounting" worksheet for budgeting purposes.

d. Orders placed for non-ABI products are based on the entries in the Orders and Receiving Database.

i. An order is placed with a vendor via telephone, fax, or internet, referencing an applicable purchase order. Copies of order acknowledgements are retained.

ii. If no blanket purchase order exists, a requisition for purchase order is entered into the OCME procurement software.

iii. The "order date" for each item is entered into the Orders and Receiving Database. Order information is also entered into an "accounting" worksheet for budgeting purposes.

C. Reception and Storage of Supplies, Reagents and Consumable Materials

1. Forensic Biology Materials Management staff collects packages received by the OCME Receiving Department.

2. Packages of basic consumables are opened by Materials Management in the Receiving Department and the contents are verified against the packing slip; the packing slip is returned to the Receiving Department.

3. Packages of reagents, chemicals, test kits and non-basic consumables are delivered to the QA Unit.

4. A member of the QA Unit opens each package and verifies the contents of the package against the packing slip and purchase request (in the Orders and Receiving Database) to verify if the correct materials have been received.

a. A "Receiving/Inspection Form" is completed. Any discrepancies, including inconsistencies with respect to the original order, are recorded on the Form.

b. The packing slip is signed and dated.

c. The QA Unit retains copies of the Receiving/Inspection Form and the packing slip.

d. Non-critical reagents are presumed to comply with laboratory requirements as long as the materials received meet the technical specifications on the purchasing document.

e. Critical reagents must be performance tested prior to use.

i. **Critical reagents** as defined by the "Quality Assurance Standards for Forensic DNA Testing Laboratories" are those reagents that "*are determined by empirical studies or routine practice to require testing on established samples before use on evidentiary or casework reference samples.*"

ii. The reagents that the Department classifies as "critical" are listed in the REAGENTS procedure in the Quality Assurance/Quality Control Manual. Purchased critical reagents must pass QC testing in order to be used for casework. See the REAGENTS procedure and various reagent QC procedures and forms.

5. Data entry into the Order and Receiving Log on the Department server and in the LIMS is completed.

6. Any reagent or item (i.e. 3130 capillary) that has been entered into the LIMS and assigned a LIMS lot number will be labeled with a LIMS label. This label details the Reagent Type ID, reagent lot number and expiration date. The label also has a barcode, which can be scanned and utilized in the LIMS.

7. Reagents, test kits, and similar materials are stored as per the manufacturer's recommendations.

8. General consumables are stored at room temperature.

D. Evaluation of Suppliers

The Quality Assurance Unit maintains a list of critical reagents, supplies, and services which affect the quality of testing results; the approved manufacturer(s)/provider(s) for each item; the basis for approval; the initials of the approver; and the date of the most recent approval. The following are examples of possible justifications for approval:

- For providers of calibration services, proof of accreditation to ISO 17025
- For providers of proficiency test services, proof of approval by ASCLD/LAB
- The Department's past experience with the quality of reagents and supplies received from the supplier, such as passing internal Quality Assurance performance checks.

Revision History:

February 9, 2010 – Initial version of procedure.

July 16, 2012 – Added LIMS references in Section C, Steps 5 and 6; removed QA/QC Raw Material form reference.

Removing records from the electronic case logbook

GUIDING PRINCIPLES AND SCOPE

The Forensic Biology electronic case logbook is a database originally created using the Microsoft Access program. A **Case Record** is a screen/window in this database that contains administrative information (case numbers, dates evidence received, analyst identifiers, etc.) associated with a "scheduled analysis" for a Forensic Biology case. Each Forensic Biology case is associated with one or more Case Records, depending upon the complexity of the case. On the other hand, "record" is a generic term for documented information or data, whether electronic or hardcopy, administrative or technical, associated with Forensic Biology cases.

A variety of circumstances can lead to the creation of Case Records or vouchers that are extraneous and need to be removed from the database. Incorrect laboratory metrics and/or loss of data can result from failure to remove extraneous records or from removing records in an incorrect manner.

Extreme caution should be exercised when deleting information from the database. Deleted information cannot be easily recovered, which means that records deleted in error must be recreated manually using information from the physical case file.

This procedure describes in detail the steps taken to delete Case Records and vouchers.

PROCEDURE

One or more members of staff ("Access Database Administrators") are authorized to delete Case Records and vouchers from this database.

