Management System Manual		
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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 Scope

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, competence, impartiality, and with references to supporting documents.

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

Established in 1991, the OCME Department of Forensic Biology performs DNA testing in criminal cases. Criminal evidence from most crime categories is submitted to the laboratory and the biological evidence is examined and processed according to the standard operating procedures. DNA results from evidence 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 and Validation unit, a Training unit and a CODIS unit.

The Department performs testing for jurisdictions outside of New York City of missing person and unidentified human remains cases from jurisdictions within New York State, pursuant to grant awards from the National Institute of Justice (NIJ).

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

2 Normative References

For the purposes of this document and conformance with accreditation requirements, the currently authorized versions of the following documents constitute the requirements of this document:

ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration"

ANAB, "**ISO/IEC 17025:2017 (AR 3125)** Forensic Science Testing and Calibration Laboratories Accreditation Requirements"

Federal Bureau of Investigation, "Quality Assurance Standards for Forensic DNA Testing Laboratories" (2011)

3 Terms and Definitions

For the purposes of this document and conformance with accreditation requirements, the definitions given in the currently authorized versions of the documents from Section 2 apply.

4 General Requirements

4.1 Impartiality

Laboratory management is committed to impartiality. All laboratory activities are undertaken to ensure and safeguard impartiality of the work product. Laboratory personnel

are expected to conduct laboratory activities free from commercial, financial or other pressures. Risks to impartiality are identified through regularly scheduled meetings between Laboratory Management and its customers as well as with laboratory personnel.

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 Chapter 68 of the New York City Charter.

The "ANAB 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 "ANAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists" is reviewed by all laboratory personnel on an annual basis. This review is coordinated by the Quality Assurance Manager and is performed through Qualtrax. Records of this review are maintained in Qualtrax by the Quality Assurance Team.

When a risk to impartiality is identified, laboratory members should use the PREVENTIVE ACTION procedure of the Quality Assurance/ Quality Control Manual.

4.2 Confidentiality

4.2.1 All Department of Forensic Biology personnel are bound by OCME policies on confidentiality as found in the OCME POLICY MANUAL. Such policies oversee the management of information obtained from customers pertaining to sensitive case related information, as well as the confidential management of testing results. Specific requirements in support of these policies as they relate to the Department of Forensic Biology are found in the Administrative Manual and the Quality Assurance/Quality Control Manual.

4.2.2 The Department only releases confidential information (ex. case reports, DNA Hits, FOIL requests, subpoena requests) under the guidance of applicable law and ensures notification of the applicable customer. Release of confidential information is overseen and coordinated by the OCME Legal Department. See the ATTORNEY / CUSTOMER REQUESTS section of the Administrative Manual for more detail.

4.2.3 All communications with customers remain confidential.

4.2.4 Any supporting personnel acting on behalf of the Department are bound by the same confidentiality policies and applicable laws as Forensic Biology personnel.

5 Structural Requirements

5.1 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.

5.2 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.

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

5.3 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 the ANAB accreditation program.

5.4 All Department of Forensic Biology laboratory testing activities subject to ANAB accreditation are conducted at the OCME Charles S. Hirsch Center for Forensic Sciences Building, 421 East 26th Street, New York, New York 10016. The laboratory operates in accordance with the ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration" as well as the ANAB, "ISO/IEC 17025:2017 Forensic Science Testing and Calibration Laboratories Accreditation Requirements". Both documents can be found in Qualtrax.

As an NDIS participating laboratory, the Department conforms to all requirements in the NDIS Operational Procedures Manual as well as the FBI Quality Assurance Standards. The current NDIS OPERATIONAL MANUAL and FBI DNA QUALITY ASSURANCE STANDARDS can be found in Qualtrax.

5.4.1 The laboratory conforms to the ANAB policy on the laboratory's claim to accreditation status. The laboratory does not use the ANAB accreditation symbol on any laboratory documents.

5.4.2 The laboratory operates under the New York City Charter, section 557 (f). Additionally, the laboratory performs testing under the approval of the Division of Criminal Justice Services as per Executive Law 49-B Commission on Forensic Science and Establishment of DNA Identification Index; 995-b Powers and Duties of the Commission as well as in accordance with the rules and regulations found in Title 9 of New York Codes, Rules and Regulations (NYCRR) Part 6190 NYS Accreditation program for Forensic Laboratories. These documents, or links to the documents, can be found in Qualtrax.

5.5 (a) The Department of Forensic Biology is a single operational unit having multiple responsibilities. 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. Additionally, the organizational chart defines the relationships of the managerial and technical personnel and support staff who are responsible for the implementation, maintenance, and improvement of the management system.

(b) The Department of Forensic Biology roles and responsibilities of the Director, Deputy Directors, Assistant Directors, Criminalists I-IV, Quality Assurance Manager, DNA Technical Leaders, City Research Scientists, Casework CODIS Administrator, Administrative Manager, Administrative staff, Laboratory Helper, Stock Worker and Customer Liaison are described in the STAFF ROLES AND RESPONSIBILITIES and DNA TECHNICAL LEADER sections of the Administrative Manual**.**

"Top management" in the Department of Forensic Biology consists of those individuals with the highest levels of administrative and operational authority: Director, Deputy 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, Deputy Director, Assistant Directors, Quality Assurance Manager, DNA Technical Leaders, Casework CODIS Administrator, and LIMS Administrator(s).

