LSD&FC
LAGOS STATE DNA AND FORENSIC CENTER

Quality Manual

DNA & Forensic Biology Section

Version 4.0

Effective Date: January 25, 2019

Contents

1 Statement of Quality Policy

The Lagos State DNA & Forensic Center (LSD&FC) is responsible for the provision of scientific analysis of evidential material and DNA relationship samples upon the request of its customers, which include law enforcement, the Lagos State Judiciary, investigators, medical practitioners and the citizens of Lagos. The LSD&FC is committed to follow professional practices accepted by the international forensic community and to provide high quality and reliable service by adhering to the following:

- Use of validated methods and international best practices.
- Timely Performance of examination of samples according to relevant accreditation standards.
- Interpreting analytical results free of bias and free of any type of undue influence.

2 Vision and Mission Statement

2.1 Vision Statement

The Lagos State DNA & Forensic Center shall be a leading and comprehensive forensic science center that supports law enforcement, the judiciary, investigators and the public for efficient, reliable and faster resolution of criminal and civil cases in Nigeria.

2.2 Mission Statement

The Lagos State DNA and Forensic Center shall utilize advanced scientific techniques, state-of-the-art equipment and international best practices to provide fast, unbiased and reliable forensic services to allow law enforcement and the judiciary resolve cases and enhance public safety.

3 Lagos State DNA & Forensic Center: Overview and Mandated Functions

Lagos State is the most populated state in Nigeria and located in the south-western part of Nigeria. It is bordered to the North and East by Ogun State, to the West by the Republic of Benin and to the South by the Atlantic Ocean. About 22% of its 3,577 km^2 area are lagoons and creeks. The city of Lagos is Nigeria's largest city and has the largest economy. According to Heinrich-Boll-Stiftung (HBS) Foundation report, if Lagos State were a country, it's economy will rank number 7 in Africa and its economy will be bigger than Kenya, Cote D'Ivoire, and Ghana. With a population of about 21 million (Nigerian Population Report, 2014), Lagos is the 7th fastest growing city in the world. The Borgen Project reports an annual growth rate of 2 to 3 percent. The Lagos economy is diversified and, it includes manufacturing, transportation, construction, services, wholesale, retail sectors and more recently oil. The State accounts for over 60 percent of the industrial and commercial output of Nigeria and a 2015 report by the Economist states that Lagos State generates $90 billion dollars in goods and services annually. As would be expected in many mega cities different kinds of crime, including kidnappings, extortion, carjacks, assaults, rapes, human trafficking, armed muggings, sale of controlled substances and burglaries occur in Lagos, which is why the United States Overseas Security Advisory Council (OSAC) gives Lagos a crime rating of "critical".

The Lagos State DNA & Forensic Center (LSD&FC) was established as a crime laboratory to help fight crime and make Lagos a safe place to live, work, visit and play. LSD&FC is owned by the Lagos State government. It was conceptualized, established and currently operated and managed by ITSI-Biosciences, LLC, a Johnstown, PA, USA based company. LSD&FC is organized under the Lagos State Ministry of Justice (MOJ), and a committee chaired by the Permanent Secretary and Solicitor General. The Ministry of Justice provides oversight. The design, construction, staffing and equipping of the DNA section occurred

between June 2016 and August 2017, this section was commissioned on 27th of September 2017 by His Excellency Mr. Akinwunmi Ambode, the Governor of Lagos State.

The initial plan was to establish only a DNA forensic section. However, in recognition of the fact that no single forensic discipline will be sufficient to solve every type of crime, a decision was made in July 2017 to include other forensic disciplines, such as Toxicology, Fire arms, Tool marks, Trace evidence, Fingerprint, Digital Forensics and Questioned Documents. In phase 2 of LSD&FC development, the Toxicology and Chemistry disciplines, together with a center administration, and training sections will be established. It is expected that in phase 3, the remaining forensic disciplines will be established as needed between 2020 and 2023.

4 Ethics, Impartiality, and Confidentiality

4.1 Ensuring Ethical and Professional Practice

The LSD&FC Management recognizes the importance of ethical and professional practices of its personnel as it relates to the quality and reliability of the analytical work conducted at the Center. Consequently, LSD&FC Management has created a policy titled LSD&FC Code of Ethics and Conduct. This policy incorporates the ***ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists.*** The contents of this document (see Appendix A) shall be reviewed annually by all personnel and the review shall be documented on the ***ASCLD/LAB Guiding Principles Review Form*** (LSD&FC Form #QAC 002).

4.2 Impartiality

4.2.1 Preventing Conflicts of interest

All laboratory personnel will avoid conflicts of interest including involvement in activities that would diminish confidence in their competence, impartiality, judgment or operational integrity.

Laboratory personnel will not alter data. This does not preclude the issuance of an amended report when necessary and only with the concurrence of the Center Director.

There may be instances when customers may request that their case take priority over all others. In any of those instances, analysts will prioritize their work based on one or more of the followings:

- Discussion with his/her supervisor;
- Instruction received from his/her supervisor;
- Compliance with laboratory prioritization guidelines;
- Consideration that the integrity of the evidence is not compromised.

In rare instances, an analyst may be a relative, friend, or romantic partner of an individual involved in a case. In this event, the analyst will immediately inform his/her supervisor and ask that the case be assigned to another analyst.

4.2.2 Preventing Undue Influence:

The LSD&FC has a parent organization, the Lagos State, that does not perform activities such as forensic and DNA testing. Though the Center Director reports to the State of Lagos executive management, the Center Director has sole authority for making final decisions on the Management, Scientific and Technical issues concerning the Center.

The Center Director recognizes that laboratory staff are under competing demands and evidence is assigned for examination based upon careful evaluation of the followings:

- Court Date
- Severity of the crime
- Request for investigative leads
- Availability of manpower
- Probative value of the submitted samples

- Customer's requests

Under no circumstances will the quality of the work be sacrificed to meet a quota of cases to be worked or to meet a deadline.

Undue influence maybe placed on LSD&FC staff by customers requesting that data may be interpreted or reported in a way that allows misuse or misinterpretation of the provided information. Analysts shall follow LSD&FC policies and procedures to ensure that information in reports or presented in court is accurate, clear, unambiguous, and objective. In addition, analysts will ensure that all opinions are supported by examination and analytical documentation. Analysts are encouraged to request assistance, if needed, from supervisor(s) in resolving requests from customers that require them to violate LSD&FC policies and procedures.

4.3 Ensuring Confidentiality:

LSD&FC will protect the confidential information of customers including the electronic storage and transmission of results.

All LSD&FC Staff sign confidentiality and non-disclosure agreements and will maintain confidentiality with all information obtained in performance of their duties. Results will be released only to the client, which could be the customer or to the courts. The release of test results to anyone other than the entity identified on the evidence receiving form requires the written permission of the Center Director and/or a judicial order. Such documentation will be filed with the case record.

Violation of this policy may result in formal discipline, including discharge from employment.

5 Structure: Management and Authority

5.1 Overview of Organization

The Lagos State DNA & Forensic Center (LSD&FC) was incorporated in Nigeria on the 24th of May 2018 under the Companies and Allied Matters Act 1990. The Registered Office is 48 Broad Street, Lagos Island, Lagos, Nigeria. LSD&FC provides Forensic Services to support law enforcement, the judiciary, investigators and the public. Currently, only the DNA and Forensic Biology section is in operation. A forensic science committee at the Ministry of Justice provides oversight.

Management Team

The organization of the DNA and Forensic Biology section is illustrated below (Figure 1). The management team consists of the:

- Center Director
- DNA Section Director
- Quality Manager
- DNA Technical Leader
- Office Manager
- ICT Manager

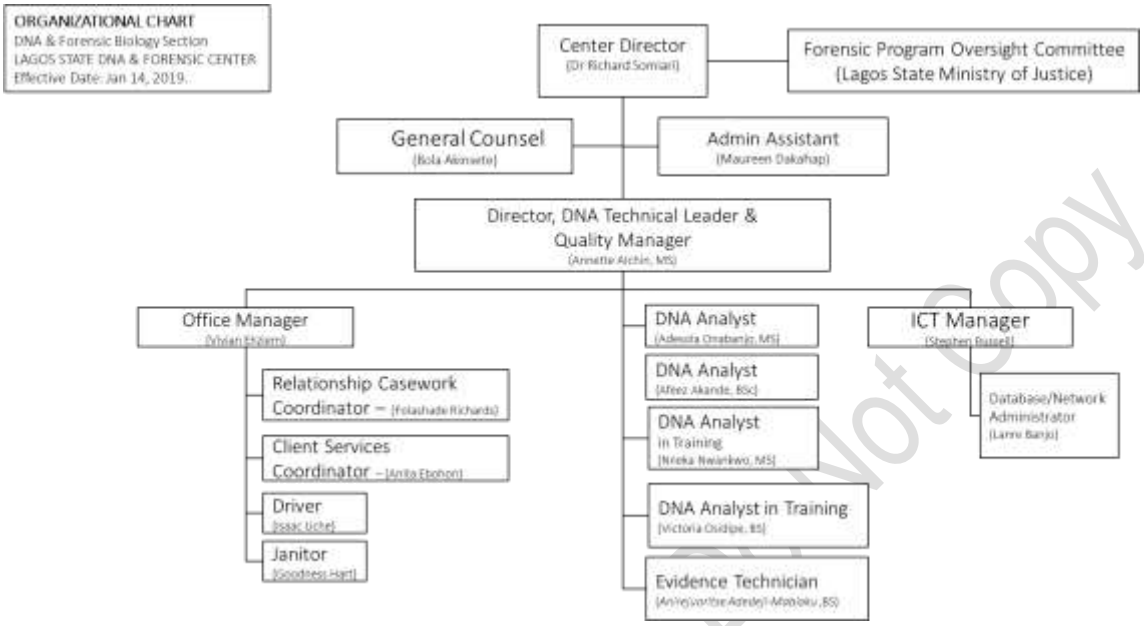

Figure 1: DNA & Forensic Biology Section Organizational Chart

5.2 Responsibilities and Authority

This section describes only LSD&FC management team. It also describes authority of personnel and lines of communication to ensure the effectiveness of the management system.

