

FORENSIC BIOLOGY ADMINISTRATIVE MANUAL

Approving Authority: Mechthild Frinzi, Ph.D., Director

Procedures	Effective Date	Comments
Staff Roles and Responsibilities	5/20/2010	
Document Control	5/20/2010	
Control of Records	5/20/2010	
Management System Review	2/9/2010	
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Removing Records from the Electronic
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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:

All requests from attorneys **must** be brought to the attention of the Legal Department.

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 Files

An attorney who wishes to receive a certified copy of the Forensic Biology case and/or suspect file 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.

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 file 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

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All received written requests are brought by the OCME Legal Department to the Department of Forensic Biology Administrative Team.

The Administrative Team will incorporate the written request or judicial subpoena duces tecum into the associated DNA case file.

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

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

As soon as the certified copy is prepared, the Administrative Team will telephone the requesting attorney and advise him/her the file is ready for pick up.

Certified copies of DNA case files 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 files 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 file shall be directed to the Administrative Team at 212-323-1200.

All requests that a request for a certified copy of a DNA case file 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 file (e.g., Forensic Biology protocols applicable to testing performed in a specific case; the Forensic Biology QA/QC manual; certificate of accreditation; 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).

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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 file will be handled/coordinated by the Legal Department.

This section will not address the process of fulfilling all of the above possible-requested documents.

IN GENERAL:

Protocols

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).

For the production of “protocols applicable to testing performed in a specific case,” the Quality Assurance Manager or designee will determine the section(s) of the Department of Forensic Biology documents to be provided. The copy will be provided on an official OCME protected Adobe PDF formatted CD. The Department of Forensic Biology does not produce “paper copies” of protocols – only on an official OCME protected Adobe PDF formatted CD.

Production of Forensic Biology protocols takes a minimum of 10 business days.

Three CDs are prepared – one to be kept within the OCME Department of Forensic Biology case file, one for the requesting attorney, and one for the non-requesting attorney.

A certification cover page is not provided.

The request from the attorney shall be incorporated into the associated DNA case file(s).

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Raw Data

Production of raw data is an extremely time-consuming process, and therefore takes a minimum of four weeks to compile.

An analyst or supervisor will identify the case-specific raw data and transfer it onto an official OCME CD disk.

Two CDs are prepared – one to be kept within the OCME Department of Forensic Biology case file, one for the requesting attorney.

A certification cover page is not provided.

The request from the attorney shall be incorporated into the associated DNA case file(s).

CDs of protocols or raw data or other documents will not be mailed to the requesting prosecutor; they must be picked up by a messenger or representative of the prosecutor's office.

All CDs of documents fulfilled in accordance with a judicial subpoena duces tecum will be mailed by the OCME Legal Department to the Court which issued the subpoena.

The OCME is not permitted to provide licensed and/or copyrighted software (necessary to view the raw data).

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).

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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 an OCME VISITOR 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 placed in the associated DNA case file(s).

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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.

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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 placed in the associated DNA case file(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.

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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.

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All meetings with attorneys – the date and names of all persons present – shall be documented in the case contact section of the Forensic Biology case file.

If an attorney or expert witness wishes to communicate via the telephone, the criminalist must document the conversation in the case contacts section of the Forensic Biology case file. 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 contacts section of the DNA case file.

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.

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 assigned criminalist or her/his supervisor shall place a copy of the Protective Order in the associated DNA case file(s) and should make a case contact concerning notification of the Protective Order.

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G. Expungement Requests

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

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 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, as well as to the Assistant Director & Criminalist IV in the Exemplar Team.

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.

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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 placed into the associated DNA case file(s).

Archived 07/16/12
Document Control Coordinator

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.

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GUIDING PRINCIPLES AND SCOPE:

The Department of Forensic Biology seeks to provide maximum transparency of operations and assistance to prosecuting and defense attorneys consistent with maintaining appropriate laboratory security, confidentiality, and minimum disruption to laboratory operations.

This document provides guidance for dealing with various types of requests from prosecuting or defense attorneys for laboratory information or access.

PROCEDURE:

A. Requests for Forensic Biology Case Files

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

1. Prosecuting attorneys: A simple letter of request is sufficient. However, the letter must be signed by a prosecuting attorney; it is not sufficient if signed by a paralegal or trial preparation assistant.
2. Defense attorneys: The written request must include an original judicial subpoena duces tecum.
3. Written requests must also include:
 - i. The name of the complainant or victim
 - ii. The name of the defendant
 - iii. The Forensic Biology case number
 - iv. A contact telephone number for the attorney
4. Production of a certified copy of a Forensic Biology case file by the Administrative Team (A-Team) takes a minimum of ten (10) business days.
5. An OCME staff attorney reviews the certified copy prior to its release; the OCME staff attorney may make redactions in accordance with NYS Executive Law §995-d.