Within the Department of Forensic Biology, the Technical Leaders and Quality Assurance Manager, in association with the Laboratory Director, Deputy Director and Assistant Directors, define the Guiding Principles for Quality.

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 DNA QUALITY ASSURANCE STANDARDS. The laboratory may utilize assistant technical leaders who report directly to the DNA Technical Leaders.

The Quality Assurance 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 Assurance Manager's responsibilities are varied and reflect the requirements of ISO 17025, the ANAB accreditation program, and the Quality Assurance Standards for Forensic DNA Testing Laboratories. The duties, responsibilities, and authorities of the Quality Assurance Manager are described in various documents within the Administrative, Quality Assurance/Quality Control, and Evidence and Case Management Manuals.

The position of the Quality Assurance Manager in the organization is found in the Forensic Biology Organizational Chart.

The Quality Assurance Team, under the direction of the Quality Assurance 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.

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 sections of the Administrative Manual, and "Tasks and Standards" documents.

(c) 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)

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.

5.6 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.

Statement of Quality Principles
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 ANAB.
- The scientific staff performing casework meets all proficiency testing and continuing education program requirements.
- Technical issues are noted, and appropriate correction is taken and documented.
- The preventive action program is used to identify opportunities for improvement.

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 principles 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.

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.

(b) 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. Deviations from technical procedures must be approved by the applicable technical leader as described

in the GENERAL GUDIELINES FOR DNA CASEWORK section of the Protocols for Forensic STR Analysis Manual. Deviations from quality procedures must be approved by the Quality Assurance Manager.

(c) All personnel have the authority and responsibility to implement preventive measures to minimize deviations from the Management System. See the procedure for PREVENTIVE ACTION in the Quality Assurance/Quality Control Manual.

(d) The Quality Assurance Manager, in conjunction with the Technical Leaders, the CODIS Manager, the LIMS Manager and the Director, prepares the Management Review report for consideration by, and discussion with, all laboratory managers. The Management Review references the performance of the management system over the course of the previous year as well as any needs for improvement. Laboratory personnel may request changes and updates to operating manuals via Qualtrax. Refer to the DOCUMENT CONTROL procedure of the Administrative Manual.

(e) The Quality Assurance Manager is responsible for the overall implementation and maintenance of the management system related to quality. The responsibilities include, but are not limited to, 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 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 as well as recommending training to improve the quality of laboratory staff.

The Department's Technical Leaders (Serology, Nuclear DNA Technical Leader and Mitochondrial DNA Technical Leader) 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. The 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 the Management Review; and review and approve the forensic DNA training, quality assurance, and proficiency testing programs in the Department.

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

5.7 (a) Communication takes place at many levels within the Department. Regularly scheduled meetings are held amongst managers; between supervisors and managers; and within work groups. Quarterly 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.

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.

(b) Prior to planned changes to the management system being implemented, the risks of such change are assessed by lab management. Once changes to the management system have been implemented, various metrics are collected, such as case turnaround, backlog size, etc. These metrics are reviewed and discussed by management to ensure that the integrity of the management system has not been impacted in a negative fashion by the newly implemented changes.

6 Resource Requirements

6.1 General

The Department recognizes that many factors contribute to the accuracy and reliability of the tests conducted on submitted evidence, including human factors (personnel education, training, and skills); laboratory facilities and the associated environmental conditions; suitability of equipment utilized by the laboratory; measurement traceability; the use of externally provided products and services; review of submitted items for testing; selection, verification and validation of testing methods; sample selection; handling of evidence, maintaining technical records; ensuring the validity of results; ensuring accurate reporting

of results; assessment of non-conforming work and ensuring the safeguarding and maintenance of the Laboratory Information Management System.

6.2 Personnel

6.2.1 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 foundational scientific knowledge and practical skills. The laboratory refers to the date of hire and/or promotion (as applicable) as the defined date to be used for determining the applicable version of the *Quality Assurance Standards for Forensic DNA Testing* for requirements to assess education, experience and training.

The Department's training program 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.

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 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 ANAB. 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.

6.2.2 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. Demonstration of competency is an integral part of the Department's training 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.

All technical personnel are required to meet the education and competency test requirements of ANAB and the FBI Quality Assurance Standards.

6.2.2.1 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.

6.2.2.2 The Forensic Biology training program has a courtroom testimony training component as well as training in ethical practices in forensic science, general knowledge of forensic science and applicable criminal and civil law procedures.

The training program includes procedures for retraining and maintenance of skills and expertise as well as criteria for acceptable performance.

6.2.3 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.

Deviations and their impact on casework are addressed during training. Refer to the training module ROOT CAUSE ANALYSIS AND WORK PROCESS.

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

The Department maintains general City position descriptions for all job classifications used. Tasks and Standards plans are prepared annually for each laboratory employee and contain position responsibilities and performance expectations.

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

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. The competency test includes practical examinations that cover the spectrum of anticipated activities related to Serology and DNA testing. Demonstration of competency prior to independent casework is required for technical support personnel and analysts that conduct Serology and DNA testing.

6.2.3.2 Training and competency testing in technical review is included in the Department's training program.

6.2.4 All supervisors within the Department are responsible for discussing the required tasks and standards with each of their direct reports. This discussion and the signing of the tasks and standards is typically performed before the end of the first quarter of the year. Additionally, an analyst is issued a new task and standard to sign upon promotion to a new level. See Memo titled Employee Development, Evaluations and Accountability.

