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MISSION, VALUES, AND COMMITMENTS FOR THE DEPARTMENT OF FORENSIC BIOLOGY

Our Mission Statement:

- **D**NA testing – providing high quality results in a timely fashion
- **N**ew York City – helping make our community a safer place
- **A**dvancement – leading through innovation, research and education

Our Values:

- **Quality**
- **Objectivity**
- **Integrity**
- **Respect**

Our Commitments:

Service	We serve the needs of the people of New York City by providing results to the medical examiners and the criminal justice community.
Excellence	We always expect the best of ourselves and pursue the highest standards in our work.
Accuracy	We use validated scientific practices and are diligent in all aspects of our work.
Independence	We report results based on proven scientific principles, independent of undue influence.
Accountability	We honor our obligations and stand behind our work.
Professionalism	We foster an environment of trust and integrity, respecting our colleagues and those we serve.
Cooperation	We acknowledge our common goals to work in partnership with our professional community and other agencies.
Efficiency	We manage time and resources responsibly without sacrificing accuracy or quality.
Innovation	We develop and optimize methods to enhance the scope of our services.
Education	We encourage intellectual and professional growth through learning, innovation and exchange of knowledge.

1. INTRODUCTION

This document is the Management System Manual for the New York City Office of Chief Medical Examiner (OCME) Department of Forensic Biology. It is the top tier document in the management system and provides an overall guide to the management/quality system of the Department. It describes the Management System under which the Department of Forensic Biology conducts its testing activities, including the guiding principles related to quality, and with references to supporting documents. In terms of Standard 4.2.2 of ISO 17025:2005, this is our "quality manual."

2. SCOPE OF WORK

The OCME Department of Forensic Biology serves as the public forensic DNA laboratory for the City of New York – a geographical jurisdiction of approximately 8 million people throughout the five boroughs. Customers include, but are not limited to, the New York City Police Department (NYPD) ,the District Attorney's Offices (DAO) in each borough, the Mayor's Office, the New York City Council, the Citizens of New York.

The OCME Department of Forensic Biology performs DNA testing in criminal cases and has been doing so since 1991. Homicide, sexual assault and other crime evidence submitted to the laboratory is examined and subjected to body fluid identification as well as DNA extraction and typing. The results are compared to DNA profiles of named suspects, to profiles stored in a local DNA database (LDIS), and/or to forensic and convicted offender DNA profiles maintained in the FBI CODIS (**Co**mbined **D**NA **I**ndex **S**ystem) database. The Forensic Biology Missing Persons Group performs DNA testing and kinship analysis in identification cases, as well as DNA typing of unidentified remains, personal references and family comparison samples for the FBI CODIS Missing Persons Database; this database permits comparison of reference data across jurisdictions and thus provides closure to many families with missing relatives.

The Department of Forensic Biology investigates new methods to be used for the analysis of biological specimens so that its capabilities and service remain state-of-the-art. The Department is a CODIS local laboratory.

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

The Department of Forensic Biology also has work units that conduct testing in areas not specifically related to criminal casework: a WTC unit that conducts DNA testing on remains and exemplars related to the 2001 terrorist attacks on the World Trade Center in order to effect identifications of the recovered remains; a Quality Assurance unit, a Research/Development and Implementation unit, a Training unit and a CODIS unit.

The Department performs testing under the following circumstances for jurisdictions outside of New York City: (1) missing person and unidentified human remains cases from jurisdictions within New York State, pursuant to grant awards from the National Institute of Justice (NIJ) and (2) fee-for-service high sensitivity DNA testing for government units of other states or jurisdictions.

The scientific analyses covered by this management system include, but are not limited to, the following:

1. Biological fluid detection
2. DNA analysis
   a. Autosomal short tandem repeats (STRs)
   b. Y-chromosome STRs
   c. Mitochondrial DNA

3. DEFINITIONS

For the purposes of this document and conformance with accreditation requirements, the definitions given in the currently authorized versions of the following documents apply:

ASCLD/LAB-International "Supplemental requirements for the accreditation of forensic science testing laboratories"

Federal Bureau of Investigation, "Quality Assurance Standards for Forensic DNA Testing Laboratories"

4. MANAGEMENT REQUIREMENTS

4.1 ORGANIZATION

4.1.1 The Department of Forensic Biology is a publicly funded forensic testing laboratory within the Office of Chief Medical Examiner (OCME). The OCME is a part of the New York City Department of Health and Mental Hygiene (DOHMH). The forensic testing authority of the NYC OCME is established in Section 557 (f) of the New York City Charter.

4.1.2 The Department of Forensic Biology provides the users of its laboratory services access to scientific analyses conducted in criminal investigations. These analyses are conducted independently, objectively, reliably, and in accordance with a management system that conforms to the requirements of ISO 17025, the ASCLD/LAB-International accreditation program, the "Quality Assurance Standards for Forensic DNA Testing Laboratories" issued by the Federal Bureau of Investigation (FBI), and the accreditation program of the New York State Commission on Forensic Science.

4.1.3 All Department of Forensic Biology laboratory testing activities subject to ASCLD/LAB-International accreditation are conducted at the OCME DNA Building, 421 East 26th Street, New York, New York 10016.

4.1.4 The Department of Forensic Biology is one of several departments within the Office of Chief Medical Examiner. See the OCME Organizational Chart. The Director of Forensic Biology reports to the Chief of Laboratories; however, the Chief of Laboratories gives the Director of Forensic Biology authority and responsibility to conduct the operations of the Department such that all test results are free of bias and outside influence. Support services, such as Human Resources and Finance, are provided to the Department of Forensic Biology by other departments within the OCME, but these departments have no authority over the testing activities of Forensic Biology.

4.1.4.1 The Director of Forensic Biology has responsibility and authority for the overall scientific, quality, and administrative operations of the Department.

4.1.4.1.1 The Director of Forensic Biology has the responsibility and authority to direct the operations of the Department of Forensic Biology.

