

Department of Forensic Biology

Administrative Manual

Version 4.0

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## I. Introduction

Effective this date, this Administrative Manual Version 3.0 supersedes all previous administrative manuals used in the Department of Forensic Biology.

The following are the managerial staff of the Department of Forensic Biology.

Robert C. Shaler, Ph.D.	Director
Howard J. Baum, Ph.D.	Assistant Director and DNA Technical Manager.
Marie Samples, M.S.	Assistant Director
Mechthild Prinz, Ph.D.	Assistant Director
Karen Dooling, M.S.	Assistant Director
Pasquale Buffolino, M.S.	Assistant Director

The Quality Assurance program and Quality Control functions are managed as follows: The Deputy Director of the Department of Forensic Biology is ultimately responsible, as described in the Department's Quality Manual. The Department of Forensic Biology has a quality assurance manager who is responsible for ensuring that the quality aspects of the laboratory testing are fully operational.

Paul Goncharoff, Ph.D.	QA Manager
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The Department of Forensic Biology's Quality Assurance program is designed to provide a program through which all laboratory operations are scrutinized in order to provide a reliable laboratory result. To that end, the following definitions apply.

### Quality Control

Those procedures used to maintain acceptable limits of variation for products and services. More specifically, these are the internal activities or activities according to externally established standards used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

### Quality Assurance

Quality assurance pertains to those procedures used to insure that quality control parameters are appropriate and sufficient measures of variation. These are the planned and systematic actions necessary to provide sufficient confidence that a laboratory's product or service will satisfy given requirements for quality. For example, measuring and recording the pH of a solution is a common quality control to insure that the variation between lots of solutions is maintained within a specified range. But this parameter is a meaningful measure of quality only if the pH meter has been

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calibrated, the technician making the measurement knows how to operate the pH meter, the water is sufficiently pure, and the technician has added the proper reagents. Quality assurance insures that quality control measures are meaningful measures of variation.

## II. Planning and Organization

### A. Goals and Mission

The mission of the Department of Forensic Biology is to provide users of its laboratory services - the NYPD, District Attorneys, Legal Aid, Capital Defenders Attorneys, and other agencies and attorneys within or serving New York City's criminal justice system - access to scientific analyses conducted in criminal investigations. These analyses are conducted independently, objectively, and reliably, such that the test results meet New York State and Federal Standards. Consistent with available resources, testing results and reports are available and represent high quality, integrity, and accuracy as dictated by the department's Quality Assurance (QA) program, described in the Quality Manual and other procedural manuals. The Department of Forensic Biology also seeks new methods to analyze biological specimens so that its capabilities and service remain state-of-the-art. Additionally, the Department is a CODIS (Combined DNA Indexing System) local laboratory.

The Department is responsible for DNA testing for backlog rape cases subcontracted to private forensic DNA laboratories by the NYPD. The SCME role in this contract is: the scientific reliability of DNA testing, the review of DNA profiles and the entry of eligible profiles into CODIS

The Department of Forensic Biology develops information through the identification and individualization of physiological fluids such as blood, semen, urine and saliva obtained from investigating agencies or from post-mortem specimens. In addition to being a powerful courtroom aid and mechanism to help identify unknown bodies, this information can tie a victim to a crime scene, connect a suspect to a crime scene, or eliminate a suspect from suspicion. The Department of Forensic Biology may perform crime reconstruction in order to ascertain the events of the crime.

The scientific analyses include but are not limited to the following. For details, see the appropriate Departmental procedures manuals:

1. Biological Fluid identification
2. Species identification
3. Genetic marker/DNA analysis
4. Forensic Paternity
5. Crime Reconstruction/Bloodstain Spatter Pattern Analysis
6. Report Preparation
7. Expert Testimony

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8. Enter eligible DNA profiles into CODIS and verifying database search results.
9. NYPD backlog project

To comply with the laboratory's mission, the management will endeavor to promote a professional and safe laboratory environment within which the staff can discharge their duties and obligations.

## **B. QA Objectives**

1. Monitor, on a routine basis, all scientific testing performed in the laboratory by means of Quality Control (QC) standards, proficiency tests, and audits.
2. Verify that all scientific analyses and equipment operate within the established performance criteria and that the quality and validity of the analytical data is maintained.
3. Ensure that performance criteria, established in the Department's QC Manual and Laboratory Methods Manuals for each of the routine scientific procedures performed in the laboratory, are followed.
4. Ensure the quality and validity of data generated by the quality control (QC) program for both critical reagents prepared in the laboratory and those obtained commercially. Ensure the reliability of instruments employed in the laboratory's routine testing, as guaranteed by the quality assurance (QA) program, as delineated in the Quality Manual.
5. Checks with director to ensure that qualifications of the laboratory staff meet Department of Personnel of the City of New York requirements and the educational requirements imposed by regulating bodies such as New York State, the Federal DNA Advisory Board (DAB), and/or SWGDAM. Also, ensure that the scientific staff performing casework meet all proficiency testing program standards and continuing education as an integral part of the overall QA program of the Department of Forensic Biology.
6. Maintain records for in-house reagent manufacture and the QC documentation of their acceptability, retain vendor QC documents, such as specification sheets and maintain instrument calibration and diagnostic records.
7. Insure that problems are noted and that corrective action is taken and documented and reviewed by the Deputy Director.

## **C. Authority and Accountability for the QA Program**

The organizational structure, Section D, defines the relationships within the Department of Forensic Biology among individuals and the operational units of the department. Within this structure, the QA



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Manager, in association with the laboratory Director and the Deputy Director defines the QA/QC policy. The Department of Forensic Biology has chosen to have the QA Manager report directly to the Deputy Director. In the absence of the Deputy Director, the QA Manager will report directly to the Director. Each Criminalist working on casework in the Department of Forensic Biology must adhere to the QA/QC program standards, as they relate to their work and responsibilities.

## **D. Organizational Structure**

The OCME is organized such that the Director of the Department of Forensic Biology reports directly to the head of the agency, the Chief Medical Examiner, as do the other laboratory directors. The managerial structure of the Department of Forensic Biology is seen in Appendix A.

The Department of Forensic Biology is a single operational unit having multiple responsibilities. The Deputy Director(s) - also functions as Technical Manager(s) - and report directly to the Director. Assistant Directors report directly to the Deputy Director. Clerical personnel report to an office manager, who reports to the Director. Also, the Medical Examiner Scientific Assessment and Training Team (MESATT) reports to the Director.

### **Director**

The Director is responsible for the overall scientific, quality, and administrative operation of the Department of Forensic Biology. The Director performs an administrative review on all casework and crime scene work and technical reviews on selected cases. Additionally, he/she is responsible for 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.

### **Deputy Director**

The Deputy Director is the administrative second-in-command in the laboratory, and will assume these responsibilities in the Director's absence. Assistant Directors report directly to the Deputy Director. He/she is also the technical manager as defined by the DNA Advisory Board (DAB). As such, he is responsible for the daily technical operation of the DNA laboratory. The Deputy Director may perform scientific analyses, perform selective technical reviews of cases, train subordinates, testify in court, monitor testimony of subordinates, and prepare annual reviews of subordinates.

### **Assistant Directors**

Each Assistant Director supervises one or more Criminalist IV's and their subordinates; performs technical reviews of cases supervised by and/or worked on by subordinates; trains new hires, police

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investigators, or attorneys; represents the Department of Forensic Biology in meetings with other NYC law enforcement and/or criminal justice agencies; testifies in court; and evaluates the testimony of each subordinate once annually. In the absence of the Director and Deputy Director, a designated Assistant Director will assume responsibility overseeing the administrative operation of the Department of Forensic Biology. An Assistant Director may perform scientific analyses on casework and testify in court. Additionally, the Assistant Directors prepare annual reviews of subordinate personnel, usually Criminalist IV's, and prepare monthly reports to the Director.

Assistant Directors may be responsible for other laboratory functions such as CODIS, NYPD Backlog, Purchasing, Training, Computers, Research and unspecified projects as they arise.

### Technical Manager

The Deputy Directory has the responsibility of DNA Technical Manager as defined by the DNA Advisory Board (DAB), section 5.2. The Technical Manager is accountable for the technical and quality operations of the DNA laboratory. The QA Manager reports directly to the Technical Manager.