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6. As soon as the certified copy is ready for pick up, a member of the A-Team will telephone the requesting attorney's office. The certified copy must be picked up in person, either by the requesting attorney or a messenger. Copies of Forensic Biology case or suspect files are never faxed or mailed.
7. The original request or subpoena should be placed into the Forensic Biology case file.

B. Complex Discovery Requests

On occasion, an attorney may make a complex discovery request that seeks more than a certified copy of the case file.

Forensic Biology Manuals or Procedures

An attorney who wishes to receive a section of a Department of Forensic Biology Manual or Procedure must submit a written request to the OCME Legal Department.

1. Prosecuting attorneys: A simple letter of request is sufficient; however, the letter must be signed by a prosecuting attorney; it is not sufficient if signed by a paralegal or trial preparation assistant.
2. Defense attorneys: The written request must include an original judicial subpoena duces tecum.
3. If the attorney's request is unclear or requires further specification, an OCME staff attorney will follow up with the attorney. The OCME Staff Attorney will convey the request to the Forensic Biology Quality Assurance Manager, as well as the assigned case criminalist.
4. OCME will only provide copies of its own Department of Forensic Biology documents. OCME is not permitted to provide documents of another laboratory (such as the FBI or Bode Technology). The OCME is not responsible for producing a document that does not already exist.

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5. The Quality Assurance Manager will determine the section(s) of the Department of Forensic Biology documents to be provided. The copy will be provided on CD format. A certification cover page is not provided. Production of a copy of Forensic Biology protocols takes a minimum of 10 business days.
6. Copies must be picked up in person, either by the attorney, a paralegal or a messenger.
7. The request document(s) and a CD copy of the documents sent to the attorney should be placed into the Forensic Biology case file.

Electronic Test Data

A defense attorney who wishes to receive 'electronic data' (raw data or analyzed data) associated with a case must provide the OCME with a judicial subpoena duces tecum. The original subpoena must be sent to the attention of the OCME Legal Department.

1. If the written request is unclear or requires further specification, an OCME staff attorney will follow up with the defense attorney.
2. The OCME Staff Attorney conveys the request to the Forensic Biology Quality Assurance Manager, as well as the assigned case criminalist. An OCME staff attorney sends a brief letter to the attorney (cc'd to the Court) indicating that this electronic data discovery request will take approximately one month to complete.
3. The assigned case criminalist or supervisor transfers the case-specific electronic data onto a CD disk.
 - i. A minimum of two disks are prepared –one to be kept within the OCME Department of Forensic Biology case file and at least one for the attorney.
 - ii. The criminalist also prepares a certification page to accompany the CD disk.
4. OCME will only provide copies of electronic test data that it produces. OCME is not permitted to provide licensed and/or copyrighted software. The OCME is not responsible for producing electronic test data that does not already exist.

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5. An OCME staff attorney may prepare a brief letter (cc'd to the Court) to accompany the CD explaining the contents of the CD.
6. The certified copy of the CD must be picked up in person, either by the attorney or a messenger. CD copies of OCME Forensic Biology Electronic Data should never be mailed to an attorney.
7. The attorney's original subpoena should be placed into the OCME Forensic Biology case file, along with the CD copy of the electronic data provided to counsel.

C. Defense Request to be Present for Testing

On rare occasions, a defense attorney and/or their expert requests (via the prosecuting attorney) to be present for DNA testing. The Department of Forensic Biology permits an attorney and/or technical expert(s) 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.

1. The attorney must submit a written request to the attention of 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 defense attorney's written request, Forensic Biology testing will NOT cease unless a Court Order directs the Department of Forensic Biology to do so.
3. At a minimum, defense attorney's written request must reference:
 - i. the name of the defendant and indictment number;
 - ii. the name of the presiding Judge;
 - iii. the name of the assigned Assistant District Attorney;
 - iv. the name of the defense expert who wishes to observe;
 - v. items of evidence [and NYPD voucher number if known] which the attorney or expert believes were submitted to the OCME for DNA analysis.
4. If the written request is unclear or requires further specification, an OCME staff attorney will follow up directly with the requesting attorney.