4.1.5 **(a)** The Department of Forensic Biology is a single operational unit having multiple responsibilities. The organizational chart of the Department of Forensic Biology describes the relationships of the managerial and technical personnel who are responsible for the implementation, maintenance, and improvement of the management system. The roles and responsibilities of the Director, Deputy Directors, Assistant Directors, Criminalists I-IV, Quality Manager, DNA Technical Leaders, City Research Scientists, Casework CODIS Administrator, Administrative Manager and Administrative staff are described in the STAFF ROLES AND RESPONSIBILITIES and DNA TECHNICAL LEADER documents in the Administrative Manual**.**

All personnel have the authority and responsibility to identify departures from the management system. See the procedures for CONTROL OF NONCONFORMING WORK and QUALITY INCIDENT REVIEW in the Quality Assurance/Quality Control Manual.

(b) All Department of Forensic Biology personnel are required to abide by the NYC DOHMH "Standards of Conduct for Departmental Employees." In addition to rules which prescribe conduct that could influence and adversely affect the quality of the work performed by the Department of Forensic Biology, the Standards include the "Conflict of Interest Law" that is set forth in Charter 68 of the New York City Charter.

The "ASCLD-LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists" also provides guidance with respect to conduct expected of Department personnel. Laboratory management ensures that the "ASCLD-LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists" is reviewed with all laboratory personnel on an annual basis. This review is coordinated by the Quality Assurance Manager. Records of this review are maintained by the Quality Assurance Team.

(c) All Department of Forensic Biology personnel are bound by OCME policies on confidentiality as found in the OCME Policy Manual. Specific requirements in support of these policies as they relate to the Department of Forensic Biology are found in the Administrative Manual and Quality Assurance/Quality Control Manual.

(d) The Department of Forensic Biology's Quality Assurance program is designed to provide a program through which all Department operations are transparent and may be scrutinized in order to provide assurances of a reliable testing result. See the "Conflict of Interest Law" that is set forth in the New York City Charter.

(e) The OCME Organizational Chart defines the location of the Department of Forensic Biology within the Office of Chief Medical Examiner. The Forensic Biology Organizational Chart defines the relationships between individuals and within operational units of the Department of Forensic Biology. Within this structure, the Technical Leaders and Quality Manager, in association with the Laboratory Director and Deputy Directors, define the Guiding Principles for Quality.

The Quality Assurance Team, under the direction of the Quality Manager, provides support to the quality and technical operations of the laboratory. The

Criminalists in the Department of Forensic Biology must adhere to the Management System guiding principles and procedures as they relate to their work and responsibilities.

(f&f.1) Information regarding the responsibilities, authorities and interrelationships of all personnel who manage, perform or verify work affecting the quality of tests is found in the Department of Forensic Biology organizational chart, the STAFF ROLES AND RESPONSIBILITIES and DNA TECHNICAL LEADER documents in the Administrative Manual**,** and "Tasks and Standards" documents.

(g) It is a guiding principle of the Department of Forensic Biology to provide adequate supervision of testing staff at all times. The supervision provided to trainees is described in the Forensic Biology Training Manual. The various case examination and testing rotations are staffed with supervisors who provide technical assistance and review test results.

(h) The Department has two DNA Technical Leaders, one responsible for nuclear DNA technical operations (which includes autosomal STR testing and Y-STR testing) and one responsible for mitochondrial DNA technical operations, and a Serology technical Leader. The DNA Technical Leaders meet the qualifications and responsibilities defined by the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories

(i) The Quality Manager is responsible for the overall implementation and maintenance of those aspects of the Department of Forensic Biology management system related to quality. The Quality Manager's responsibilities are varied and reflect the requirements of ISO 17025, the ASCLD/LAB-International accreditation program, and the Quality Assurance Standards for Forensic DNA Testing Laboratories. The duties, responsibilities, and authorities of the Quality Manager are described in various documents within the Administrative, Quality Assurance/Quality Control, and Evidence and Case Management manuals.

The position of the Quality Manager in the organization is found in the Forensic Biology organizational chart. The Quality Manager reports to the Director.

(j) Deputies are appointed for extended absences of a key manager or whenever it is necessary to ensure that the critical functions of a position continue during the manager's absence. E-mail is one medium that may be used to notify Forensic Biology staff regarding the appointment of deputies.

The Department's contingency plan for a vacancy in the DNA Technical Leader position is found in the DNA TECHNICAL LEADER document in the Administrative Manual.

(k) The Department utilizes its training program to provide its personnel with an initial orientation on the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system. On-going communications within the laboratory reinforce the concepts introduced during training.

4.1.6 Communication takes place at many levels within the Department. Regularly scheduled meetings are held for managers; for supervisors and managers; and within work groups. Bi-monthly, all-staff meetings are conducted to inform staff of workload metrics and other issues of importance including those related to quality assurance and the effectiveness of the management system. Electronic communications are utilized within the Department on a daily basis.

4.1.7 The Department of Forensic Biology follows a safety program developed and administered by the OCME Department of Health and Safety. The Forensic Biology Safety Coordinator has the responsibility and authority to work with an OCME Health and Safety Officer to ensure that the health and safety program is implemented and followed within the Department of Forensic Biology.

4.1.8 "Top management" in the Department of Forensic Biology consists of those individuals with the highest levels of administrative and operational authority: Director and Assistant Directors. "Key management" consists of individuals who, irrespective of administrative authority, perform job functions that are critical to the administrative and/or technical operations of the Department: Director, Assistant Directors, Quality Manager, DNA Technical Leaders, Casework CODIS Administrator, and LIMS Administrator(s).

4.2 MANAGEMENT SYSTEM

4.2.1 The Department of Forensic Biology documents, implements and maintains a management system appropriate to the scope of its activities and in conformance with ISO 17025 and other accreditation requirements.

4.2.2 Statement of Quality Principles. The Department of Forensic Biology supports the Criminal Justice system of the City of New York by providing high quality Forensic Biology testing in a timely fashion. The management of the Department of Forensic Biology is committed to conducting its operations in accordance with a management system that meets the requirements of ISO 17025 and all supplemental accreditation requirements, and to strive for continual improvement of this system.