### QA Manager

The QA Manager is responsible for the quality system. His/her responsibilities are varied and mirror ASCLD/LAB and DAB standards. They include maintaining and updating the quality manual, monitoring laboratory practices to verify continuing compliance with Departmental policies and procedures, evaluating and maintaining instrument calibration and maintenance records, coordinating with the Assistant Director responsible for research to ensure that the validation of new DNA casework procedures meet DAB standards, investigating technical problems and implementing corrective and/or remedial action, administering proficiency testing and evaluating results, conducting or coordinating internal quality audits, proposing corrections and improvements in the quality system, and recommending training to improve the quality of laboratory staff. The QA Manager conducts an annual review of laboratory's quality system. The Quality Manager supervises Criminalists and Laboratory Associates who are assigned to him/her.

### Criminalist IV

The responsibilities of Criminalist IV's are described in the Civil Service specifications for that title. Generally, a Criminalist IV may supervise one or more Criminalist III's, II's, I's, and/or Laboratory Associates; participates in the training of subordinates; performs scientific analyses on evidence submitted to the laboratory; performs technical reviews of cases; prepares annual performance evaluations, as requested by OCME management; testifies in court; evaluates the court testimony of each subordinate annually; takes one proficiency test every 183 days, as required by regulating

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and accrediting bodies; prepares written scientific reports; may supervise rotations in the laboratory.

### **Criminalist III**

The responsibilities of Criminalist III's are described in the Civil Service specifications for that title. Generally, Criminalist III's may supervise Criminalist II's, Criminalist I's or Laboratory Associates. Criminalist III's may also supervise and/or work in rotations: DNA extraction, DNA quantitation, and P30 Elisa, perform scientific analyses on evidence submitted to the laboratory, prepare written scientific reports, perform technical reviews of simple cases, take DNA proficiency tests every 183 days according to accreditation requirements, and testify to results. In the absence of a Criminalist IV, a Criminalist III may assume those responsibilities on an interim basis.

### **Criminalist 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, taking proficiency tests every 183 days according to accreditation standards, preparing written scientific reports which reflect testing, and testifying in court.

### **Criminalist I**

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 on other simple cases, prepare written scientific reports and may testify in court, if required by an Assistant District Attorney. Criminalist I's take proficiency tests.

### **Laboratory Associate**

Laboratory Associates assigned to the Department of Forensic Biology function either as technicians as described by the DAB or as research associates. In the former capacity, a Laboratory Associate may help with QC testing, and work in support rotations and perform other scientific and administrative duties that enhances the flow of cases through the laboratory. As research associates, Laboratory Associates may help to validate new testing methods. Laboratory Associates take proficiency tests.

### **Consultant**

The Department of Forensic Biology may employ one or more consultant scientists. These Scientists work on specific projects, such as helping with validation studies, completing research projects,

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developing new methods, helping with QC, and helping with the administrative activities involved in casework backlogs, if they have the appropriate credentials and training. These scientists are technicians, as defined by the DAB.

### **Codis Manager/NYPD Backlog Project**

An Assistant Director is responsible to manage all CODIS activity in the laboratory. Part of this responsibility encompasses the NYPD Backlog Rape Project.

### **Training Manager**

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

### **III. Documentation**

Laboratory personnel record all significant laboratory activities to create a useable audit trail that documents the department's routine scientific testing. The documentation will be kept for the following topic areas:

#### **A. Manuals**

##### **1. Scientific Procedure Manuals**

These manuals detail current procedures used for all the analytical testing of biological specimens and include standard operating protocols, and must be approved by the Director before they may be used as an acceptable manual. Changes can be documented by written memo, which are distributed to the entire scientific staff and then placed in a memo binder. Updates of the manuals will reflect these changes. Manuals include the following information.

- a. Date the procedure was adopted
- b. Revision dates
- c. The Director's initials and date approved (in footer), signifying the manual's official start for use in the laboratory.

##### **2. Case Management Manual**

The Case Management Manual defines how cases are handled in the laboratory.



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- a. Evidence examination guidelines
- b. Handling, evaluation, and troubleshooting of cases that are in progress.
- c. Report writing

### **3. Quality Manual**

The Department's Quality Manual is an overview of the Department's quality system, and details the procedures used to:

- a. Prepare reagents used in the laboratory
- b. Determine the quality of reagents
- c. Document QC testing procedures for reagents, instruments, and equipment
- d. Calibrate and maintain instruments and equipment

### **4. Administrative Manual**

The Administrative Manual details the planning and organization and documentation in the laboratory.

### **5. Equipment Instruction Manuals**

Equipment instruction manuals are maintained by the Department of Forensic Biology.

### **6. Training Manual**

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

## **B. Case Records and Policies**

Written reports will be prepared when observations and conclusions are made as a result of examinations performed by appropriate members of the Department. These reports become a part of the case record. They represent analytical findings and, where appropriate, the conclusions formed from these findings. The bench notes, worksheets and other work products used to reach these conclusions are an integral part of the case record. All reports will be signed by the criminalist responsible for the case and a second scientist, usually that person's supervisor, an Assistant Director, or the Director.

Case files contain sufficient information for an outside assessment of the laboratory's work product, see Case Management Manual. Section C, "Data Analysis and Reporting", discusses other relevant



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considerations of the case record: Scheduled Analysis and Case Prioritization, Case Management, Data Analysis, Reporting, Case Review, and Dissemination of Reports and Disclosure of Results.

## **C. Data Analysis and Reporting**

### **1. Scheduled Analysis and Case Prioritization**

When cases are received into the laboratory they may be assigned a target date for completion, determined after a discussion with detectives and/or district attorneys. Cases that do not require immediate attention may be assigned a default target date. Cases that require special attention may be assigned shorter target dates, and high priority cases may be started immediately. See Case Management Manual.

### **2. Case Management**

Generally, a single Criminalist, who acts as an interpreting analyst, is responsible for stewarding samples through the analytical process. Usually, samples are processed in bulk, using a rotation system in which Criminalists and/or Laboratory Associates rotate through rotations. See Case Management Manual for a detailed discussion.

Since sample analysis in the laboratory is a part of case management, an interpreting Criminalist (usually Criminalist II-IV's) is responsible for all facets of the case analysis. See Case Management Manual for details. Criminalist I's will examine rape kits and will generate reports for those cases that are semen negative.

Generally, the analytical scheme employs a rotation system in which samples move through the laboratory in a logical fashion, progressing through workstations: Evidence examination, serological testing (P30/Amy) DNA extraction, DNA quantification, PCR set-up, PCR amplification, STR analysis, and data interpretation and report preparation (case management). The Criminalist working at that workstation is referred to as a rotating analyst and has no responsibility other than ensuring that the work done in that rotation is performed properly.

### **3. Data Analysis**

#### **a. Data interpretation**

All analytical case data are interpreted independently and in sequence by the Criminalist who is assigned to a support and/or functional rotation, by the Criminalist while preparing a report, and by the supervisor, an Assistant Director, the Deputy Director, or the Director, who reviews the report.

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b. Discrepancies and disputes

While infrequent, discrepancies may occur from mishandling of samples in the laboratory, such as mix-ups on gel loading, during DNA extraction, or selecting the wrong sample for analysis. Usually, these discrepancies are spotted early during the analysis, and the interpreting analyst for case, with the consent of his/her supervisor, can correct the problem by re-analysis. However, if the discrepancy is not discovered before the report is prepared, an investigation concerning the nature of the problem is necessary. This investigation can be initiated by the Criminalist IV and/or an Assistant Director, with assistance, if necessary, from the Deputy Director (Technical Manager), or the Director. If the source of the problem is not readily apparent, the QA Manager may attempt to identify the source of the problem to learn whether it is an isolated event or a systemic problem and whether other casework has been affected. Finally, a solution to the problem must be sought. If the problem is an isolated event, remedial and/or corrective action may be minimal or not necessary. However, a systemic problem may necessitate extensive corrective and/or remedial and possibly even a change in laboratory policy and/or procedures. In any situation where a discrepancy occurs in which the problem is discovered after a report has been prepared, QA action must be initiated and documented. See section P for a discussion of corrective action.

