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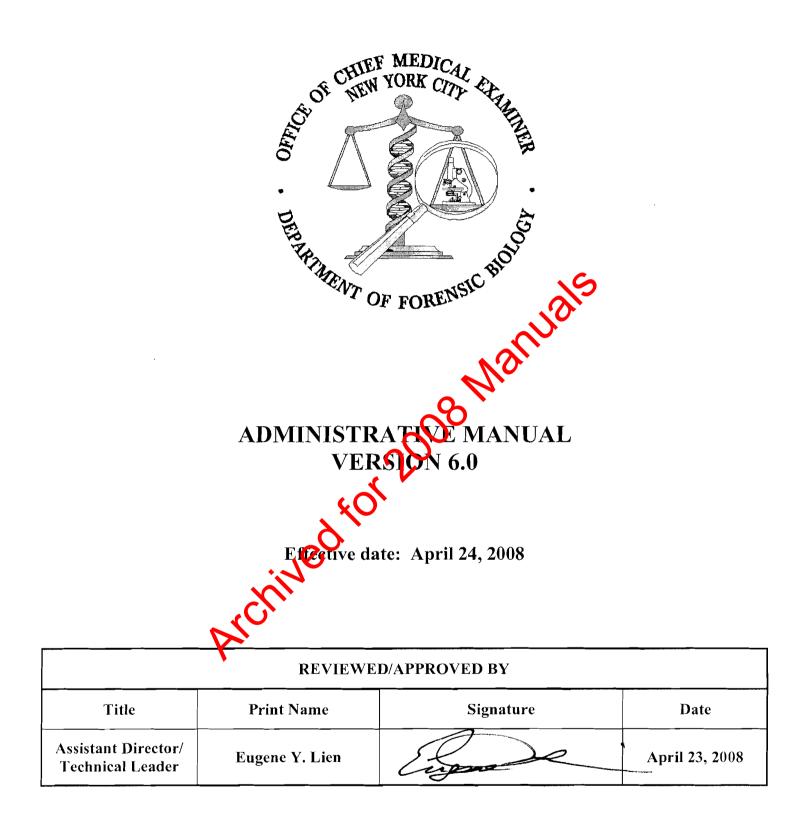
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As of the effective date above, this version of the Administrative Manual supersedes all previous administrative manuals used in the Department of Forensic Biology.

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

Director:	Mechthild Prinz, Ph.D.	
Assistant Directors:	Samia Basilious, M.S. Theresa Caragine, Ph.D. Mark Desire, M.S., J.D. Eugene Y. Lien, M.S.	Mary Quigg, M.S. Helen R. Kafaniello, M.S. Marie Samples, M.S. Eli Shapiro, Ph.D. Yingying Tang, M.D., Ph.D.
Technical Leaders:	Eugene Y. Lien, M.S. – Nuclear D. Eli Shapiro, Ph.D. – Mitochondriar D	
Quality Assurance M	lanager: Eugene Y. Coo, M.S.	

The Technical Leaders are ultimately responsible for the Quality Assurance program and Quality Control functions, as described in the Department's Quality Assurance 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 Biorogy'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, performed according to externally established standards that are 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 measure performed 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.

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A. Goals and Mission

The mission of the Department of Forensic Biology is to support the New York City Criminal Justice system by providing high quality DNA testing in a timely fashion. This testing is 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 Opartment is a CODIS (Combined DNA Indexing System) local laboratory.

The Department is responsible for the quality of DNA test done for specialized projects subcontracted to private forensic DNA laboratories by the NYPD. The Department's specific role in this contract is to review the controls and standards, to review the DNA profiles and the entry of eligible profiles into CODIS, to prepare Quality Control samples for testing of contract laboratories, to manage and report DNA matches and testify in a court of law.

The Department of Forensic Biology develops information through the identification and individualization of physiological fluids such as blood, semen, and saliva obtained from investigating agencies or from post-nortem specimens. In addition to being a powerful courtroom aid and mechanism to happidentify 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 Haid identification
- 2. DNA analysis
- 3. Forensic Paternity
- 4. Report Preparation
- 5. Enter eligible DNA profiles into LINKAGE, and/or CODIS and database management.
- 6. Expert Testimony

- 7. Special NYPD projects
- 8. Unknown Body Identification
- 9. Mass disaster remains processing and identification.
- 10. Mass disaster Family Assistance Center
- 11. Molecular Genetics/Molecular Autopsy Diagnostics
- 12. Special OCME Projects

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To comply with the laboratory's mission, laboratory 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 standards, proficiency tests, and artists.
- 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 Quality Assurance Manual and Standard Operating Procedures 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 Assurance program for both critical reagents prepared in the laboratory and those obtained commercially.
- 5. 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.
- 6. Check with the Director, Neputy Director, and/or Technical Leaders to ensure that qualifications of the aboratory staff meet City of New York requirements and the educational requirements imposed by regulating bodies such as New York State, the CODIS Program, the FBI DNA Quality Assurance Standards, and/or SWGDAM Arso, 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. Ensure that technical problems are noted and that corrective action is taken and documented and reviewed by the respective Technical Leader and/or the Quality Assurance Manager.

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C. Authority and Accountability for the Quality Assurance Program

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

The Quality Assurance Unit, under the direction of the Quality Assurance Manager, will provide support to the Technical Leaders. 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. The managerial structure of the Department of Forensic Biology is seen in <u>Appendix A</u>.

The Department of Forensic Biology is a single operational unit having multiple responsibilities. The Deputy Director reports directly to the Director. Assistant Directors report directly to the Deputy Director. Clerical personnel report to an Administrative Manager, who reports to the Director.

Director

The Director is respective for the overall scientific, quality, and administrative operations of the Department of Fornsic 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.

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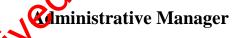
Deputy Director

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; communicate with stakeholder agencies regarding testing requests and recults; triage evidence. 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.



The Administrative Manger is in charge of the overall administrative functions of the Department. As such the Administrative Manager supervises a team of administrative professionals and casewers the proper handling of phone coverage, administrative review of casework files, faxing reports, generating certified copies of casework files for attorneys, maintenance of casework files in archive, timecard and payroll handling, etc. The Administrative Manager also oversees the management of Departmental databases, all Departmental budgetary matters, the planning and development of grant applications, and all Departmental human resource functions including recruitment, retention, employee relations, and performance evaluations.