6.2.5 Procedures for the selection/ promotion of personnel is defined as per the Memo titled External Hiring Process for Criminalists and the Memo titled Promotion Process for Criminalists. All documents pertaining to the hiring/ promotion process are retained by the Human Resources Department.

Procedures pertaining to training, competence (initial and monitoring), and authorization are found in the TRAINING MANUAL. All such records are retained by the Training Group either in hardcopy form and/or in Qualtrax.

Procedures pertaining to the supervision of lab personnel is defined as per the Memo titled Definition of Levels of Supervision.

6.2.6 The development of new casework techniques, modification to casework techniques, verification and validation of casework techniques as well as the coordination of implementation of casework techniques is carried out by the Research and Validation Team. Occasionally, casework analysts who apply for temporary assignment to the Research and Validation Team. Those assigned are selected by Laboratory Management. Interns assigned to the Research and Validation Team are selected and approved by Laboratory Management. Vendors are contractually approved by Laboratory Management to perform validation work on an as-needed basis.

All analysts reporting the results and interpretations of casework analyses are authorized to do so by the Technical Leader via a written letter. All technical reviewers must pass the relevant training competency in order to technically review casework interpretations. All employees performing administrative review prior to authorizing the results must pass the relevant training competency in order to administratively review case records.

6.3 Facilities and Environmental Conditions

6.3.1 The facilities utilized by the Department offer environmental conditions that are suitable for the work performed. If the environmental conditions of the labs are not suitable for the work performed (ex. the room temperature is too hot or too cold), the situation should be reported to the Quality Assurance Team at FBiology_QATeam@ocme.nyc.gov, or the Facilities Department at extension x1660. Alternatively, any analyst may submit a Facilities Repair Ticket by accessing the request button on the OCME home intranet page.

6.3.2 Procedures utilized by the Department of Forensic Biology specify any facility or environmental condition that may be important for optimized testing activities.

6.3.3 The Department of Forensic Biology monitors the temperatures of all freezers, refrigerators, heat blocks and incubators that are used for testing purposes. See Quality Control Procedure QC270- TEMPERATURE CONTROL.

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

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

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.

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.

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

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.

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

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 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.

A listing of access granted to OCME employees can be found in the SECURITY section of the Administrative Manual.

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 section of the Quality Assurance/Quality Control Manual and the GENERAL GUIDELINES FOR FORENSIC BIOLOGY AND DNA CASEWORK section of the STR Procedures Manual.

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

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 separated from each other by space or time.

The laboratory does not perform any activities away from the primary facility location of 421 East 26th Street New York NY.

6.4 Equipment

6.4.1 The Department of Forensic Biology uses equipment (ex. instruments, software, reference materials and data, reagents and consumables) which are suitable for the tests conducted by the Department.

6.4.2 The laboratory performs applicable Quality Control checks on all equipment outside of the Departments' control (ex. CODIS, STRmix, LIMS, FST).

6.4.3 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 "critical equipment" maintenance, calibration, and performance check programs; and equipment identification, labeling, and records.

Any computers, automated equipment or software (such as the LIMS) utilized by the Department must be deemed suitable through either appropriate checks performed in a systematic manner or by going through a full validation. See the CONTROL OF DATA section of the Quality Assurance/ Quality Control Manual for detailed procedures used to ensure the proper functioning of such equipment or the relevant QC procedure in the Quality Assurance/ Quality Control Manual.

Reliable testing depends not only on the equipment used but also 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.

6.4.3.1 Reagents used in casework are received and/or prepared by the Departments Quality Assurance Group are labeled with the identity of the reagent, the date prepared and/or the lot number for identification during casework testing. All records of reagent preparation and Quality Control testing are maintained by the Quality Assurance Group as outlined in the REAGENTS procedure in the Quality Assurance/Quality Control Manual.

Consumables used in casework are received and monitored by the Quality Assurance Group. Consumables are irradiated, as needed, to minimize the potential for contamination (QC243-STRATALINKING OF PLASTICWARE). Glassware is also autoclaved (QC 115- AUTOCLAVING) as needed. Additionally, there are protocols for the disinfection of consumables (QC142-DISINFECTING ITEMS LEAVING POST AMP and QC 143-DISINFECTING PLASTICWARE FOR LABORATORY CLEAN-UP) as well as protocols for general cleaning of the laboratory (QC144-LABORATORY CLEAUP).

6.4.3.2 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 and the CONTROL OF REFERENCE COLLECTIONS procedure in the Quality Assurance/Quality Control Manual.

6.4.4 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. See the EQUIPMENT CALIBRATION AND MAINTENANCE procedure, and the individual calibration, performance check, and maintenance procedures in the Quality Assurance/Quality Control Manual which ensure that specific requirements be met before equipment is placed or returned to service. See relevant QC procedures for verification of conformance to required specifications in the Quality Assurance Quality Control Manual.

6.4.5 Procedures for the calibration of standard weights used by the Department for intermediate performance checks of balances; calibration of pipettes, 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.

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. Calibration and maintenance specifications, requirements and intervals are outlined in the individual procedures in the Quality Assurance/Quality Control Manual.

All calibration and maintenance records are retained by the Quality Assurance Group either in Hardcopy, the LIMS, or Qualtrax.

6.4.6 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.

6.4.7 Details on traceability requirements for specific equipment are found in the individual calibration and maintenance programs/procedures in the Quality Assurance/Quality Control Manual.

6.4.8 All calibrated equipment is labeled to indicate date of previous calibration and date next calibration is required.