Sometimes legitimate differences of opinion, disputes, concerning the interpretation of results occur. In these instances, if the differences of opinion cannot be resolved by either the Criminalist IV or Assistant Director, the Deputy Director (Technical Manager) will be the final arbiter.

c. Archives

All original data pertaining to all analyses must be archived by one of several acceptable methods (if possible or if applicable; i.e., densitometry, photography, and xerox), for future retrieval and analysis. Archives are maintained at the OCME for at least 5 years.

d. Data matching

Where identifications are made using DNA profiling, specific matching criteria have been established and are part of the methods manual, see Protocols for Forensic STR Analysis.

e. Data standards

Known standards are recorded and monitored by means of criteria established by the DNA Advisory Board (DAB) and are included in the DNA Quality Manual.

f. Additional and amended reports

In those instances when a report is issued containing an error, an amended report is issued correcting



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the mistake. Additional reports will contain additional analyses.

#### 4. Reporting

All reports accurately reflect the data produced, and all opinions are based upon objective scientific observations, see Protocols for Forensic STR Analysis and Case Management Manuals.

#### 5. Case Review

##### a. Technical review

A technical review is performed on all cases for which reports are written and normally takes place in distinct phases before final reports are released. This is an in-depth review of all analytical testing performed in the case. It ensures that laboratory procedures were followed, the QA/QC procedures were followed, data was interpreted correctly, and that the final report accurately reflects the underlying data. The technical review is performed by a minimum of one supervisor, Assistant Director, Deputy Director or Director.

The technical review is documented by dating and initialing the "technical review" line on the Scheduled Analysis sheet. Depending on the category of case, the level of technical review may vary (see Tables 1-4).

##### b. Administrative review

The administrative review is performed on all cases for which reports are written and is performed by the Director or designee. It is conducted after the technical review, and checks that notes and worksheets reflect accreditation standards; case numbers, victim and suspect names, and police evidence control numbers are correct; data pages are numbered and initialed correctly; scheduled analysis makes sense and had been completed; items reported correspond with items described in the case notes; the data obtained for items listed in the report concur with the summary descriptions in the report; and that the report fully documents testing done in the case.

The administrative review is documented by dating and initialing the "administrative review" line on the Scheduled Analysis sheet.

Rush cases are those that may require immediate a written or verbal report. In these instances, the review process may be shortened and the administrative review may not take place until after the report has been issued.

Reviewing takes place in phases. Under routine circumstances, the case review process is illustrated in the tables below.

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- c. Cases that do not include DNA typing results may have the technical review performed by a Criminalist III or Criminalist IV.

Table 1

Step	Assigned Scientist	Activity
1	Assigned Criminalist	A report is prepared for the case.
2	Criminalist III or Criminalist IV	<p>Technical review of the casefile and report.</p> <p>If needed, the case is returned to the Criminalist for additional testing to resolve a discrepancy in the data, to complete work that had not been done, or to correct the report of the casefile. When this happens, the case reverts to Step 1.</p> <p>In some instances, the case is returned to the Criminalist to correct deficiencies in the casefile and/or report such as missing paperwork, typographical errors in the report, etc. When this happens, the reporting process continues with Step 3.</p>
3	Assigned Criminalist	The casefile is completed and/or the report is corrected.
4	Criminalist III or Criminalist IV	Final technical review of the casefile and report
5	Director or Designee	Perform administrative review and enter productivity data into database.

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- d. Cases that include no DNA typing results suitable for CODIS (no DNA foreign to the victim and/or Y STR typing only) may have the technical review performed by a Criminalist IV.

Table 2

Step	Assigned Scientist	Activity
1	Assigned Criminalist	A report is prepared for the case.
2	Criminalist IV	<p>Technical review of the casefile and report.</p> <p>If needed, the case is returned to the Criminalist for additional testing to resolve a discrepancy in the data, to complete work that had not been done, or to correct the report of the casefile. When this happens, the case reverts to Step 1.</p> <p>In some instances, the case is returned to the Criminalist to correct deficiencies in the casefile and/or report such as missing paperwork, typographical errors in the report, etc. When this happens, the reporting process continues with Step 3.</p>
3	Assigned Criminalist	The casefile is completed and/or the report is corrected.
4	Criminalist IV	Final technical review of the casefile and report
5	Criminalist IV	Enter DNA profiles of suspects into the OCME local DNA Database to check for profiles "seen" before.
6	Director or Designee	Perform administrative review and enter productivity data into database.

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- e. Cases that include DNA typing results suitable for LINKAGE and/or CODIS and do not have mixtures in probative samples (e.g., clean sperm cell fraction but a mixture in the epithelial cell fraction or a clean sperm cell fraction in one sample and mixtures in the other samples with no deduced profiles) must have a technical review performed by an Assistant Director, Deputy Director, and/or the Director.

Table 3

Step	Assigned Scientist	Activity
1	Assigned Criminalist	A report is prepared for the case.
2	Assistant Director or Deputy Director	<p>Technical review of the casefile and report.</p> <p>If needed, the case is returned to the Criminalist for additional testing to resolve a discrepancy in the data, to complete work that had not been done, or to correct the report of the casefile. When this happens, the case reverts to Step 1.</p> <p>In some instances, the case is returned to the Criminalist to correct deficiencies in the casefile and/or report such as missing paperwork, typographical errors in the report, etc. When this happens, the reporting process continues with Step 3.</p>
3	Assigned Criminalist	The casefile is completed and/or the report is corrected.
4	Assistant Director or Deputy Director	Final technical review of the casefile and report
5	Assistant Director or Deputy Director	<p>Enter eligible DNA profiles into the OCME local DNA Database to check for profiles "seen" before.</p> <p>Forward eligible profiles to CODIS group for entry into CODIS</p>
6	Director or Designee	Perform administrative review and enter productivity data into database

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- f. Cases that include DNA typing results suitable for CODIS and have mixtures in probative samples, including those with deduced profiles, must have a technical review performed by a Criminalist IV and Assistant Director, Deputy Director, and/or the Director.

Table 4

Step	Assigned Scientist	Activity
1	Assigned Criminalist	A report is prepared for the case
2	Criminalist IV	<p>Technical review of the casefile and report</p> <p>If needed, the case is returned to the Criminalist for additional testing to resolve a discrepancy in the data, to complete work that had not been done, or to correct the report of the casefile. When this happens, the case reverts to Step 1.</p> <p>In some instances, the case is returned to the Criminalist to correct deficiencies in the casefile and/or report such as missing paperwork, typographical errors in the report, etc. When this happens, the reporting process continues with Step 3.</p>
3	Supervisor	Final technical review of the casefile and report
4	Assistant Director or Deputy Director	Performs steps 2-5 in Table 3 as needed
5	Director or Designee	Perform administrative review and enter productivity data into database

At times, a Criminalist IV, Research Scientist, Assistant Director, Deputy Director, or Director may conduct or direct independent scientific investigations on casework. In these instances, the technical review process begins at the next higher level of authority in the laboratory. If the Director initiates such investigations, the Deputy Director or an Assistant Director will review the case.



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6	Director or Designee	Perform administrative review and enter productivity data into database
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(2). Cases that go to Criminalist supervisor prior to going to Assistant Director

These are cases with mixtures, including those with deduced profiles.

Table 2

Step	Assigned Scientist	Activity
1	Assigned Criminalist	A report is prepared for the case
2	Criminalist Supervisor	Technical review of the casefile and report  If needed, the case is returned to the Criminalist for additional testing to resolve a discrepancy in the data, to complete work that had not been done, or to correct the report of the casefile. When this happens, the case reverts to Step 1.  In some instances, the case is returned to the Criminalist to correct deficiencies in the casefile and/or report such as missing paperwork, typographical errors in the report, etc. When this happens, the reporting process continues with Step 3.
3	Supervisor	Final technical review of the casefile and report
4	Assistant Director	Performs steps 2-5 in Table 1 as needed
5	Director or Designee	Performs step 5 in Table 1

At times, a Criminalist IV, Research Scientist, Assistant Director, Deputy Director, or Director may conduct or direct independent scientific investigations on casework. In these instances, the review process begins at the next higher level of authority in the laboratory. If the Director initiates such investigations, the Deputy Director or an Assistant Director will review the case.

Initials: RC

## 6. Dissemination of Reports and Disclosure of Results

Reports are prepared as described in section III. B. During the review process, the Director, Deputy Director, Assistant Director, or Criminalist will prepare a Report Route Sheet, which reflects the agency and/or the individual who is to receive the report. Copies of reports in cases involving deceased individuals are sent to the OCME records department and/or to the NYPD and/or District Attorney. Reports in other case types – assaults, sexual assaults, burglaries, robberies – will be sent to the NYPD and/or the district attorneys.