Technical Leader

Section 5.2 of the FBI DNA Quality Assurance Standards, defines the qualifications and responsibilities of a DNA Technical Leader. The Technical Leader is accountable for the technical operations of the laboratory.

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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 DNA Quality Assurance 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 DNA Quality Assurance 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 pulity of laboratory staff. The Quality Assurance Manager must take a proficiency with a sequence by regulating and accrediting bodies. The Quality Assurance Manager must take a proficiency with a sequence by regulating and accrediting bodies. The Quality Assurance Manager must take a proficiency with a sequence by regulating and accrediting bodies.



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, and/or I's, perform scientific analyses on evidence submitted to the laboratory, perform technical reviews of cases, prepare scientific reports, prepare annual performance evaluations as requested by OCME management, communicate with stakeholder agencies regarding testing requests and results, triage evidence, participate in the training of subordinates, testify in court, take proficiency tests as required by regulating and accrediting bodies, work on designated projects, and supervise 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 and/or Criminalist I's. Criminalist III's may also supervise and/or work in rotations: DNA extraction, DNA quantitation, P30 ELISA, STR analysis and review, perform scientific analyses on evidence submitted to the laboratory, prepare written scientific reports, perform technical reviews of simple cases, perform administrative reviews on DNA cases, train new Laboratory Associates and Criminalists, take proficiency tests as required by regulating and accrediting bodies, and testify to results. In the absence of a Criminalist IV, a Criminalist III may assume those responsibilities on an interim basis.

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Criminalist, Level II

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

Criminalist, Level IA & IB



The responsibilities of Criminalist I's are described in the Circl Service specifications for that title. Generally, Criminalist I's are responsible to work in reasons in the laboratory and, after appropriate training, may examine rape kits and other small items of evidence, 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 as required by regulating and accrediting bodies. These scientists are technicians as defined by the FBI Quality Assurance Standards.



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

Evidence Scheduling Coordinator

The Evidence Scheduling Coordinator supports the Criminalist, Level IV DNA casework supervisors with evidence triaging and scheduling tasks.

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

A. Manuals

The Technical Leader, or his/her designee, must approve all Department Manuals before they may be used. Changes to policies may be documented by writen memo, which are distributed and then placed in a memo binder. Changes to the table of contents, hyperlinks, or appendices do not require an approval by the Technical Leader 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. Revision history (if applicable).
- d. Approval from the Technical Leader, or his/her designee, signifying the manual's official start for use in the laboratory.

Only the Quality Assurance Manger has the authority to release Department Manuals to an external organization. The process may require further documentation from the requestor in regards to the specific use of the manual and may require consultation with an OCME Counsel.

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:

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

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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, instructents, and equipment
- d. Calibrate and maintain instruments and equipments

4. Administrative Manual

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

5. Training Manual

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

B. Case Records and Policies

Written reports will be prepared when observations, opinions, 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.

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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 the NYPD Liaison Unit 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 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 (Isuilly Criminalist II-IV's) is responsible for all facets of the case analysis. See Case Management Manual for details. Criminalist I's may be responsible for generating reports for those cases that are semen negative and/or contain instruction DNA for testing.

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 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

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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.

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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 and an Incident Report may be written. The rotation supervisor (if applicable) and/or a Criminalist 10 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 any necessitate extensive remedial and/or corrective action and possibly oven a change in laboratory policy and/or procedures. (Refer to Section O of the manual for a discussion of corrective action).

Legitimate differences of opinion or 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 matering

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

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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 printions are based upon objective scientific observations (refer to Protocols as Forensic STR Analysis and Case Management Manuals).

Case Review

Case review takes place in phases. Under routine circumstances, the case review process is illustrated in Table 1 through Table 3. For the majority of cases a single level of technical review is sufficient. A combination of technical and management review process ensures that findings in complex cases with interpretable mixtures of INA, multiple single-source DNA profiles, and/or large quantities of items are accurate. However, a single level of technical review by management is alloyed for all case types.

Technical Ver

A technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions. 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 were interpreted correctly, and that the final report accurately reflects the underlying data.

A technical review is performed on all cases with DNA extraction, quantitation, amplification and/or typing before final reports are released. A technical review is performed on at least three (3) serology cases per month for each analyst issuing serology reports.

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For cases without STR typing attempted: technical review for cases that were negative for biological fluids, yielded insufficient DNA, and/or yielded sufficient DNA but were not amplified, is performed by Criminalists II and above

For cases that proceeded to STR typing: technical review for cases that yielded sufficient DNA and were amplified is performed by a minimum of one Criminalist IV, Assistant Director, Deputy Director, or Director.

Technical reviews must be documented by dating and initialing the "technical review" line on the Scheduled Analysis sheet. The reviewer may return the case file to the assigned Criminalist for corrections and/or additional work.

Management Review

Depending on the case type and complexity (refer to Table 1 through Table 3 for rules and examples), a case may a so indergo additional review by management. This step wise technical/ management review process is a mechanism for samples in complex cases with interpretable mixtures of DNA, multiple single-source DNA profiles, and/or large quantities of examined items to receive additional scrutiny. For multiple volucier cases the numerical threshold and the need for an additional review is left to the manager's discretion.

At a minimum, amanager shall inspect the most critical elements of a case file. These must include a review of the probative STR data, and may include the relevant evidence exam notes, the comparisons made, and the conclusions which are relaxed in the report. This review ensures that findings in complex cases with interpretable mixtures of DNA and/or large quantities of items examined are correct.

Alternatively, a manager may chose to perform a technical review of the case. Moreover, a single level of technical review by management is allowed for all case types.

Reviews by management must be documented by dating and initialing either the "management review" and/or the "technical review" line on the Scheduled Analysis sheet accordingly. The reviewer may return the case file to the assigned Criminalist for corrections and/or additional work.

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Data Review for CODIS Profiles

This type of review focuses on certain probative samples within a case file and involves the relevant STR data and the associated controls. The reviewer indicates this review on the Scheduled Analysis sheet with the term "CODIS." At least one level of Data Review is necessary prior to CODIS upload and it can be performed by either one supervisor, Assistant Director, Deputy Director, or Director as indicated in Table 1 through Table 3. The reviewer will enter or review previously entered eligible DNA profiles in the local OCME database NLPKAGE), and forward eligible profiles to the CODIS Group for entry in OCDIS.

Administrative Review

An administrative review is an evaluation of the report and supporting documentation for consistency with addresory policies and for editorial correctness.