6.4.9 The EQUIPMENT CALIBRATION AND MAINTENANCE procedure in the Quality Assurance/Quality Control Manual outlines the handling of equipment that has shown to be outside of specifications.

6.4.10 All Quality Control procedures related to intermediate checks necessary to maintain confidence in the performance of equipment may be found in the Quality Assurance/Quality Control Manual.

6.4.11 Forensic Biology does not rely on reference values or corrections factors that need to be updated or changed to meet requirements.

6.4.12 Unintended adjustments of equipment are prevented by verification of analytical controls, confirmation of listed software settings as indicated in standard operating procedures, limited access to the equipment, and regular Quality Control checks on the equipment.

6.4.13 Records are retained in the LIMS, on the associated Forensic Biology network, or in hard copy format for all equipment that can influence laboratory activities. Equipment Maintenance Logs provide details as to the identity of the equipment (including software and firmware versions), type of equipment, serial numbers or other unique identifiers, location, and calibration records. Maintenance Logs also contain information pertaining to the maintenance or repairs of equipment and actions taken prior to being placed back into use for casework. Evidence of verification that equipment conforms with specified requirements can be found in the initial Validation and Performance Check of the equipment, as well as in the LIMS when further testing was necessary. The Quality Assurance/Quality Control Manual provides guidance as to acceptance criteria and calibration intervals and periods of validity of equipment.

6.5 Metrological Traceability

6.5.1 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.

6.5.2 The laboratory ensures that measurement results are traceable to SI units by ensuring that calibrations are performed by competent vendors who are accredited to ISO standards.

6.6 Externally Provided Products and Services

6.6.1 The laboratory ensures that only suitable externally provided products and services are used for laboratory activities by obtaining such services and supplies in accordance with our PURCHASING SERVICES AND SUPPLIES procedure. Purchasing of laboratory equipment must be approved by the Laboratory Director. Once approved, the typical procurement process is followed.

6.6.2 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.

6.6.3 The procurement procedures that allow the Department to obtain the appropriate services and supplies are found in the PURCHASING SERVICES AND SUPPLIES procedure in the Administrative Manual.

Vendor evaluation criteria are established and coordinated through the OCME Procurement Department.

The laboratory only uses Proficiency testing vendors that are approved by ANAB and are accredited to ISO 9001 and/or ISO 17025. See the PROFICIENCY TESTING section of the Quality Assurance/Quality Control Manual.

The laboratory only utilizes external auditors that are qualified by the FBI QAS standards or ANAB approved assessors to ISO 17025. See the AUDITS and ASSESSMENTS section of the Quality Assurance/Quality Control Manual.

Records pertaining to the approval of externally provided services and products are maintained in Qualtrax.

6.6.4 Any Department requirements that pertain to vendor services and supplies may be found within the Requests for Proposals section of Service Contracts. Such requirements pertain to the products and services to be provided, acceptance criteria and competence.

7 Process Requirements

7.1 Review of Requests, Tenders and Contracts

7.1.1 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.

The staff of the Department of Forensic Biology reviews all customer requests for testing submitted evidence and cooperates with such requests whenever feasible and reasonable. The procedure encompasses a review of the requirements of the request, the capability and resources needed to carry out the request and that the appropriate methods and procedures exist to carry out the request. See the CASE ACCEPTANCE AND EVIDENCE SIGN-IN procedure in the Evidence and Case Management Manual.

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

The laboratory does not routinely sub-contract for casework purposes. See the SUBCONTRACTING section of The Evidence and Case Management Manual.

7.1.2 If the Department is unable to comply with the requested testing (e.g. the requested testing methodology is no longer employed by the laboratory) the Department will inform the customer.

7.1.3 Customers of the Department of Forensic Biology do not require reported results to reference statements of conformity, specifications or standards.

7.1.4 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) [or occasionally the defense]. Any deviations in testing methods requested by the customer shall not impact integrity of the laboratory's results.

7.1.5 Any deviations in testing methodology from those specified in a contract are documented and contained within the case record.

Should there be any discrepancies between what was submitted for testing and what was received, the customer shall be notified via a deviation. The discrepancy shall also be noted in the examination notes as described in the EVIDENCE EXAMINATION section of the Evidence and Case Management Manual.

7.1.6 The scheduled analysis of evidence may change if the examination of additional evidence is needed for completion of the case based on Laboratory determination or Customer request. Documentation of the additional testing is contained in the case record.

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

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 / CUSTOMER REQUESTS procedure in the Administrative Manual.

7.1.8 Records of oral or email discussions with customers are maintained in the LIMS case record communication log.

7.1.9 CODIS database searches that result in a hit or match are communicated to the Customers via case reports and/or DNA Hits, a web-based application which notifies relevant customers (NYPD and ADAs) of DNA matches. The use of DNA Hits is outlined in the VERIFYING and REPORTING DNA MATCHES section of the CODIS Manual.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and Verification of Methods

7.2.1.1 The Department of Forensic Biology uses methods appropriate to the purposes for which testing is conducted. The procedures for evaluating the results of DNA testing of evidentiary samples, performing statistical evaluations of those samples, and comparison to known samples is outlined in the GENERAL GUIDELINES FOR FORENSIC BIOLOGY AND DNA CASEWORK section and the interpretation s and comparison procedures sections of the Protocols for Forensic STR Analysis Manual.

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.

7.2.1.2 The DOCUMENT CONTROL procedure in the Administrative Manual describes how procedures are created, revised to maintain currency, and made available to staff.