Disclosure of preliminary and/or verbal reports may be issued before a report is prepared only after results are reviewed by an appropriate supervisor and then only in cases where the results are critical to an on-going investigation. Disclosure of the test results of work-in-progress must be approved by an Assistant Director, the Deputy Director or the Director.

### D. Court Testimony

Court testimony is the culmination of the work performed by the laboratory's scientists. Each testifying Criminalist will be monitored by another member of the laboratory staff at least once a year, providing testimony is rendered. Ideally, the monitoring staff member will be in a supervising capacity, but this may not be possible in all instances. Although monitoring can take different forms, direct court room observation is preferred. Each evaluation will be documented in a written memorandum to the testifying scientist and will include comment on the following areas.

1. Appearance
2. Poise
3. Effectiveness of presentation (technical knowledge, ability to convey scientific concepts).
4. Interpretation of laboratory results.

A form will be filled out and maintained in the laboratory's DAB "REVIEW" binder. The review may prescribe remedial action, if the evaluation is unsatisfactory. A copy of the evaluation will be given to the testifier by the reviewer, which must be signed. Problems with the testimony will be discussed, and deficiencies in the testimony will be corrected by having the testifier watch someone who is experienced and accomplished at providing court room testimony. Deficiencies in knowledge will be addressed through remedial education.

Remedial education might include one or both of the following:

- Retraining on technical information if the testimony was inaccurate.
- Moot court if the testimony showed deficiencies in the ability to express the



Initials: *RL*

concepts clearly.

Sometimes scheduling conflicts occur and an appropriate reviewer is not available. In these instances, a letter from the District Attorney, Defense Attorney, or Judge will suffice.

## **E. Evidence Handling Protocols**

### **1. General Guidelines**

The Department of Forensic Biology operates in two separate locations. Evidence examination takes place at Bellevue Hospital and evidence storage is in that location. Chain of custody refers to the documentation that allows evidence tracking from receipt of evidence (either post-mortem autopsy specimens or physical evidence obtained through investigations), through the analytical process, until it leaves the control of the laboratory.

The laboratory receives evidence primarily from the OCME Evidence Unit at the OCME headquarters building at 520 First Avenue. The Evidence Unit assigns a number (EU number) to the evidence and transports it to the Bellevue facility, where it is placed in locked evidence rooms that are manned by Evidence Unit personnel. Scientists in the Department of Forensic Biology do not have access to these rooms.

Sometimes the NYPD and other agencies and jurisdictions may bring evidence directly to the laboratory. Evidence from the OCME are received from all of the OCME locations by courier. Normally, at the conclusion of the scientific testing, the evidence is returned to the Evidence Unit, if an NYPD case, or returned directly to the submitting agency. For specifics, see the Case Management Manual.

Sometimes there may be conflicts concerning what constitutes "evidence" versus "work product." The Department of Forensic Biology defines work product as information generated during the course of a scientific examination such as graphs, 35 mm slides, photographs, electropherograms, or stained slides.

#### **a. Case numbers**

See discussion in the Case Management Manual.

#### **b. Item numbers**

An item refers to a single piece of evidence received by the laboratory. Each item is assigned a unique number, which is cross-referenced to a police voucher number, i.e., Item 1 on voucher

Initials: (2)

H996103. Items received from the OCME, such as after an autopsy, are assigned a sequential PM (post-mortem, i.e., PM1, PM2, and etc, which is made unique by the FB Number, i.e., FB99-0000, and etc, and by the ME Number, i.e., K99-00173.

c. Evidence receipt

All evidence received in the laboratory must be properly sealed. Staples are not an acceptable seal. All evidence must be packaged in paper when it is received by the laboratory. Most evidence is accepted into the OCME by the Evidence Unit and is assigned an Evidence Unit number, the EU number.

The paperwork transferred with the evidence is reviewed to ensure that the evidence belongs in the Forensic Biology Department. Generally, the following items are not accepted:

- (1). items requiring fingerprint exams
- (2). items intended for hair/fiber exams
- (3). items intended for gunshot residue exams
- (4). hair, fiber, or other trace evidence
- (5). clothing from the deceased

Decisions whether evidence is accepted by the laboratory are made by a Criminalist IV, an Assistant Director, Deputy Director or the Director.

d. Signatures

Evidence from user agencies are transferred from the Evidence Unit, where it is stored, to a member of the Forensic Biology Department. The chain-of-custody form is filled out to reflect this. All dates are recorded contemporaneously. The following reflect how a chain-of-custody form is filled-out.

- (1). For evidence delivered from an outside agency directly to a member of the Forensic Biology Department. **This is not a routine occurrence.**

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	Det. Smith	4567	P. Ryan	1.2.99
F123456	1-6	P. Ryan	----	Evidence Unit	
F123456	1-6	Evidence Unit	----	Shelf B (storage)	1.2.99

- (2). For evidence delivered from an outside agency, the Evidence



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Unit signs in the evidence then signs it over to the Department of Forensic Biology when it is ready to be examined.

- (3). Evidence from the OCME is received in sealed boxes containing a chain-of-custody form. This evidence is taken into the laboratory by a Criminalist assigned to this task and then assigned an appropriate FB Number.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
-----	PM 1-3	autopsy PM specimens	----	P. Ryan	1.2.99
-----	PM 1-3	P. Ryan	----	PM storage	1.2.99

e. Storage of evidence

Evidence is generally stored in secure storage until it is assigned for analysis. Normally, evidence is delivered to the Evidence Unit, assigned an EU number, stored in the Evidence Unit and then transferred to the Forensic Biology Department when the evidence is examined.

f. Case assignment

See the Case Management Manual for a discussion on how cases are assigned.

When a Criminalist begins the examination of the evidence, the chain of custody will be filled out to reflect that the work has begun. The date in the case notes reflects the first day that the work began. Evidence in progress is stored in a secure location within the laboratory.

Disposition - NYPD vouchered items

After the analytical work is completed, the evidence is packaged according to NYPD protocols and returned to the Evidence Unit. The date and signatures are recorded on the chain-of-custody form.

h. Disposition - retained items

Retained evidence from casework refers to those specimens that have been chosen for analysis and have not been consumed. Examples of these are stains cut from clothing, blood swabbed off of items, or entire small items such as blood samples collected at the scene.

All DNA extracts have a separate tracking sheet which is part of the casefile.

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i. Disposition - non NYPD cases

If a case comes into the laboratory from a non-NYPD agency, all evidence, with the exception of retained items, is returned directly to the submitting agency.

j. OCME transport of specimens from outer boroughs

Autopsy evidence sent from the OCME offices in Manhattan, Brooklyn, Queens, The Bronx, and Staten Island is received in sealed, plastic containers. Inside each container is a Transport Manifest that has a Transport Container Number and is dated. Pasted to that Transport Manifest are stickers with case numbers and/or bar codes for those specimens inside the container.

k. Sample tracking in the laboratory

After samples are removed from the evidence, and to insure that mix-ups do not occur, a witnessing procedure is used to show that testing is being performed on the correct sample. Witnessing occurs at several points during the analysis: when exemplar whole bloods are removed from a blood tube and made into a dried stain, DNA extraction, DNA quantitation, amplification set-up, and during gel loading/capillary set-up stages to insure that the sequence of tubes containing DNA or sample matches the appropriate worksheet. The witnessing person must initial the worksheet.

l. Consumption of samples

If analysis will consume a sample, testing on that sample must be stopped. Testing will resume only after appropriate information is received by the Director, Deputy Director, Assistant Director, or a Criminalist IV that indicates that the testing can continue. See the Case Management Manual.