An administrative review is the final review performed on all cases. This ensures that notes and worksheets review careditation 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 are generally performed by the Forensic Biology Administrative Team, but Criminalists and other titles can be tasked with performing administrative reviews as well.

Administrative reviews must be documented by dating and initialing the "administrative review" line on the Scheduled Analysis sheet. The administrative reviewer may return the case file to the assigned Criminalist to make corrections.

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.

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Table 1Technical and Management review requirements for sexual
assault cases and PM rape kits.

Result	Technical Review by	Management Review?
Negative for biological fluids, insufficient DNA, or yielded sufficient DNA but no STR typing performed	Criminalist II or above	No
Autosomal results - No DNA foreign to victim	Criminalise V or above	No
Autosomal or Y Results – Mixture, the DNA profiles of individual donors could not be determined	or above	No
Y Results – Single-source Y profile, no autorous results foreign to victim	Criminalist IV or above	No
Y Results – Single-source Y profile, upsomal male profile	Criminalist IV or above	No
Y Results – Multiple semestionors, all single-source autosomal and single-source Y profile(s)	Criminalist IV or above	No
Y Results- Single-source Y profile, low level mixture on autosomal level	Criminalist IV or above	Yes
CODIS profile – Single-source sample yielding CODIS profile; mixture in EF and/or other samples okay.	Criminalist IV or above	No
CODIS Profile – Mixture in sample yielding CODIS profile Deduced profiles	Criminalist IV or above	Yes
CODIS Profile – Complex case with multiple single-source DNA profiles	Criminalist IV or above	Yes

Controlled versions of Department of Forensic Biology Manuals only exist electronically on the OCME intranet. All printed versions are non-controlled copies.

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Table 2Technical and Management review requirements for homicide,
assaults, suspects, and mtDNA cases (including High Sensitivity
DNA testing).

Result	Technical Review by	Managemen t Review?
Negative for biological fluids, insufficient DNA, or yielded sufficient DNA but no STR typing performed	Criminalist II or above	No
DNA matching victim, no mixtures –	with	
Simple Cases (for example ≤3 vouchers examined)	Criminalist IV or above	No
Complex Cases (for example >3 your research or multiple DNA profile)	Criminalist IV or above	Yes
CODIS Profile – Single-source sample yielding ODIS profile + mixtures with some profile.	Criminalist IV or above	No
DNA matching victum, probative mixtures mesent	Criminalist IV or above	Yes
CODIS Profile Mixture in cample yielding CODIS profile Deduced profiles	Criminalist IV or above	Yes
CODIS Profile Complex case with multiple single-source DNA profiles	Criminalist IV or above	Yes
Forensic Paternity Cases	Criminalist IV or above	Yes
Body Identification Cases - Direct Comparison Body Identification	Criminalist IV or above	No
Kinship Body Identification	Criminalist IV or above	Yes

Controlled versions of Department of Forensic Biology Manuals only exist electronically on the OCME intranet. All printed versions are non-controlled copies.

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Result	Technical Review by	Managemen t Review?
Suspect file DNA cases, matching or not matching	Criminalist IV or above	
Suspect file DNA cases, suspect is either "included", cannot be excluded", or "excluded" from a mixture in the associated case.	Criminalist V or above	Yes
Autosomal or Y Results – Mixture, the DNA profiles of individual donors could not be determined	Criminalist IV or above	No

Table 3 Technical and Management review requirements for Property Crimes Crimes

	Result	Technical Review by	Management Review?
	Negative for biological Nuds, insufficient DNA, or yielded sufficient DNA but no STR typing performed	Criminalist II or above	No
	Single source profiles	Criminalist IV or above	No
	CODIS Profile Single-source sample yielding CODIS profile + mixtures with same profile	Criminalist IV or above	No
	Mixtures present, not deduced	Criminalist IV or above	No
0	Mixtures present, not deduced compared to elimination samples or non-probative victim samples for inclusion and exclusion	Criminalist IV or above	No
	Mixtures present, not deduced, compared to suspect profile for inclusion or exclusion (and probative comparisons to victims)	Criminalist IV or above	Yes

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Result	Technical Review by	Management Review?
Mixtures present, deduced profiles (only)	Criminalist IV or above	ex
Complex cases with multiple vouchers (for example > 3) examined	Criminalist IV or above	Yes

Deviations from the above requirements are allowed. For example, analysts that have recently completed training may receive two levels or review on all of their cases, including simple non-mixture DNA cases.

At times, a Criminalist IV, Research Sofentist, Assistant Director, Deputy Director, or Director may conduct or direct independent scientific investigations on casework. In these instances, the review process begins at the same 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. A Criminalist IV, Assistant Director, the Deputy Director or the Director must approve disclosure of the test results of workin-progress.

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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.

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 **Geshnical** knowledge, ability to convey scientific concepts).
- 4. Interpretation of laboratory results.

In the event of a Grand Jury Testimony or if sscheduling conflicts occur, an appropriate reviewer may not be available. In these instances, the District Attorney may fill out the Forensic Biology Court Testimony Evaluation Form and send it to the Forensic Biology Department.

Immediate supervisors must review the testimony monitoring results with each individual, serving roudentify 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.

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E. Evidence Handling Protocols

1. General Guidelines

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 stores it 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 QUME is received from all of the OCME locations via the Evidence Unit. Cornally, 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, amplified DNA, electropherograms, FTIR cards, or stand 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.

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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 breathable paper or Tyvex 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 example O
- (2) Items intended for hair/fiber exems
- (3) Items intended for gunslo residue exams
- (4) Hair, fiber, or other tract ordence
- (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 is transferred from the Evidence Unit, where it is stored, to a member of the Forensic Biology Department. The chainof-custody form is filled out to reflect this. All dates are recorded tomemporaneously. The following reflect how a chain-of-custody form is completed.

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

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- (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	RECEIVEOBY	DATE
	PM 1-3	autopsy PM specimens		P. Ryan	1/2/99
	PM 1-3	P. Ryan		IM storage	1/2/99

e. Storage of evidence

Evidence is stored in a secure location until it is assigned for analysis. Normally, evidence is dollvered to the Evidence Unit, assigned an EU number, stored in the Evidence Unit and then transferred to the Forensic Biology Department for examination. Evidence in progress (pending examination, percent eview, etc.) is securely stored with the Evidence Unit.

f. Case assignment

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

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h. Disposition – retained items

The laboratory shall retain (if possible) exemplars from suspects only 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 trens, is returned directly to the submitting agency.

j. OCME transport of speciment 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 using 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, 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.