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5. The attorney and/or expert must complete and sign an OCME VISITOR DNA SAMPLE CONSENT FORM and provide a DNA sample to the Department of Forensic Biology prior to entering the laboratory.
 - i. A criminalist within the Department of Forensic Biology Exemplar Group [X- Team] will collect an oral swab from the attorney or expert.
 - ii. A record of the DNA profile(s) generated will be placed in the associative case evidence or suspect exemplar Forensic Biology file. A cross reference to the specific case will be noted in all cases possibly affected.
 - iii. The original consent form is delivered to and maintained by the Forensic Biology Exemplar Group [X- Team]; a copy of the consent form is placed into the associated case file.
6. The OCME will only permit defense counsel or expert(s) to be present for observation during normal business hours: Monday to Friday, 9 am to 5 pm.
7. Defense counsel and/or expert will be escorted by an OCME Department of Forensic Biology criminalist at all times.
8. Defense counsel or expert must gown up to OCME specification prior to entering a laboratory. A defense counsel or expert who does not follow the OCME gowning specifications will not be permitted to enter the laboratory.
9. Defense counsel and expert may bring paper and pen into the laboratory.
10. Defense counsel and expert are prohibited from bringing cameras, cell phones or tape recording devices into the laboratory.
11. Defense counsel and expert are prohibited from photocopying any OCME documents.
12. Defense counsel and expert may not remove anything from the OCME Department of Forensic Biology laboratories or facility.
13. Defense counsel and expert will not be given a tour of the OCME DNA Facility.

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14. This is not an occasion or opportunity for the attorney or expert to question or quiz a criminalist about the testing process or technology or equipment utilized. If a defense attorney wishes to speak with the assigned criminalist in advance of trial concerning case-specific DNA testing and results, the attorney may return to the OCME DNA Building at a later time to speak with the criminalist in person.

ARCHIVED 04/30/2012

Revision History:

February 9, 2010 – Initial version of procedure.

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COMPLAINTS		
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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 record.

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- 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.

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- 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.

Archived 07/16/12
Document Control Coordinator

Revision History:

February 9, 2010 – Initial version of procedure.

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CONTROL OF RECORDS		
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GUIDING PRINCIPLES AND SCOPE

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

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

PROCEDURE

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

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

A. Identification

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

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

B. Indexing

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

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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 paperwork that is associated with the same laboratory number and stored in the same case file; calibration records are collected with other calibration records associated with the same equipment and stored in the same binder/folder.

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

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

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

- Most hard-copy case files are stored in the OCME Records department.
- Quality records that have any degree of confidentiality (such as personnel qualifications and court testimony monitoring records) are stored in the Quality Assurance Unit and are accessible only to Quality Assurance personnel.
- Other technical and quality records are stored either in the OCME Records department or in the Quality Assurance Unit.

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

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

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E. Retention

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

F. Disposal

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

Archived 07/16/12
Document Control Coordinator

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.”

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DNA TECHNICAL LEADER		
EFFECTIVE DATE 12-29-2011	APPROVING AUTHORITY LABORATORY DIRECTOR	PAGE 1 OF 2

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

A 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 where a permanent DNA Technical Leader has been appointed to.

EDUCATION AND EXPERIENCE

A 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.

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A 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 where a permanent DNA Technical Leader has been appointed to. Therefore, if a permanent DNA Technical Leader is on leave and cannot be contacted for an immediate matter, 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 shall serve as the interim DNA Technical Leader. Within fourteen (14) calendar days, 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 any 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.

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.

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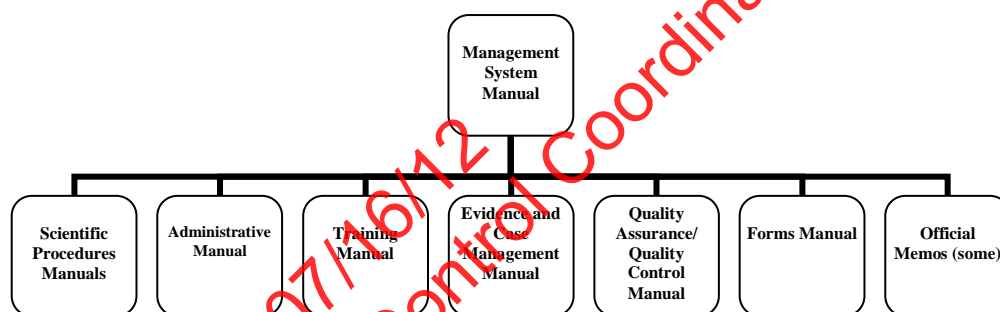
DOCUMENT CONTROL		
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I. GUIDING PRINCIPLES AND SCOPE