All internally generated technical procedures are maintained in electronic format in the Forensic Biology folder in Qualtrax and are available to all Department staff. Controlled procedures and/or instructions externally generated are available to staff in the External Documentation folder in Qualtrax. Reference data (such as Lab Types) is maintained in LDIS and can be searched by all interpreting analysts.

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. The latest version of all technical procedures available to the staff are the current versions found in Qualtrax. Any supplements or updating of technical records shall be done via the DOCUMENT CONTROL procedure in the Administrative Manual.

7.2.1.3 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.

The Department uses validated test methods that are accepted by the general forensic community. Additionally, the Department is fortunate to have competent personnel dedicated to the Validation of new techniques and methodologies. These individuals are part of the Research and Validation Team. This team meets periodically with management to supply updates as to the progress of various on-going validation projects as well as to ensure that the methods being developed meet the needs of the laboratory and the customers.

7.2.1.4 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 and/or the relevant Guidelines established by the Scientific Working Group on DNA Analysis Methods.

Serology test procedures are validated to the extent necessary to ensure that test results are reliable. Validation records are maintained as per the DOCUMENT CONTROL section of the Administrative Manual.

7.2.1.5 The decision to develop and/or validate new or revised test procedures is a planned activity 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 section of the Quality Assurance/ Quality Control Manual.

7.2.1.6 Technical deviations from laboratory procedures must be technically justified by the analyst performing the deviation, authorized by the relevant Technical Leader, and documented via a LIMS deviation. The TECHNCIAL DEVIATIONS section of the GENERAL GUIDELINES FOR FORENSIC BIOLOGY AND DNA CASEWORK section of the Forensic STR Procedure manual details the process for deviating from laboratory procedures. Quality deviations are also documented via a LIMS deviation and are approved by the Quality Assurance Manager.

7.2.2 Validation Methods

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

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.

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

7.2.2.1.1 Internal validation studies are conducted in such a way as to establish guidelines for data interpretation and reporting of results. The VALIDATION procedure in the Quality Assurance/Quality Control Manual describes the Department's approach to validation of analytical procedures.

7.2.2.2 When it is necessary to revise or modify a previously validated method the laboratory follows the VALIDATION procedure in the Quality Assurance/Quality Control Manual to ensure the reliability of the new method.

7.2.2.3 Validation projects are designed to meet the needs of the customers and this laboratory as well as 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.

The extent to which the testing factors 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.

7.2.2.4 The Department maintains all records pertaining to validations implemented by casework. The procedure for maintaining these records is found in the VALIDATION section of the Quality Assurance/Qulaity Control Manual as well as the CONTROL OF RECORDS section of the Administrative Manual.

7.3 Sampling

7.3.1 During the examination of evidence, 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 section of the Evidence and Case Management Manual contains guidance with respect to selecting appropriate samples for testing.

7.4 Handling of Test Items

7.4.1 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 be detrimental to 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, tracks, 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.

7.4.2 The procedure for the unambiguous identification and documentation of the examination of all evidentiary items received for testing by the laboratory is outlined in the EVIDENCE EXAMINATION section of the Evidence and Case Management Manual.

7.4.3 Some evidentiary items received by the laboratory may be deemed unsuitable for testing once evidence examination has begun due to the presence of mold, etc. The EVIDENCE EXAMINATION section of the Evidence and Case Management Manual addresses such instances and when a deviation in LIMS needs to be recorded for the case. Some evidence may be determined unsuitable for testing before the evidence has been signed into the laboratory. The CASE ACCEPTANCE AND EVIDENCE SIGN-IN section of the Evidence and Case Management Manual addresses the deferral of evidence.

7.4.4 Conditions under which evidence and work product is stored is maintained by a temperature monitoring system. QC procedure QC270-TEMPERATURE CONTROL details the specifications and documentation of temperature monitoring by the laboratory's Quality Assurance/Quality Control Group.

7.5 Technical Records

7.5.1 Technical records (also referred to as Examination Records) generated by the laboratory contain all relevant information including, but to limited to, the task performed, the date and time the task was performed, and the personnel performing the task, such that any analyst may review, interpret and/or replicate the task as necessary.

7.5.1.1 What constitutes Technical (Examination) Records is outlined in detail in the CASE FILES section of the Evidence and Case Management Manual.

7.5.1.2 All abbreviations used by the laboratory in the general course of testing are listed in the ABBREVIATIONS section of the Evidence and Case Management Manual.

7.5.1.3 Case records are maintained in such a way that any person possessing the relevant knowledge, skills and abilities can evaluate the work that has been performed and interpret the results independently.

7.5.1.4 All Technical Records generated after 2012 are maintained in the LIMS. Technical records generated prior to 2012 are maintained in hardcopy and/or electronic format. All technical records generated by the laboratory are maintained indefinitely in hardcopy or electronic format.

7.5.1.5 Any rejection of a technical record is recorded on the record itself, in the LIMS or captured by the LIMS audit trail.

7.5.1.6 The procedure for addressing and documenting irregularities seen in the performance and/or calibration of an instrument is outlined in the EQUIPMENT CALIBRATION AND MAINTENANCE section of the Quality Assurance/ Quality Control Manual.

7.5.2 Modifications to hardcopy non-LIMS technical records are noted on the document itself. Such notes include the nature of the modification, the date of the modification and the author of the modification. All modifications to technical records generated within the LIMS are either recorded on the LIMS record or tracked via the LIMS audit trail. The nature of the modification, the date of the modification, the author of the modification is noted in the LIMS record or the LIMS audit trail. Amended case reports are indicated as such within the body of the report itself.