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I. 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-morter blood

A stain is prepared of State cards and is retained in the laboratory. Eventually the stain cards are transferred to long-term storage. For disposal and disposition guidelines, see Forensic Biochemistry Manual, version 4.6,

(2) PM sexual assault evidence

Servel assault evidence obtained after an autopsy is secured until processed. Following the guidelines in the Case Management Manual, all items are returned to the Evidence Unit. This will be reflected in the chain-of-custody.

VOUCHER	ITEM(%)	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		Evidence Unit	1/2/99

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(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 of disease diagnosis will be retained frozen. Bones for subsequent missing person identification will be retained

b. Non-FB cases

(1) Bloo

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.

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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	-0.1	F. Baldi	2/4/99
F123456	1-6	F. Baldi	(OXO)	R. Burgos	2/4/99
Retained	Items	F. Baldi	00	Retained storage	2/4/99
Retained	Items	Retained Storage	\mathbf{O}	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
	Ç,				

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Evidence is occasionally transferred to another OCME department, such as a knife to a medical examiner, who wishes to examine it. The chain-ofcustody 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 discarced.

f. Submittal to other agencies

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

VOUCHER	ITEM(A)	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.

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If additional items, such as DNA extracts, are returned, a new chain-ofcustody 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 the OCME ONA Building at 421 East 26th Street.

The main entrance to the OCME DNA Building is on 26th Street, at the west end of the bundling. Retractable vehicular bollards remain in the up position to prevent vehicular access to this area. In the event that vehicle access is authorized the bollards may be controlled by officers in the command conter located on the 3rd floor or by a portable device that will allow the officer at the location outside to retract the bollards. As a safety measure, the bollards will never be operated without an officer on site to prevent pedestrians from sustaining injury while the bollards are in notion. The other entrance to the building is through a vehicular breezeway off of 26th street, accessing sub-level 1 (evidence intake) and sub-level 2 (parking garage). A guard booth is situated at the entrance to this breezeway. The guard within this booth controls a gate that allows vehicular access. This guard booth is also situated near the building dock as well. Guard presence at both locations is 24 hours/day, 7 days/week.

The OCME DNA Building is equipped with a high-tech security monitoring system. Cameras are situated throughout the inside of the building and also at key spots outside the building. Cameras are monitored by OCME Security in the security command center located on the 3^{rd} floor.

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Inside the main lobby is a security desk. Visitors to the building must sign a guest logbook at the security desk before being escorted throughout the building. Employees gain access to the staff elevators and other parts of the building through turnstiles equipped with ID card readers.

Once inside the building access to various floors and rooms is obtained via ID card readers. OCME Security has the ability to program ID cards so as to allow or deny individuals access to specific areas within the building (i.e. a member of the Human Resources Department does not have card access to a laboratory – they would only be aboved to enter with a Forensic Biology escort).

Building Security is present 24 hours date 7 days/week. During normal business hours the security desk in metobby will be manned by security personnel. After normal business hours security will be limited to a rover and OCME staff needing to emer the lobby will either have to use a card reader or an intercom. After hears access for OCME staff will be dictated by department heads.

b. Laboratory Security

The Laboratory is accessible only by authorized personnel. This includes members of the Forensic Biology Department, student-interns, and other selected OCME employees, such as custodial staff. As mentioned above, access is obtained and controlled via ID card readers. Anyone who is not parmitted access to the laboratories via their ID card must be escorted by a Forensic Biology employee.

See

Security of Evidence and Records

All evidence brought into the OCME DNA Building is kept secure under the custody of the OCME Evidence Unit. The Evidence Unit has various evidence storage areas that are accessed via an ID card reader that only select members of the Evidence Unit have access to. Evidence Unit personnel are present 24 hours/day, 7 days/week.

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Evidence being processed by a Forensic Biology analyst may be left opened on a desktop during normal working hours, but must be returned to the Evidence Unit at the end of each day. Any item returned to the Evidence Unit must be sealed, dated, and initialed across the seal.

Retained samples are kept in a secure location with the Evidence Unit, accessed only by members of the Evidence Unit.

Post-mortem blood stain cards and other exempters are stored in two secure areas. Current items are kept in a locked erge within the laboratory that only members of the Forensic Biology Exemplar Team have access to. Older items are stored in a secure location with the Evidence Unit, accessed only by members of the Evidence Unit. Post-mortem items that must be kept frozen are stored in frequents that are located on the 4th and 6th floors. These freezer rooms are accessed by ID card readers that only members of Forensic Biolog have access to.

Current case files and records are located in filing cabinets and file storage rooms inside the Department of Forensic Biology. Archived case files and records are stored in the 4th floor OCME Records room and are accessed by Records Department staff.

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.

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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 (<u>Section O</u>) 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 environment 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

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.

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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 speet, which is a checklist completed by the supervisor (usually a Criminalist 10) 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 texts 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 are competent only in selected areas of the analytical process – Chelex, M48, and Organic extractions, P30 ELISA, Rotorgene, 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), Cellmark Diagnostics (IQAS), and the College of American Pathologists (CAP).

The Quality Assurance Manager, and/or his/her designee shall manage the Proficiency Testing Program. A summary of al proficiency tests for the department must be submitted to the Technical Leader on an annual basis.

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2. Corrective Action – External Proficiency Testing Program

It is the responsibility of the Quality Assurance Manager (and/or his designee) to inform 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 werk.

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 deficience was the result of an analyst's analytical or interpretive error or if there is a denciency 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 Leader must manage a feview of 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 reimplementation of the method or protocol.

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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 d sult of a lapse in the analyst's abilities, the analyst will be prohibited than performing the test in casework until he/she has been re-trained.

The Quality Assurance Manager and or the Technical Leader must manage a review of all casework performed during the relevant period. If necessary, selected samples must be repeated to Ver 6 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 or 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 elerical 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 reinstructed in the appropriate procedures, which will be documented on the Proficiency Evaluation sheet.

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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

Sciencific 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.

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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 Crimital 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 Lestures

Seminars and leatures 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.

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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 essurance Standards and/or NDIS Standards – which demonstrate that the methods are capable of providing reliable results from specimens commonly received are 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 randating 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.