The Health and Safety Program shall be assigned to a senior analyst within the section.

5.2.1 The Center Director

LSD&FC Center Director:

- Provides the highest level of management, administrative, accounting and quality oversight at the Center.
- Selects and assigns staff in hiring and promotion.
- Direct disciplinary actions that may include counseling, demotion, or discharge of personnel.
- Set priorities and direct the work of subordinate personnel

- Evaluates and verifies employee performance through the review of annual goals and objectives
- Identifies personnel development and training needs and ensures that training is obtained
- Conducts staff meetings to discuss operating problems, organization, budgetary and supplies matters, technical problems or achievements, case metrics, customer feedback, and status of programs and projects
- Formulates and executes plans, procedures, and priorities designed to improve laboratory operations and services within the geographic region
- Serves as the LSD&FC principal liaison with law enforcement agencies within the geographic region; establishes and maintains cooperative working relationships with community agencies and organizations, courts, attorneys, medico-legal professionals, and news media on matters relating to the center's practices, directives, requirements, and abilities.
- Informs subordinates of new or revised policies, procedures, law court decisions, and other information which may affect the performance or practice of the center's work.
- Conducts yearly management reviews and reports pertinent information to the accrediting body.
- Manages the political, administrative, business, and technical affairs of the center.
- Ensures the proper, efficient and economical care, custody and usage of the State of Lagos owned, leased or maintained property and equipment assigned to LSD&FC.
- Select suppliers and ensures that supplies are in sufficient quantity to meet the operational needs of the center.
- Monitors personnel activities to ensure compliance with policies and procedures. Intercedes in case of deviance from policies.
- Assigns normal or special duties to LSD&FC Personnel.
- Serves as the liaison with LSD&FC Facility Maintenance Division to ensure proper maintenance and repairs.

- Formulates and executes plans, procedures, and priorities designed to improve the center's operations.
- Develops budget recommendations for capital outlay, personnel services, equipment, and materials
- Ensures security of all records and files as required by the State of Lagos Laws and Procedures, accreditation requirements, or other directives.
- Ensures security of all evidence and DNA samples in the custody of LSD&FC.
- Ensures proper documentation of examination results and the proper transmittal of those results to the submitting authority.
- Ensures the availability of LSD&FC personnel for court testimony regarding the results of their examinations of forensic evidence and DNA testing.
- Performs administrative review of reports or designates person to perform the task.

5.2.2 The Section Director

- Maintains discipline and ensure the proper performance of duties of all personnel assigned to the section and will perpetuate the direction and policies of the Center Director.
- Makes written notice to the Director when any personnel assigned to the section willfully violates any policy or upper management directive.
- Makes written recommendation to the Centre Director for promotion, demotion, disciplinary action or discharge of any staff serving under his/her supervision.
- May, at the direction of the Director, participate in the interview process for applicants for positions within the Laboratory.
- Issue sectional memoranda to disseminate information to section personnel useful in the performance of their duties.
- Is responsible for the proper and efficient use of all equipment and supplies issued to and used by section personnel and for the maintenance of such equipment and supplies in sufficient quantity to meet the operational needs of the section.

- Is responsible for the maintenance and security of all section records and files that are required by Center's policies or other directives.
- Is responsible for the assignment of normal or special duties to section personnel.
- Ensures that all newly appointed personnel within the section receive introductory and ongoing training in their area of expertise.
- Is responsible for the management of the quality assurance program within his/her section including proper distribution and completion of external and/or internal proficiency testing
- Recommends to the Center Director a person assigned to the section to serve as acting section director in his/her absence.
- Is responsible for maintaining the chain of custody on submitted evidence.
- Ensures that evidence is stored properly and protected from deleterious changes.
- Is responsible for proper documentation of examination results and the transmittal of those results to the customer.
- Ensures that ISO 17025 Accreditation requirements are instituted and maintained
- Directs and manages caseload and turnaround time.
- Overseas section specific databases, if applicable
- Performs administrative and technical reviews of reports.
- Issues reports and provides expert testimony.
- Ensures compliance within the section with applicable safety rules and regulations.
- Prepares a monthly case metrics reports and provides this report to the Centre Director.
- Prepares a monthly budget report for the Centre Director that includes expenditures for equipment, consumables, repairs, and calibration or maintenance of instruments.
- Is responsible for instructing law enforcement officers in the proper identification, collection, and submission of evidence as it relates to his/her area

of expertise and may designate other personnel assigned to the section to perform instructional duties, as needed.

- Performs all other duties as directed by the Center Director.
- Report directly to the Center Director.

5.2.3 The Office Manager

- Manage the Office and coordinate business development.
- Setup, direct and participate in all business activities.
- Provide leadership, guidance and support for all staff.
- Prepare and present business and financial reports to management.
- Ensure that the office runs efficiently, and all the needs of the technical team are fulfilled.
- Provide input, support and roll-out for corporate initiatives at all levels.
- Provide administrative support.
- Perform other duties as assigned by senior management
- Report to the Section Director.

5.2.4 The DNA Technical Leader

- Manages and is accountable for the technical operations of the Biology/DNA laboratory
- Evaluates all methods used by the DFB laboratory and proposes new or modified analytical procedures to be used by analysts
- Solves technical problems of analytical methods. If necessary, requires the suspension of analyses using a particular assay or procedure until the problem can be resolved.
- Has the authority to initiate, suspend, and resume analytical operations for the laboratory or an individual
- Participates in the annual review of the quality system.

- Reviews corrective and preventive actions
- Reviews internal and external audits documents and, if applicable, corrective actions to ensure that findings, if any, were appropriately addressed.
- Assists the section director and quality manager in managing and implementing the section's training and quality assurance programs.
- When hiring experience analysts/technicians, the technical leader shall be responsible for assessing their previous training and ensuring it is adequate and documented. Modification to the training program may be appropriate and shall be documented by the technical leader.
- Prepares validation plans
- Directs validations of new methods
- Evaluates and document approval of all validations and methods used by the DFB Section.
- Proposed new or modified analytical procedures to be used by analysts.
- Report to the Section Director.

5.2.5 The Quality Manager

The title Quality Assurance/Quality Control Manager and Quality Manager is used interchangeably throughout this manual.

- Accomplishes quality assurance human resources objectives by helping recruit qualified employees and ensuring that all employees are adequately trained,
- Communicate job expectations; planning, monitoring, appraising, and enforcing policies and procedures.
- Achieves quality assurance operational objectives by contributing information and analysis to strategic plans and reviews; preparing and completing action plans; implementing measures that improve productivity, quality, and customer-service

standards; identifying and resolving problems; completing audits; determining system improvements; implementing change.

- Meets quality assurance financial objectives by estimating requirements; preparing an annual budget; scheduling expenditures; analyzing variances; initiating corrective actions.
- Develops quality assurance plans by conducting hazard analyses; identifying critical control points and preventive measures; establishing critical limits, monitoring procedures, corrective actions, and verification procedures; monitoring inventories.
- Validates quality processes by establishing specifications and quality attributes; measuring production; documenting evidence; determining operational and performance qualification; writing and updating quality assurance procedures.
- Prepares quality documentation and reports by collecting, analyzing and summarizing information and trends including failed processes, stability studies, recalls, corrective actions, and re-validations.
- Updates job knowledge by studying trends in and developments in quality management; participating in educational opportunities; reading professional publications; maintaining personal networks; participating in professional organizations.
- Enhances department and organization reputation by accepting ownership for accomplishing new and different requests; exploring opportunities to add value to job accomplishments.
- Reports to the Center Director.

5.2.6 The ICT Manager

- Supervise Database and Network Administrators
- Managing information technology, software and computer systems,
- Evaluate, organize, plan & control IT related electronic data operations,

- Ensure the security and integrity of the data, the network and access to the network as well as its back-up system,
- Manage the laboratory's phone/intercom system,
- Train laboratory staff and administration on the use and maintenance of the server and software applications available within the laboratory,
- Oversee troubleshooting of IT systems, computers, equipment, system back-ups, archiving and disaster recovery,
- Provide expert support when needed,
- Suggest and manage the purchasing of software, hardware and other IT related supplies,
- Suggest areas for IT improvement
- Maintain and present system status reports to management.
- Reports to the Section Director.

Note: all above-listed positions can be assigned to a designee by the Center Director. The designee(s) will have the specific skills and/or expertise to carry-out the duties for the temporary assignment.

5.3 Center Activities:

The LSD&FC provides the following services to its customers at its permanent location on 48 Broad Street, Lagos:

- Examination of items of evidence for the presence of human body fluids that include blood and semen.
- DNA analysis of items of evidence and reference samples through Short Tandem Repeat (STR) Analysis.
- Comparison of DNA profiles between reference samples and evidentiary items.
- Issuance of reports for all above-listed activities.
- Provision of court testimony as needed.

5.4 Quality System Documents:

5.4.1 Internal Documents

The Quality Manual is the overarching document describing the Center's operations. Other internal quality system documents include:

- Section Technical Procedure Manuals.
- Section Training Manual.
- Safety Manual.
- Center Administrative Policies and Procedures.
- Information Technology Policies.
- Forms and worksheets.