All staff is required to be familiar with the management system documentation and to implement its principals and procedures in their work. This ensures that testing is conducted independently, objectively, and reliably, according to best professional practice, and that the test results meet New York State and Federal standards. The Department of Forensic Biology also seeks new methods to analyze biological specimens so that its capabilities and service remain state-of-the-art.

Quality Objectives

- All scientific testing performed in the Department is monitored on a routine basis by means of Quality Control standards, proficiency tests, and audits.
- All scientific analyses and equipment operate within established performance criteria and the quality and validity of the analytical data is maintained.
- Performance criteria are followed.
- The quality of critical reagents is verified prior to their use in casework.
- The Department uses equipment and instruments with a performance standard appropriate to the requirements of the tests for which they are used.
- Qualifications of the laboratory staff meet City of New York requirements and the educational requirements imposed by regulating bodies such as the New York State Commission on Forensic Science, the National DNA Index System (NDIS) Program, the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories, and ASCLD/LAB.
- The scientific staff performing casework meets all proficiency testing and continuing education program requirements.
- Technical problems are noted and appropriate correction is taken and documented.
- The preventive action program is used to identify opportunities for improvement.

4.2.3 The management of the Department provides evidence of its commitment to the development and implementation of the management system and its continual improvement through a variety of mechanisms such as: 1) the Statement of Quality Principals and Quality Objectives, 2) the provision of time and money for training and continuing education of staff, including attendance at scientific meetings; 3) the provision of financial and human resources for validation and research; and 4) increasing the knowledge of staff with respect to quality standards and accreditation by allowing staff to participate in quality-related activities in the greater forensic community, e.g., as members of accreditation assessment teams or as members of scientific working groups.

4.2.4 The management of the Department is committed to providing excellent customer service. It is also critically important that the Department meet all accreditation and statutory requirements. These goals are met through the guiding principles described in the Department's management system documents and in other ways: 1) maintenance of good customer communication with the NYPD, District Attorney's Offices, and the Criminal Justice Coordinator (CJC) via regular meetings, the results of which may be communicated to staff; 2) attendance at meetings of the NYS Commission on Forensic Science, its DNA Sub-committee, and its Technical Working Groups (TWGs) including the New York Crime Laboratory Advisory Committee (NYCLAC); and 3) responsiveness to communications from ASCLD/LAB.

4.2.5 The Management System Manual is an overall guide to the management/quality system of the Department of Forensic Biology. It contains the Department's guiding principles related to quality and makes reference to supporting management and technical procedures.

The management system documentation has three levels; levels I and II comprise "controlled documents". Many of the manuals listed as "supporting documents" consist of collections of individual procedures or forms.

I. Management System Manual (top level document)
II. Supporting Documents

- Serology Manual
- STR Analysis Manual
- Mitochondrial DNA Manual
- CODIS Manual
- Administrative Manual
- Quality Assurance/Quality Control Manual
- Evidence and Case Management Manual
- Forms Manual
- Training Manual
- LIMS User Manuals
- External Documents

III. Records (Technical and Quality)

4.2.6 The Department has three Technical Leaders, one for nuclear DNA technical operations, one for mitochondrial DNA technical operations, and one for serology technical operations. In general, the Technical Leaders oversee the technical operations and have the authority to initiate, suspend, and resume analysis. The qualifications and responsibilities of the two DNA Technical Leaders are in conformance with the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories. DNA Technical Leaders evaluate and approve validations and technical procedures and propose new or modified analytical procedures; review academic transcripts and training records for newly qualified analysts; approve the qualifications of analysts prior to allowing them to conduct independent casework; approve the technical specifications for outsourcing agreements; review internal and external DNA audits and approve follow-up actions when necessary; conduct an annual review of the management system manual and technical procedures used by the Department as part of Management Review; and review and approve the forensic DNA training, quality assurance, and proficiency testing programs in the Department.

The Quality Manager is responsible for the overall implementation and maintenance of the management system related to quality. The responsibilities include monitoring laboratory practices to verify continuing compliance with Departmental guiding principles and procedures; evaluating and maintaining instrument calibration and maintenance records; coordinating the document control process; investigating technical problems in association with the DNA Technical Leader(s) and implementing remedial action as needed; administering proficiency testing and evaluating results; conducting or coordinating internal

quality audits; proposing corrections and improvements in the quality system; recommending training to improve the quality of laboratory staff; and assisting in the preparation of a Management Review report for consideration by, and discussion with, the laboratory managers.

Additional details are found in the STAFF ROLES AND RESPONSIBILITIES document in the Administrative Manual.

4.2.7 The processes for documenting changes to the management system are described in the DOCUMENT CONTROL procedure in the Administrative Manual. The requirements for review and approval ensure that all proposed changes are considered thoroughly with respect to their effect on Department operations and conformance with accreditation requirements.

4.3 DOCUMENT CONTROL

The Department of Forensic Biology controls the documents that comprise its management system. This ensures that staff conducts their work in accordance with the most current authorized guiding principles and procedures. See the DOCUMENT CONTROL procedure in the Administrative Manual.

4.4 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

A **request** occurs when evidence is submitted to the Department for testing; a **tender** is the Department's response to that request; and a **contract** is a written or oral agreement between the Department and the requesting agency to provide testing services.

All requests are reviewed to determine whether the Department performs the testing requested, and whether the testing can provide a reasonable attempt to answer the questions at issue.

The Department's acceptance of evidence for NYC cases establishes a contract with the submitting agency for the particular case.

Formal written agreements are required when testing is requested from outside jurisdictions. The templates for the written agreements are legal documents provided to the Department and are classified as "Externally Controlled Documents."

- A separate "High Sensitivity DNA Testing for Outside Jurisdictions" agreement must be completed for each individual case submitted for testing.

- A "Forensic Anthropological and/or DNA Testing for Outside Jurisdictions" agreement is completed on a per agency basis, and is applicable to each case the agency submits subsequent to the completion of the agreement.

By submitting evidence to the Department of Forensic Biology, our customers agree to allow the Department to select the appropriate methods to be used in its analysis.

4.4.1 The EVIDENCE SIGN-IN procedure in the Evidence and Case Management Manual includes the processes for the review of requests for analysis, documentation of such reviews, and acceptance for testing.

