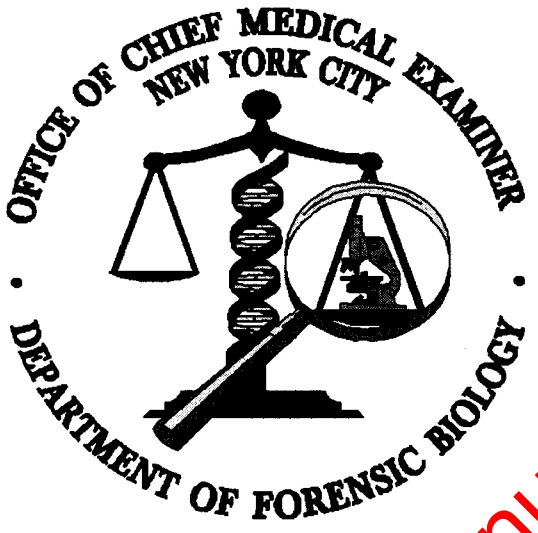

ADMINISTRATIVE MANUAL
VERSION 5.0

Effective date: January 7, 2005

APPROVED BY			
Title	**Print Name**	**Signature**	**Date**
Deputy Director/ Technical Manager	**Howard J. Baum, Ph.D.**	Howard J. Baum	**January 7, 2005**

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APPENDIX A (ORGANIZATIONAL CHARTS)

DATE EFFECTIVE	REVISED ON	VERSION	PAGE
01-13-2005	06-03-2005	5.0	1 OF 1

This Appendix contains links to the current organizational charts of the Department of Forensic Biology. Organizational charts will be displayed in Microsoft PowerPoint.

Forensic Biology Management

Case Work Tree – Samia Basilious, Assistant Director

Case Work Tree – Mecki Prinz, Assistant Director

Case Work Tree – Helen Rafaniello, Assistant Director

Case Work Tree – Marie Samples, Assistant Director

Quality Assurance Unit

CODIS Group

Mitochondrial DNA Analysis, Missing Persons, and High Sensitivity Group

W.T.C. Identification Group

Forensic Research and Validation

Molecular Genetics

Anthropology Group

Administrative Staff

Forensic Analysis and Reconstruction Unit

REVISION HISTORY:

June 3, 2005 – Updated Organizational Charts

1. INTRODUCTION

DATE EFFECTIVE	DATE REVISED	VERSION	PAGE
01-07-2005	08-18-2006	5.0	1 OF 1

Effective this date, this Administrative Manual Version 5.0 supersedes all previous administrative manuals used in the Department of Forensic Biology.

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

Director: Mechthild Prinz, Ph.D.

Deputy Director: Howard J. Baum, Ph.D. (DNA Technical Leader)

Assistant Directors:
Samia Basilious, M.S.
Theresa Caragine, Ph.D.
Eugene Y. Lien, M.S.
(Quality Assurance Manager)
Helen R. Kaganiello, M.S.
Marie Samples, M.S.
Eli Shapiro, Ph.D.
Yingying Tang, M.D., Ph.D.

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 (as listed above) who is responsible for ensuring that the quality aspects of the laboratory testing are fully operational.

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 ensure 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 ensure 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 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 ensures that quality control measures are meaningful measures of variation.

Revision History:
August 18, 2006 – List of managerial staff updated. See Approval Form.

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 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 the quality of DNA tests done for specialized projects subcontracted to private forensic DNA laboratories by the NYPD. The OCME role in this contract is: the review of controls and standards, the review of DNA profiles and the entry of eligible profiles into CODIS, preparing Quality Control samples for testing of contract laboratories, managing and reporting DNA matches, and testifying in a court of law.

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

1. Biological Fluid identification
2. Species identification
3. DNA analysis
4. Forensic Paternity
5. Report Preparation
6. Enter eligible DNA profiles into LINKAGE, and/or CODIS and database management.
7. Expert Testimony
8. Special NYPD projects
9. Unknown Body Identification
10. Mass disaster remains processing and identification.
11. Molecular Genetics/Molecular Autopsy Diagnostics
12. Anthropology
13. Special OCME Projects

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. Quality Assurance 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 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 FBI NDIS Program, the FBI Quality Assurance Standards, and/or SWGDAM. Also, ensure that the scientific staff performing casework meets all proficiency testing program standards and continuing education as an integral part of the overall Quality Assurance program of the Department of Forensic Biology.
6. Maintain records for in-house reagent manufacture and the Quality Control documentation of their acceptability, retain vendor Quality Control 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 Quality Assurance Program

The organizational structure, Appendix A, defines the relationships within the Department of Forensic Biology among individuals and the operational units of the department. Within this structure, the Quality Assurance Manager, in association with the laboratory Director, Deputy Director, and Technical Manager define the Quality Assurance/Quality Control policy.