5.4.2 External Documents

Examples of external documents include but are not limited to:

- ISO/IEC 17025:2017 (E).
- A2LA Accreditation Requirements.
- SWGDAM Validation Guidelines.
- SWGDAM DNA Interpretation Guidelines.
- ASCLD/LAB *Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists*.

5.5 Communication:

Managerial and supervisory staff shall ensure that appropriate communication occurs with subordinate staff. This communication may be accomplished in many different ways including but not limited to the following:

- Weekly staff meetings;
- Emails;
- Text messages;

- Technical meetings.

This communication shall include implementation and effectiveness of the quality system.

6 Resources

6.1 Personnel and Training:

6.1.1 Policy

This policy applies to LSD&FC employees and staff under contract to the Center. The knowledge, skills, abilities, education, continuous training and on the job experience of personnel are essential to achieving quality results. LSD&FC management shall ensure the competence of all personnel who operate specific equipment, perform tests and/or calibrations, evaluate results, provide a conclusion based on those results. Personnel shall be qualified on the basis of relevant education, training, experience, and/or demonstrated skills.

The Center shall provide adequate supervision of testing staff, including trainees, by individuals familiar with methods and procedures, the purpose of each test, and with the assessment of the test. Each subordinate shall be accountable to one and only one immediate supervisor per category of testing.

The Center shall have personnel who can provide technical management with overall responsibility for the technical operations and the provision of the resources needed to ensure the required qualify of the center's operations. The technical leader assigned to each section is responsible for the technical work in the section. The Section Director is responsible for the provision of the resources needed to ensure the required quality of the section's operations.

Upon completion of training, personnel shall be able to carry out the duties outlined in their job description. Training programs shall be relevant to the present and anticipated tasks.

The Center shall provide to new employees assigned to the laboratories an orientation session covering administrative practices, Ethics, Impartiality, Confidentiality, IT, Safety, and Security Policies.

Each section of the Center shall have a training program coordinated by the Director and Technical Leader assigned to the section. The training program shall include a training manual(s) outlining goals and objectives, a general outline of the training material, a check-list that indicates completion of training and review by the Technical Leader. In addition to technical components specific to the section, this program shall incorporate LIMS training and court testimony. The quality manager shall maintain a training file for each staff member. The training file shall include:

- University Transcript(s)
- Copies of Diploma(s)
- Current Curriculum Vitae (updated yearly)
- Statement of Qualifications
- Training records (training outline and training check-lists)
- Work Authorization
- Continued Education

Staff previously trained at a facility other than LSD&FC shall be assessed by the technical leader to ensure that the training was adequate. A modified training program is acceptable insofar as it is recorded by the technical leader and approved by the section supervisor, quality manager, and LSD&FC director.

The trainee, regardless of previous technical qualifications, shall successfully demonstrate competence in the relevant categories of testing prior to conducting independent casework.

Experienced personnel shall routinely participate in a program of continued education and literature review specific to their area of work.

The effectiveness of the training program shall be evaluated annually as part of the annual management audit.
Additional information can be found in the LSD&FC SOP titled *Personnel Management*

6.1.2 Position Requirements and Job Descriptions

The Center Director shall establish the following for each position:

- Educational Requirements
- Knowledge and Skills
- Experience, if required
- Certifications and/or licenses, if required
- Roles, responsibilities and authority

The Center Director is responsible for selecting personnel for specific positions. The selection shall be based on the following:

- The individual meets the educational, knowledge, and skills requirements as described in the job description
- The individual underwent a job interview to assess that the individual has good communication skills and would be a good fit for the position.

A copy of each current job description shall be maintained on-file by the Office Manager. The current job description shall be communicated to personnel and the quality manager.

6.1.3 Personnel Evaluations:

Personnel evaluations are performed annually by the employee's direct supervisor and reviewed by the Center Director for final approval.

The following elements shall be appraised:

- Ability to work independently
- Adherence to policies and procedures
- Observance of Health & Safety
- Communication Skills
- Customer Service
- Punctuality
- Quality of work
- Professional behavior
- Presentation of reports

  Suggestions for improvement

The supervisor will meet with the employee and discuss content of the performance appraisal. The supervisor will provide the employee with a list of goals and objectives to be met for the next performance appraisal period. The employee will have the opportunity to discuss content of all documents presented to him/her.

6.1.4 General Training

All newly hired personnel will go through a new employee orientation program that includes:

- Tour of the facility

- Introduction to all personnel including key management personnel and lines of authority
- Introduction to new specific tasks or duties & job description.
- Security.
- Health and Safety.
- Ethics.
- Confidentiality of records and documents.
- Instruction on how to access LSD&FC administrative policies and procedures.
- Proper usage of email.
- Work attendance.
- How to find necessary resources.
- Answering customer enquiries.

This orientation will be documented with in the LSD&FC New Employee Orientation Checklist (LSD&FC Form # Adm 001).

6.1.5 Technical Training

LSD&FC ensures the competence of technical personnel who operate equipment, perform tests, evaluate results, and sign reports through a variety of measures including the following:

- Using documented training programs that are appropriate for the test or method and that culminate in competency testing;
- Using an employee development program;
- Hiring appropriately skilled and/or educated personnel.
- Providing access to appropriate literature resources.

The technical leader assigned to the section is responsible for the establishment and maintenance of a formalized technical training program. Each training program will be described in a Section Training Manual.

Technical training programs shall include essential elements such as the following:

a) List of topics and skills to be addressed.
b) Description of the training process (e.g. on-line training, literature, demonstrations, practical exercises, supervised practice, moot court, etc.)
c) Milestones of achievement to the specific training program
d) Description of how theoretical and practical competency will be demonstrated
    - Description of the practical competency tests (i.e. extraction of x number of blood samples etc.)
    - Report writing
    - Written or oral knowledge tests including standard for successful performance (i.e. passing grade of 80%)
    - Responsibility for evaluating performance
e) Description of training documentation which includes:
    - Description of the training documentation to be included in the individual's training file
    - Description of how required elements will be documented. This documentation shall include dates of training and acknowledgement from the trainee, instructor, section technical leader, and section director
f) Issuance of a certificate for the successful completion of training dated and signed by the technical leader. Multiple certificates maybe issued if the training consists of separate modules.
g) A program for individuals with prior training and experience in the discipline. This program shall be specifically designed for the individual based on his/her prior training and experience. This program may be limited to a practical demonstration of competency, report writing, and a moot court.
h) An individual specific remedial training program when it is determined that an analyst (or other technical staff) needs remedial training. This determination

could arise from a corrective action, a preventive action, or a customer complaint. The remedial training shall include the essential elements “a through f” as described above.

The analyst will be presented with a written remedial training program and will be required to acknowledge this document. In addition, the analyst will be informed of possible actions to be taken by management in case of failure to successfully complete the remedial training and demonstration of competency. Upon successful demonstration of competency, the training file shall be reviewed by the trainee, instructor, technical leader, and section director.

6.1.6 Work Authorization

The Center Director authorizes personnel who have successfully completed a training program to perform work within the discipline, sub-discipline, or methodology covered by the training program. The LSD&FC Work Authorization Form (LSD&FC Form QAC #018) shall serve as documentation of this authorization.

Specifically, completion of a training program authorizes the analyst to independently:

- Perform all methodology covered in the training program and documented in the section training manual;
- Operate all equipment covered in the training program and documented in the section training manual;
- Issue test reports;
- Give opinions and interpretations;
- Perform technical reviews; and
- Testify in court.

Note: an authorization may be issued for only one or several of the above listed functions. For example, an individual may be authorized to perform a methodology, operate equipment, but not issue test reports.

6.1.7 Continuing Education and Training

LSD&FC supports continuing education to maintain skills and expertise of personnel by encouraging personnel to continually develop/enhance relevant knowledge and skills. LSD&FC will, when possible:

- Support professional organization affiliation and participation;
- Support presentations at professional meetings;
- Provide personnel available information on training courses and seminars for personal career development;
- Provide discipline-relevant internal and/or external training;
- Provide access to discipline specific literature

Management and personnel are encouraged to set aside time to review current literature, participate in webinars, perform on-line searches of specific topics, present at technical meetings, and participate in university and other specialized courses.

Such activities are dependent on the availability of resources and will be coordinated by management.

Requests for meeting attendance, purchase of new literature, participation in specialized courses, or any other form of continued education that requires funding, will be submitted in writing to the center director through the section director. Requests will include cost estimate including time to be spent by the attendee out of the laboratory. The Center Director will evaluate each request to determine if this would benefit both the employee and the Center.

Employees are responsible for procuring records documenting participation in continued education and training and forwarding these records to the Quality Manager to be added to their personal training file.

6.1.8 Literature Review

Section Directors shall maintain or provide access to relevant books, journals, and other forensic literature specific to their discipline to technical personnel. Personnel shall document the review of relevant forensic reading material on the LSD&FC Literature Review Form (Form # QAC 014).

6.2 Facilities and Environmental Conditions

6.2.1 Policy

LSD&FC shall provide adequate, safe, and secure facilities, equipment, and supplies for its employees. Environmental conditions that may affect the quality of results will be addressed in section-specific manuals. Facility functions such as energy sources, lighting, water supply, heating and cooling, and environmental conditions will be monitored by the facility maintenance manager to ensure correct performance.