4.4.2 The Department maintains records of reviews of requests for analysis in various locations, including deferrals and records of case communications.

4.4.3 While the Department of Forensic Biology does not routinely subcontract work to outside laboratories, the possibility exists that this might become necessary. Should that occur, the reviews will cover the subcontracted work.

4.4.4 In most cases – except for those submitted by outside jurisdictions for high sensitivity DNA testing – differences between the analyses requested and the analyses performed by the Department are permitted as long as customers are informed of those differences via the written analysis report or through e-mail or telephonic notification. Telephone calls and e-mails are documented in the case communication log.

If a deviation from a written agreement for "High Sensitivity DNA Testing for Outside Jurisdictions" is necessary, a new written agreement must be prepared.

4.4.5 If the testing agreement with a customer needs to be amended, the proposed amendment is reviewed in the same manner as the original agreement. Customers are notified as described in 4.4.4 above. Affected Department personnel are notified verbally or in writing.

4.5 SUBCONTRACTING

The Department of Forensic Biology does not routinely subcontract (outsource) work, but reserves the right to do so. When testing that is within the scope of the Department's accreditation is subcontracted by the Department to an outside laboratory, the Department ensures that the work is placed with a competent subcontractor. The Department also ensures that subcontracting requirements of the FBI's "Quality Assurance Standards for DNA Testing Laboratories" are met when it uses vendor laboratories for forensic DNA testing.

See the SUBCONTRACTING procedure in the Evidence and Case Management Manual.

4.6 PURCHASING SERVICES AND SUPPLIES

The quality of the tests conducted by the Department of Forensic Biology depends upon various services and supplies that meet prescribed specifications. The procurement processes that allow the Department to obtain the appropriate services and supplies are found in the PURCHASING SERVICES AND SUPPLIES procedure in Administrative Manual.

4.7 SERVICE TO THE CUSTOMER

The staff of the Department of Forensic Biology consider customer requests for information related to testing on submitted evidence and cooperate with such requests whenever feasible and reasonable.

4.7.1 The decisions regarding the analyses that are to be performed is made by the Department after evaluation of the evidence submitted and/or available, and through review of the information supplied by the submitting agency (e.g., NYPD vouchers, requests for laboratory examinations, and NYPD reports), discussions with the NYPD DNA Liaison Unit, discussions with the outside jurisdiction's representative(s), and/or discussions with assistant district attorneys (ADAs). The scheduled analysis can change if prioritized items are negative and additional evidence must be examined, or if additional evidence is accepted by the Department. Records of oral discussions with customers are maintained in the communication logs.

Requests by customers for visits to the Department offices to discuss evidence, case analyses, and/or court testimony preparation are handled on a case-by-case basis. Visits to the laboratories are minimized in order to lessen work disruptions; however, entry is allowed if all required practices for gowning and provision of a DNA sample (as described in the SECURITY procedure in the Administrative Manual) are followed.

Requests by defense attorneys and/or experts to observe testing must be submitted in writing. See details in the ATTORNEY REQUESTS procedure in the Administrative Manual.

The Department holds regular meetings with the NYPD DNA Liaison Unit to discuss Liaison Unit requests and to clarify issues regarding submission of evidence for biological testing.

4.7.2 The Department utilizes several mechanisms to obtain feedback from its customers. These include, but are not limited to: (1) Regular meetings with representatives of the NYPD DNA Liaison Unit to discuss operational issues; (2) Attendance at task force meetings conducted by New York City Criminal Justice Coordinator or the New York District Attorney's offices; and (3) a customer satisfaction survey.

4.8 COMPLAINTS

The Department of Forensic Biology is committed to high standards of quality in testing and customer service. Complaints about the performance of the Department of Forensic Biology that are received from customers or other parties, or from laboratory employees regarding the quality related aspects of the Forensic Biology management system, indicate possible problems with the Department's management system and are treated seriously.

The processes for addressing complaints are found in the COMPLAINTS procedure in the Administrative Manual.

4.9 CONTROL OF NONCONFORMING TESTING

It is critical that all technical discrepancies that may compromise evidence integrity or the accuracy of casework analysis are dealt with upon discovery or at the earliest opportunity so that the non-conforming testing work can be appropriately evaluated and corrected. In some situations the evaluation may indicate that a formal quality incident review is necessary.

The identification of nonconforming work or testing activities can occur during a variety of activities: data or case file reviews, instrument calibration checks, reagent performance checks, and audits, to name a few.

See the CONTROL OF NONCONFORMING WORK procedure in the Quality Assurance/Quality Control Manual.

4.10 IMPROVEMENT

The management and staff of the Department of Forensic Biology recognize that quality assurance is an ongoing process, and that any management system, no matter how effective, can always be improved. The Statement of Quality Principles, internal and external audits, quality incident reviews, Non-Conforming Work Root Cause Analyses, preventive action reviews, management review, and analysis of miscellaneous operational data allow the

Department to identify opportunities for improving the effectiveness of the management system.

4.11 QUALITY INCIDENT REVIEWS

Quality incident review is a reactive process to deal with complaints or problems. The Department of Forensic Biology implements its quality incident review process when deviations to the management system have occurred.

Problems with the management system or the technical operations may be identified through a variety of activities, such as case file reviews, audits, management reviews, feedback from customers, and staff observations.

See the QUALITY INCIDENT REVIEW procedure in the Quality Assurance/Quality Control Manual.

Where Non-conforming work has been identified resulting in a failure to comply with the guiding principles and procedures of the laboratory—whether administrative or technical—The laboratory's Control of Non-Conforming Work procedure is followed A timely and thorough Root Cause Analysis is necessary in order to ensure that a problem is effectively corrected and to minimize the likelihood that the problem will recur.

See the Control of Non-Conforming Work procedure in the Quality Assurance/Quality Control Manual.

4.12 PREVENTIVE ACTION

Preventive action is a pro-active process to identify opportunities for improvement and to prevent problems before they occur rather than a reaction to the identification of problems or complaints. Department of Forensic Biology staff are expected to recognize areas in the management system that could be improved or that present potential sources of non-conformities and to follow the PREVENTIVE ACTION procedure in the Quality Assurance/Quality Control Manual to bring those issues to management's attention.