2. Specific guidelines for different evidence types

a. FB Cases

(1). Whole blood and post-mortem blood

A stain is prepared on stain cards and is retained in the laboratory. Eventually, the stain cards are transferred to the Evidence Unit. For disposal and disposition guidelines, see Forensic Biochemistry Manual, version 4.0,

(2). PM sexual assault evidence

Sexual assault evidence obtained after an autopsy is secured until processed. Following the

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guidelines in the Case Management Manual, specific items are retained or sent to the Evidence Unit. This will be reflected in the chain-of-custody.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
-----	PM 1-3	autopsy	----	P. Ryan	1.2.99
-----	PM 1-3	P. Ryan	----	PM storage	1.2.99
-----	PM 2	PM storage	----	P. Ryan	1.5.99
-----	PM 2D-H	P. Ryan	----	retained samples	1.6.99
-----	PM 2A-C	P. Ryan	----	W. Morrow	1.6.99

(3). other PM items

Hairs, fingernails, tissues, etc. may also be received from the autopsy and then retained. With exception of tissues froze for subsequent disease diagnosis, most will be transferred to the Evidence Unit. Specimens with a dried bloodstain may be discarded, which will be reflected on the chain-of-custody form.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
-----	PM 1-3	autopsy	----	P. Ryan	1.2.98
-----	PM 1-2	P. Ryan	----	PM storage	1.2.98
-----	PM 3	P. Ryan	----	PM freezer	1.2.98
-----	PM 3	P. Ryan	----	discarded	2.3.99

Tissues obtained for disease diagnosis will be retained frozen. Bones for subsequent missing person identification will be retained.

b. Non-FB cases

(1). blood

The Forensic Biology department receives EDTA blood, if available, from most autopsies. Most of these do not fall within the mission of the Department of Forensic Biology because they are not the subject of a felony investigation or a body identification. The isolated DNA from these samples may be retained in the laboratory for research purposes (subject to approval), method validation, or population databasing. For disposition and disposal guidelines of these samples, see the Forensic Biochemistry Methods Manual.

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(2). other PM items

Other post-mortem items are occasionally received on non-FB cases. These items are usually discarded within two months.

c. Additional analysis on retained samples

When analysis is done on samples that were previously retained, the chain-of-custody will reflect this:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	A. Anzalone	----	P. Ryan	1.2.99
F123456	1-6	P. Ryan	----	shelf B	1.2.99
F123456	1-6	shelf B	----	F. Baldi	2.4.99
F123456	1-6	F. Baldi	----	R. Burgos	1.6.99
retained	items	F. Baldi	----	retained storage	2.4.99
retained	items	retained storage	----	P. Buffolino	3.4.99
retained	items	P. Buffolino	----	retained storage	4.4.99

d. Items transferred to or from other OCME departments

Specimens are sometimes brought into the laboratory from other OCME departments. For example, sometimes evidence is received on cases for which autopsy specimens are not received by the Department. In these instances, appropriate specimens may be obtained from the Forensic Toxicology Department, the Histology Laboratory, or from DNA database specimens. The chain-of-custody must reflect this:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
toxicol.	blood	B. Marker (toxicology)	----	M. Samples	1.2.99

Evidence is occasionally transferred to another OCME department, such as a knife to a medical examiner, who wishes to examine it. The chain-of-custody must reflect this:

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
F123456	1-6	A. Anzalone	----	P. Ryan	1.2.99

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F123456	1-6	P. Ryan	----	shelf B	1.2.99
F123456	1	shelf B	----	P. Ryan	1.3.99
F123456	1	P. Ryan	----	Dr. Gilson	1.3.99
F123456	1	Dr. Gilson	----	M. Samples	1.3.99
F123456	1	M. Samples	----	shelf B	1.3.99

e. Unlabeled items

Occasionally autopsy specimens are received with no identifying case numbers, specimen types or other identifying information. These specimens are discarded.

f. Submittal to other agencies

Instances arise that require the Department of Forensic Biology to send evidence to other agencies or laboratories. Under most circumstances this is accomplished using overnight mail services; the shipping paperwork is kept in the case file. The chain-of-custody will reflect this.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
retained	items	M. Samples	----	FBI via FedEx	1.2.99

When the evidence is returned to the Forensic Biology Department through mail services, the chain-of-custody must be filled out similarly.

If additional items, such as DNA extracts, are returned, a new chain-of-custody form must reflect that.

VOUCHER	ITEM(S)	RECEIVED FROM	SHIELD	RECEIVED BY	DATE
retained	items	M. Samples	----	FBI via FedEx	1.2.99
retained	items	FBI via reg mail	----	M. Samples	1.4.99
extracts	----	FBI via reg mail	----	M. Samples	4.4.99
extracts	----	M. Samples	----	DNA storage	4.4.99

3. Security

a. Building Security



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All Department of Forensic Biology laboratory functions for the OCME are carried out at either its Manhattan or Bellevue facilities.

The Manhattan building has two entrances: One on the 30th Street side and the other, the main entrance, on First Avenue. Each entrance is guarded during the day by either a security guard or by an OCME employee. All visitors are required to sign a logbook before being escorted into the building. After normal working hours, the entrance on First Avenue is locked with an electronic keypad. The 30th Street entrance, the morgue entrance, is guarded by Evidence Unit personnel twenty-four hours a day, seven days a week.

The Bellevue facility is located on the 4<sup>th</sup> Floor of the Administrative Building. Building security is maintained by Bellevue Police. The 4<sup>th</sup> floor has a single entrance that is electronically and key locked, and the security of the laboratory is maintained by Evidence Unit personnel. The laboratory is open seven days a week during normal working hours and closes at 7 p.m. daily.

b. Laboratory Security

The Department of Forensic Biology has access only by authorized personnel: departmental, visiting and consultant staff and students and selected other OCME employees. Entrance into the laboratories is afforded by an electronic keypad, which is on all exterior doors of the laboratory. With permission from the Director, Deputy Director or Assistant Director, students and staff may use the laboratory after normal working hours.

Evidence inside the laboratories is locked inside a room. Keys to these areas are kept inside a drawer, which is locked at all times with a combination lock; a keylog is available. Only Forensic Biology staff have access.

Evidence being processed may be open on a desktop during normal working hours, but is returned to a secure evidence storage area at night; a keylog is available. This evidence may not have a permanent seal until the work is completed. During over-night storage, it will be protected from contamination from other evidentiary specimens with a temporary seal.

Post-mortem blood cards and other exemplars are stored in a file cabinet. Only Forensic Biology Laboratory staff have access.

Current case files are located in file cabinets inside the Department of Forensic Biology.

c. Offsite Storage

Current retained specimens are located at the OCME Main Headquarters Manhattan facility on the

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6<sup>th</sup> floor in a locked room. Non-current case files, records, and retained specimens are not located on the 6<sup>th</sup> floor. Depending on year, they are located on the 3<sup>rd</sup> floor in a locked room or in a locked room in the basement of Bellevue Hospital (not the same location as the separate laboratory described above). Entry into the basement of Bellevue is through a guarded security entrance. Only OCME employees have keys to the room; a keylog is available. Bellevue security does not have access.

## F. Equipment Calibration and Maintenance Logs

Each piece of essential scientific apparatus has a usage logbook and requires QC monitoring. **Essential is defined as equipment that is required for a testing procedure and which if malfunctioning, will compromise the reliability and accuracy of the results obtained. Such equipment has QC records.** Specific equipment QC procedures for essential scientific apparatus are found in the Quality Manual.

The first step for all preventative maintenance is cleanliness. If there is any kind of spill, inside or outside a piece of equipment, it is to be cleaned up **IMMEDIATELY**. Some spills may be corrosive to the equipment and cause more damage than necessary. It is easier to clean reagents before they dry rather than to wait and have to chisel them off.

If a usage log for items exists, it begins with the date of purchase of the piece of equipment. In addition to routine entries into the log, each calibration of the apparatus is also maintained in the usage log. For equipment purchased before the institution of this manual, if the date of purchase is known, that date will be used; if the date of purchase is not known, then the date the manual was placed into service will be used instead. An approximate date of purchase will be entered into the log beside the date.

Irregularities observed during routine monitoring or use of all equipment are recorded in the comments section of the log and reported to the Criminalist supervising the affected rotation, as per departmental guidelines concerning corrective action (Section O). Whether equipment is unsuitable for casework use is a decision made by the QA Manager and/or Technical Manager, and either may take corrective action. Any action taken must be recorded in an appropriate log. If the equipment has been removed from use, for whatever reason, an entry is made into the appropriate log. All scientists in the laboratory are notified by e-mail that the equipment is "Offline." Additionally, a sign is put on the equipment so that it is not used until appropriate repairs are made.