A Forensic Biology staff member who needs a Case Record or voucher deleted from this database should send their request via e-mail to *all* Access Database Administrators.

a. A request for Case Record deletion must specify the case number and, if applicable, the Case Record number (e.g., 2 of 3).
b. A request for voucher deletion must specify the voucher number and preferably the case number as well.

All subsequent steps are conducted by an Access Database Administrator.

A. Case Record Deletion

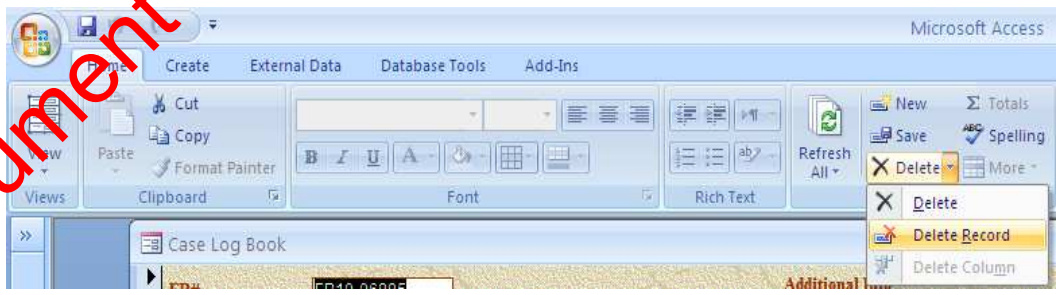
1. Use the Search Dialog form to locate the appropriate case.

2. Verify that the number of Case Records associated with the case is consistent with the request.
   a. For example, if there is only one (1) Case Record associated with the case number, but the request is to delete Case Record "2 of 2" or "the second record," follow up with the requestor to resolve the discrepancy.

3. Follow up with the requestor with respect to any details of their request that are unclear.
   a. For example, if the request is to delete the "second record," question if that means that Case Record 2 of 3 should be deleted. This is important because, based on sorting (or how the database was queried), the "second record" could be something else.
   b. Some requestors will add "DELETE ME" into the Additional Info box in the Case Record. This helps to clarify which screen should be removed.

4. Select the appropriate Case Record to be deleted.
   a. If the case has only one Case Record ("1 of 1"), delete that screen.
   b. If the case has multiple Case Records, delete only the specific screen(s) requested.

5. Use the **Delete Record** menu option to delete the selected Case Record(s).



6. When one or more Case Records are deleted from a case with multiple Case Records, edit the Case Record # field in the remaining Case Record(s) to correctly reflect the revised numbers.

a. For example, if Case Record "2 of 2" was deleted, Case Record # "1 of 2" in the remaining case screen must be changed to "1 of 1".

7. Send an email to the requestor and the other database administrators when the request has been fulfilled. This serves two purposes:
   a. It prevents confusion with respect to whether the request was done and
   b. It provides an opportunity for the requestor to see that the correct Case Record was deleted.

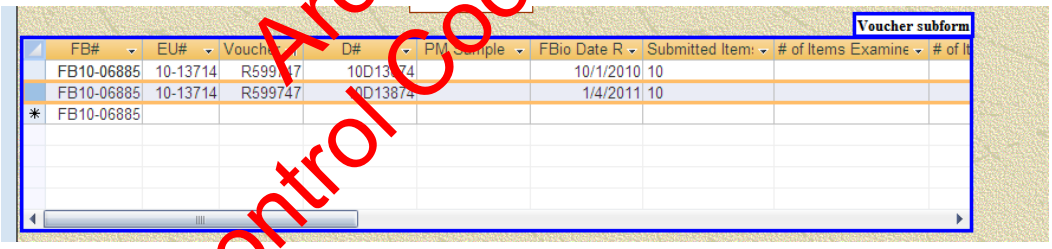
8. Save all requests in an Outlook folder as documentation of what was done and the reason for removing the Case Record(s).

B. Voucher Deletion

1. Use the Search Dialog form to find the case associated with the voucher.

2. Locate the voucher that is to be deleted.

3. Highlight the entire line.



4. Use the **Delete** key to delete the highlighted voucher line.

5. Send an email to the requestor and the other database administrators when the request has been fulfilled. This serves two purposes:
   a. It prevents confusion with respect to whether the request was done and
   b. It provides an opportunity for the requestor to see that the correct voucher was deleted.

6. Save all requests in an Outlook folder as documentation of what was done and the reason for removing the voucher record.

Revision History:
April 19, 2011 – Initial version of procedure.