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.

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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, 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

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. Complex Discovery Requests

An attorney may request additional documents from the Department of Forensic Biology beyond the DNA case record (e.g., c.v. of the assigned criminalist and supervisor(s) who performed technical review; job description of the assigned criminalist and supervisor(s) who performed technical review; proficiency test results of the assigned criminalist and supervisor(s) who performed technical review; list of commercial software utilized in testing performed in a specific case, raw data, etc).

Prosecuting attorneys may submit a subpoena or letter of request which must be signed by the prosecuting attorney; defense attorneys must submit a judicial subpoena duces tecum.

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

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.

The OCME may only provide copies of its own protocols; the OCME may not disseminate protocols of another laboratory (e.g., the FBI or Bode Technology).

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 Exemplar Group will collect an oral swab from the attorney and/or expert.

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

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 criminalist at all times.

10. The attorney and/or expert must gown up to OCME specification 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.

16. 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 should 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.

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 meeting here at the OCME DNA Laboratory Building with the assigned analyst.

The OCME Legal Department is always available to assist a criminalist in conveying this in-person pre-trial meeting with the attorney.

In general, if an attorney wishes to speak with the assigned criminalist concerning reported case-specific DNA results, the attorney is welcome to. 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 that has not been formally reviewed.

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 never reveal the subject of conversation with one attorney to the opposing counsel involved in the same case.

F. Protective Orders

An attorney may agree to or request that the collection and comparison of a defendant's DNA sample be afforded two 'protections': that the defendant's known DNA profile be strictly compared to specific case evidence, and further, that the defendant's known DNA profile not be entered into the local NYC DNA databank (LDIS).

The OCME requires a Court Order stating such.

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 FBIOLOGY_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).

Any attorney 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 assent of the District Attorney's Office.

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. At the discretion of the supervisor, the OCME Legal Department may also be invited to attend.

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

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.

SECURITY		
EFFECTIVE DATE 07-16-2012	APROVING AUTHORITY LABORATORY DIRECTOR	PAGE 35 OF 49

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
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
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	Limited	Limited	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.

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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 6, 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).

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 and other parties, and from employees concerning the quality system.

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.

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 and/or procedures, 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 Complaint Number 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.

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

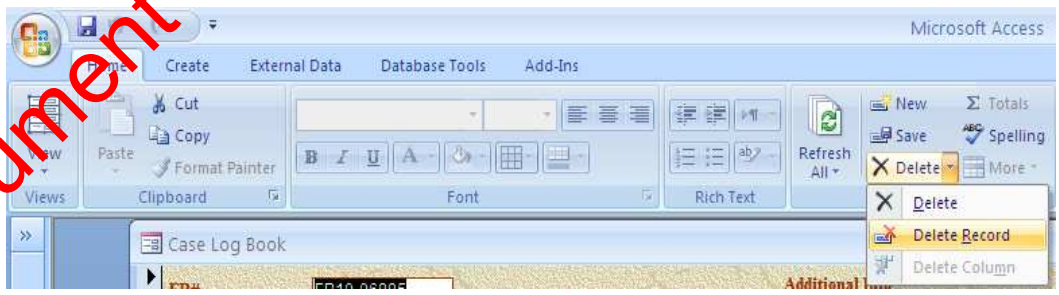
1. Use the Search Dialog form to locate the appropriate case.

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.

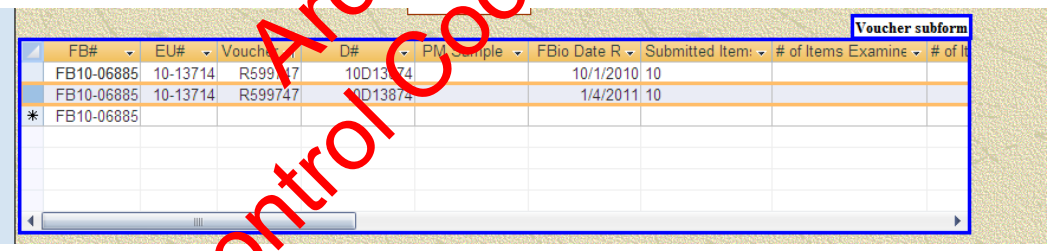
8. Save all requests in an Outlook folder as documentation of what was done and the reason for removing the Case Record(s).

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.