After appropriate repair and/or re-calibration, the QA Manager or Technical Manager may re-certify that the equipment is available for case work. Re-certification requires that the QA Manager or a member of the QC group records that the instrument is available for casework in the instrument's log. Staff will be notified that the equipment is available for use and the "Offline" sign is removed.

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## **G. Proficiency Testing**

### **1. Overview**

Proficiency testing is used to demonstrate the quality of the scientific service offered by the laboratory, and it serves as a mechanism for critical self-evaluation. This is accomplished by the analysis and reporting of results from appropriate biological specimens submitted to the laboratory as open and/or blind case evidence. All specimens submitted as part of a proficiency test must be analyzed like any case -- including all DNA systems typed by the Department in casework, case folder, review, report preparation, etc. The only difference from a case is the Proficiency Evaluation sheet, which is a check-list filled-out by the supervisor (usually a Criminalist IV) and also the Assistant Director and gives supervisors a mechanism to evaluate scientists' overall performance. It also gives the Director and Assistant Director a mechanism to evaluate the supervisor's case review skills.

All scientific staff performing routine scientific testing on casework must take proficiency tests according to guidelines or standards established by DAB, NYS and/or ASCLD/LAB standards. Acceptable NYS and ASCLD/LAB external proficiency test providers are available: The Collaborative Testing Service (CTS), The Serological Research Institute (SERI), Cellmark Diagnostics (IQAS), and the College of American Pathologists (CAP).

All scientific staff take proficiency tests. However, unlike other analysts, Criminalist I's and Laboratory Associates are competent in only selected areas of the analytical process - Chelex extraction, P30 ELISA, QuantiBlot, and amp set-up - and cannot interpret the final DNA typing data or prepare an associated written scientific report. Thus, their participation in proficiency tests will be limited to those functional specialties in which they work in the laboratory - those mentioned above. They will be listed on the dissemination documentation to the proficiency provider as "persons responsible for these results."

When required, proficiency test results and associated data are available to an external accreditation review committee, American Board of Criminalistics, the ASCLD Proficiency Review Committee (PRC) and the NYS Commission of Forensic Science.

### **2. Definitions**

#### **a. Types of Proficiency Testing**

##### **(1). Open Proficiency Testing**

Open proficiency test specimens are presented to the laboratory staff as proficiency specimens and



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are used to demonstrate the capability of the laboratory's analytical methods as well as the interpretive capability of its scientists. Proficiency testing is one of the primary means by which the quality performance of the laboratory is judged.

All scientific staff must successfully pass a proficiency test prior to being assigned casework. The first proficiency is normally prepared internally, and is referred to as a competency test (CT). All subsequent proficiency tests are obtained from approved external proficiency providers.

(a). Personnel

Each required member of the scientific staff who interprets laboratory data, writes reports, and testifies must take and pass at least one open proficiency tests every 183 days as defined by the DAB and NYS accreditation standards. Additionally, the QA Manager and Criminalists performing QC functions must take these proficiency tests.

(b). Specimens

Each open proficiency test may consist of dried specimens of blood and/or other physiological fluids, either singly or as a mixture. Each sample to be analyzed will contain sufficient sample so that a conclusion can be drawn from the results of the analysis.

(c). Sample Preparation and Storage

All specimens and proficiency tests should be uniformly prepared on washed cotton cloth, swabs, or other suitable material to ensure their integrity and identity. Each analyzed specimen must be labeled with a unique identifier that can be independently verified by at least one other person to ensure proper assignment. A portion of each specimen used to prepare the test should be retained by the preparing laboratory until sufficient time has passed for all participating individuals to register complaints and reference analysis and comparison is completed.

The QA Manager is responsible for issuing proficiency tests to the laboratory staff and tracking these tests.

(2). Case Retesting

Reanalysis of case work may permit an estimate of the laboratory's error rate. Reanalysis samples may be performed on casework samples, where sufficient sample remains. The QA Manager is responsible for assigning reanalysis samples, ensures that the analysis is performed, and reviews the results, comparing them to the original analyses. If the results do not agree, a second reanalysis must be performed, if the reason for the discrepancy cannot be determined. A corrective report must be issued, if necessary.

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### (3). Blind Proficiency Testing

If a procedure for blind proficiency testing is established, blind proficiency tests will be administered to the laboratory annually and will be presented as a routine case. The samples in the "blind case" will be analyzed as a regular case and reported as such.

### b. Deficiency and Corrective Action

It is the responsibility of the QA Manager to inform the Director and the Technical Manager of any discrepancies, to ensure that deficiencies are acknowledged, and that any corrective or remedial action is taken and documented. If an error is found, the QA Manager must ascertain the cause of the error, i.e., a determination of what class the error(s) is and document what has been done to correct the error. In the case of a Class I error, the QA Manager must ensure that the analyst has not made this same type of error in casework.

#### (1). Class I or Analytical/Interpretative Errors

These errors, i.e., mistyping or misinterpreting analytical results whether correct or not, raise immediate concern regarding the quality of the individual's work product. A class I error is cause for failure of the proficiency test and requires suspension from performing the test in casework and re-training. Casework can be resumed after passing a new proficiency test. Documentation of re-training and the successful completion of a second proficiency test is required.

An appropriate supervisor monitors the performance of the specific test until a satisfactory performance is obtained. At that time a proficiency test will be administered.

In addition, the QA Manager and/or the Technical Manager must review cases signed by the Criminalist since the last successful proficiency test in order to ascertain whether similar errors have gotten past the case review process.

#### (2). Class II Errors

This discrepancy is due to a problem which may affect the quality of the work, but is not persistent or serious enough to cause immediate concern for the overall quality of the individual's work product. Retraining is necessary. Documentation of the retraining is required.

A class II error may be the result of equipment, materials, environment, etc., and may require a review of all relevant casework since the unit's last successfully completed proficiency test. Once the cause of the error has been identified and corrected, all analysts will be notified in writing of the appropriate corrective action in order to minimize the recurrence of the discrepancy. The QA Manager must document this review process.

Initials: *CS*

The QA Manager and/or the Technical Manager must review all casework performed during the relevant period. If necessary, selected samples must be repeated to verify that initial typing results are correct.

(3). Class III or Administrative Errors

This discrepancy is determined to have only minimal effect or significance, be unlikely to recur, is not systematic and does not significantly affect the fundamental reliability of an individual's work product.

Class III or Administrative errors, i.e., clerical, sample switching, improper storage, documentation, etc., once identified as such, will be corrected by instructing the analyst of the problem. Depending on the nature of the error, the analyst may be required to submit to re-training in the relevant area. For example, if the error is in sample storage, the analyst will be re-trained concerning the proper storage of biological specimens. Documentation of this re-training is necessary.

Simple clerical errors will be pointed out to the scientist. Subsequent casework will be closely monitored by casework supervisors, more than normal checking, for clerical errors.

In the event of an unresolved disagreement between the QA Manager and the laboratory, the matter will be resolved by the Technical Manager. The Director will be notified.

Errors of failing to follow established laboratory QA/QC procedures will result in documentation on the Proficiency Evaluation sheet. The scientist will be re-instructed in the appropriate procedures, which will be documented on the Proficiency Evaluation sheet.

Each scientist will receive a copy of the Proficiency Evaluation Sheet and their comments will be recorded there.

Documentation of Open Proficiency Testing Results

Proficiency test results will be maintained by the department and will be documented as follows:

- (1). Proficiency Testing Identification Number (Lab Number)
- (2). Name of analyst
- (3). Dates:  
receipt by analyst  
completion date (report date)
- (4). Copies of all data sheets, notes, photographs and reports
- (5). All data will conform to casework standards and include lot numbers, QC numbers, and etc.
- (6). The Proficiency Evaluation sheet will be filled out by the



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supervising scientist.

## H. Personnel Training and Qualification Records

Training falls into several categories: Courses taken at universities and colleges, workshops designed to educate on specific topics and techniques, on-the-job training where theoretical and practical information and experience is obtained from the scientific staff, seminars and lectures held at local universities where scientists are invited to speak on various topics, scientific literature, and professional meetings. Each of these will be discussed in relation to training requirements in the Department of Forensic Biology. The laboratory has a training coordinator who is responsible for in-house training of new staff and continuing education of existing staff.

Training records for all scientific staff maintained.