The Department of Forensic Biology has chosen to have the Quality Assurance Manager report directly to the Deputy Director. In the absence of the Deputy Director, the Quality Assurance Manager will report directly to the Director. Each Criminalist working on casework in the Department of Forensic Biology must adhere to the Quality Assurance/Quality Control 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 departmental 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, currently functioning also as the Technical Manager, reports directly to the Director. Assistant Directors report directly to the Deputy Director. Clerical personnel report to an office manager, who 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 may perform administrative 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. The Deputy Director may perform scientific analyses, perform technical reviews of cases, review proficiency tests performed by Assistant Directors, 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 investigators, or attorneys; represents the Department of Forensic Biology in meetings with other NYC law enforcement and/or criminal justice agencies; testifies in court. 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. Each Assistant Director associated with casework must take a proficiency test as required by regulating and accrediting bodies. Additionally, the Assistant Directors prepare annual performance evaluations of subordinate personnel, usually Criminalist IV's.

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 FBI Quality Assurance Audit Document, Section 5.2, defines the responsibilities of the DNA Technical Manager. The Technical Manager is accountable for the technical and quality operations of the DNA laboratory. As such, he/she is responsible for the daily technical operation of the DNA laboratory.

Quality Assurance Manager

The Quality Assurance Manager is responsible for the quality system. His/her responsibilities are varied and mirror ASCLD/LAB and the FBI Quality Assurance Audit 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 the FBI Quality Assurance Audit 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 Quality Assurance Manager conducts an annual review of laboratory's quality system. The Quality Assurance Manager must take a proficiency test as required by regulating and accrediting bodies. The Quality Assurance Manager supervises Criminalists and Laboratory Associates who are assigned to him/her. The Quality Assurance Manager reports directly to the Technical Manager.

Criminalist, Level 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 written reports; prepares annual performance evaluations, as requested by OCME management; testifies in court; take proficiency tests as required by regulating and accrediting bodies; prepare written scientific reports; may supervise rotations in the laboratory.

Criminalist, Level 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, perform administrative reviews on DNA cases, train new Laboratory Associates and Criminalists; take proficiency tests as required by regulating and accrediting bodies, and testify to results. In the absence of a Criminalist IV, a Criminalist III may assume those responsibilities on an interim basis.

Criminalist, Level II

The responsibilities of Criminalist II's are described in the Civil Service specifications for that title. Generally, Criminalist II's are responsible for the daily examination and scientific work performed on evidence in casework, working in rotations, train new Laboratory Associates and Criminalists; take proficiency tests as required by regulating and accrediting bodies, prepare written scientific reports which reflect testing, and testify to results.

Criminalist, Level 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, prepare written scientific reports and may testify in court, if required by an Assistant District Attorney. Criminalist I's who are performing casework must also take proficiency tests.

Laboratory Associate

Laboratory Associates assigned to the Department of Forensic Biology function either as technicians as described by the FBI Quality Assurance standards or as research associates. In the former capacity, a Laboratory Associate may help with quality testing, and work in support rotations and perform other scientific and administrative duties that enhance the flow of cases through the laboratory. As research associates, Laboratory Associates may help to validate new testing methods. Laboratory Associates who are performing casework must also 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, developing new methods, helping the Quality Assurance Unit, examine evidence, 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 FBI Quality Assurance Standards.

Training Manager

The 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.

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

A. Manuals

The Director, or his/her designee, must approve all Department Manuals before they may be used. Changes to policies may be documented by written memo, which are distributed and then placed in a memo binder. Changes to the Table of Contents or Appendices do not require an approval from the Director or his/her designee. Updates of the manuals will reflect these changes. Manuals shall include the following information.

a. Effective date of the manual.
b. Revision dates (if applicable).
c. Approval from the Director, or his/her designee, signifying the manual's official start for use in the laboratory.

1. Scientific/Procedure Manuals

These manuals detail current policy and procedures used for all analytical testing of biological specimens.

2. Case Management Manual

The Case Management Manual defines how cases are handled in the laboratory and shall include policy and procedures used concerning:

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

3. Quality Assurance Manual

The Department's Quality Assurance Manual is an overview of the Department's quality system, and details the policy and 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. 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/file. They represent analytical findings and, where appropriate, the conclusions formed from these findings. Bench notes, worksheets and other work products used to reach these conclusions are an integral part of the case record. Reports are signed by the responsible Criminalist.

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 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, which is 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. Refer to the 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 work 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/Amylase) DNA extraction, DNA quantification, PCR set-up, PCR amplification, STR analysis, and data interpretation and report preparation. 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 during the technical review process of the case file.

b. Discrepancies and disputes

While infrequent, discrepancies may occur from mishandling of samples in the laboratory, such as mix-ups during DNA amplification, or selecting the wrong sample for analysis. Usually, these discrepancies are spotted early during the analysis, and the rotation supervisor and/or the interpreting analyst for the case (with the consent of his/her supervisor), can correct the problem by re-analysis. An investigation concerning the nature of the problem is necessary to determine the root cause of the discrepancy. The rotation supervisor (if applicable) and/or a Criminalist IV or above can initiate this investigation, with assistance if necessary, from the Quality Assurance Manager, Deputy Director, Technical Manager, or the Director. 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. (Refer to Section O of this manual for a discussion of corrective action).

Legitimate differences of opinion, disputes, concerning the interpretation of results may occur. If differences of opinion cannot be resolved by the Criminalist IV or Assistant Director, the Technical Manager will be the final arbiter.

c. Data matching

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

d. Data standards

Known standards are recorded and monitored by means of criteria established by the FBI Quality Assurance Standards and are included in the Forensic Biology Quality Assurance Manual.

e. Additional and amended reports

If a report is found to contain an error, an **amended report** must be issued to correct the error. When additional analyses are performed after a report has been issued, an **additional report** will be issued.