6.2.2 Facility Criteria

- Employees will have adequate work space for technical and administrative functions
- Sufficient space will be provided for storage of supplies, equipment, and tools
- Sufficient space will be provided for long and short-term storage of records, reference works, literature, and documents
- Work areas will be designed to permit efficient workflow of evidence from the time of its receipt to return

- Adequate space will be available for each instrument, and for the nearby storage of accessories and supplies
- Airflow and space allocation/separation will be designed to minimize or prevent cross contamination.
- Laboratory areas will be separate from common/office areas
- Adequate lighting, plumbing, heating, cooling, and ventilation will be provided. This includes hoods and biological safety cabinets.
- Each Section's entry and exit points will be controlled by digital access controllers that require a 4-digit code and access card.
- The Center will be secured 24/7 by means of physical security monitoring and surveillance cameras located at strategic locations.
- Work areas will be cleaned weekly. A cleaning log will be maintained for each area of the Section where evidence is processed and items of evidence are analyzed.
- Trash will be collected daily during business hours.
- Biohazard will be disposed of at least monthly or sooner based on volume generated.
- Appropriate receptacles will be provided for disposal of biohazard and sharps.
- Technical personnel shall always be mindful of the potential for cross-contamination. The following measures shall be followed by all personnel to avoid cross-contamination:
    - Gloves shall be worn at all times when handling items of evidence and reagents
    - Lab coats shall be worn at all times in the evidence processing and analytical areas
    - Lab coats and equipment assigned to post PCR areas shall not be used in other areas of the Center.

- Each item of evidence shall be processed separately in time and/or space from other items of evidence.

6.2.3 Security

- Personnel access to, and within, the Center is controlled by access systems employing keys and a combination of access cards/code unique to a specific access card. These security measures are augmented by a closed-circuit television system.
- The Center Director is responsible for granting access to each employee to specific areas of the Center. The Center Director will maintain or designate employee(s) to maintain logs of keys and combination locks. The Center Director will grant access to employees for specific areas of the laboratory and communicate this information to the ICT Manager on the LSD&FC Access Authorization Form (LSDFC Form # Sec 007) for proper setting of access cards. Any unassigned keys or cards will be stored in a secure area with access limited to the Section Director and Center Director.
- Employees shall be responsible at all times for ensuring the safekeeping of their assigned keys and/or access cards. Employees are strictly forbidden from loaning/giving their assigned access keys and/or cards, combination codes to any other person including other employees of LSD&FC.
- The loss or theft of any key, access card, or written or electronic record of combination code shall be immediately reported to the Center Director or Section Director.
- Any employee leaving employment through resignation or termination shall immediately return all LSD&FC access media to the Center Director or Section Director.

- All employees will be assigned an employee identification card by the Center Director. This card will be worn at all times for proper identification by security personnel. In the event that this card is lost or damaged, the Center Director will be notified in writing immediately.
- Visitors will be issued a visitor's badge upon being granted access to the facility. Further information on this policy is available in the LSD&FC Visitor's Policy.

6.2.4 Safety

A forensic analyst shall be designated by the Center Director as the Safety Officer and shall be responsible for the implementation of the Center's Health and Safety Program. The Safety Officer shall ensure that all laboratory personnel follow the Safety program. The Safety Officer shall conduct an annual safety audit to ensure that:

- All safety equipment is operational;
- First aid kits are fully stocked and placed in strategic areas;
- Fire extinguishers are inspected and are placed in strategic areas;
- All personnel participated in at least one fire drill and received instruction on how to use a fire extinguisher;
- All new personnel received instruction on safety and chemical hygiene;
- Safety incident (s) have been adequately addressed and documented;
- Exit routes are clearly marked and unobstructed.

The annual safety audit and recommendations for improvement shall be forwarded to the Center Director to be included in the Annual Management Review.

6.3 Equipment

6.3.1 Policy

The terms "equipment" and "instrument" are used interchangeably throughout this chapter. The Center shall ensure that equipment is adequate for the work to be performed. This includes proper maintenance as per manufacturer recommendation. The Center shall also ensure that instruments used to perform measurements are verified and/or calibrated according to a pre-determined schedule. The Center shall follow the A2LA Policy on Measurement Traceability for Life Sciences Testing and Forensic Conformity Assessment Bodies for all calibrations and verifications of measurement and test equipment.

6.3.2 General Requirements

6.3.2.1 Inventory:

Each analytical section shall maintain a list of equipment and software significant to the tests performed. The list shall contain the following information:

- The identity of the equipment and software;
- The location of the equipment;
- The manufacturer's name, type or model information and serial number or another unique identifier;
- Reference to preventive maintenance, verification, or calibration schedule and due date;
- Equipment that is currently "out-of-service" or "Not in Use".

The inventory of equipment shall be maintained and updated by the quality manager assigned to the section. The inventory of software shall be maintained and updated by a designee.

6.3.2.2 Maintenance Procedures:

- Equipment shall be maintained in working condition.

- Equipment shall be handled, transported and stored in a manner to prevent contamination or deterioration.
- Equipment not in working condition or not in use shall be clearly marked as “Not in Use”.
- Maintenance procedures for equipment are defined in the Section ***Equipment and Instrument SOP.***

The Equipment and Instrument *SOP* shall include*:*

- A list of the equipment, maintenance requirements for each, and how this maintenance will be documented;
- A list of reference materials, measurement standards, and reference data required for the correct performance of equipment.
- Procedure for verification of conformance to specific requirements after maintenance or repair of equipment;
- Validation or verification requirements after installation of a new piece of equipment and prior to utilization for casework.

All repairs and routine maintenance performed on instruments and other analytical equipment shall be documented. This documentation will be kept in a log book.

Any potential problems with any equipment shall be immediately addressed by technical personnel utilizing the equipment. If appropriate steps do not correct the problem, the issue shall be immediately reported to the supervisor. The issue shall be documented in the equipment log book. In the event that the problem cannot be corrected immediately, the equipment shall be clearly marked “out of service” until the issue is resolved.

6.3.2.3 Equipment Calibration and verification

Calibration and verification requirements for equipment are defined in the Section *Equipment and Instrument SOP.* The terms verification and control checks are used interchangeably in this section.

The Equipment and Instrument SOP shall address equipment calibration and verification and shall include:

- A list of designated equipment subject to a schedule of calibration or verification;
- The time interval for calibration or verification;
- A procedure and list of supplies, reagents, certified reference materials, or other material required for verification:
- Measuring equipment such as balances, thermometers, and pipettes shall be calibrated by an external company that is accredited to ISO/IEC 17025 with a scope of accreditation covering calibration and that is accredited by an ILAC MLA signatory. In the event that this requirement cannot be fulfilled, the Center may use a National Metrology Institute or a non-accredited laboratory insofar as this NMI or laboratory meets the following:
  - use calibration reference standards traceable to SI units;
  - issue a calibration report for the measurement result that includes the associated measurement of uncertainty.

Appropriate documentation from any evaluations conducted or from any in-house activities performed shall be maintained by the section quality manager.

6.3.2.4 Reference Standards

The Center shall ensure that the following reference standards have appropriate calibration certificates:

- NIST-Traceable thermometers
- NIST-Traceable weights

Upon expiration of calibration, the NIST Traceable thermometers shall be replaced with thermometers meeting the same calibration requirements
The NIST-Traceable weights shall be re-calibrated no later than the date specified by the calibration laboratory that performed the last calibration. This calibration laboratory shall be accredited to ISO /IEC 17025 Standards.
All calibration documentation shall be maintained by the section quality manager.

6.4 Externally Provided Products and Services

6.4.1 Purchasing*:*

The Center will purchase supplies or procure services of the quality specified by the section director or technical leader in appropriate documents.

6.4.2 Specification of Supplies and Services*:*

Personnel shall follow the Center's policy and procedure with respect to the procurement of supplies and services. Specifically, for supplies and services that affect the quality of the tests and/or verification checks conducted by the laboratory. The following procedure shall be followed:

- Section directors and/or technical leaders shall identify critical supplies and services. Critical supplies and services are those that require a quality assurance check of the supply or equipment prior to use in

casework. For critical supplies, a certificate of analysis can be used in lieu of a quality check to meet this requirement.

- The section director or technical leader shall provide guidance and input for technical content in the preparation of the *Supply and Service Request Form (LSD&FC Form # Adm 003)*.
- Admin assistant When ordering a supply or service, vendors shall be provided with the specifications of the item or service desired. This information may include the type, class, grade, specific identification such as a catalog number, or other technical information. In the event that the requested supply is no longer available or is out-of-stock, the section director shall be notified immediately.
- Purchased supplies and services shall meet or exceed specified quality levels.
- When available, reference materials will be traceable to SI Units or be certified reference materials obtained from suppliers accredited to ISO Guide 34:2009 or 17034: 2016

- Vendors providing calibration services or preventive maintenance shall ensure that equipment they have calibrated or serviced is labeled with the date of calibration or service and due date for next calibration or service.
- Section directors shall ensure that requests for supplies or services are done in a timely manner to avoid interruption of the Center's activities.

6.4.3 Receipt and storage of supplies

6.4.3.1 Receipt:

Personnel receiving supplies shall perform a physical check of the materials received to ensure that they meet the specifications listed on the Supply and Service Request Form. This check shall be documented on the corresponding Supply and Service Request Form. Discrepancies

will be brought to the attention of the vendor and the supervisor immediately. A supply not meeting established criteria will be discarded or returned to the vendor.

The information that shall be recorded on the bottle or most internal packaging of all purchased reagents and reference material shall include:

- Date of receipt;
- Initials of the person receiving the supply;
- The expiration date determined by the laboratory (See "LSD&FC Reagent Formulary SOP"), if none is provided by the manufacturer,
- Date of the quality control check and initials of the person who performed the quality control check for critical reagents.