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

II. GENERAL STRUCTURE OF MANAGEMENT SYSTEM DOCUMENTS

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



- **Management System Manual:** The Management System Manual is the top tier document in the management system. It provides an overall guide to the management/quality system of the Department of Forensic Biology. It contains references to other management system documents that have more detailed information. In terms of Standard 4.2.2 of ISO 17025:2005, this is our “quality manual.”
- **Scientific Procedures Manuals:** These manuals contain current procedures pertaining to the analytical testing of biological specimens. The manuals are: Serology Manual, STR Analysis Manual, Mitochondrial DNA Analysis Manual, and CODIS Manual.
- **Administrative Manual:** This manual contains procedures with laboratory-wide application pertaining to laboratory planning, organization, and documentation.

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- **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.

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III. RESPONSIBILITY AND AUTHORITY FOR DOCUMENT CONTROL

- **The Laboratory Director and/or Deputy Directors** have the primary responsibility and authority for approval of the Management System Manual and all guiding principles and procedures that are under the Administrative Manual. The directors may also act as back-up approvers for all other documents; however, where DNA Technical Leader authorization is needed, the approval can be done only where the director is acting as the designated deputy Technical Leader in the absence of the primary DNA Technical Leader.
- **The Quality Assurance Manager (QAM)** has the primary responsibility and authority for implementation and maintenance of the document control system. The QAM is also the primary approver of all guiding principles and procedures that are under the Quality Assurance/Quality Control Manual, Evidence and Case Management Manual, and Serology Manual.
- **The Nuclear DNA Technical Leader** has the primary responsibility and authority for approval of procedures in the Protocols for Forensic STR Analysis Manual; is principal or co-approver of the proficiency testing program; and is principal or co-approver of the Nuclear DNA training program content in the Training Manual.
- **The Mitochondrial DNA Technical Leader** has the primary responsibility and authority for approval of procedures in the Mitochondrial DNA Analysis Manual; principal or co-approver of the proficiency testing program; and principal or co-approver of mitochondrial DNA training program content in the Training Manual.
- **The Training Manager** has the responsibility and authority for approval of the Training Manual.
- **The CODIS Manager** has the responsibility and authority for approval of the CODIS Manual.
- **The Document Control Coordinator (DCC)** works under the direction of the Quality Assurance Manager and has the primary responsibility and authority to ensure that: guiding principles and procedures are in the correct format, the most current approved internal management system documents are on the Forensic Biology server, the Master Lists of documents are accurate, and obsolete documents are suitably marked and archived.

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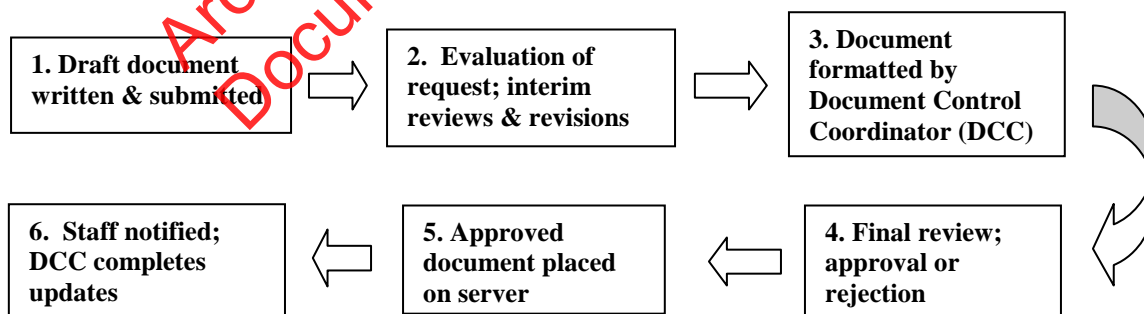
- **Assistant Directors** have the authority and responsibility to propose new and revised guiding principles and procedures and to provide expertise for the review of document proposals.
- **All Forensic Biology staff** has the authority and responsibility to propose new and revised management system documents.

IV. DOCUMENT FORMAT

1. All management system documents generated by the laboratory are marked with:
 - a) Name or title of the document
 - b) The name and/or title of the approving authority
 - c) The effective date and/or date of approval
 - d) 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.

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

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



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Step 1. Draft document written & submitted

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

Step 2. Evaluation of Request; Interim reviews & revisions

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

Step 3. Document formatted by Document Control Coordinator

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

Step 4. Final review; approval or rejection

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

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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.