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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

The OCME Department of Health and Safety is responsible for the overall health and safety of all members of the Office of Chief Medical Examiner, including the Department of Forensic Biology. The Forensic Biology Health and Safety Officer, who reports to the Director of OCME Health and Safety, is in charge of all health and safety issues related to the Department of Forensic Biology. Designated individuals within the Forensic Biology Department are assigned as liaisons to the Department of Health and Safety and may assist the Forensic Biology Health and Safety Officer in his/her duties.

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1. Manuals

The OCME Department of Health and Safety maintains a number of safety manuals for the department and the agency, including: Jal 9/8

- **Exposure Control** a.
- **Exposure Determination** b.
- **Infection Control** c.
- d. **Hazard Communication Plan**
- **Hazard Contingency Plan** e.
- f. **Chemical Hygiene Plan**
- **Blood Borne Pathogens** g.
- **Respiratory Protection** h.

2. **Right to Know Training**

The OCME has a Right to Know raming program that is provided annually. Each OCME employee is required to attend. Documentation and a Right to Know manual are available from the OCME Safety Officer.

Material Safety Pata Sheets (MSDS) 3.

MSDS sheets are the a separate binder for all reagents and chemicals used in the departmental aboratories. 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.

Historical or Archival Records М.

Records for all laboratory operations are maintained with the case file under the laboratory case number (FBXX-01234), 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.

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N. Quality Audit

An annual quality audit is required by New York State and by the FBI DNA 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 ensure that an audit of the quality system is done annually. All audit reports are sent to the Technical Leader and/or 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 the quality of the work performed in the laboratory. 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 Technical Leader and/or Director, who will reply to the auditor's comments. The reply will discuss corrective action taken, and/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 imperative that all Forensic Biology managers, including the Technical Leader and the Quality Assurance Manager, are 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.

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It is also important that all potential or actual errors and deficiencies are 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.

1. Incident Report

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

2. Corrective Action Report

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

All forms may be found on the Foreisic Biology main network drive and should be 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.

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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 personne

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 Connical Leader and/or Quality Assurance Manager deem 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.

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- 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 Actorney'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 corresponding 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 tiles.

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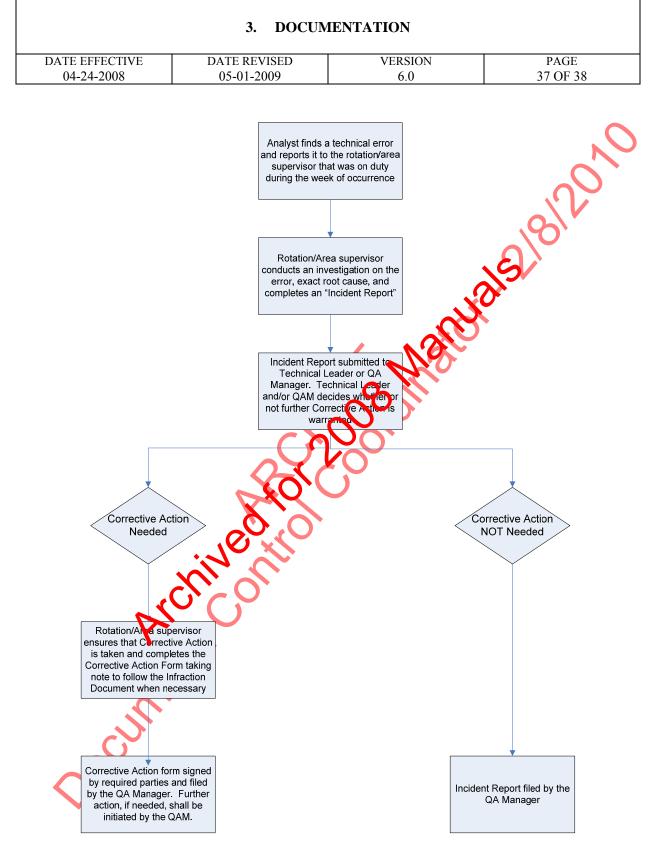


Figure 1: Flow chart depicting the initiation of Incident Reports and Corrective Action Reports.

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

Revision History:

- September 24, 2008 Case Review requirements (Section 3.C.4. Reporting) revised. Inserted Management Review and Data Review for CODIS Profiles section; overall clarification of review requirements (including Tables) were done. See <u>Approval Form</u>.
- April 6, 2009 Case Review requirements (Section 3.C.4. Reporting) revised to allow Criminalist, Level II analysts to conduct Technical Reviews on specified cases. See <u>Approval Form</u>.
- May 1, 2009 Security of evidence (Section 3.E.3.c Security of Evidence and Records) revised: all items returned to the Evidence Unit must have a permanent seal. See <u>Approval Form</u>.

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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 Technical Leader, or his/her designee, must approve all Department Manuals before they may be used. Changes to policies may be documented by writen memo, which are distributed and then placed in a memo binder. Changes to the table of contents, hyperlinks, or appendices do not require an approval by the Technical Leader 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. Revision history (if applicable).
- d. Approval from the Technical Leader, or his/her designee, signifying the manual's official start for use in the laboratory.

Only the Quality Assurance Munger has the authority to release Department Manuals to an external organization. The process may require further documentation from the requestor in regards to the specific use of the manual and may require consultation with an OCME Counsel.

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 which are in progress.
- c. Report writing.

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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, instructions, and equipment
- d. Calibrate and maintain instruments and equipments

4. Administrative Manual

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

5. Training Manual

The Training Manual dealern-house training in the Department.

B. Case Records and Policies

Written reports will be prepared when observations, opinions, 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.

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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 the NYPD Liaison Unit 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 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 may be responsible for generating reports for those cases that are semen negative and/or contain instruction DNA for testing.

Generally, the analytical scheme employs a rotation system in which samples move through the laboratory in a logical fashion, progressing through wortstations: Evidence examination, serological testing (P30/Amylase), DNA extraction, DNA quantification, 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.

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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 and an Incident Report may be written. The rotation supervisor (if applicable) and/or a Criminalist 10 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 way necessitate extensive remedial and/or corrective action and possibly even a change in laboratory policy and/or procedures. (Refer to Section O or the manual for a discussion of corrective action).

Legitimate differences of opinion or 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 matering

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

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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. 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 either one supervisor, Assistant Director Deputy Director, or Director.

A technical review is performed on all DNA cases and takes place in distinct phases before final reports are released. A technical review is performed on at least three (3) serology cases per month for each analyst issuing serology reports.

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 Tables 1, 2, and 3 for further details.

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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 type and supporting documentation for consistency with laboratory polices and for editorial correctness.