7.6 Evaluation of Measurement Uncertainty

7.6.1 The Department of Forensic Biology is not a calibration laboratory, nor does it perform its own calibrations. The test results reported by the Department are identifications and comparisons that are qualitative in nature, and per ANAB 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.

7.7 Ensuring the Validity of results

7.7.1 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 the validity and reliability of laboratory test results. The measures used in the program are varied and include, but are not limited to:

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

7.7.1.1 The PROFICIENCY TESTING PROGRAM section of the Quality Assurance/Quality Control Manual details the Blind Reanalysis Program.

7.7.1.2 Technical reviews are conducted by those laboratory members who have been trained and authorized in technical review by the Technical Leader. Documentation of technical review occurs in the LIMS and includes the identity of the technical reviewer as well as the date the technical review was performed. Any discrepancies between the interpreted results of the reporting analyst and the technical reviewer are documented via the DOCUMENTATION OF DISCREPANCIES IN INTERPRETED RESULTS form.

The procedure for performing technical review of case records is outlined in the TECHNCIAL REVIEW section of the Evidence and Case Management Manual.

The procedure for review of court testimony is outlined in the COURT TESTIMONY MONITORING section of the Quality Assurance/Quality Control Manual.

7.7.2 The external Proficiency Testing Program and the internal Blind Reanalysis Proficiency Testing Program demonstrate the quality of the scientific service offered by the Department of Forensic Biology and serve as mechanisms for critical self-evaluation. The Department's Proficiency Testing Program and Blind Reanalysis (DNA and Serology) Proficiency Testing Programs are described in the PROFICIENCY TESTING PROGRAM section of the Quality Assurance/Quality Control Manual. These procedures are designed to conform to all ANAB requirements and the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories.

The laboratory does not take part in interlaboratory comparisons other than proficiency testing.

7.7.3 The Quality Assurance Team and the 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 NONCONFORMING WORK and/or the QUALITY INCIDENT REVIEW procedures.

Test data, including all controls for a particular test set are reviewed by an analyst 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. Data related to failing controls, failed test batches or underperforming instrumentation are logged by a supervisor in the Lab Supervisor Issues Log. This log is checked periodically by members of the Quality Assurance Group for possible systemic issues that need addressing.

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.

7.7.4 Personnel performance is monitored through proficiency testing, yearly performance evaluations and non-conforming work documentation.

7.8 Reporting of results

7.8.1 General

7.8.1.1 All reported results undergo review and authorization by the reporting analyst. See the CASE MANAGEMENT and CASE FILES sections of the Evidence and Case Management Manual. The case record and report then undergoes technical and administrative review prior to release to the customer.

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.

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.

7.8.1.1.1 The "authorizer" of the results in the technical record is the Reporting Analyst. Authorization of the results is documented via analyst initials on the technical records and as an electronic signature in the LIMS.

7.8.1.2 All test reports accurately, clearly, unambiguously and objectively reflect the test data. The Department meets regularly with its customers to ensure that the way case results are reported are meeting the needs of the customer. All reports are retained as technical records as reflected in the CONTROL OF RECORDS section of the Administrative Manual.

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.

7.8.1.2.1 Test results are distributed to the customer in a written report.

7.8.1.2.2 The REPORTS procedure found in the Evidence and Case Management Manual outlines the requirements for a case report based on ISO/ IEC 17025, ANAB requirements, 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.

7.8.1.3 Department seeks to report results in a manner that is simplified in a way such that the customer will understand the results while the scientific integrity of the reported results is maintained. The Department utilizes report templates to ensure that all necessary information is included and to promote clarity of content.

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.

7.8.1.3.1 The customer is informed when significant changes are made to the report template.

7.8.2 **Common Requirements for Reports**

7.8.2.1 The REPORTS section of the Evidence and Case Management Manual provides instructions for report preparation and formatting that incorporate the requirements of ISO/ IEC 17025:2017, ANAB, 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.

7.8.2.2 Case information provided by the customer is maintained in the greater case record and is considered to be Administrative Records. These Administrative Records do not typically contain test data of any kind. The CASE FILES section of the Evidence and Case Management Manual contains a listing of the various types of Administrative Records the laboratory receives.

7.8.2.3 When additional analyses are performed after a report has been issued, an **additional report** is prepared. The procedure for issuing additional reports is in the REPORTS section of the Evidence and Case Management Manual.

7.8.3 Specific Requirements for Test Reports

7.8.3.1 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. Environmental testing conditions are not reported as they are not necessary for the interpretation of test results. Uncertainty of measurement is not calculated by the Department as there are no measurements that are reported.

7.8.3.2 The Department of Forensic Biology does not perform sampling of items of evidence.

7.8.4 Specific Requirements for Calibration Certificates

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

7.8.5 Reporting Sampling-Specific Requirements

7.8.5.1 The Department of Forensic Biology does not perform sampling of items of evidence.

7.8.6 Reporting Statements of Conformity

7.8.6.1 The Department of Forensic Biology does not provide statements of conformity to specifications or standards.

7.8.7 Reporting opinions and Interpretations

7.8.7.1 Only analysts who have completed DNA analysis training (as specified in the Training Manual) and have been authorized by the relevant Technical Leader may issue interpretations in a written report.