4. Reporting

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

Case Review

Technical Review

A technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions (ref. FBI QAS 7/2004)

A technical review is performed on all cases and 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, 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.

Technical reviews must be documented by dating and initialing the "technical review" line on the Scheduled Analysis sheet. Depending on the type, a case may receive one or two levels of technical review. See Table 1 and 2 for further details.

The technical reviewer may return the case file to the assigned Criminalist for corrections or additional work.

The reviewer will enter eligible DNA profiles into the local OCME database (LINKAGE), and review and forward eligible profiles to the CODIS group for entry into CODIS.

Administrative review

An administrative review is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness. (ref. FBI QAS 7/2004)

An administrative review is performed on all cases and is conducted after the technical review. This ensures that notes and worksheets reflect accreditation body standards; case numbers, victim and suspect names, and police evidence control numbers are correct; and data pages are numbered and initialed correctly.

Administrative reviews must be documented by dating and initialing the "administrative review" line on the Scheduled Analysis sheet.

Rush cases are those that may require an immediate written report. Even in these circumstances an administrative review must be conducted prior to issuing the report.

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

Table 1 Review requirements for sexual assault cases and PM rape kits.

Result	Criminalist IV Review?	Management Review?
Negative results, no DNA testing	Yes (or Criminalist III)	No
Autosomal results No DNA foreign to victim	Yes	No
Y Results – Simple Y Profile, no autosomal results foreign to victim	Yes	No
Y Results – Simple Y Profile, matching suspect	Yes	No
Y Results – Simple multiple semen donors	Yes	No
Y Results – Simple Y Profile, low level mixture on autosomal level	Yes	Yes
CODIS profile – No mixture in probative sample Mixture in EF okay	Yes	No
CODIS Profile – Mixture in probative samples, Deduced profiles	Yes	Yes
CODIS Profile – Complex case with multiple DNA sources, even if no mixtures	Yes	Yes

Table 2 Review requirements for homicide, assaults, and other cases.

Result	Criminalist IV Review?	Management Review?
Negative results, no DNA testing	Yes	No
DNA matching victim, no mixtures Simple Cases (≤3 Vouchers) Complex Cases (>3 Vouchers or >3 DNA sources)	 Yes Yes	 No Yes
CODIS Profile – Simple (no mixtures in case) Complex (mixtures in case)	 Yes Yes	 No Yes
DNA matching victim, Mixtures present	Yes	Yes
CODIS Profile – Mixtures present, deduced profiles	Yes	Yes
Forensic Paternity Cases	No	Yes
Body Identification Cases Direct Comparison Body Identification Kinship Body Identification	 Yes Yes	 No Yes
Suspect file DNA cases	Yes	No

Deviations from the above requirements are allowed. For example, analysts that have recently completed training may receive two levels of technical review on all of their cases, including non-DNA mixture cases; a rush case or a DNA mixture case managed by a Criminalist IV could be reviewed by only an Assistant or Deputy Director.

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.

5. Dissemination of Reports and Disclosure of Results

During the review process, the Criminalist, Assistant Director, Deputy Director, or Director 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, and robberies – will be sent to the NYPD and/or the district attorneys.

Verbal disclosure of preliminary results is allowed only after results are reviewed by an appropriate supervisor and then only in cases where the results are critical to an on-going investigation. **An Assistant Director, the Deputy Director or the Director must approve disclosure of the test results of work-in-progress.**

D. Court Testimony

Court testimony is the culmination of the work performed by the laboratory's scientists. To ensure that court testimonies are well documented, relevant, and presented in a clear and professional manner, each testifying examiner will have their testimony monitored at least once a year, providing testimony is rendered. Ideally, another member of the laboratory staff who is acting in a supervising capacity should monitor the testimony, but this may not be possible in all instances.

Although monitoring can take different forms, direct courtroom observation is preferred. Each evaluation by another member of the laboratory staff will be documented on the Forensic Biology Court Testimony Evaluation Form. The Form includes evaluations/comments on the following areas:

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

Scheduling conflicts do occur, and an appropriate reviewer may not be available. In these instances, a letter from the District Attorney's Office will suffice. The contents of such letter are out of the control of the Department of Forensic Biology, and therefore, there are no requirements of what it must contain.

Immediate supervisors must review the testimony monitoring results with each individual, serving to identify areas of strengths and weaknesses. The review may prescribe remedial action if the evaluation is unsatisfactory. Problems with the testimony will be discussed, and deficiencies in the testimony may require retraining. Deficiencies in knowledge will be addressed through remedial education and 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 concepts clearly.

The review must be documented with the immediate supervisor's signature and the individual's signature on the evaluation. All evaluations will be maintained in a designated binder.

E. Evidence Handling Protocols

1. General Guidelines

The Department of Forensic Biology operates in two separate locations. Evidence storage and examination takes place off-site from the 520 First Avenue facility. Chain-of-custody refers to the documentation that tracks the 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. The Evidence Unit assigns a number (EU number) to the evidence and transports it to the Forensic Biology evidence examination facility, where it is stored under lock and key. Only Evidence Unit personnel have access to these locations.