An administrative review is performed on al 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 dat passes are numbered and initialed correctly. Administrative reviews are generally performed by the Forensic Biology

Administrative Team.

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

The administrative viewer may return the case file to the assigned Criminalist to make corrections

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. The technical review process ensures that complex cases with interpretable mixtures of DNA, multiple single-source DNA profiles, and/or large quantities of items that were examined generally require scrutiny by the most experienced members of the laboratory (management). In most situations, this additional scrutiny is gained by having two levels of technical review (supervisory and management) but a single level of technical review by management is allowed for all case types.

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

Result	Criminalist IV Review?	Management Review?
Negative results, negative DNA quantitation, no DNA testing	Criminalist III only selected cases	No
Autosomal results No DNA foreign to victim	Yes	No
Autosomal or Y Results – Mixture, the DNA profiles of individual donors could not be determined	Ves	No
Y Results – Single-source Y profile, no autosomal results foreign to victim	Yes	No
Y Results – Single-source Y profile, autosorial male profile	Yes	No
Y Results – Multiple semen doners, all single- source autosomal, and single-source Y profile(s)	Yes	No
Y Results – Single-source Y profile, low level mixture on autosomal level	Yes	Yes
CODE profile – Single-source sample yielding CODIS profile; mixture in EF and/or other samples okay.	Yes	No
CODIS Profile – Mixture in sample yielding CODIS profile Deduced profiles	Yes	Yes
CODIS Profile – Complex case with multiple single- source DNA profiles	Yes	Yes

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<u>Table 2</u> Technical review requirements for homicide, assaults, suspects, and mtDNA cases.

Result	Criminalist IV Review?	Management Review?
Negative results, negative DNA quantitation, no DNA testing	Criminalist III only selected cases	No
DNA matching victim, no mixtures Simple Cases (≤3 vouchers examined) Complex Cases (>3 vouchers examined	Yes	No
or >3 DNA profiles)	Tes	Yes
CODIS Profile –		
Single-source sample yielding CODIS profile + mixtures with same profile	Yes	No
DNA matching victim, Mixtures present	Yes	Yes
CODIS Profile – Mixture in sample yielding COLUS profile Deduced profiles	Yes	Yes
CODIS Profile – Complex case with multiple single- source DNA profiles	Yes	Yes
Forensic Paternity Cases	No	Yes
Body departication Cases: Opert Comparison Body		
Identification	Yes	No
Kinship Body Identification	Yes	Yes
Suspect file DNA cases, matching or not matching	Yes	No
Suspect file DNA cases, suspect is either "included" or "cannot be excluded" from a mixture in the associated case.	Yes	Yes
Autosomal or Y Results – Mixture, the DNA profiles of individual donors could not be determined	Yes	No

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<u>Table 3</u> Technical review requirements for Property Crimes and High Sensitivity Cases.

Result	Criminalist IV Review?	Management Review?
Negative results, negative DNA quantitation, no DNA testing	Criminalist III only selected cases	No
DNA matching victim, no mixtures All Property Crimes Cases & Simple LCN Cases (≤3 vouchers	Yes als	No
examined) Complex LCN Cases (>3 vouchers examined or >3 DNA profiles)	Yes	Yes
CODIS Profile – Single-source sample yielding CODIS profile + mixtures with same profile	Yes	No
Mixtures present, not deduce	Yes	No
Mixtures present, not deduced, compared to suspect profile for inclusion or exclusion	Yes	Yes
CODIS Profile – Mixtures present adduced profiles (only)	Yes	Yes

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 simple non-mixture DNA cases; a rush case or a DNA mixture case managed by a Criminalist IV could be reviewed by only an Assistant or Deputy Director. Technical review of all case types by management only is allowed.

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.

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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. A Criminalist W. Assistant Director, the Deputy Director or the Director must approve discussive of the test results of workin-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.

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.

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In the event of a Grand Jury Testimony or if sscheduling conflicts occur, an appropriate reviewer may not be available. In these instances, the District Attorney may fill out the Forensic Biology Court Testimony Evaluation Form and send it to the Forensic Biology Department.

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 revairing. Deficiencies in knowledge will be addressed through remedial education and reight include one or both of the following:

- Retraining on technical information if the test was inaccurate.
- Moot court if the testimony showed define cles 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

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 stores it under lock and key. Only Evidence Unit personnel have access to these locations.

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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 via the Evidence Unit. 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, amplified DNA electropherograms, FTIR cards, or stained slides.

a. Case numbers

See discussion in the Case Manual.

b. Item numbers

An item refers to a single piece of evidence received by the laboratory. Each item is as issued a unique number, which is cross-referenced to a police vouche number, i.e., Item 1 on voucher H996103.

c. Evidence receipt

All evidence received in the laboratory must be properly sealed. **Staples the not an acceptable seal.** All evidence must be packaged in breathable paper or Tyvex 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.

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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 is transferred from the Evidence Unit, where it is stored, to a member of the Forensic Biology Department. The chainof-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 memory of the Forensic Biology Department. This is not a course 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.

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(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 stored in a secure location 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 for examination. Evidence in progress (pending examination, pending review etc.) is securely stored with the Evidence Unit.

f. Case assignment

g.

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.

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.

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h. Disposition – retained items

The laboratory shall retain (if possible) exemplars from suspects only 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 tems, is returned directly to the submitting agency.

j. OCME transport of speciment 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 part 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, 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.

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I. 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 type

a. FB Cases

(1) Whole blood and post-mortely blood

A stain is prepared of some cards and is retained in the laboratory. Eventually the stain cards are transferred to long-term storage. For disposal and disposition guidelines, see Forensic Biochemistry Manual, version 46,

(2) PM sexual assault evidence

Served assault evidence obtained after an autopsy is secured until processed. Following the guidelines in the Case Management Manual, all items are returned to the Evidence Unit. This will be reflected in the chain-of-custody.

VOUCHER	ITEM(5)	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		Evidence Unit	1/2/99

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(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 of disease diagnosis will be retained frozen. Bones for subsequent missing person identification will be retained.

b. Non-FB cases

 $(1) \quad Bloo$

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.

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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	l C	R. Burgos	2/4/99
Retained	Items	F. Baldi	P	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

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Evidence is occasionally transferred to another OCME department, such as a knife to a medical examiner, who wishes to examine it. The chain-ofcustody 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		Snelf 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 discarced.

f. Submittal to other agencies

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

VOUCHER	ITEM(A)	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.

