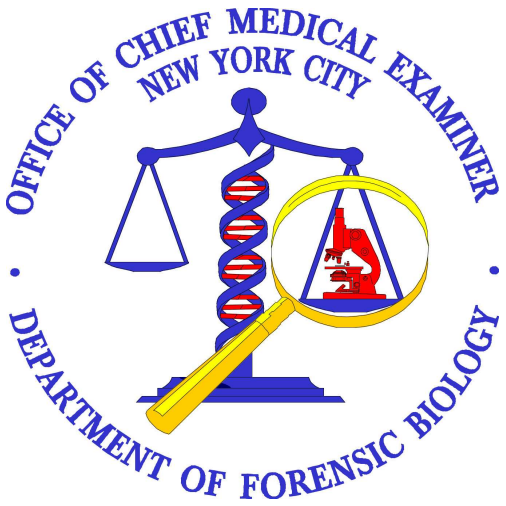


FORENSIC BIOLOGY ADMINISTRATIVE MANUAL

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

Procedures	Effective Date	Comments
Attorney Requests	2/9/2010	
Complaints	2/9/2010	
Control of Records	5/20/2010	
DNA Technical Leader	2/9/2010	
Document Control	5/20/10	
Management System Review	2/9/2010	
Purchasing Services and Supplies	2/9/2010	
Security	9/27/2010	
Staff Roles and Responsibilities	2/9/2010	

COMPLAINTS		
DATE EFFECTIVE 02-09-2010	APPROVED BY MECHTHILD PRINZ	PAGE 1 OF 3

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.

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.

CONTROL OF RECORDS		
DATE EFFECTIVE 05-20-2010	APPROVED BY MECHTHILD PRINZ	PAGE 1 OF 3

GUIDING PRINCIPLES AND SCOPE

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

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

PROCEDURE

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

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

A. Identification

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

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

B. Indexing

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

C. Collection

Records are collected for filing and/or storage in a timeframe which varies according to the specific type of record. . For example, electropherograms are collected with other 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.

E. Retention

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

F. Disposal

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

Revision History:

February 9, 2010 – Initial version of procedure.

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

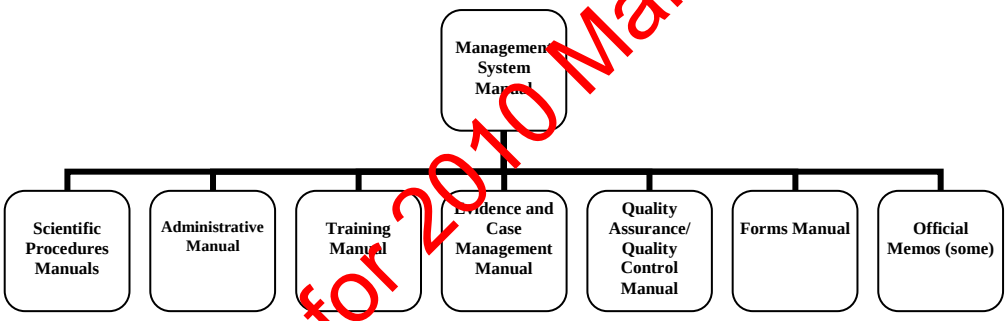
DOCUMENT CONTROL		
DATE EFFECTIVE 05-20-2010	APPROVED BY MECHTHILD PRINZ	PAGE 1 OF 8

I. GUIDING PRINCIPLES AND SCOPE

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

II. GENERAL STRUCTURE OF MANAGEMENT SYSTEM DOCUMENTS

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



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

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

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

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

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

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

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

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

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

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

III. RESPONSIBILITY AND AUTHORITY FOR DOCUMENT CONTROL

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

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

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

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

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

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

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

- **Assistant Directors** have the authority and responsibility to propose new and revised guiding principles and procedures and to provide expertise for the review of document proposals.

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

IV. DOCUMENT FORMAT

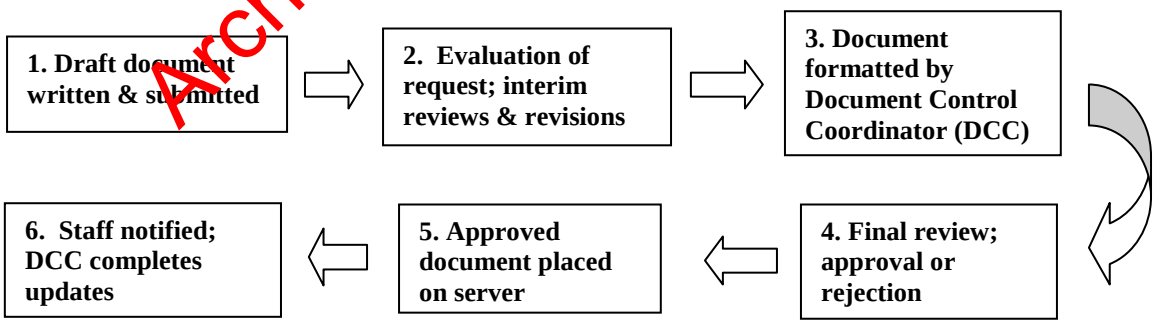
1. All management system documents generated by the laboratory are marked with:

   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:



Step 1. Draft document written & submitted

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

Step 2. Evaluation of Request; Interim reviews & revisions

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

Step 3. Document formatted by Document Control Coordinator

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

Step 4. Final review; approval or rejection

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

Step 5. Approved document placed on server

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

Step 6. Staff notified; Document Control Coordinator completes updates

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

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

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.

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.

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.

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.

MANAGEMENT SYSTEM REVIEW		
DATE EFFECTIVE 02-09-2010	APPROVED BY MECHTHILD PRINZ	PAGE 1 OF 2

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.

PURCHASING SERVICES AND SUPPLIES		
DATE EFFECTIVE 02-09-2010	APPROVED BY MECHTHILD PRINZ	PAGE 1 OF 4

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

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 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.

SECURITY		
EFFECTIVE DATE 09-27-2010	APPROVED BY MECHTHILD PRINZ	PAGE 1 OF 5

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.

- 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.

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.

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 (3, 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 I Desktop Support	No Access	Limited	Limited
OCME Security	Unlimited	Unlimited	Unlimited
EU-Non-Supervisory	Unlimited 5	Unlimited 5	Unlimited
EU Supervisors	Unlimited 5	Unlimited 5; Limited 11 & 12	Unlimited
Facilities-Engineers	Limited	Limited	Limited
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.

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.