The NYPD and other agencies and jurisdictions may bring evidence directly to the laboratory. Evidence from the OCME is 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.

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, FTIR cards, 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 H996103.

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 the laboratory receives it. 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

A Criminalist IV, an Assistant Director, Deputy Director or the Director makes decisions whether the laboratory accepts evidence.

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 completed.

(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**	1/2/99
F123456	1-6	**Evidence Unit**	----	**Shelf B** (storage)	1/2/99

(2) For evidence delivered from an outside agency, the Evidence 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. Evidence in progress (pending examination, pending review, etc.) is stored in a secure location within the laboratory.

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 completed to reflect that the work has begun.

g. 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

The laboratory shall retain (if possible) exemplars from each case for further analysis, if necessary. These must be documented in the Chain of Custody form of the case.

All DNA extracts are retained and have a separate tracking sheet, which is part of the casefile.

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, 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, P30 detection, Amylase detection, FT-IR/condom lubricant detection, DNA extraction, DNA quantitation, amplification set-up, and during 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 a sample

If possible, the entirety of an item or sample should not be consumed during analysis. It is recommended that at least 25% of the sample be saved for future analysis, if needed. However, if in the opinion of the analyst, consumption of the sample is necessary to have the best chance to obtain results, the item or sample may be consumed; the notes must clearly state this.

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 a long-term storage facility. 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 guidelines in the Case Management Manual, all items are retained. 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 2D-H	P. Ryan	----	Retained samples	1/6/99
-------	PM 2A-C	P. Ryan	----	W. Morrow	1/6/99
-------	PM 1-3	P. Ryan	----	PM storage	1/2/99

(3) Other PM items

Hairs, fingernails, tissues, etc. may also be received from the autopsy and then retained. 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	PM freezer	----	P. Ryan	1/20/99
-------	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 body identification. For disposition and disposal guidelines of these samples, see the Forensic Biochemistry Methods Manual.

(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	2/4/99
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
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

All Department of Forensic Biology laboratory functions for the OCME are carried out at either its 520 First Avenue or Bellevue Hospital facility.

The 520 First Avenue 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. All visitors are required to sign a logbook before being escorted into the building. After normal business hours, the entrance on First Avenue is locked with an electronic keypad. OCME Evidence Unit personnel guard the entrance on 30th Street twenty-four hours a day, seven days a week.

The Bellevue Hospital facility is located on the 8th and 9th Floors of the Bellevue Hospital Administrative Building. Building security is maintained by Bellevue Police.

b. Laboratory Security

The Laboratory is accessible only by authorized personnel. This includes departmental, visiting and consultant staff, students-interns and other selected OCME employees.

Access points into the Laboratory at the 520 First Avenue facility is controlled by an electronic keypad 24 hours, 7 days a week. There are no emergency exits within the Laboratory at this facility.

Main access into the Laboratory at the Bellevue Hospital facility is controlled by the OCME Evidence Unit during normal business hours. After normal business hours, main access into the Laboratory at the Bellevue Hospital facility is controlled with magnetic door locks accessible with a FOB keycard. The Bellevue Hospital 8th floor facility has one emergency entrance and one main entrance. The Bellevue Hospital 9th floor facility has four emergency entrances and one main entrance. All emergency entrances are electronically locked and are accessible by a FOB key. The Bellevue Hospital facility is open seven days a week and closes at 7 p.m. daily.

Evidence stored inside the laboratory must be in secure locations. Keys to these areas are controlled and a log is available. Evidence being processed may be left opened on a desktop during normal working hours, but must be returned to a secure evidence storage area at night. Evidence need 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 secure locations that only Forensic Biology Laboratory staff has access.

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

c. Offsite Storage

Non-current retained items and case files are generally stored at the storage facility in Long Island City. This facility is secured by an electronic code lock and padlock. Only Forensic Biology employees have access to this facility.

F. Equipment Calibration and Maintenance Logs

Each essential scientific apparatus must have a usage and maintenance logbook associated. "**Essential" is defined as equipment that is required for a testing procedure and if malfunctioning, will compromise the reliability and accuracy of the results obtained. Such equipment must have QC records.** Specific equipment QC procedures for essential scientific apparatus are found in the Quality Assurance Manual.

The first step for all preventative maintenance is cleanliness. Spills must be cleaned **IMMEDIATELY.** Some spills may be corrosive to neighboring equipment and cause more damage than necessary. It is easier to clean reagents before they dry.

Irregularities observed during routine monitoring or use of all equipment are recorded in the comments section of the log and reported to the supervisor on rotation, as per departmental guidelines concerning corrective action (Section O). Whether or not equipment is unsuitable for casework use is a decision made by the Quality Assurance Manager and/or the 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 must be made in the appropriate log. A sign is placed on the equipment so that it is not used until appropriate repairs are made.

After appropriate repair and/or re-calibration, the Quality Assurance Manager or Technical Manager may re-certify that the equipment is available for casework. Re-certification requires that the Quality Assurance Manager or a member of the Quality Assurance Unit 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.

G. Proficiency Testing Program

1. Overview – External Proficiency Testing Program

All DNA Interpreting Analysts must undergo two external proficiency tests per year. One test must be performed in the first six months of the calendar year and the second in the last six months of the calendar year. The interval between consecutive tests must be at least four months and not to exceed eight months. The interval shall be calculated utilizing the date that the proficiency test was issued.