VI. 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.

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

VII. 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.

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VIII. 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.

Archived 07/16/12
Document Control Coordinator

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.

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MANAGEMENT SYSTEM REVIEW		
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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.

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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 managers 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.

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PURCHASING SERVICES AND SUPPLIES		
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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.

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

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PURCHASING SERVICES AND SUPPLIES		
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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.

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PURCHASING SERVICES AND SUPPLIES		
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- 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.

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- 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 Receiving Log and the Expiration Log (if applicable) on the network server is completed.
6. Individual containers of chemicals, kits, and reagents are initialed (by the recipient) and dated (date of receipt). A QA/QC Raw Material Form is completed for later documentation of quality testing results and is filed in a QC Reagent Binder once complete.
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.

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FORENSIC BIOLOGY ADMINISTRATIVE MANUAL

REMOVING RECORDS FROM THE ELECTRONIC CASE LOGBOOK		
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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 request for Case Record deletion must specify the case number and, if applicable, the Case Record number (e.g., 2 of 3).
- 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.

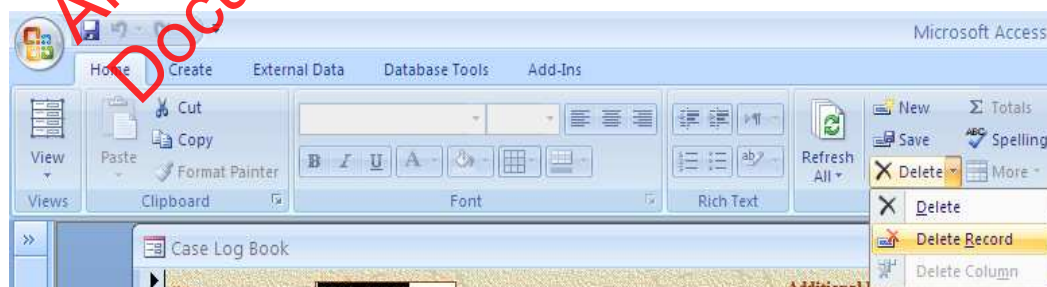
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A. Case Record Deletion

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”.

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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.

Voucher subform								
FB#	EU#	Voucher	P#	P# Sample	FBio Date R	Submitted Item	# of Items Examine	# of Items
FB10-06885	10-13714	R599747	10D13874		10/1/2010	10		
FB10-06885	10-13714	R599747	10D13874		1/4/2011	10		
* FB10-06885								

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.

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SECURITY		
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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

1. 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.
2. 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, an officer at the vehicle entrance, and a roving security officer.
3. The building has two entrances:
 - Main entrance at the west end of the building
 - Vehicular breezeway off 26th Street
4. Main Entrance Security
 - Retractable vehicular bollards at the entrance exterior prevent unauthorized vehicular access to the plaza.
 - The reception desk is staffed by administrative support personnel 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.

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- 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.
5. Vehicular Breezeway Security
- A guard booth is situated at the entrance and is staffed by OCME security personnel 24 hours a day, 7 days a week
 - The guard controls a gate which allows vehicular access
 - The guard monitors access to the loading dock
6. 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.

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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 the Memorandum concerning Visitors to the OCME DNA Building.

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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 areas 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.

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STAFF ROLES AND RESPONSIBILITIES		
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GUIDING PRINCIPLES AND SCOPE

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

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

ORGANIZATIONAL STRUCTURE

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

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

ROLES AND RESPONSIBILITIES

Director

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

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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.

IT Manager

The Forensic Biology IT Manager is responsible for the planning and control of the LIMS implementation and serves as the LIMS Administrator for the Department. The IT Manager acts as a liaison between Forensic Biology and the OCME Information Technology department in all aspects pertaining to LIMS and other computer applications.

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DNA Technical Leaders

The DNA 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. Each technical leader has the authorities and responsibilities described in the FBI DNA Quality Assurance Standards. For specific information see the DNA TECHNICAL LEADERS document in the Forensic Biology Administrative Manual.

CODIS Custodian/Supervisor

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

Quality Assurance Manager

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

Criminalist, Level IV

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

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Criminalist, Level III

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

Criminalist, Level II

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

Criminalist, Level IA & IB

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

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.

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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 Manager

The Administrative Manager is in charge of the administrative support functions of the Department. The Administrative Manager supervises 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. The Administrative Manager also oversees the management of all Departmental procurement matters and Departmental human resource functions including recruitment, retention, employee relations, and performance evaluations.

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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.

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