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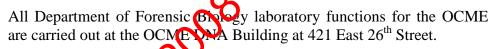
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If additional items, such as DNA extracts, are returned, a new chain-ofcustody form must reflect that.

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



The main entrance to the OCME DNA Building is on 26th Street, at the west end of the building. Retractable vehicular bollards remain in the up position to prevent vehicular access to this area. In the event that vehicle access is authorized the bollards may be controlled by officers in the command conter located on the 3rd floor or by a portable device that will allow the officer at the location outside to retract the bollards. As a safety meanere the bollards will never be operated without an officer on site to prevent pedestrians from sustaining injury while the bollards are in motion. The other entrance to the building is through a vehicular breezeway off of 26th street, accessing sub-level 1 (evidence intake) and sub-level 2 (parking garage). A guard booth is situated at the entrance to this breezeway. The guard within this booth controls a gate that allows vehicular access. This guard booth is also situated near the building dock as well. Guard presence at both locations is 24 hours/day, 7 days/week.

The OCME DNA Building is equipped with a high-tech security monitoring system. Cameras are situated throughout the inside of the building and also at key spots outside the building. Cameras are monitored by OCME Security in the security command center located on the 3^{rd} floor.

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Inside the main lobby is a security desk. Visitors to the building must sign a guest logbook at the security desk before being escorted throughout the building. Employees gain access to the staff elevators and other parts of the building through turnstiles equipped with ID card readers.

Once inside the building access to various floors and rooms is obtained via ID card readers. OCME Security has the ability to program ID cards so as to allow or deny individuals access to specific areas within the building (i.e. a member of the Human Resources Department does not have card access to a laboratory – they would only be allowed to enter with a Forensic Biology escort).

Building Security is present 24 hours day 7 days/week. During normal business hours the security desk in belobby will be manned by security personnel. After normal business hours security will be limited to a rover and OCME staff needing to energine lobby will either have to use a card reader or an intercom. After hours access for OCME staff will be dictated by department heads.

b. Laboratory Security

The Laboratory is accessible only by authorized personnel. This includes members of the Forensic Biology Department, student-interns, and other selected QCME employees, such as custodial staff. As mentioned above, access n obtained and controlled via ID card readers. Anyone who is not permitted access to the laboratories via their ID card must be escorted by a Forensic Biology employee.

c.

Security of Evidence and Records

All evidence brought into the OCME DNA Building is kept secure under the custody of the OCME Evidence Unit. The Evidence Unit has various evidence storage areas that are accessed via an ID card reader that only select members of the Evidence Unit have access to. Evidence Unit personnel are present 24 hours/day, 7 days/week.

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Evidence being processed by a Forensic Biology analyst may be left opened on a desktop during normal working hours, but must be returned to the Evidence Unit at the end of each day. A temporary seal is sufficient to protect the evidence from contamination or deleterious change until it is picked up for further examination. Evidence need not have a permanent seal until the work is completed.

Retained samples are kept in a secure location with the Evidence Unit, accessed only by members of the Evidence Unit.

Post-mortem blood stain cards and other exemplars are stored in two secure areas. Current items are kept in a locked cage within the laboratory that only members of the Forensic Barlooy Exemplar Team have access to. Older items are stored in a secore location with the Evidence Unit, accessed only by members of the Evidence Unit. Post-mortem items that must be kept frozen are stored in Greezers that are located on the 4th and 6th floors. These freezer rooms are accessed by ID card readers that only members of Forensic Bopg, have access to.

Current case files and records are located in filing cabinets and file storage rooms inside the Department of Forensic Biology. Archived case files and records are stored in the 4th floor OCME Records room and are accessed by Records Department staff.

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.

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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 (<u>Section O</u>). 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 environment 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

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.

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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 10) and the Assistant/Deputy Director. The Proficiency Evaluation sheet give, 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 texts 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 are competent only in selected areas of the analytical process – Chelex, M48, and Organic extractions, P30 ELISA, Rotorgene, 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), Cellmark Diagnostics (IQAS), and the College of American Pathologists (CAP).

The Quality Assurance Manager, and/or his/her designee shall manage the Proficiency Testing Program. A summary of al proficiency tests for the department must be submitted to the Technical Leader on an annual basis.

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2. Corrective Action – External Proficiency Testing Program

It is the responsibility of the Quality Assurance Manager (and/or his designee) to inform 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 york.

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 denciency 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 Leader must manage a feview of 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.

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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 Leader must manage a review of all casework performed during the relevant period. If necessary, selected samples must be repeated to verfe 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 ar 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 reinstructed in the appropriate procedures, which will be documented on the Proficiency Evaluation sheet.

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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

Science 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.

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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 Crimital 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 leatures 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.

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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 raidating 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.

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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 Procedure

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

4. Calibration/Maintenance Løgs

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

L. Safety

The OCME Department of Health and Safety is responsible for the overall health and safety of all members of the Office of Chief Medical Examiner, including the Department of Forensic Biology. The Forensic Biology Health and Safety Officer, who reports to the Director of OCME Health and Safety, is in charge of all health and safety issues related to the Department of Forensic Biology. Designated individuals within the Forensic Biology Department are assigned as liaisons to the Department of Health and Safety and may assist the Forensic Biology Health and Safety Officer in his/her duties.

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1. Manuals

The OCME Department of Health and Safety maintains a number of safety manuals for the department and the agency, including:

- **Exposure Control** a.
- **Exposure Determination** b.
- **Infection Control** c.
- d. **Hazard Communication Plan**
- **Hazard Contingency Plan** e.
- **Chemical Hygiene Plan** f.
- **Blood Borne Pathogens** g.
- **Respiratory Protection** h.

2. **Right to Know Training**

8 Manuale The OCME has a Right to Know raining program that is provided annually. Each OCME employee is required to attend. Documentation and a Right to Know manual are available from the OCME Safety Officer.

Material Safety Pata Sheets (MSDS) 3.

MSDS sheets are to in a separate binder for all reagents and chemicals used in the departmental aboratories. 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.

М. **Historical or Archival Records**

Records for all laboratory operations are maintained with the case file under the laboratory case number (FBXX-01234), 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.

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N. Quality Audit

An annual quality audit is required by New York State and by the FBI DNA 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 ensure that an audit of the quality system is done annually. All audit reports are sent to the Technical Leader and/or Director and are available for inspection by accrediting or NYS regulating bodies.