The external proficiency testing program demonstrates the quality of the scientific service offered by the Department of Forensic Biology, and serves as a mechanism for critical self-evaluation. All specimens of an external proficiency test must be analyzed according to current standard operating procedures with the exception that we are required by ASCLD/LAB to report every locus for all samples included in the proficiency test.

This means that the following sample types, which during normal casework analysis might only be tested in one or two multiplex reactions, must be amplified at all applicable loci:

1) Excluded suspects
2) Mixtures, even though there are other clean profiles
3) Epithelial cell fractions from an unknown stain or from a body orifice swab, even if the results match the victim type.

The proficiency test contains a Proficiency Evaluation sheet, which is a checklist completed by the supervisor (usually a Criminalist IV) and the Assistant/Deputy Director. The Proficiency Evaluation sheet gives supervisors a mechanism to evaluate an analyst's overall performance. It also gives the Assistant and Deputy Director a mechanism to evaluate the supervisor's case review skills.

All technical personnel who participate in DNA analysis of casework must undergo two external proficiency tests every year as defined by the FBI Quality Assurance Standards. One test must be performed in the first six months of the calendar year and the second test must be performed in the last six months of the calendar year. The interval between consecutive tests must be at least four months and not to exceed eight months. Additionally, the Quality Assurance Manager and all technical personnel who are trained in performing Quality Assurance/Quality Control functions must also take proficiency tests.

Unlike other analysts, Criminalist I's and Laboratory Associates are competent only in selected areas of the analytical process - Chelex extraction, P30 ELISA, QuantiBlot, and PCR Amplification setup - 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 the functional specialties listed above and will be paired with an Interpreting Analyst (IA).

All proficiency tests shall be obtained from acceptable NYS and ASCLD/LAB external proficiency test providers. This includes Collaborative Testing Service (CTS), Serological Research Institute (SERI), Cellmark Diagnostics (IQAS), Quality Forensics (QF), and the College of American Pathologists (CAP).

The Quality Assurance Manager, and/or his/her designee shall manage the Proficiency Testing Program.

2. Corrective Action – External Proficiency Testing Program

It is the responsibility of the Quality Assurance Manager (and/or his designee) to inform the Director and/or the Technical Leader of any discrepancies found by the test vendor, to ensure that deficiencies are acknowledged, and that any corrective or remedial action is taken and documented. If an error is found, the Quality Assurance Manager must ascertain the cause of the error, determine the severity of the error, and document any corrective action taken. In the case of an analytical/interpretation error, the Quality Assurance Manager must ensure that the analyst has not made this same type of error in case work.

Analytical/Interpretative Error
Analytical/Interpretative errors raise immediate concern regarding the quality of the laboratory and/or individual's work product. An investigation must be performed to determine if the deficiency was the result of an analyst's analytical or interpretive error or if there is a deficiency in a method or protocol (i.e., equipment malfunction).

Corrective Action
If investigation determines that the deficiency was the result of analyst's lack of understanding of the methods, procedures, and/or protocols used by the laboratory, the analyst will be prohibited from performing the test in casework until he/she has been re-trained, and a new proficiency test has been successfully completed. The Quality Assurance Manager and/or the Technical Manager must manage a review all cases signed by the analyst since the last successful proficiency test in order to ascertain whether similar errors have occurred and slipped past the case review process.

All re-training must be performed in accordance to the Forensic Biology Training Manual. Only until an analyst has been retrained, another proficiency test may be administered.

If investigation determines that the deficiency was in a method or protocol, all casework utilizing that method or protocol will cease immediately. Any necessary changes to the method or protocol must be validated and approved by the Quality Assurance Manager and/or the Technical Leader prior to the re-implementation of the method or protocol.

All investigations and actions shall be documented and filed with the Quality Assurance Unit.

Intermediate Errors
An Intermediate Error is due to a problem that 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 and/or individual's work product.

Corrective Action
If investigation determines that the deficiency was the result of a lapse in the analyst's abilities, the analyst will be prohibited from performing the test in casework until he/she has been re-trained.

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

Administrative Error
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.

Corrective Action
Administrative errors (i.e., clerical, sample storage, documentation, etc.), once identified as such, will be corrected by notifying the analyst of the problem. Depending on the nature of the error, the analyst may require 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 for administrative errors.

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.

3. Reanalysis Proficiency Testing Program

The Re-analysis Proficiency Testing Program is a quality assurance program where a previously examined sample is re-examined by a different person to check for correctness. The Quality Assurance Unit is responsible for reanalyzing samples, reviewing the results, and comparing them to the original analyses. Each month, a random selection of a minimum of two (2) samples will be selected from cases completed within the previous year. Each sample shall be submitted for extraction, quantitation, amplification (on at least one casework multiplex system), analyzed for STR results, and compared. Original and re-examined results must be documented. A second reanalysis must be performed if the results do not agree. All corrective action must be documented and maintained.

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.

1. Courses at Universities

Scientific staff in the Department of Forensic Biology has met the minimum educational requirements necessary to meet the title descriptions. 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, but staff will be made aware of appropriate courses.