### 1. Courses at Universities

The scientific professional staff in the Department of Forensic Biology have met the minimum educational requirements necessary to meet the title descriptions. However, continuing education is important and recognized as a mechanism of maintaining a state-of-the-art staff and fostering an academic environment within the service mission of the Department of Forensic Biology. However, because tuition reimbursement through the City of New York is not normally available, the department cannot require staff to attend courses at universities however, staff will be made aware of appropriate courses.

### 2. Workshops

Workshops are routinely offered in the local area by companies on specific topics, usually as an aid to their marketing functions. Normally there is a charge for these courses. The staff will be made aware of these workshops, but because reimbursement cannot be guaranteed, attendance will not be mandatory.

Workshops are also offered in conjunction with local universities specializing in forensic science training, i.e., John Jay College of Criminal Justice, University of New Haven, as well as through professional organizations such as The Northeastern Association of Forensic Scientists and the New Jersey Association of Forensic Scientist. Although the staff cannot be guaranteed reimbursement for the workshop costs, recommendations will be made to attend those which seem important to the mission of the department.

### 3. On-The-Job-Training



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The specifics of on-the-job training can be found in the Training Manual.

#### **4. Seminars and Lectures**

Seminars and lectures offered at the OCME, at local universities, the Department of Forensic Biology, the Department of Health, at NYU Medical Center, and by corporations on selected topics will be announced to staff members.

#### **5. Scientific Literature**

All scientific staff are required to read the appropriate scientific literature related to the forensic aspects of the analytical work performed in the department.

The supervisory staff will provide copies of articles deemed to enhance the scientific theoretical background necessary for the understanding of current testing procedures or for current research being conducted in the department.

#### **6. Professional Meetings**

Each staff scientist can have time up to one week to attend a scientific conference annually, depending on the approval of the Chief Medical Examiner and Mayor's Office. Budgetary constraints may prevent reimbursement of expenses.

There are several annual forensic specific conferences in addition to the annual national meeting of forensic scientists (AAFS), the Promega Conference, the CODIS annual conference, Frenzy and the regional association of forensic scientists (NEAFS and NJAFS) are recommended. Other scientific meetings of interest to the department, i.e., American Society of Human Genetics Meetings, Gene Probe Conference, AAAS conference, Int. Assn. Forensic Scientists, NY Acad. Sci., FEBS and etc., are acceptable substitutions for forensic conferences.

#### **7. Certification of Scientific Staff**

Certification of all staff scientists by the American Board of Criminalistics is desirable, and the department will encourage all staff to attain certification.

### **I. Method Validation Procedures and Records**

Methods used in the departmental laboratories must be validated using accepted procedures -- according to DAB and/or SWGDAM Standards -- which demonstrate that the methods are capable of providing reliable results from specimens commonly received for forensic analysis. Procedures

Initials: *RS*

used will be approved for use, if appropriate, by any New York State regulating bodies having proper jurisdiction. The specific validation protocols for each laboratory procedure must be rigorously followed (see below). The analytical test results and the validation protocols used for each test must be available and must be kept on file in the laboratory.

### **1. Validation Procedures**

The laboratory will follow DAB standards, DAB Standard 8.1, for validating methods.

## **J. Quality Assurance and Audit Records**

Records documenting that the QA program is implemented and maintained are kept as a normal course of business. The QA Manager is responsible for maintaining these records.

## **K. Equipment**

### **1. Inventory**

An inventory of all equipment is maintained in the department. The QA Manager is responsible for maintaining the inventory.

### **2. Operations Manuals**

All equipment operations manuals are kept as a part of a centralized operations manual. The QA Manager is responsible for maintaining these manuals.

### **3. Calibration/Maintenance Procedures**

Procedures for the calibration and maintenance are part of the Quality Manual.

### **4. Calibration/Maintenance Logs**

Calibration and Maintenance logs are located at or near each specific piece of equipment for which these logs are required.

## **L. Safety**

### **1. Manuals**

Initials: *eej*

The Departmental Safety binder is a compendium of manuals maintained at the OCME.

a. Chemical Spill and Clean-up

This manual details the OCME guidelines and regulations specifically related to chemical spills and notification procedures.

b. Blood Borne Pathogen Standard

This manual provides the regulations regarding blood borne pathogens standard 29 CFR 1910.1030.

c. NYC Department of Health Infection Control Manual

This manual has been prepared to provide DOH employees with the information required to protect their own safety and their patients. It provides specific precautionary techniques and guidelines in order to reduce injury and disease.

d. OCME Hazard Communication Plan

This manual is to ensure that OCME is in compliance with the OSHA Hazard Communication Standard (HCS) 29 CFR 1910.1200 and delineates responsibilities regarding chemical hazards.

e. OCME Hazard Contingency Plan

This plan applies to all unplanned releases of hazardous waste or hazardous waste constituents at the OCME. Its purpose is to minimize hazards to human health or the environment from an unplanned or sudden release of hazardous waste or its constituents.

f. Chemical Hygiene Plan

The chemical hygiene plan delineates responsibilities, procedures and guidelines regarding the handling of chemicals at the OCME.

g. NYFD Regulations on Chemical Storage

This manual delineates the fire department's regulations for the storage and use of chemicals, acids and gases in college, university, hospital, research and commercial laboratories.

h. Working With Chemicals

This manual provides information for employees on how to use the NYS Right to Know Law.

Initials: *RD*

## **2. Right to Know Training**

The OCME has a Right to Know training program which is provided annually. Each OCME employee is required to attend. Each employee is required to take a written test annually. Documentation is available from the OCME Safety Officer.

## **3. Material Safety Data Sheets (MSDS)**

MSDS sheets are kept in a separate binder for all reagents and chemicals used in the departmental laboratories. The OCME is also required to have a copy of the most current MSDS sheets for those materials used in the OCME building. The sheets are updated as required and they are readily available in the laboratory.

## **M. Historical or Archival Records**

Records for all laboratory operations are maintained with the case file under the laboratory case number (FBXX-), where XX refers to the year, as discussed in the Case Management Manual. For years prior to 1990 the records are maintained using a different nomenclature system.

## **N. Quality Audit**

An annual quality audit is required by New York State and by DAB. The Department's accreditation requires an external audit every other year. The Department of Forensic Biology is audited annually either by an independent, external evaluator who has no responsible function in the Department, or by laboratory Staff (on odd years). The QA Manager must perform an audit of the quality system annually. All audit reports are sent to the Director and are available for inspection by accrediting or NYS regulating bodies.

### **1. Guidelines**

The quality audit is a primary tool used to evaluate, confirm or verify activities related to laboratory quality. Its purpose is to assess compliance with the operational requirements of the quality system. Periodic audits, coupled with day-to-day review of scientific reports and external proficiency testing, provide an effective means for ensuring that quality control activities are being implemented continuously and that each forensic examiner performs in a manner consistent with the quality system.

Internal and external quality audits will be scheduled by the Director. Audit results will be sent to the Director who will reply to the auditor's comments. The reply will discuss corrective action taken or reasons why corrective action will not be taken.



Initials: *Ref*

## O. Non-Conformity and Corrective Actions

Problems or difficulties can arise in all phases of laboratory operations, and these must be dealt with appropriately. Listing each potential problem is impractical, and this topic is considered in general terms. Generally, laboratory problems are divided into major categories, which reflect the laboratory's operations, and may include the following:

- Operations which reflect the laboratory's mission
- External influences which reflect the laboratory's proper functioning
- Problems of a specialized nature

### 1. Problems affecting the Laboratory's Mission

These are usually technical problems and may include, among others, a method that has ceased to work properly or a laboratory error. The source of these problems must be identified and solved as soon as possible and then corrective action taken, if necessary.

The solution of the problem may be simple or complex. At its inception, the problem will be identified at some level, perhaps with a Criminalist I or II who is performing a specific task. In all cases, problem solving will assume an hierarchical structure (Criminalist I to II to III to IV to QA Manager and/or Technical Manager), until the problem's source is identified and solved. The QA Manager will document the problem, its solution, and any corrective action taken, if necessary. After a problem is identified and solved, the QA Manager must investigate the cause of the problem and take appropriate corrective action. Corrective action depends on the seriousness of the problem or non-conformity identified.