1. Guidelines

The quality audit is a primary tool used to avaluate, confirm or verify activities related to the quality of the work performed in the laboratory. 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 Technical Leader and/or Director, who will reply to the auditor's comments. The reply will discuss corrective action taken, and/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 imperative that all Forensic Biology managers, including the Technical Leader and the Quality Assurance Manager, are 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.

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It is also important that all potential or actual errors and deficiencies are 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.

1. Incident Report

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

2. Corrective Action Report

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

All forms may be found on the Foreisic Biology main network drive and should be 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.

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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 procems)
- 2. Contamination of evidence
- 3. Equipment or reagent failure
- 4. Errors in approved standard operating procedures
- 5. Failure to follow proper protocols by personne

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 Connical Leader and/or Quality Assurance Manager deem 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.

3. DOCUMENTATION

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- 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 Anorney'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 corresponding 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.

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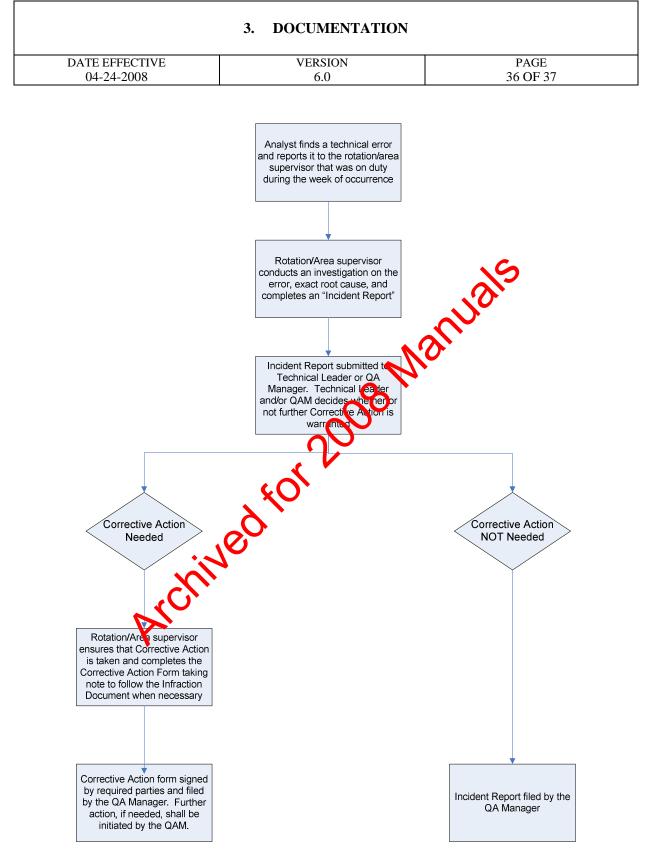


Figure 1: Flow chart depicting the initiation of Incident Reports and Corrective Action Reports.

Controlled versions of Department of Forensic Biology Manuals only exist electronically on the OCME intranet. All printed versions are non-controlled copies.

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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 DNA Quality Assurance Standards. •
- Obtain existing FBI DNA QAS audit or equivalent reports from the • subcontracting laboratory.

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4. MANAGEMENT INFORMATION SYSTEM (MIS)

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OCME A.

OCME's headquarters (520 First Avenue), the five county mortuaries, (The Bronx, Brooklyn, Queens, Staten Island, and Manhattan) and the OCME DNA Building (421 East 26th Street) are all linked by a computer network. The components of the system include:

- 1. Software programs for word processing & databasing, such SMicrosoft (MS) Word, MS Office Access, MS Office Excel and other components of MS Office, DataEase database, etc. Nani
- 2. Medical Examiners' Casework Database
- 3. Procurement database/ordering system
- 4. Intranet and Internet Systems
- E-mal system through MS Office Outlook 5.
- Departmental and individual official account 6.

B. **Departmental**

The Forensic Biology Laboratory directory is located on the OCME network under Network Drives: 'csc.nycnet\ocmt()CME_FileShare'' (M:). Employees have access to their own official directories under a different drive name.

Departmental functions nontained on the network include:

- 1. Case repor
- 2. Productivity statistics (created in MS Office Access)
- 3. Current updates of Departmental manuals (in MS Word and HTML format) and form
- 4. Management databases (logbooks) defined in MS Office Access
- Case linkage databases defined in MS Office Access and in CODIS (maintained 5. 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 M:\FBIOLOGY MAIN\REPORTS\ARCHIVE.

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



6.	TIME AND LEAVE POLICY	
6.	TIME AND LEAVE POLICY	

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The collectively bargained Citywide Agreement between the City of New York and District Council 37, AFSCME, AFL-CIO includes the time and leave policy for City employees. The current DOHMH Time and Leave Manual are available in the Departmental Training Room (OCME DNA Building, Suite 801).

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7. POLICIES AND PROCEDURES OF THE OCME

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Employees are bound by the policies and procedures of the Office of Chief Medical Examiner and of the Department of Forensic Biology. OCME policies and procedures can be found in the Office Policies and Procedures binder, for which employees sign a receipt at the time of orientation and which may be distributed at other times as well.

Procedures of the Department of Forensic Biology are available in the Departmental Training Room (OCME DNA Building, Suite 801).

Employees are responsible for knowing and complying with all applicable policies, procedures, rules and regulations.

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	8. COMPLAINTS	
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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. Sexual harassment and discrimination claims may be brought to OCME's EEO (Equal Employment Opportunity) officer.

B. Union Issues

Specific issues may fall within the purview of the employee. Union and/or collective bargaining. In such instances the employees' rights and options may be governed by Civil Service Law or the applicable Collective Bargaining Agreement.

9. REFERENCES

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- 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:
 - Administrative Manual •

 - Protocols for Forensic High Sensitivity Analysis
 Protocols for Forensic Mitochondrial DNA Analysis
 Protocols for Forensic STR Analysis
 Quality Assurance Manual
 Training Manual
- 4. FBI DNA Quality Assurance Audit Document, Issue Date July 1, 2004.
- American Society of Crime Laboratory Directors/Laboratory Accreditation Board, 2003 6. Archived Manual. April 2003.

APPENDIX A (ORGANIZATIONAL CHARTS)

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This Appendix contains a link to the current organizational chart of the Department of Forensic Biology. Organizational charts are displayed in Microsoft Excel.

Current Organizational Chart

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REVIEWED/APPROVED BY			
Title	Print Name	Signature	Date
Technical Leader, Nuclear DNA Operations	Eugene Y. Lien	Engrade	S eptember 23, 2008