2. Workshops

Companies routinely offer workshops in the local area, 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. All applications to workshops must be submitted to the Training Coordinator and approved by Forensic Biology Management.

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

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 may apply to have up to one week's time to attend a scientific conference annually. Approval will depend on the Office of the Chief Medical Examiner and the Mayor's Office as budgetary constraints may prevent reimbursement of expenses. All applications to professional meetings must be submitted to the Training Coordinator and approved by Forensic Biology Management.

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 Department must be validated using accepted procedures – conforming to the FBI DNA Quality Assurance Standards and/or NDIS Standards – which demonstrate that the methods are capable of providing reliable results from specimens commonly received for forensic analysis. Analytical test results and the validation protocols used for each test must be available and must be kept on file in the laboratory.

The laboratory will conform to the criteria in Standard 8.1 of the FBI Quality Assurance Standards, when validating methods.

J. Quality Assurance and Audit Records

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

K. Scientific Equipment

1. Inventory

An inventory of all scientific equipment is maintained in the Department. The Quality Assurance Unit is responsible for maintaining the inventory.

2. Operations Manuals

All scientific equipment manuals are kept as a part of a centralized operations manual. The Quality Assurance Unit 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 scientific equipment for which these logs are required.

L. Safety

1. Manuals

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.

2. Right to Know Training

The OCME has a Right to Know training program that 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 the FBI Quality Assurance Standards. The Department's accreditation requires an external audit every other year conducted by an independent, external evaluator who has no responsible function in the Department. In between these years, the Department of Forensic Biology may choose to conduct an internal audit by qualified laboratory staff, or to request an external audit. The Quality Assurance 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.

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.

The Director will schedule internal and external quality audits. 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.

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.

It is important that all Forensic Biology managers, including the Technical Leader and the Quality Assurance Manager, be informed of technical errors that may compromise evidence integrity or the accuracy of casework analysis, so that they are in a position to provide advice to the staff concerned and to the clients involved.

It is also important that all potential or actual errors and deficiencies be identified and reported so that appropriate corrective action can be implemented. The identification of problem areas will improve quality through encouraging innovative solutions and avoiding the potential for future errors.

An ***Incident Report*** must be initially completed for all incidents that may have compromised evidence integrity or the accuracy of casework analysis.

If the incident reported is of a serious nature, a ***Corrective Action Report*** will be initiated the Technical Leader and/or Quality Assurance Manager. This documents the required follow-up and planned action to remedy any problems or errors.

All forms may be found on the Forensic Biology main network drive under the folder "FORMS\CAR."

Authority and Responsibility

Any member of staff who discovers a technical error or realizes that there is a technical discrepancy must inform the relevant rotation/area supervisor immediately. The rotation/area supervisor must document the event on an Incident Report. Corrective Action Reports are initiated by the Technical Leader and/or Quality Assurance Manager. Incident Reports must be forwarded to the Technical Leader and/or Quality Assurance Manager immediately to ensure that all errors are acknowledged and investigated properly from the beginning.

It is the responsibility of the Quality Assurance Manager to review and track all Incident and Corrective Action Reports to ensure that all errors are corrected and all remedial actions are completed. The Quality Assurance Manager should review incident reports on a regular basis to determine if any trends exist that may require further corrective action.

Examples of Situations Requiring Action

It is impossible to anticipate all situations in which an Incident and/or Corrective Action Report must be completed. Sound judgment is required in determining the extent and level of reporting and documentation required.

Situations which require some form of action include, but are not limited to:

1. Continuity errors (mis-labeled samples, chain of custody problems)
2. Contamination of evidence
3. Equipment or reagent failure
4. Errors in approved standard operating procedures
5. Failure to follow proper protocols by personnel

The Technical Leader and/or Quality Assurance Manager should be consulted if there is any question as to which action is required and taken.

Policy

1. All technical errors that may compromise evidence integrity or the accuracy of casework analysis must be reported to the appropriate rotation/area supervisor upon discovery or at the earliest opportunity.
2. Rotation/Area supervisors must investigate the problem, determine what error occurred, the exact root cause, what actions are required to correct the problem, and properly document it on an Incident Report where appropriate. The Incident Report must be forwarded to the Technical Leader or Quality Assurance Manager immediately.
3. If the Technical Leader and/or Quality Assurance Manager deems that the incident requires further corrective action, a Corrective Action Report shall be initiated and shall be completed by the rotation/area supervisor. The Report must include the proper steps to ensure that the problem/error does not recur.
4. In cases of corrective action that requires personnel action, the rotation/area supervisor must refer to the Department of Forensic Biology "General Procedures for Infractions" and work with the analyst's Immediate Supervisor. However, it will be the responsibility of the Rotation Supervisor to ensure that Corrective Action has been taken and properly documented.
5. If Corrective Action taken is due to analyst error, the Report is forwarded to 1) the Assistant Director of the analyst, 2) the Quality Assurance Manager, and then 3) the Technical Leader. All individuals must agree that the corrective action has been satisfactorily implemented and all follow-up actions completed.
6. If Corrective Action taken is due to a procedural error, the Report is forwarded to 1) the Quality Assurance Manager, and then 2) the Technical Leader. All individuals must agree that the corrective action has been satisfactorily implemented and all follow-up actions completed.
7. The final, signed report is forwarded to the Quality Assurance Manager and is filed with the Quality Assurance Unit.