#### a. Corrective Action

When non-conformity exists or is suspected as a result of analytical errors, proficiency errors, internal or external audits, user agency complaints, or equipment malfunction, its occurrence must be reported immediately to an appropriate supervisor. For example, if the non-conformity occurs at the Chelex rotation, the Criminalist IV supervising that rotation must be informed. If the problem is not trivial, that Criminalist IV must notify the QA Manager. The QA Manager must ascertain the seriousness of the non-conformity according to the following criteria:

#### Class I Non-conformity

Definition: The nature of the non-conformity raises concern about the quality of the work product. In these instances, the following procedures must be followed:

Initials: *RC*

- If necessary and appropriate, laboratory activities pertaining to that non-conformity will be stopped until the investigation is completed.
- The ensuing investigation will document the following:
  - ▶ Identify the problem source.
  - ▶ Identify an appropriate solution.
  - ▶ Identify any cases that may be affected.
- Re-work affected cases and re-issue reports, if necessary.
- Re-train analysts, if necessary.
- Document the non-conformity and the corrective actions

#### Class II Non-conformity

Definition: A problem exists which may affect the quality of the work, but is not persistent or serious enough to cause immediate concern for the overall quality of the laboratory's work product. The following procedures must be followed:

- The QA Manager must be informed that the problem exists.
- The QA Manager must insure that the steps described above, if necessary, are done.

#### Class III Non-conformity

Definition: The problem is unlikely to recur and is not likely to significantly affect the reliability of the laboratory's work. These problems are readily corrected. The following procedures must be followed.

- The scientist who identified the problem may also correct it. If the problem does not have casework implications or require re-training, the QA Manager may not become involved.

## **2. External influences**

Some problems, i.e., the building's heating, cooling, lighting, etc., are operational problems that are solved by OCME support staff. In these instances problems can be directed to the OCME support staff either by the first level supervisory personnel or directly by the person who discovers the problem.

Initials: *RQ*

### 3. Specialized Problems

Certain laboratory functions require specialized support. In these instances, i.e., health and radiation safety, there are appropriate personnel designated in the laboratory and at the OCME who are responsible for these functions. For example, there is a laboratory representative on the health and safety committee whom is consulted in these instances.

### P. Subcontracting

While the Department of Forensic Biology does not routinely subcontract work to outside laboratories, the possibility exists that this might become necessary. In these instances, the Department of Forensic Biology will ensure that the subcontracting laboratory adheres accreditation standards by one of the following:

- Evaluate the laboratory against DAB standards.
- Obtain existing DAB audit - or equivalent - reports from the subcontracting laboratory.

The Department is currently working with the NYPD on its contract to three private laboratories to reduce its backlog of rape cases. The role of the Department is to insure the quality of the work and to enter eligible profiles into CODIS.

## IV. Management Information System (MIS)

### A. OCME

The OCME's Manhattan headquarters, satellite autopsy suites (The Bronx, Brooklyn, Queens, Staten Island and Manhattan) and Bellevue Laboratory are linked by a computer network. The components of the system include:

#### 1. Software programs for word processing & databasing

- a. WordPerfect, WordPerfect Suite, and WordPerfect Office
- b. Paradox (Department of Forensic Biology and Evidence Unit only)
- c. DataEase
- d. CODIS/SQL Server : although not part of the OCME MIS system, the Forensic Biology Department is linked to NYS DCJS and the NYSP via the CODIS network.



Initials: *Rg*

2. Medical Examiner casework database is created in DataEase
3. Procurement database/ordering system is created in DataEase.
4. E-Mail
5. Departmental and individual accounts

## B. Departmental

The Forensic Biology Laboratory is located on the OCME network under g:\users\fbiology. Individuals have access to their own private directory.

Departmental functions maintained on the network include:

1. Reports (created in WordPerfect) Archived cases compressed with Pkzip.
2. Productivity statistics (created in Paradox).
3. Current updates of Departmental manuals and forms are created in WordPerfect.
4. Management databases (logbooks) defined in Paradox
5. Case linkage databases defined in Paradox and in CODIS, which is maintained on a separate network.
6. Local DNA population databases

## V. CODIS

CODIS is the FBI's national DNA index. The Department is a local CODIS laboratory.

## VI. Time and Leave Policy

The City of New York's collective Citywide Contract between the City of New York and District Council 376, AFSCME, AFL-CIO dictates the time and leave policy for city employees. The most current manual is available in the Departmental conference room and from the Department of Personnel at the OCME headquarters building in Manhattan.



Initials: *RC*

## **VII. Policies and Procedures of the Office of Chief Medical Examiner**

General guidelines, directives, that govern the behavior of OCME employees is available in the Departmental conference room.

## **VIII. Complaints**

### **A. Personnel Disputes**

Disputes and complaints among employees is inevitable. When these occur, the parties in question may approach their individual supervisors. If the complaint cannot be resolved at that level, it will be taken to the first managerial or higher levels. Harrassment complaints are investigated by the OCME's Public Relations Officer.

### **B. Union Issues**

Some disputes and complaints are clearly union issues. In these instances, employees have rights and recourse under the City's Collective Bargaining Agreement with the Unions.

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Initials: *RG*

## IX. References

- A. Quality Assurance Standards for Forensic DNA Testing Laboratories. DNA Advisory Board, U.S. Department of Justice, Federal Bureau of Investigation, October, 1, 1998.
- B. The Evaluation of Forensic DNA Evidence. National Research Council. National Academy Press, Washington, DC, 1996.
- C. Laboratory manuals:
  - Case Management manual
  - Forensic Biochemistry Manual
  - Protocols for STR Analysis Manual
  - Quality Assurance Manual
  - CODIS Manual
- D. FBI DNA Quality Assurance Document, Rev # 5). Quality Assurance Audit for Forensic DNA and Convicted Offender DNA Databasing Laboratories, 10/00.

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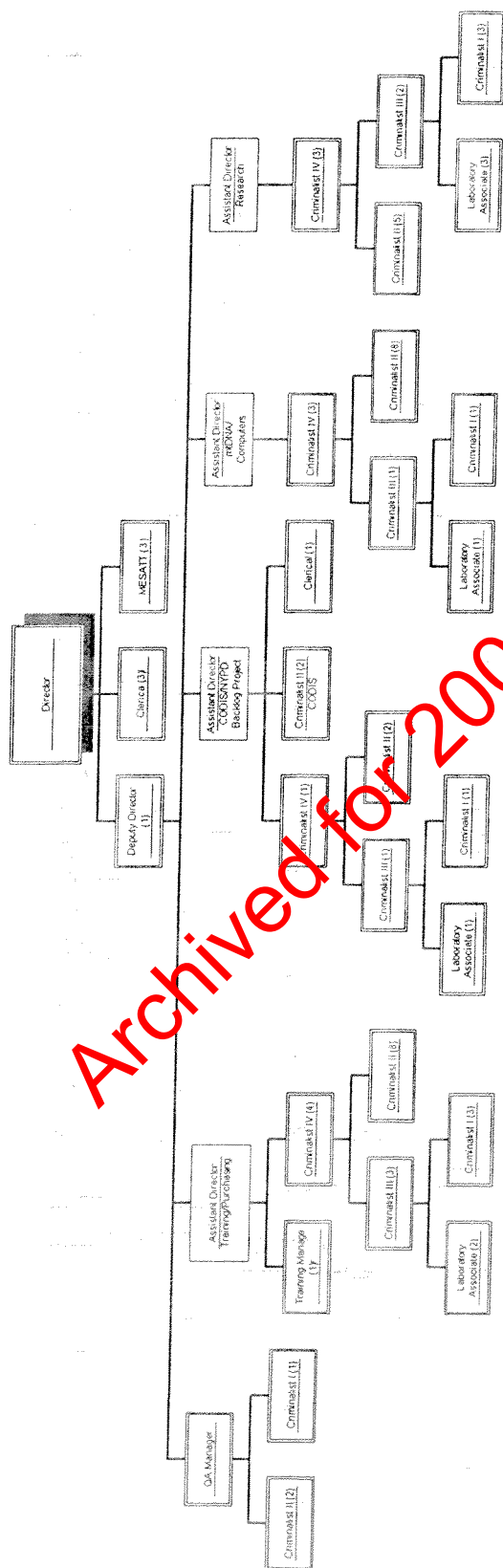
Initials: *RE*

## X. Appendix A: Organizational Chart

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1. What is the purpose of the study?  
 2. What are the research objectives?  
 3. What is the research methodology?  
 4. What are the results of the study?  
 5. What are the conclusions of the study?

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