6.4.3.2 Storage:

Supplies will be handled, transported, stored, and used in a manner that maintains their quality and prevents contamination. This may include storage in a temperature and humidity-controlled storage area or other specific requirements.

Hazardous chemicals will be stored in appropriate storage cabinets.

All reagents and consumables shall be stored and maintained according to the manufacturer's recommendations. In the absence of manufacturer's recommendations, common sense and knowledge of the item being stored may be used to determine the best method of storage.

7 Process Requirements

7.1 Service to the customer

The Center will provide quality services to its customers through the following:

- Maintain good working relationships and clear communications with its customers;
    - Customer communications shall be documented and retained in each case record (ex. emails, phone calls, face-to-face discussions, etc.).
- Clarify any ambiguous request;
- Suggest possible changes to a request to provide added value to the service;
- Communicate any delay in the delivery of the requested service;
- Provide training sessions or present at stake holders seminars in technical matters such as proper evidence collection, new technologies, and other relevant topics;

- Provide explanations of the examinations performed, interpretation of results, and conclusions;
- Seek feedback and suggestions from customers to improve its quality system.

7.2 Review of requests, tenders and contracts

7.2.1 Request(s) acceptance criteria

The service request(s) shall meet the criteria listed below before work can be accepted:

Request for forensic services shall only be accepted from representatives of law enforcement, military, embassies, and public safety agencies (e.g. the Lagos State Domestic and Sexual Violence Response Team, fire departments, police agencies, Department of Health, registered Non-Government Organizations) or the Office of the Attorney General.

Request for forensic services directly from defendants and/or their counsel will not be honored unless ordered or approved by the Office of the Attorney General.

Request for forensic services from law enforcement, military, embassies and public safety agencies operating outside the State of Lagos may be accepted

upon approval by the Center Director or the execution and approval of a signed contract that includes financial reimbursement for the services provided.

The Center may not accept evidence for the purpose of conducting a re-examination unless the customer requests a different type of analysis from the one originally performed and, under the condition, that this analysis would provide added value to the case.

The Center may not accept evidence previously examined by another laboratory. The Center will make a concerted effort to accommodate the customer's request to evaluate the laboratory performance in relation to its testing activities insofar as this process would not result in a breach of confidentiality, jeopardize the integrity of evidence, or disrupt the efficiency of the Center's operations.

7.2.2 Contracts

The Forensic Case Submission Form (LSD&FC Form For #002) is used for evidence submission and represents the contract for testing between the customer and the Center. The Forensic Case Submission Form shall be retained in each case record.

Court ordered examinations are contracts between the court and the Center.

The Center shall notify the customer if it does not have the resources to perform the requested testing; if the requested test is inappropriate; or if it is out-of-date. This notification shall be documented in the case record.

The following statement on the Forensic Case Submission Form constitutes an agreement between the customer and the Center:

"The customer agrees that the Lagos State DNA & Forensic Center will choose the appropriate course of analysis based on several criteria, including, but not

limited to the type of evidence submitted, the requested analysis, and the technology available to its technical personnel. The appropriate course of analysis may include sending the evidence to a subcontracting laboratory. If this course of action is selected by the Center, the customer will be notified prior to submission of the evidence to a subcontracting laboratory. The Center will work with the customer in clarifying request (s) for analysis, if necessary, and will maintain communication with the customer regarding the completion of the analysis."

Any differences between the contract and the customer's request shall be resolved prior to initiation of casework. Any request from the customer that represents a deviation from the contract shall be carefully reviewed by the Center Director to ensure that it will not impact the validity of the results or the integrity of the Center. Deviations shall be approved by the Center Director and such approval shall be documented in the case record.

7.2.3 Procedure for the review of requests:

The analyst assigned to the case shall review the Forensic Case Submission Form and record their signature and the date of review. This review encompasses acknowledgement of the contract terms for analysis with the customer. If at any time in the course of analysis it is determined that there are any significant changes to the original contract, these changes shall be documented and retained with the case record. Furthermore, any pertinent discussions with the customer relating to the customer's requests or results of lab activities shall be documented and retained in each case record. The analyst assigned to the case may proceed to an inventory of the evidence submitted. The analyst shall then use his/her training, expertise, and available resources for the selection of items to be tested and analyses to be conducted on the selected items of evidence. The documentation of the selection of analyses and probative

items is captured in the technical and administrative documentation located in the case record.

Evidence containers shall be examined during this initial review to ensure that they comply with safety standards and the criteria described in the *LSD&FC Evidence Handling and Submission* SOP. Any item that is not properly packaged and could contaminate other items of evidence during storage shall be packaged in a secondary container or bag that shall be marked with the case number and initials of the individual repackaging the item of evidence. This process shall be documented in the casefile. The customer shall be informed if the integrity of an item of evidence has been lost because of improper packaging and is no longer suitable for examination.

In some instances, an additional review and communication with the customer may be necessary to determine the probative value of evidence submitted or to clarify the customer's request. This communication may be documented in the Phone Contact Form (LSD&FC Form #012) or other appropriate media such as an email printout and stored in the case file.
The above-listed procedure shall be repeated if the contract is amended after analysis has commenced. A record of this change shall be documented and stored in the case file.

7.2.4 Subcontractors

- The Center shall select subcontractors competent to perform forensic testing. Competence is defined by ISO 17025 accreditation through an accrediting body which is a signatory of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for Testing.

- The Section Quality Manager shall maintain a list of all subcontractors used for testing including supporting documentation of competency.
- If requested, the customer shall be informed of the subcontractor that is selected to perform any service.

7.3 Methods

7.3.1 Selection

Generally accepted methods or standards in the forensic community shall be selected. Supporting documentation shall be available for the selected methods and shall be maintained by the technical leader assigned to the section.
In-house development of methods shall be performed by qualified personnel for such activities and supported by appropriate data gathered and recorded in a scientific manner. Data shall support that the method is fit-for-purpose through an appropriate range of certified reference standards/material and mock samples. Records shall be maintained by the section quality manager.

7.3.2 Validation and Verification of Methods

- New methods, new equipment, significant modifications of existing methods, and significant modifications to equipment (hardware or software) shall be validated or verified, as appropriate, prior to their first use for casework analysis.
- Management must ensure that adequate resources and staff is assigned to the validation or verification project.
- Minor modifications shall be evaluated to determine the effect on the accuracy and precision, if applicable, or on the validity of the test results.
- A validation or verification plan shall be prepared by the technical leader and reviewed by the section director prior to execution. The plan shall include a description of the samples to be used during the study. Known

and/or previously characterized samples shall be used for the study. The plan should include acceptance criteria.

- The validation or verification plan shall include evaluation of performance characteristics relevant to the applications of the new method or equipment. Performance characteristics may include any combination of the following:
  - Precision using reference standards or reference materials
  - Sensitivity
  - Specificity
  - Repeatability
  - Reproducibility
  - Limit of Detection
  - Limit of Quantitation
  - Linearity
  - Uncertainty of Measurement
  - Cross-Contamination
  - Matrix interference

New procedures validated or verified to replace existing ones shall generate comparable or better results to the previously used method.

The Section technical leader shall review all data from validation and verification studies and determine if the new method or equipment is fit for use on casework. This evaluation shall be documented and retained with the validation or verification records. The evaluation shall be forwarded to the section director, quality manager and Center Director for approval prior to implementation.

7.3.4 Documentation

Methods used in each Section shall be documented in Standard Operating Procedures (SOPs) and accessible to technical staff assigned to the Section through the Center's file server. The Technical Leader assigned to the section will work with the Quality Manager for the generation, maintenance and revision

of the SOPs. The quality manager assigned to the section shall ensure that all SOPs are controlled.

- The current version of the LSD&FC SOP titled "Procedure Writing Review & Revision" shall be used for the revision of an existing SOP or the drafting of a new SOP.
- Each section shall maintain the analytical data supporting the validation of new methods in use on casework.
- Each section shall maintain the analytical data generated throughout the verification of new equipment that is not part of a new method.

7.3.5 Training

Technical personnel shall be trained, and competency tested on a new method prior to usage on casework.

Training may include:

- Reading material
- Lecture
- Demonstration
- Practical exercise (s) of case-like material

The competency test shall be developed by the technical leader assigned to the section and shall consist of the following:

- An oral or written competency test. This test shall assess the trainee's knowledge of the underlying principles of the new method. The trainee shall demonstrate sufficient technical knowledge to perform the test unsupervised and draw correct conclusions.
- Practical competency test that includes mock case samples. The practical competency test shall include a description of the samples to be tested

and a time-line for completion of the test. All generated data and drawn conclusions by the individual taking the test shall be graded as satisfactory or unsatisfactory. The individual shall obtain the expected conclusion to be deemed competent.

Personnel that participated in the validation, verification, modification or development of a new method shall be deemed competent without proof of competency through a test as described above.

7.4 Sampling

Sampling is not performed in the DNA and Forensic Biology Section. Sample selection guidelines shall be defined in the work instructions for evidence examination. Each sample is treated and reported as a unique sample and not a representative untested sample of a similar appearance. Work instructions shall be available for working at the bench, if needed.

7.5 Handling of Test Items

LSD&FC specifies its practices for the handling of test items in the LSD&FC Evidence Collection and Handling SOP and the LSD&FC Evidence Management SOP.

7.5.1 Chain of Custody

LSD&FC uses a chain of custody form (LSD&FC Form # For 002) to record all external and internal transfers of evidence from the day and time of receipt. This record demonstrates that the item of evidence examined and reported on was that which was submitted to the Center. This chain of custody form identifies each LSD&FC Personnel taking custody of an item of evidence or the location of that item. This form includes:

- A signature or initials, at the time of transfer, of the person/location, receiving evidence:
- The date and time of receipt and transfer;
- The description of the item of evidence being received and the packaging unique identification assigned by LSD&FC upon receipt of the item of evidence.