4.13 CONTROL OF RECORDS

Records provide documentation that activities required by the management system guiding principles and procedures have been performed. Records that must be maintained include technical records related to the testing of submitted evidence and quality records such as audit reports and quality incident review reports.

The Department's overall processes with respect to the identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records are found in the CONTROL OF RECORDS procedure in the Administrative Manual. Individual management or technical procedures may also contain requirements specific to the records that are created during a procedure.

4.14 INTERNAL AUDITS

Internal audits are a critical component of the Department of Forensic Biology's management system. The internal audit program of the Department is designed to verify that its management system is functioning correctly and in compliance with its own procedures and with ISO 17025, ASCLD/LAB-International policies and supplemental requirements, the Quality Assurance Standards for Forensic DNA Testing Laboratories, and New York State accreditation requirements.

See the AUDITS AND ASSESSMENTS procedure in the Quality Assurance/Quality Control Manual.

The laboratory will submit an Annual Report to ASCLD/LAB within thirty (30) calendar days following the laboratory's accreditation anniversary date. The Annual Report is prepared by the Quality Assurance Manager and addresses all points covered in Appendix A of the ASCLD/LAB-*International* Program Overview.

4.15 MANAGEMENT REVIEWS

Management review is a tool used by the management of the Department on an annual basis to (1) ensure the continuing suitability and effectiveness of the management system and its testing activities and (2) identify and introduce necessary changes and improvements. Whereas internal audits are used to demonstrate that the laboratory is "doing things right," management review is a mechanism to ensure that the laboratory is "doing the right things.".

Management reviews take account of many types of information, including, but not limited to: the suitability of guiding principles and procedures; reports from managerial and supervisory personnel; internal audit reports; corrective and preventive actions; external audit and assessment reports; the results of proficiency tests and case reanalysis; changes in the volume and type of work; customer feedback; complaints; recommendations for improvement; the laboratory's quality objectives; and miscellaneous factors if relevant, such as quality control activities, resources, and staff training.

See the MANAGEMENT SYSTEM REVIEW procedure in the Administrative Manual.

5. TECHNICAL REQUIREMENTS

5.1 GENERAL

5.1.1 The Department recognizes that many factors contribute to the accuracy and reliability of the tests conducted on submitted evidence, including human factors e.g., personnel education, training, and skills; laboratory facilities and their associated environmental conditions; test and calibration methods; method validations; equipment; measurement traceability; sample selection; and the handling of evidence.

5.1.2 The extent to which the factors listed in section 5.1.1 contribute to variations in test results can vary considerably between types of tests. Although the types of tests conducted by the Department do not require a rigorous evaluation of uncertainty of measurement, it is nevertheless important for staff to understand the limits and inherent variability of the tests being conducted so that the forensic significance of the test results is not overstated.

5.1.3 Reliable testing depends upon reagents that work as expected. A significant portion of the Department's quality assurance program is dedicated to reagent preparation, labeling, and performance verification. See the REAGENTS procedure in the Quality Assurance/Quality Control Manual.

5.2 PERSONNEL

5.2.1 The quality of testing conducted by the Department of Forensic Biology can only be assured if the staff that conducts the testing has the requisite education, training, and experience. This includes both theoretical knowledge and practical skills. The training program in Forensic Biology methods is designed to establish consistency of performance between individual analysts and maintain the highest possible level of performance over time. The TRAINING MANUAL describes in detail the Department's guiding principles and procedures with respect to analyst training.

5.2.1.1 The training program is documented in the TRAINING MANUAL. The program includes procedures for retraining and maintenance of skills and expertise.

5.2.1.2 The Forensic Biology training program has a courtroom testimony training component.

5.2.1.3 The Forensic Biology training program contains training in ethical practices in forensic science, general knowledge of forensic science and applicable criminal and civil law procedures.

5.2.2 The overall goal of the training program is to prepare analysts to reliably and accurately perform the functions required by their specific positions. It is a guiding principle and goal of the Department of Forensic Biology that the qualifications of the Department staff meet or exceed City of New York requirements and the educational requirements imposed by the New York State Commission on Forensic Science, the NDIS Program, the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories, and ASCLD/LAB. The scientific staff performing casework must meet all proficiency testing program and continuing education standards as an integral part of the overall Quality Assurance program.

Analyst training is divided into modules. The number of modules taken depends on the job title and prior forensic experience of the trainee; fewer or additional modules may be given depending on the particular job assignment of the trainee. Members of specific teams may be trained in techniques used only by that team or by experienced members of that specialty team. Training follows the standard model of observation, practice, and competency. Training samples may be provided by the Training team or a specialty team.

The training needs of the Department depend upon many factors including statutory and regulatory requirements, the number and type of case submissions, the available testing technologies, and the intended work assignments of staff and their existing levels of expertise. Because changes in any of these factors can change the Department's training needs, the Serology and DNA training programs are monitored by upper management, supervisors, and the DNA and Serology technical leaders. A section in the Training Manual on "supplemental training" addresses how staff is trained in new procedures.

The effectiveness of training is evaluated at various stages. This is described in the TRAINING MANUAL. By having a multiphase training program with various levels of review and demonstration of competency, it is anticipated that an analyst's weak points will be noticeable and can be addressed. After training has been officially completed, ongoing supervisory observations, case file review, and proficiency testing programs serve to monitor whether the training programs have effectively prepared staff to perform their assigned job tasks.

5.2.3 Casework in the Department is generally conducted by Department employees; however, the Department reserves the right to use contract personnel as necessary.

5.2.4 The Department maintains general City position descriptions for all job classifications, e.g. Criminalist series. Tasks and Standards plans are prepared annually for each laboratory employee, and contain position responsibilities and performance expectations.

5.2.5 The TRAINING MANUAL describes (1) how authorizations to perform testing and/or function in a particular position are documented and (2) the maintenance of training records.