7.8.7.2 The basis upon which interpretations are made is documented in the greater case record in the Examination Records (as defined in the CASE FILES section of the Evidence and Case Management Manual) as well as in the laboratory's interpretations procedures in the Protocols for Forensic STR Analysis Manual. Results are typically reported to the customer via a written case report. The REPORTS section of the Evidence and Case Management Manual details under what conditions verbal results may be released.

7.8.7.3 Documentation of communication with the customer is recorded in the LIMS case communication log. On occasion (ex. a high priority request), verbal results may need to be reported to the customer prior to a completed case report.

7.8.8 Amendments to Reports

7.8.8.1 If a report is found to contain an error that affects the reported results, an **amended report** is issued to correct the error. The change in previously reported results as well as the reason for the amendment is included in the newly issued report. The procedure for issuing amended reports is in the REPORTS section of the Evidence and Case Management Manual.

In instances where an amended report is necessary to correct an error, the CONTROL OF NON-CONFORMING WORK procedure is followed to document the error and its resolution.

7.8.8.2 Amended reports are identified as such in a newly issued report via report template wording that has been created for such instances. The format and content comply with all requirements of ISO/IEC 17025:2017, ANAB and the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories.

7.9 Complaints

7.9.1 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 quality related aspects of the Forensic Biology management system, indicate possible problems with the Department's management system and are treated seriously. Laboratory employees may also file complaints against customers or other parties. The Department evaluates all complaints received and determines how best to resolve the complaint.

7.9.2 The process for addressing complaints is found in the COMPLAINTS procedure in the Quality Assurance/Quality Control Procedures Manual. This procedure addresses the receiving, assigning, evaluating, validating, investigating, recording, resolving and reviewing of complaints.

7.10 Nonconforming Work

7.10.1 Technical work which does not meet the Department of Forensic Biology's stated standards, either with respect to the mode of execution or outcome may compromise the integrity of evidence or the accuracy of casework analysis. When such instances occur, they are dealt with upon discovery or at the earliest opportunity so that the non-conforming work can be appropriately evaluated and corrected. In some situations, the evaluation may indicate that a formal root cause analysis is necessary.

The identification of nonconforming work of testing activities can occur during a variety of activities: data or case file reviews, instrument preparation, sample processing and audits, to name a few. Where non-conforming work has been identified resulting in a failure to comply with the guiding principles and procedures, the laboratory's CONTROL OF NONCONFORMING WORK procedure is followed. A timely and thorough Root Cause Analysis may be necessary to ensure that a problem is effectively corrected and to minimize the likelihood that the problem will recur.

The Non-Conforming Work procedure details the assignment, risk assessment of the significance of impact on lab results, root cause identification, resolution (including any necessary communication with customers), recommendations for future preventive actions, documentation and review of non-conforming work.

Quality Incident Review is a reactive process to deal with 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 may be identified through a variety of activities, such as audits, management reviews, feedback from customers, and staff observations. See the QUALITY INCIDENT REVIEW procedure in the Quality Assurance/Quality Control Manual. The Quality Incident Review procedure details the assignment, assessment, root cause identification,

resolution, monitoring actions, documentation and review of the identified deviation from the management system.

7.10.2 Documentation of non-conforming work is detailed in the CONTROL OF NONCONFORMING WORK procedure.

7.10.3 Most non-conforming work are errors that are easily corrected, may or may not have been discovered in the general course of daily quality system checks and have no significant impact on the affected samples, cases or reported results. Such non-conforming work requires typically only requires corrections as opposed to corrective actions.

However, if an error rises to the level of a Significant Event (as defined by Title 17, Chapter 2, Section 17-207 of the Administrative Code of the City of New York), corrective actions will be implemented as appropriate and in direct proportion to the scope of the event. See the CONTROL OF NON_CONFORMING WORK section of the Quality Assurance/Quality Control Manual as well as the OCME RCA GUIDELINES procedure located in Qualtrax to determine what constitutes a Significant Event and what actions need to be taken to correct it.

7.11 Control of data and information management

7.11.1 All data and information needed to perform laboratory activities is contained within Qualtrax, the LIMS and on the Forensic Biology network. This data is accessible to all departmental employees.

7.11.2 The LIMS Superusers test all LIMS functionality updates prior to implementation for casework use.

7.11.2.1 Records of computer software validation developed by the OCME are maintained at the laboratory.

7.11.3 Use, safeguarding, and maintenance of the LIMS is addressed in the CONTROL OF DATA procedure in the Quality Assurance/Quality Control Manual.

7.11.4 The LIMS utilized by the Department of Forensic Biology is maintained on-site at the OCME.

7.11.5 The LIMS Process Manual details all instructions on use of the LIMS and is maintained in Qualtrax.

7.11.6 The checking of calculation and data transfers are addressed in the TECHNICAL REVIEW section of the Evidence and Case Management Manual. Additionally, the

CONTROL OF DATA procedure in the Quality Assurance/Quality Control Manual discusses the measures that the Department takes 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.

8 Management System Requirements

8.1 General

8.1.1 The management of the Department is committed to providing excellent customer service. It is 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, Officers of the Court, and the Mayor's Office for Criminal Justice 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 ANAB and DCJS.

8.1.2 The management system of the laboratory includes but is not limited to; documentation of all laboratory activities, document control of technical and quality records, assessment of risks to and opportunities to improve laboratory operations, non-conforming work resulting in corrections and/or corrective actions, internal and external audits and management reviews.