Any discrepancy between the documentation provided by the customer listing the items being submitted and the inventory performed by LSD&FC at evidence intake shall be brought to the attention of the customer and the section director. Notification to the customer shall be documented in the case file. Upon receipt of the evidence, the condition of the packaging is evaluated and any condition adverse to the quality of the testing to be performed shall be recorded on the LSD&FC Chain of Custody Form (# For 002)

7.5.2 Sub-Items

Sub-items shall be tracked on the appropriate chain of custody form.

7.5.3 Storage of Items

LSD&FC shall ensure the integrity of evidence by protecting items from loss, cross-contamination or deleterious change during storage, handling, and preparation of items according to the LSD&FC Evidence Collection and Handling SOP and the LSD&FC Evidence Management SOP. When Items of evidence require specific environmental conditions for storage or handling, these conditions will be maintained, monitored, and recorded.

All items of evidence not in the process of examination shall be maintained in a secured and limited-access storage area. These items of evidence shall be maintained under proper seal.

Items of evidence in the process of examination may be stored in a secure holding location within the examination area. These items of evidence are

considered to be work-in-progress and are not required to be returned to Secure Evidence Storage Room until after the examination.

All items of evidence shall be marked with a unique identifier. If the evidence itself does not lend itself to marking, its proximal packaging or container shall be marked.

7.5.4 Special Handling

Apparent problems or safety issues affecting the integrity of the evidence (e.g. leaking containers, wet items of evidence, and torn packaging) at the time of submission or examination shall be promptly addressed. Remedial action may include:

- Placing the item of evidence in a secondary bag or container. The secondary bag or container shall be marked with the corresponding unique identifier and maintained under proper seal.
- Placing the wet item in a biosafety cabinet and allowing it to air dry.

Such problems shall be documented in the case file.

7.5.5 Transfer of Evidence

The Chain of Custody Form shall contain a complete transaction history of evidence transfer.

When evidence is transferred within LSD&FC, the individuals who participate in the transfer shall acknowledge the transfer by signing and dating the LSD&FC Chain of Custody Form. The new evidence location shall be recorded on this form.

7.5.6 Evidence Return or Disposition

Evidence may be returned to the customer by courier or may be picked up at the Center. Evidence may also be released directly to an Officer of the Court as directed by a court order.

The standard disposition of evidence shall be by pick-up by the customer within 30 days of receipt of the associated report. LSD&FC may return the evidence via courier per request from the customer. After 30 days, LSD&FC may dispose of the evidence unless contrary instructions are received from the customer at the time of the submission or within 30 days of receipt of the report. Under special circumstances, and if feasible, the item(s) will be securely stored by LSD&FC for twelve months or until adjudication of the case, whichever comes first.
The person receiving the evidence from LSD&FC shall sign for the evidence and record the date on the LSD&FC Chain of Custody Form

7.5.7 Evidence from Field Investigations

- Evidence received or collected by LSD&FC personnel in the field shall be marked and packaged appropriately for the type of evidence at the scene. The evidence shall be separated according to storage requirements. The packaging number, initials of individual collecting or receiving the evidence, and date and time shall be recorded on each bag or container at the time of collection or receipt.
- The analyst receiving or collecting the evidence shall complete a Chain of Custody Form and deliver the evidence to the Center as soon as practical. Evidence shall remain in his/her custody at all times. Upon arrival at the Center, the analyst shall place the evidence in secure storage under proper environmental conditions. Date and time of this transaction shall be recorded on the Chain of Custody Form.

- Evidence shall be transported to the Center under conditions that prevent deterioration, contamination, loss or damage to the item.

7.5.8 Evidence Inventory

- Evidence inventory will be performed at least once in a calendar year to ensure that evidence is properly managed.
- The director assigned to the section is responsible for the accuracy of the evidence inventory under the custody of his/her section.
- All physical inventories will be checked against the Chain of Custody Form located in case files.
- Any discrepancy shall be noted and resolved prior to further custody transaction.
- The completion of the inventory will be documented in the Evidence Inventory Log (LSD&FC Form # For 007) a copy of which should be forwarded to the section director.

7.6 Technical Records

7.6.1 Definition

Technical records are defined as examination documentation as part of individual case files.

7.6.2 Examination Documentation

LSD&FC shall maintain all original examination documentation in a case file. The examination documentation must support the reported conclusions so that, in the absence of the analyst assigned to the examiner, another competent examiner or supervisor can evaluate and interpret the data. The following shall apply to all examination documentation:

- The case file shall include all notes, worksheets, photographs, sketches, spectra, chromatograms and any other documentation used to reach or support the conclusions in the report. All tests performed shall be identified. All results from tests performed shall be documented in the case file.
- All pages of the examination documentation shall be marked with the case unique identifier and the examiner's handwritten initials or secure electronic equivalent. The LSD&FC SOP titled "Forensic Casework Numeric Designations" outlines the procedure for assignment of a unique identifier upon forensic case intake.
- When an analyst incorporates work performed by another analyst or technician into a report, both individuals shall initial each page of documentation of the work that contributed to the report.
- Evidence examination notes shall describe the item(s) examined, the method used, and results of analysis for each tested item including controls used to ensure the validity of the method.
- Photographs used as part of the examination documentation shall be marked as described in the LSD&FC Photo Documentation SOP.
- All handwritten notes shall be recorded in ink. Pencil may be used for field sketches or tracing.
- All notes shall be made contemporaneously to the examination date.
- Examination dates shall be recorded to indicate when the work was performed.
- When any corrections are necessary, the text shall be crossed out, not erased of made illegible or obliterated. The new text shall be entered alongside. Changes, alterations and additional notations, including interlineations shall be initialed by the person making the change.

- When no definitive conclusion can be reached, the reason shall be clearly documented in the case file.

- If modification of a previously recorded conclusion is necessary due to subsequent testing, the new information and basis for an amended conclusion shall be noted in the new examination documentation. The original notes shall not be altered and will remain as part of the case record.
- Records made for analysis run in batch mode shall be assigned a unique identifier (e.g. batch date and initials of individual performing the analysis). The unique identifier shall be appropriately recorded on the printout when data from multiple cases is recorded on a single printout.
- When instrumental analyses are conducted, operating parameters and critical reagent lot numbers shall be recorded according to the directions specified in the technical procedures.

7.6.3 Storage of Case Files

- LSD&FC has developed a written policy titled “Case Files Organization and Storage”. This policy addresses local control of case file access, distribution, and return, and the associated documentation.
- Case files shall be stored in a secure area under the control of the section director.
- Case files transfers shall be tracked internally through the Case File Tracking Log (Form # For 007).
- Case files checked out of the section director’s office shall not be transferred from employee to employee unless this transfer is recorded on the Case File Tracking Log (Form # For 007).

- Case files checked out of the section director's custody shall be locked in the analysts' drawer and not be left on top of the desk at any time unattended.
- Case files will be returned expeditiously to the section manager's office and should not remain in circulation unless there is an exigent need.

Case records shall be disposed of after ten years, or sooner if the Center receives an expunction order from the court which has jurisdiction over the case.

7.6.4 Case Records Security

LSD&FC will ensure the security, confidentiality and integrity of records, both written and electronic.

Case files, including all information received from the customer and the results reached in the examination of items of evidence, shall be treated as confidential. For privacy and confidentiality, only Case numbers (not personal names or any other personal identifier such as phone numbers, date of birth, house address, etc.) shall be written on the cover of Case file folders.
When information from case files must be removed from the laboratory for purposes such as court testimony, every effort should be made to avoid loss of original documentation. This includes photocopying portions of, or the entire case file as practicable. The procedure for records security is described in detail in the LSD&FC Record and Data Management SOP.

7.6.5 Release of Case Records Information

Examination of results must be reviewed for technical and administrative correctness prior to their release to the customer or an officer of the court.

Copies of the content of a case record shall not be provided to anyone without a written request and approval by the Center Director.

7.6.6 Expunction of Case Records

Expunction of any case record shall be performed after ten years have passed since the date of receipt of the items of evidence.

The Quality Manager shall expunge case records as follows:

- All paper copies shall be shredded
- All electronic records shall be deleted from the Computer Server
- The case shall be marked “Expunged” in the LIMS

Any associated DNA profile shall be de-identified and may be retained indefinitely in the Small Pond DNA database unless an expunction order is received from the court which has jurisdiction over the case. In which case, the DNA profile shall be deleted. Upon deletion of the DNA profile, the Quality Manager shall inform the Center Director of the expunction from the DNA database. The Center Director will then inform the court in writing of the Center’s compliance with the court order.

7.7 Measurement of Uncertainty

Measurement of Uncertainty shall be determined and reported as follows where applicable.

- Where possible, systems and equipment will be calibrated/tested with NIST traceable standards or reference materials.
- Calibration facilities providing services such as balance calibration and pipette calibration will be provided by a vendor accredited to the ISO 17025 or equivalent standard.
- Calibration shall occur at a minimum frequency of once per year. Additional performance verifications may be conducted internally as

appropriate.

- Serological/DNA analysis is a qualitative analysis rather than a quantitative analysis process. As such total uncertainty of measurement is not applicable to the Serology/DNA section.
- Following a service call for the ABI3500 instrument, the instrument will be performance checked using a known control ladder or standard to ensure correct performance.
- Following an external calibration of pipettes, the pipette(s) must be verified in-house prior to being returned to service.