5.2.6 All technical personnel are required to meet the education and competency test requirements of ASCLD/LAB.

5.2.6.1 All analysts have a baccalaureate or advanced degree in a natural science, criminalistics, or a closely related field. Further, all DNA analysts, DNA technical leaders, and the casework CODIS administrator meet or exceed the minimum coursework requirements of the FBI's "Quality Assurance Standards for Forensic DNA Testing Laboratories." Educational requirements are included in the City job descriptions.

Demonstration of competency is an integral part of the Department's training programs. See the TRAINING MANUAL.

5.2.6.1.1 At the conclusion of training in any particular analytical procedure, an analyst trainee must successfully complete a competency test using that procedure in order to use that procedure in casework. In general, a competency test is prepared in-house with the key to the results being supplied to the supervisor, Assistant Directors, relevant technical leader(s), and/or Director.

5.2.6.1.2 Crime Scene processing is not a function assigned to the Department of Forensic Biology. However, Forensic Biology staff may occasionally assist the NYPD to provide specialized crime scene reconstruction expertise.

5.2.6.1.3 Technical support personnel complete competency testing for each procedure for which they have been trained.

5.2.6.1.4 Demonstration of competency prior to independent casework is required for technical support personnel and analysts that conduct Serology and DNA testing.

5.2.7 Each member of the scientific staff has access to literature references and reference books maintained by the Department. Methods manuals used in the laboratory contain bibliographies listing references in the scientific literature. Publications pertaining to in-house methods are given to each trainee in the form of an online Reference Binder. Additionally, OCME professional staff has internet access and may have library privileges at the New York University School of Medicine.

The Training Group electronically distributes a discipline-relevant article to all staff on a regular basis. The literature review program is described in the TRAINING MANUAL.

5.3 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

5.3.1 All technical procedures used by the Department of Forensic Biology specify any environmental conditions that may be important for the correct performance of the tests.

5.3.2 The Department of Forensic Biology monitors the temperatures of all freezers, refrigerators, heat blocks and incubators that are used for storage of evidence and casework samples. Monitoring is conducted on a daily basis when the laboratory is open. Room temperature readings are also recorded in each laboratory. Contamination is monitored with a variety of control samples used in testing.

5.3.3 To minimize the potential for carry-over contamination, the laboratory is organized so that the areas for DNA extraction, PCR set-up, and amplified DNA processing are physically isolated from each other. In addition, measures such as required use of protective clothing when in laboratories have been implemented in order to minimize the potential for contamination events. See the EXOGENOUS DNA PREVENTION procedure in the Quality Assurance/Quality Control Manual and the GENERAL GUIDELINES FOR DNA CASEWORK in the STR Procedures Manual.

5.3.4 The Department of Forensic Biology is a controlled-access environment.

5.3.4.1 The SECURITY procedure in the Administrative Manual describes measures used by the Department to maintain building and laboratory security.

(a) Entrance to Department work spaces is available only to personnel authorized by the Director to have access. Personnel with various levels of access include members of the Department of Forensic Biology,

student-interns, and other selected OCME employees, such as custodial staff. Visitors must be escorted by a Forensic Biology employee.

(b) Entrance to the OCME DNA Building is controlled by a combination of security personnel and an electronic lock system. Cameras are situated throughout the inside of the building and at key spots outside the building. Cameras are monitored by OCME Security in the security command center located on the 3rd floor.

(c) An electronic lock system controls access to all Department office and laboratory areas. Individual offices are accessible via keys.

(d) Access to various floors and rooms within the building is obtained via ID card readers. The OCME Security Department programs ID cards so as to allow or deny individuals access to specific Department of Forensic Biology office and laboratory areas within the building, as specified by the Director of Forensic Biology.

(e) The building is staffed by security officers 24 hours/day, 7 days/week.

(f) The majority of evidence brought into the OCME DNA Building is kept in the custody of the OCME Evidence Unit before and after examination by Department criminalists. The Evidence Unit is not part of the Forensic Biology forensic operations and the Evidence Unit storage areas are accessible only to select members of the Evidence Unit via ID card readers.

Post-mortem items that must be kept frozen are stored in freezers located on the 4th and 6th floors. These freezer rooms are accessible only to members of the Department of Forensic Biology.

5.3.5 OCME Facilities personnel perform routine cleaning of the Department's laboratory and office areas on a daily basis. Documented specialized cleaning of laboratory areas is conducted monthly by Department of Forensic Biology staff. See the LAB CLEAN-UP SHEET form.

5.3.6 The Health & Safety program is described in the Administrative Manual**.**

Manuals. The OCME Department of Health and Safety maintains Health and Safety program manuals for the Department and the agency. These manuals are available to all Department staff on the Department server.

a. OCME Chemical Hygiene Plan
b. OCME Bloodborne Pathogen Exposure Control Plan
c. OCME Respiratory Protection Plan

Right to Know Training. OCME Right-to-Know training is provided annually. Each Department of Forensic Biology technical employee is required to attend. Attendance records and a Right-to-Know manual are available from the OCME Safety Officer.

Material Safety Data Sheets (MSDS). MSDS sheets for reagents and chemicals used in the departmental laboratories are kept as electronic copies in the Forensic Biology main drive. The sheets are updated as required.

5.4 TEST METHODS AND VALIDATION

5.4.1 The Department of Forensic Biology uses methods appropriate to the purposes for which testing is conducted. The DOCUMENT CONTROL procedure describes how procedures are created, revised to maintain currency, and made available to staff. DNA technical procedures are checked at least annually against an appropriate and available National Institute of Standards and Technology (NIST) standard reference material or standard traceable to a NIST standard.

5.4.1.1 All internally-generated technical procedures are maintained in electronic form on the Department server and are available to all staff. Controlled procedures and/or instructions of external origin are available to staff at the locations indicated on the external documents master list.

5.4.1.2 Technical procedures specify the controls and standards that must be used during testing. The use of controlled forms ensures that the identities of the controls and standards used in a specific test are maintained in the case record.