8.2 Management System Documentation

8.2.1 Policies, procedures and objectives have been established for the daily operations of the laboratory. All policies and procedures are maintained in Qualtrax and are accessible to all Department of Forensic Biology staff. Updates to policies and procedures are disseminated to staff via a Qualtrax email. All controlled documents in Qualtrax are reviewed yearly to ensure they reflect the most current practices of the laboratory as described in the DOCUMENT CONTROL section of the Administrative Manual. The OCME POLICY MANUAL on the OCME Intranet directs OCME employees to read their email on a regular basis as one of their job responsibilities, thereby ensuring they are aware of the most recent policies and procedures utilized by the Department.

8.2.2 The laboratory's policies, procedures and objectives address the competence, impartiality and consistent operation of the laboratory.

8.2.3 Laboratory management is committed to continuously improving the development and implementation of the management system through various review practices (such as AUDITS AND ASSESSMENTS and MANAGEMENT SYSTEM REVIEWS, as well as through Lean Six Sigma practices.

8.2.4 All policies, procedures and objectives necessary to implementing the management system of this laboratory and which are needed to fulfill all accreditation requirements are referenced in the Management System Manual.

8.2.5 The Management System Manual and all other documents that comprise the management system of the laboratory are maintained in Qualtrax and are accessible to all laboratory staff.

8.3 Control of Management System Documents

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

8.3.2 The DOCUMENT CONTROL procedure references the general structure of the Management System Documents (both internally and externally generated documents), creation/ revision of documents, responsibility and authority for document review and approval, document formatting such that they are uniquely identified and the version is identifiable and the scheduled review of controlled documents such that they are appropriately updated or retired as needed.

8.4 Control of Records

8.4.1 Legible 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.

8.4.2 The Department's overall processes with respect to the identification, storage, protection, back-up, archive, retrieval, retention time 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.

8.5 Actions to Address Risks and Opportunities

8.5.1 Laboratory Management, as well as upper level supervisors, meet on a regular basis to discuss opportunities where laboratory work flow may be improved upon, as well as the risks associated with changing current laboratory policies. Any failures in the laboratory's work performance are discussed and addressed to improve work flow and output, as well as to ensure the laboratory's management system is achieving its intended results.

8.5.1.1 Risks and opportunities related to health and safety are discussed between the OCME Health and Safety Officer and the Department of Forensic Biology Health and Safety Coordinator at periodic meetings that the OCME Health and Safety Officer holds with the Health and Safety Coordinators for the various agency departments. The laboratory undergoes biannual Health and Safety Inspections where the health and safety of the lab environment is assessed. The Department Health and Safety Coordinator also annually reviews the OCME manuals related to health and safety to ensure the lab is in compliance with their requirements.

8.5.2 Opportunities for improvement in laboratory work production can take several forms; Lean Six Sigma Black Belt Projects, Lean Six Sigma Kaizen Events and interim committees all serve to assess ways in which laboratory throughput, efficiency and quality may be improved upon while assessing the risks of changing workflow.

8.5.3 Actions taken to address risk are proportional to the potential impact on the validity of laboratory results and are documented on the RISK ASSESMENT FORM.

8.6 Improvement

8.6.1 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 AND ASSESSMENTS, QUALITY INCIDENT REVIEW, CONTROL OF NON-CONFORMING WORK assessment, Root Cause Analyses, PREVENTIVE ACTION reviews, MANAGEMENT SYSTEM REVIEW, lean six sigma projects, suggestion box and analysis of miscellaneous operational data allow the Department to identify opportunities for improving the effectiveness of the management system.

8.6.2 The Department seeks feedback from internal and external customers through various means including, but not limited to, customer surveys, regular customer meetings, and received complaints. This information is reviewed by the Department's management in

order to identify ways to improve the laboratory's management system, laboratory activities and customer service.

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. Departmental 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.

8.7 Corrective Action

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

8.8 Internal Audits

8.8.1 Internal audits are a critical component of the Department of Forensic Biology's management system. Internal audits are conducted every calendar year to verify that its management system is effectively being implemented and maintained the laboratory is in compliance with its own procedures as well as with ISO 17025 standards, ANAB policies and requirements, the FBI 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.

8.8.2 The AUDITS AND ASSESSMENTS procedure in the Quality Assurance/Quality Control Manual defines the criteria and scope for an audit, documentation of the results of the audit, reporting the results to management and application of relevant corrections and/or corrective actions in a timely manner.

8.9 Management Reviews

8.9.1 Management review is a tool used by the management of the Department on an annual basis to (1) ensure the continuing suitability, adequacy and effectiveness of the management system, its policies, objectives 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".

8.9.2 Management reviews take into account many types of information, including, but not limited to: changes in internal and external issues affecting the laboratory, fulfillment of the laboratory's objectives, the suitability of guiding principles and procedures; reports from managerial and supervisory personnel; status of action items from previous management reviews, 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; effectiveness of any implemented improvement; the laboratory's quality objectives; adequacy of resources; risk identification; assurance of the validity of results; and miscellaneous factors if relevant, such as quality control activities, resources, and staff training.

See the MANAGEMENT SYSTEM REVIEW procedure in the Administrative Manual.

8.9.3 The results of the Management review in total are documented by the Quality Assurance Manager and issued to all managers for review and comment. Any decisions or actions related to the need for changes in laboratory activities and/or the management system are recorded so that the outcome of the change can be monitored and reflected in subsequent management system reviews.