7.8 Ensuring Validity of Results

LSD&FC will ensure the validity of results through the following:

- Use of appropriate reference materials and/or controls
- Use of calibrated equipment, where applicable.
- Use of preventive maintenance and/or performance checks on critical equipment.
- Technical and administrative review of case records.
- Participation in proficiency testing.
- Monitoring of court room testimony.

7.8.1 Reference materials and controls

Whenever appropriate, analytical methods shall incorporate the use of quality control samples. The resulting data shall be recorded in such a way that trends can be detected if necessary.

Other quality control activities may include replicate testing, retesting, verification analyses, correlation of results for different characteristics of an item and the use of certified reference materials. Standard Operating Procedures shall have procedures for performing these activities as appropriate.

7.8.1.1 Definitions

Control Sample – A substance used as a standard of comparison for verifying or checking the finding of an analysis.

Blank – A substance which is void of an evidence sample and/or the substance which is being analyzed for. Blanks are used to detect contamination.

Controls- Tests performed in parallel with samples and designed to demonstrate that the procedure worked correctly.

Reference Materials (Standards) – Materials or items of known or well-established composition used to prepare control samples or used as a control sample.

7.8.1.2 Control Samples and Reference Materials

LSD&FC shall follow the requirements of *A2LA Policy on Reference Material Traceability for Life Sciences Testing Laboratories* for the selection of reference materials.

Control samples and reference materials shall be specified in the applicable SOP. The SOP shall include acceptance criteria for control(s) and remedial action if control(s) fall outside the acceptance criteria.

The following characteristics should be considered when designing control samples:

- Similarity to the samples to be tested;
- Homogeneity and stability.
- The expected range of the assay for quantitative analysis.

The source of the control samples and the preparation process will be documented in the applicable SOP.

The following characteristics should be considered when selecting reference materials:

- When available, the reference materials will be traceable to SI units or be certified reference materials obtained from a competent supplier. When possible, suppliers accredited to ISO Guide 34:2009 OR 17034: 2016 will be used. Copies of the supplier's accreditation documentation will be maintained by the quality manager.

If available, appropriate reference materials shall be used for validation of new methods. Reference materials may be used for performance checks or calibration of equipment, and for evaluation of critical supplies. The DNA technical leader will specify in the applicable SOP, the proper application of these reference materials, the associated activities, and the procedure for these activities, and the acceptance criteria.

7.8.2 Technical and Administrative Review of Case Records

All reports and supporting documentation shall be technically and administratively reviewed prior to release. It is the responsibility of the section director to ensure that this review is completed prior to the release of the report. The technical review process is an in-depth evaluation to ensure that the conclusions are within the constraints of validated scientific knowledge and supported by the examination documentation. This review is conducted to verify that:

- The analytical procedures are applied appropriately;
- The tests performed meet generally accepted standards;
- The report is accurate, and the test data supports the conclusions;
- The test data and conclusions are appropriate for the work requested;
- Associations are properly qualified in the test report;
- The material included with the report contains all the work notes, charts, work sheets, chromatograms and other data necessary to support the conclusions;

- There are no additional tests within available resources which, if applied, would significantly improve the nature of the information obtained or better support the conclusions, and:
- Calculations and data transfers are free from transcription errors.

The Technical reviews shall be conducted by individuals who have the technical expertise, experience, and training to conduct the technical review of the analytical procedures used on the items of evidence. Upon completion of the review process, the reviewer shall place his/her signature and date on the Forensic Case Review Form (LSD&FC Form # Rvw 002)

Administrative reviews shall be conducted by someone other than the author of the report and may be conducted by any staff member as directed by his or her supervisor. The administrative review is not technical in nature and does not require a specific authorization.
An administrative review shall include:

- A review of the test report for spelling and grammatical accuracy
- A review of all administrative and examination records to ensure that the records are uniquely identified according to section policy; and
- A review of the test report to ensure that all required information is included.

7.8.3 Proficiency Testing

LSD&FC has implemented an external proficiency testing program for staff performing examination of evidence and analytical testing. The purpose of this program is to objectively assess the technical staff's ability to perform examination in a scientifically defensible and legally admissible manner, and to follow LSD&FC policies and procedures.

LSD&FC describes its proficiency testing program in the LSD&FC Proficiency Testing Guidelines SOP. This SOP is supplemented by a 4-year Proficiency Testing Plan.

7.8.3.1 Objectives

The objectives of the proficiency testing program are:

- To verify that technical procedures are valid and applied appropriately;
- To ensure the quality of the Center's work products;
- To demonstrate the on-going technical competence of technical personnel; and
- To identify areas of improvement.

For the fulfillment of these objectives, proficiency tests shall be completed under the same conditions and requirements as casework.

7.8.3.2 Program Administrator

The LSD&FC Proficiency Testing Program shall be administered by the Quality Manager.

The Quality Manager has the responsibility to:

- Procure external proficiency tests;
- Distribute external tests for assignment;
- Submit external test results to the appropriate vendor on or before the due date;
- Provide input on reviewing the results;
- Monitor internal proficiency testing; and
- Maintain the records of both external and internal proficiency tests for all technical personnel.

7.8.3.3 External Proficiency Testing

Each accredited discipline and sub-discipline must participate in a proficiency testing program in which samples are provided by an A2LA – approved external test provider. Such testing must be performed bi-annually in every accredited discipline.

7.8.3.4 Internal Proficiency Testing

An internal proficiency test may be used if an external proficiency test is not available for a subdiscipline.

An internal proficiency test may be any of the following:

- A sample prepared in-house either by the section technical leader or director;
- A test from an external provider used as an internal test;
- Previously analyzed case material.

7.8.3.5 Review of Test Results

The Quality Manager shall initially review the results to determine whether the analyst's response is satisfactory or unsatisfactory. This initial decision will be based upon the manufacturer's report for external tests. For internal tests, the person preparing the test shall submit the correct answers to the Quality Manager to be used for this initial review. Technical considerations from the section technical leader or director may also be considered in the decision. Should there be disagreement with the interpretation of the laboratory's response, the matter shall be discussed with the Center Director. The Center Director has the final authority in determination of a satisfactory or unsatisfactory rating for the proficiency test results.

Satisfactory test results shall be recorded as such by the Quality Manager.

For unsatisfactory test results, see Section 7.9.6 "Non-conforming Work".

7.8.4 Testimony Monitoring

Truthful, unbiased, and effective testimony is an essential component of forensic professional competence. Analysts must be able to demonstrate the following:

- Familiarity with the literature related to the applicable forensic discipline;
- Training and experience in the forensic discipline employed;
- Understanding of the scientific principles underlying the analytical procedures used in the forensic discipline;
- Knowledge of laboratory quality assurance policies and procedures;
- Ability to advise and assist officers of the court in the presentation of scientific evidence in the analyst's field of expertise;
- Effective communication skills when presenting analytical findings and interpretation of results;
- Professional appearance and demeanor; and
- An understanding of court procedures and the role of the forensic analyst within those procedures.

Training in expert testimony shall be provided to all technical personnel to teach and evaluate the above-listed skills. An analyst may not commence analytical work independently until this training has been completed in a satisfactory manner. This training and the analyst's performance shall be documented in the analyst training files by the Quality Manager.

Ongoing proficiency in court testimony shall be determined through annual monitoring.

The Section Director is responsible for the court testimony monitoring of personnel assigned to her/his section. The monitoring may be accomplished through direct observation by LSD&FC management or an analyst assigned to

the same section as the individual providing the testimony. If direct observation is not possible, then the LSD&FC Testimony Evaluation Form (Form # QAC 015) shall be submitted to a court official for the provision of feedback.

Court room testimony of technical personnel issuing reports shall be monitored at least once a year. Documentation of monitored testimony will be maintained in the employee records. Courtroom testimony monitoring records will be maintained for a minimum of 5 years. If no testimony opportunities arise during the year, then "lack of testimony opportunities" will be noted in the employee records for that year. In the event that analyst(s) did not testify during any calendar year, the section director will prepare a list of personnel that did not testify and forward it to the Quality Manager.

An analyst that has not testified in a calendar year will be provided a refresher training the following year. The section director will define the requirements for the training exercise. The Quality Manager will ensure that this refresher training is recorded in the analyst's training files.

In the event that the testimony is evaluated as less than acceptable, it shall be the responsibility of the section director to investigate the situation and decide if either additional training in the area of court testimony is needed or other action is necessary. Other action may include review of the applicable court transcript by the section supervisor with input from other management personnel, as necessary. All actions taken shall be documented in the individual's personnel records or training file.

7.9 Reporting Results

7.9.1 Policy

- The completed LSD&FC Forensic Report is the official document used to provide results to the customers.
- The issuing analyst shall be responsible for the accuracy and completeness of the report.
- Reports shall be submitted to a technical and administrative review prior to release to the customer. This review shall be documented in the case file.
- The forensic report shall be reviewed and approved by the Center Director before release to the customer or a court official. The review and approval by the Center's Director are indicated by his/her signature apposed to the signature of the analyst issuing the report.
- The results of each test carried out by the center shall be reported accurately, clearly, unambiguously and objectively. Any supplemental or amended reports shall be reported in the same manner. Each supplemental or amended report shall be clearly marked as such.

7.9.2 Report Writing Guidelines

The title of the report, case number, date, and page number shall be printed on each page of the report.