5.4.2 Test methods used in the Department are validated to ensure that they are appropriate for the intended purpose. By submitting evidence to the Department of Forensic Biology, our customer(s) agree to allow the Laboratory to select the methods to be used in the analyses. At a minimum, information regarding the methods of analysis is provided in test reports; however, at the discretion of the Director, other communication mechanisms such as website postings may be developed to provide this information.

5.4.2.1 All DNA test procedures used in the Department are validated to an extent that meets or exceeds the validation requirements of the FBI Quality

Assurance Standards for Forensic DNA Testing Laboratories. Serology test procedures are validated to the extent necessary to ensure that test results are reliable. Validation records are maintained indefinitely.

5.4.3 The decision to develop and/or validate new or revised test procedures is made by Department management based upon a variety of factors. These include, but are not limited to, the availability of new commercial products for DNA testing; the need for operational efficiencies; changes in analytical equipment or software; and casework analysis issues that require new or revised approaches to testing.

See the VALIDATION procedure in the Quality Assurance/Quality Control Manual.

5.4.4 The test procedures used by the Department are not Standard Methods as defined by ISO (i.e., a procedure published by ASTM or a similar body that is recognized as authoritative on a national or international level). Therefore, all test methods used must be validated internally.

5.4.5 The VALIDATION procedure in the Quality Assurance/Quality Control Manual describes the Department's approach to validation of analytical procedures.

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the requirements for a specific intended use are fulfilled.

5.4.5.2 Analytical procedures used in the Department are validated to ensure that they are appropriate for the intended purpose and meet the requirements of the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.

5.4.5.3 Validation projects are designed to provide information with respect to the characteristics of the testing, including precision and inherent limitations. The conclusions and results generated by tests conducted within the Department of Forensic Biology have associated ranges which constitute "positive" results. This accounts for any uncertainty inherent in the testing process.

5.4.6 The Department of Forensic Biology is not a calibration laboratory, nor does it perform its own calibrations. The test results reported by the Department of Forensic Biology are identifications and comparisons that are qualitative in nature, and per ASCLD/LAB policy, the Department is not required to have a procedure for estimating the uncertainty of measurement for qualitative results. Furthermore, the population statistics found in DNA reports are calculations, not

quantitative measurements subject to the uncertainty of measurement requirements of ISO 17025. Nevertheless, analysts should be familiar with the level of precision in their test procedures so that they do not overstate the significance of their findings in their test reports.

5.4.7 See the CONTROL OF DATA procedure in the Quality Assurance/Quality Control Manual for a discussion of measures that the Department follows to ensure that (1) manual calculations and data transfers generated during testing are suitably checked; (2) Department-developed database programs and/or modifications to commercial software—such as calculations programmed into the test methods in the LIMS—are subjected to performance checks prior to use; (3) electronic data is protected; and (4) computers and automated equipment are maintained and are used in environmental conditions suitable for correct operation.

5.5 EQUIPMENT

The Department of Forensic Biology uses equipment which is suitable for the tests conducted by the Department for casework. The Department does not use equipment that is outside of its permanent control.

Equipment performance specifications relevant to the tests conducted by the Department are established during validation and are described in the test procedures. Effective programs for conducting performance checks, calibrations and maintenance of equipment are essential for establishing confidence that the required performance specifications are attained and that the equipment can produce reliable test results. Analyst training programs and competency tests ensure that equipment is operated by properly trained staff.

See the EQUIPMENT CALIBRATION AND MAINTENANCE procedure and individual calibration, performance check, and maintenance procedures in the Quality Assurance/Quality Control Manual for detailed information on equipment maintenance, calibration, and performance check programs; and equipment identification, labeling, and records.

5.6 MEASUREMENT TRACEABILITY

Traceability supports the validity and accuracy of test measurement results. Traceability is established by means of a documented unbroken chain of calibrations or comparisons linked to the relevant primary standards. The chain of comparisons must, when possible, extend to a national or international standard.

5.6.1 **Calibration** is defined as the set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring

instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards. The EQUIPMENT CALIBRATION AND MAINTENANCE procedure identifies the "critical equipment" that the Department believes to have a significant effect on the accuracy or validity of test results and for which calibration programs have been established.

5.6.1.1 The specific requirements of the analytical work are considered when designing calibration and performance check programs for equipment. Manufacturer's recommendations, where applicable, are also considered.

5.6.2 The Department of Forensic Biology is not a calibration laboratory, nor does it, as a testing laboratory, perform its own calibrations on measuring and test equipment such as balances and pipettes. Where necessary, the Department ensures traceability of measure by using external calibration services that are accredited to ISO 17025 and that provide certificates that show that the measurements are traceable to a national or international reference standard. Details on traceability requirements for specific equipment are found in the individual calibration and maintenance programs/procedures in the Quality Assurance/Quality Control Manual.

5.6.3 Procedures for the calibration of standard weights used by the Department for intermediate performance checks of balances; documentation and traceability of reference materials and reference collections; and transport and storage of reference standards and reference materials are found in the Quality Assurance/Quality Control Manual. A procedure might be included within another procedure, for example, the program and procedure for the calibration of the Department's standard weights is included in QC 120 (Balances: Verification and Maintenance). Alternatively, a stand-alone procedure may exist, for example, the CONTROL OF REFERENCE COLLECTIONS procedure in the Quality Assurance/Quality Control Manual.

5.7 SAMPLING

During the examination of evidence by the Department of Forensic Biology, analysts use their training, experience and competence to select appropriate samples to carry through testing. The conclusions reported apply only to the samples tested and do not apply to the portions not tested. Because this is "sample selection" and not "sampling," the Department does not have documented "sampling plans" or "sampling procedures."

The EVIDENCE EXAMINATION procedure in the Evidence and Case Management Manual contains guidance with respect to selecting appropriate samples for testing.

5.8 HANDLING OF TEST ITEMS

Ensuring the integrity of evidentiary items is a critical part of the work conducted by the Department of Forensic Biology. Storing evidence under conditions that could harm the evidence might affect the Department's ability to obtain informative test results. Failing to clearly identify and track items through proper marking and chain of custody could cast doubt on test results and might prevent such results from being accepted in court.