Closing of Corrective Action

As per a cooperative agreement with the District Attorney's Offices of the City of New York, all case files containing unusual Corrective Actions, as determined by the Quality Assurance Manager, shall be clearly indicated by attaching a red sticker on the front cover of the casefile. The Quality Assurance Manager must first consult with the Director, Deputy Director, and the DNA Technical Leader on which Corrective Actions are considered "unusual." This shall be the last step in the Corrective Action process and it will be the Quality Assurance Manager's responsibility to inform the affected personnel to flag their case files.

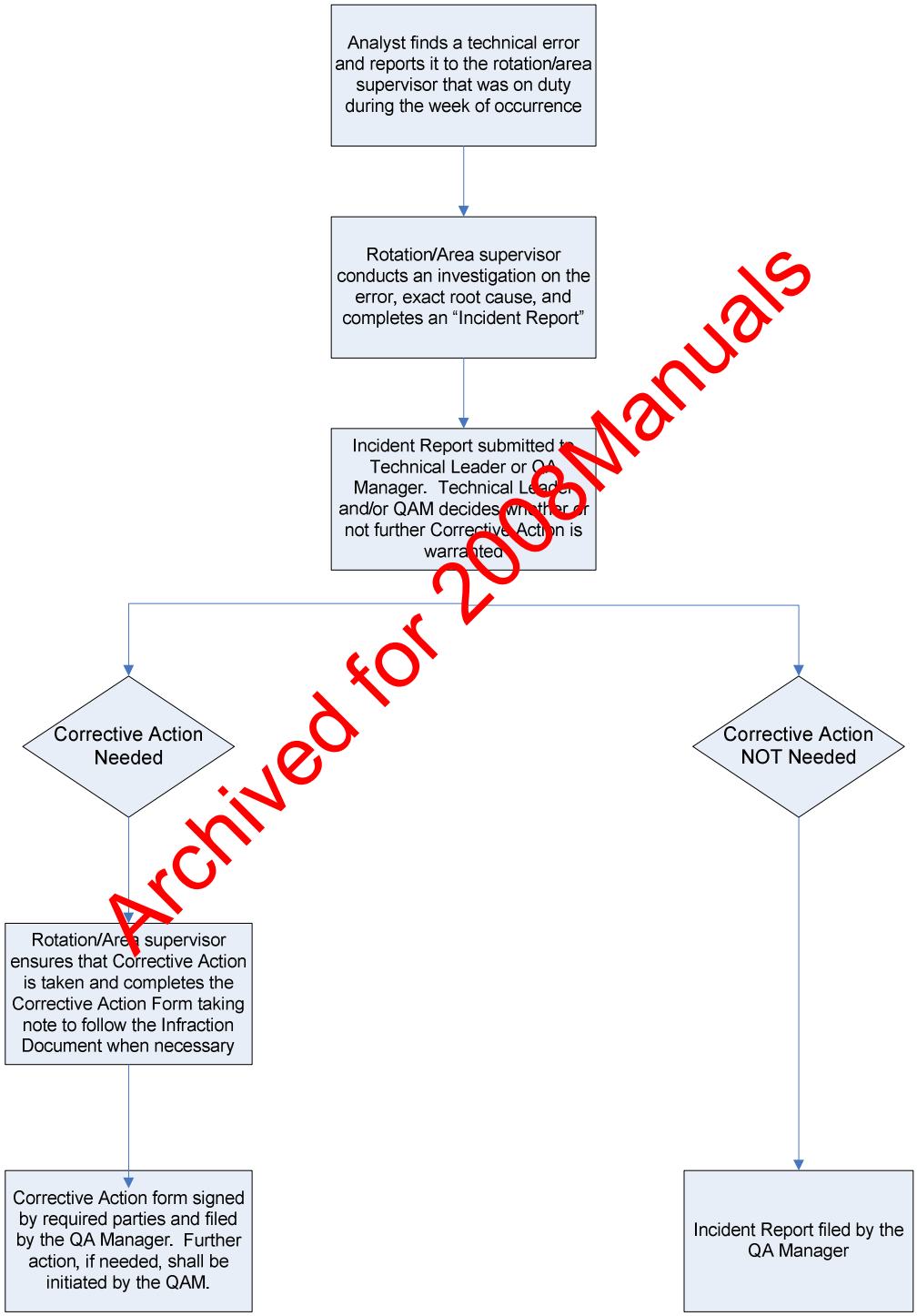

Table 1: Flow chart depicting the initiation of Incident Reports and Corrective Action Reports.

P. Subcontracting

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

- Evaluate the laboratory against the FBI Quality Assurance Standards.
- Obtain existing FBI QAS audit – or equivalent – reports from the subcontracting laboratory.

Revision History:

June 23, 2005 – Changed "Administrative Review." Rush cases must undergo administrative review prior to issuing the report. See Approval Form.

January 9, 2006 – Changed Table 1, Table 2 and wording on Page 6 and Page 8. Selected CODIS profiles may be reviewed, entered into LINKAGE, and directly forwarded to the CODIS group for entry into CODIS by a Criminalist, Level IV. See Approval Form.

March 27, 2007 – Updated Section O: Non-conformity and Corrective Actions. See Approval Form.