The EVIDENCE CONTROL procedure in the Evidence and Case Management Manual describes how the Department transports, receives, handles, protects, stores, retains and/or disposes of evidence. This includes the laboratory's specimen identification system, its definition of evidence vs. work product, and its guiding principles on sample consumption.

The Department maintains individual characteristic DNA databases on Suspect samples and "Lab Types" samples. See the Forensic Biology CODIS Manual for specific information on the operation of the suspect database; suspect samples are evidentiary samples and are handled as such. The "Lab Types" database is used as a mechanism to detect inadvertent contamination of evidentiary samples. See the LAB TYPES DATABASE procedure in the Quality Assurance/Quality Control Manual.

5.9 ASSURING THE QUALITY OF TEST RESULTS

5.9.1 The Department of Forensic Biology's Quality Assurance program is designed to provide transparency to all Department operations so they may be scrutinized in order to provide assurance of reliable laboratory test results. The measures used in the program are varied and include, but are not limited to:

- external proficiency testing
- reanalysis of selected evidence
- a system of technical and administrative review of case data and reports
- use of positive and negative controls
- performance checks of DNA typing procedures using a reference material traceable to National Institute of Standards and Technology (NIST) standard reference material(s)
- monitoring and evaluation of court testimony

The Quality Assurance Team and DNA Technical Leaders monitor the results of external proficiency testing, evidence reanalysis, results of testing with NIST-traceable materials, and court testimony. Problems in any area are dealt with via

the CONTROL OF NON-CONFORMING WORK and/or the QUALITY INCIDENT REVIEW procedures.

5.9.2 Test data, including all controls for a particular test set, are reviewed by an analyst, most often a supervisor, assigned to the rotation for the particular test. The individual test procedures describe what it means for a control to "fail" and the steps that must be taken when this occurs so that incorrect or unreliable data is not reported.

5.9.3 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. The Department's proficiency testing program is described in the PROFICIENCY TESTING PROGRAM procedure in the Quality Assurance/Quality Control Manual. It is designed to conform to all requirements of the ASCLD/LAB-International accreditation program and the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories.

5.9.4 A technical review is an evaluation of reports, notes, data, and other documents to ensure an appropriate and sufficient basis for the scientific conclusions. It 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. See the TECHNICAL REVIEW procedure in the Evidence and Case Management Manual.

5.9.5 An administrative review is an evaluation of the report and supporting documentation for consistency with reporting procedures, selected requirements for marking case documentation, and for editorial correctness. An administrative review is the final review performed on all cases. It ensures that notes and worksheets accurately reflect case numbers, victim and suspect names, and police evidence control numbers; and that examination notes are numbered and initialed correctly. See the ADMINISTRATIVE REVIEW procedure in the Evidence and Case Management Manual.

5.9.6 Court testimony is the culmination of the work performed by the Department's scientists. To ensure that court testimonies are well documented, relevant, and presented in a clear and professional manner, the testimony of each testifying analyst is monitored at least once per year, if testimony is rendered. See the COURT TESTIMONY MONITORING procedure in the Quality Assurance/Quality Control Manual.

5.9.7 Court testimony monitoring records are maintained for a minimum of one ASCLD/LAB-International accreditation cycle.

5.10 REPORTING THE RESULTS

5.10.1 All test reports accurately reflect the test data. The REPORTS procedure in the Evidence and Case Management Manual provides instructions for report preparation and formatting that incorporate the requirements of ASCLD/LAB-International, the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories as well as recommendations concerning report standardization from the New York Crime Laboratory Advisory Committee

5.10.2 The information required by these ISO 17025 clauses, where applicable, is found either in the case report or in the case record.

5.10.3 The information required by these ISO 17025 clauses, where applicable, is found either in the case report or in the case record.

5.10.4 The Department of Forensic Biology is not a calibration laboratory and does not issue calibration certificates.

5.10.5 All opinions and interpretations in case reports are based upon data and observations documented in the case record. Reports clearly indicate where conclusions/interpretations have been included.

5.10.6 The Department of Forensic Biology does not routinely subcontract work to outside laboratories. When it does, the report of the subcontracting laboratory is provided to the customer on the subcontractor's own letterhead, and the results are not incorporated into reports issued by the Department.

5.10.7 It is the routine practice of the Department of Forensic Biology to transmit reports electronically. This has no impact on the content of the reports; therefore, conformance with the requirements of ISO 17025 is maintained. The recipients are verified to ensure that appropriate confidentiality is maintained.

5.10.8 The Department utilizes report templates to ensure that all necessary information is included and to promote clarity of content.

5.10.9 If a report is found to contain an error that affects the ability to use the report, an **amended report** is issued to correct the error. When additional analyses are performed after a report has been issued, an **additional report** is prepared. The format and content comply with all requirements of ASCLD/LAB-International and the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories.

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Revision History:

February 9, 2010 – Initial version of manual.

September 24, 2010 – Added language to "1. Introduction" to clarify the place of this manual within our Management System.

March 28, 2011 – Added Section 4.1.8, definitions of "top management" and "key management." Listed positions for key management were moved from 4.1.5j to 4.1.8 and the position of LIMS Manager was added to the list.

June 11, 2011 – Added/Revised language in the following sections to reflect testing for outside jurisdictions: Sections 2, 4.4, and 4.7.

July 16, 2012 – add City Research Scientists to list of staff in Section 4.1.5; minor changes for conformance with the use of a LIMS, e.g., "communication log" instead of "case contacts", change software modification example in Section 5.4.7; clarified that annual Right-to-Know training is required for technical personnel rather than "all" personnel (Section 5.3.6); Section 5.2.3—changed "no contract employees" statement to one that keeps the use of contract employees as an option.

February 02, 2015 – Entire manual revised. Multiple changes made to various sections.

May 1, 2015 – Added section 5.2.1.3 and updated section 4.1.5.b for "ASCLD/LAB Guiding Principles" review to reflect current practices. Updated Section 4.1.5.h to indicate that there is a Serology Technical Leader (older version of manual indicated QA Manager was the Serology Technical Leader). updated section 4.14 to reference the Annual Report that is due to ASCLD/LAB each year.