4. MANAGEMENT INFORMATION SYSTEM (MIS)		
DATE EFFECTIVE 01-07-2005	VERSION 5.0	PAGE 1 OF 1

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, such as WordPerfect, Paradox, DataEase, and Microsoft Office.
2. Medical Examiner casework database.
3. Procurement database/ordering system.
4. E-Mail
5. Departmental and individual accounts.

B. Departmental

The Forensic Biology Laboratory directory is located on the OCME network under G:\USERS\FBIOLOGY. Individuals have access to their own private directory under a different drive name.

Departmental functions maintained on the network include:

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

The Forensic Biology Laboratory has non-current reports archived on the OCME network under I:\USERS\FBIOLOGY.

5. CODIS

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01-07-2005	5.0	1 OF 1

CODIS is the FBI's national DNA index system. The Department is a local CODIS laboratory. As such, all eligible profiles are uploaded to the New York State DNA Index System. Further information may be found in the Department of Forensic Biology CODIS Manual.

6. TIME AND LEAVE POLICY

DATE EFFECTIVE	VERSION	PAGE
01-07-2005	5.0	1 OF 1

The collective Citywide Contract between the City of New York and District Council 37, AFSCME, AFL-CIO dictates the time and leave policy for city employees. The current manual is available in the Departmental conference room at the OCME headquarters building in Manhattan.

7. POLICY AND PROCEDURES OF THE OCME

DATE EFFECTIVE	VERSION	PAGE
01-07-2005	5.0	1 OF 1

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

8. COMPLAINTS		
DATE EFFECTIVE 01-07-2005	VERSION 5.0	PAGE 1 OF 1

A. Personnel Disputes

Disputes and complaints among employees are 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. The OCME's Public Relations Officer investigates harassment complaints.

B. Union Issues

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

9. REFERENCES

1. Quality Assurance Standards for Forensic DNA Testing Laboratories. DNA Advisory Board, U.S. Department of Justice, Federal Bureau of Investigation, October, 1, 1998.

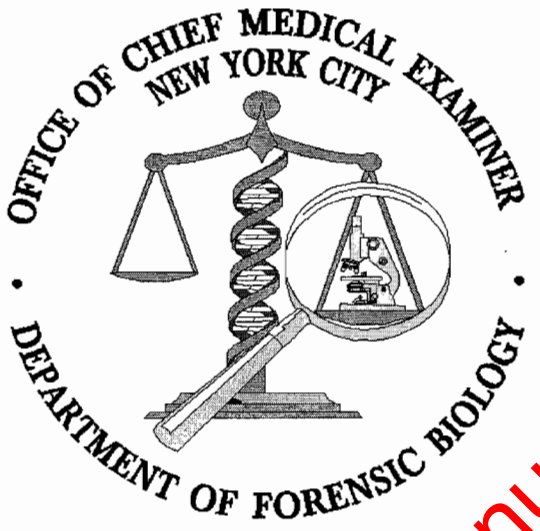
2. The Evaluation of Forensic DNA Evidence. National Research Council. National Academy Press, Washington, DC, 1996.

3. Laboratory manuals:
   - Case Management manual
   - Forensic Biochemistry Manual
   - Protocols for STR Analysis Manual
   - Quality Assurance Manual
   - CODIS Manual

4. FBI DNA Quality Assurance Document, Rev # 5. Quality Assurance Audit for Forensic DNA and Convicted Offender DNA Databasing Laboratories, 10/00.

5. FBI DNA Quality Assurance Audit Document, Issue Date July 1, 2004.

6. American Society of Crime Laboratory Directors/Laboratory Accreditation Board, 2003 Manual. April 2003.



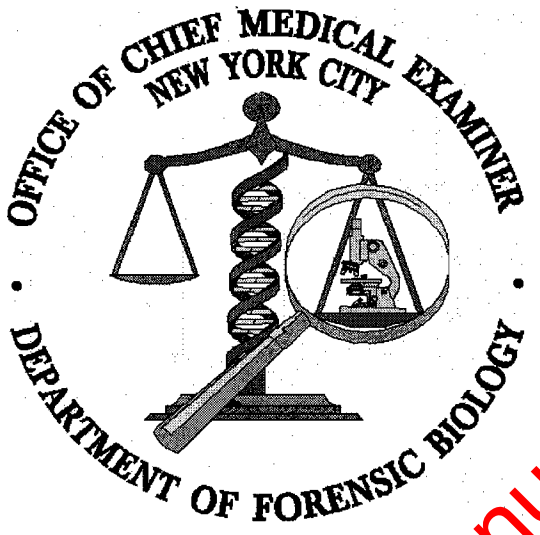
REVISION

FORENSIC BIOLOGY ADMINISTRATIVE MANUAL

(Section 3)

Effective date: March 27, 2007

REVIEWED/APPROVED BY			
Title	**Print Name**	**Signature**	**Date**
Deputy Director / Technical Leader	**Howard J. Baum, Ph.D.**	Howard J. Baum	**March 27, 2007**



REVISION

ADMINISTRATIVE MANUAL

(Section 1)

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Title	**Print Name**	**Signature**	**Date**
Deputy Director / Technical Leader	**Howard J. Baum, PhD**	Howard J. Baum	**August 18, 2006**