The report shall include the following:

- Name and address of the laboratory performing the analysis
- LSD&FC Case Number

- Date of issuance of the report
- Name, address, and authorized point of contact from the submitting agency
- Submitting agency's case number, if available
- Name of victim(s)
- Name of suspect(s), if known
- Date of offense(s), if known
- Type of offense, if known
- List of items received for examination including date of receipt, method of delivery, and item numbers. The latter shall include, in addition to the submitter's item identification system, the unique identifier assigned to each item by LSD&FC.
- An unambiguous description of each item received including its respective packaging number assigned by LSD&FC
- Examination and analytical method(s) used and date of the testing
- A statement for items excluded from examinations or analysis
- Condition of submitted item(s) if it may have affected the testing (e.g. wet, moldy, leaky, broken, unproperly packaged)
- Additions, deviations, or exclusions from the testing method(s)
- A statement for performance of controls used throughout analysis
- A result of examination or analysis section followed by an interpretation statement.
- A conclusion/opinion section following the results and interpretation section(s)
- A disposition of evidence statement, including any internal transfer to another section
- A statement clearly indicating the use of a subcontractor, if applicable

- Pagination clearly indicating all page numbers and the last page of the report (i.e. page y of y)
- Identification of the person(s) issuing the report: name, title and signature below the “conclusions” statement on the report.
- The following statement shall be included in the footer: “this report shall not be reproduced, except in full, without approval of the Center Director.”

In some instances, the Center may have to issue a supplemental report when items of evidence that were the subject of a previous report were not previously tested or require additional testing. The heading “Supplemental Forensic Report” will be typed on all pages of the report. The same case number will be used for the supplemental report. This report shall clearly indicate the tested items and will follow the same format as described above.

7.9.3 Release of reports:

Reports shall be released to the customer or a court official via pick-up, delivery by a courier, or via secure electronic transmission. The release and method of release will be documented in the *LSD&FC case tracking log*.

If a request for the release of the report is received from a court official, a cover letter will be prepared and attached to the requested report, and a copy of this letter will be forwarded to the customer.

In some extreme circumstances, the customer or court official may request a verbal release of results of analysis. This release requires prior approval by the Center Director. The verbal communication shall be documented on the LSD&FC Phone Contact Form (Form # For 012).

7.9.4 Interpretations and Opinions

- Opinion and Conclusion are used interchangeably in this section.
- Interpretations and opinions shall be formulated by analysts who have been competency tested in the applicable field of expertise and authorized by the Section Director and Center Director to issue such interpretations and opinions on an official report.
- Interpretation(s) of all reported results shall be included on the report.
- The interpretations and conclusions should relate clearly to the items tested and shall include units of measurement, when applicable.
- Items not examined or analyzed shall be reported as such.
- When no definitive conclusion can be reached (e.g., results are "inconclusive"), the reason shall be clearly stated.
- When associations are made, the significance of the association shall be communicated clearly and qualified properly in the report.

When comparative examinations result in the exclusion of an individual or an item, the report shall clearly communicate the elimination. When the inclusion of an individual or item is reported, the report shall clearly state the basis for the inclusion. Additional guidelines for reporting interpretations and opinions are located in the section "Interpretation of Results and Conclusions" SOP.

7.9.5 Amendments to Reports

The term amended will be applied to reports that will be issued to make a change to a previously released report.

- The writing "Amended" shall be apposed to the title of the report in bold type and shall be included in all report pages.
- Under the title, the following template statement will be placed in bold italic:
    - This report amends the LSD&FC Case #_____ dated_____ to
    - (select the applicable statement such as correct ____ or add_____).
- If this amendment was requested by the customer or a court official, this should be added to the statement.

An amended report shall be administratively reviewed and authorized for release by the Section Director and Center Director. If the correction or additions to the original report apply to the results of examination, interpretation or conclusions, then the report shall be technically reviewed by the technical leader assigned to the section issuing the report. The review shall be documented in the case file.

7.10 Complaints

LSD&FC shall ensure that all complaints received from employees concerning quality related aspects of the management system and from customers will be

thoroughly investigated and resolved. Records shall be maintained of all complaints and of all investigations and corrective actions taken by the Center. The section director will notify the quality manager and center director of all complaints received.

If the complaint is technical in nature, the section technical leader will be consulted with other personnel, as appropriate, to resolve the issue. If the issue cannot be resolved internally, the Center Director may call upon external experts for proper resolution.

Complaint (s) will be recorded on the LSD&FC Complaint Form (LSDFC Form # Adm 006). The quality manager will retain all documentation relating to the complaint (s) and their resolution.

A complaint received by a customer will be promptly addressed and upon conclusion of the internal investigation and resolution, a letter from the Center Director will be issued to the complainant regarding the course of action taken by the Center.

The process for receiving, validating, investigating, tracking and recording complaints is described in the LSD&FC Complaints Handling Policy and Procedure.

7.11 Non-conforming Work

Personnel that becomes aware of non-conforming work shall be responsible for immediately notifying either his or her supervisor or the supervisor of the individual or section responsible for the non-conforming work.
Non-conformities may be technical or administrative in nature. LSD&FC has categorized non-conformities in level I or II depending on the severity of the non-

conformity. Where there is indication that the nonconformity will likely reoccur or that the Center is not following its own procedures and/or policies, a corrective action will be implemented.

Level I Non-conforming Work compromise the work product or the overall quality of the laboratory work product. These are non-conformities that are:

- Are unexpected
- Require an inquiry to determine the root cause
- Require management involvement
- Raise immediate concern and may affect the overall quality of the laboratory work product

Examples include: missed identification or erroneous identification

Level II Non-conforming Work does not compromise the overall quality of the work and generally:

- Is discovered prior to case completion
- Is foreseeable
- Has a clear-cut immediate cause

Examples of Level II Non-conforming work include: clerical or transcription errors, failure of a quality control check.

The procedure for addressing non-conforming work is described in the SOP Titled Non-Conformities and Corrective actions.

7.12 Control of Data

Analytical data generated via computers or automated equipment shall be acquired, processed, and retrieved during the course of analysis. Data is

retrieved through printing a paper copy. The paper copies of the data are then placed in the case file.

Data shall be stored electronically on LSD&FC server in appropriate folders. Access to these folders is limited to appropriate personnel based on their status, section assignment and their duties within the section.

7.13 Information Management

All administrative, technical and quality records are stored and managed on a restricted access system.

All administrative, technical and quality records are stored and managed on a restricted access system. The Procedure for Record and Data Management applies to both electronic, and non-electronic records. The procedure shall include the process for identifying, collecting, indexing, accessing, filing, storing, maintaining, and disposing of quality and technical records. Quality records shall include reports from internal audits, management reviews, corrective actions, and preventive actions. Technical records include, but are not limited to, the following: forms, worksheets, external and internal test reports and calibration certificates, customer feedback.

- Electronic record systems may be compartmentalized, restricting access to various levels of both operation and information, by defining security levels and/or using other means, e.g., passwords or special procedures that would restrict access to only authorized users, and the system is maintained by the ICT Manager.
    - All documents on the central server are remotely backed up on a weekly basis.
    - The remote back-up server is audited twice a year to confirm the remote server follows the same access restrictions as LSD&FC.
- Non-electronic documents and records are stored in an access-controlled area, or secured in locked cabinets depending on the level of access allowed,

- Access to electronic and non-electronic documents is determined by the Center Director.

8.0 Management System

8.1 Management System Documentation

LSD&FC management system documents are comprised of, but not limited to, a quality manual, general policies, quality-related standard operating procedures, technical standard operating procedures, section-specific training manuals, forms, and external documents such as accreditation standards and requirements.

The quality manual is the overarching document describing the Center's operations. The following illustration (Figure 2) outlines the structure of the management system documentation.

Figure 2: Structure of the DNA & Forensic Biology Section Management System

The Quality Manager shall maintain a database of all management system documentation that includes current and past versions. The Quality Manager shall ensure that the most current version of appropriate management system documentation is available to personnel. All other versions shall be archived and controlled to prevent inadvertent use of an outdated document.

The management system shall be established to address all facets of activities, the requirements in ISO/IEC 17025, and any supplemental accreditation requirements. The Laboratory management system is outlined in the following documents:

- Quality Manual – sets forth the quality policy. Policy statements and subsequent revisions to the Quality Manual shall be approved by the Center Director and the Quality Manager.
- Procedures – written documents used to implement policies regarding the Quality Program. Procedures and subsequent revisions to the procedures shall be approved by the Center Director and the Quality Manager.
- Section policies, technical procedures, guidelines, references, forms, and records supplement lab-wide policies and procedures. The Quality Manager shall establish and maintain a Master List of procedures. Section policies and procedures and any revisions thereto shall be approved by the DNA & Forensic Biology Director, Center Director and Quality Manager. Technical procedures and subsequent revisions shall also be approved by the Section DNA Technical Leader.
- Safety Manual - sets forth occupational health and safety policy and68. Any revisions to the manual shall be approved by the Safety Manager, DNA & Forensic Biology Director and Quality Manager.

Management documents shall be accessible on the file server. When laboratory management system documents are issued, the Quality Manager shall ensure that each affected Laboratory employee signs an Acknowledgement Sheet to indicate review of the document. When Section specific management system documents are

issued, the Section Manager/Supervisor shall ensure that each affected Laboratory employee signs an Acknowledgement Sheet to indicate review of the document. The Acknowledgement Sheets shall be scanned and stored on the file server.

8.2 Control of Records

The Quality Manager is the custodian of all quality records. The Section Directors are the custodians of case files for their respective discipline and administrative records of personnel under their supervision. The Business Manager is the custodian of all purchasing records.

A case record is maintained for each request for analysis and crime scene investigation accepted by LSD&FC. Case records are identified by an assigned forensic case number.

Case records are collections of technical and case-specific administrative records and may include:

- The test report(s).
- Reference to the technical procedures used during analysis and any deviation.
- Identifiers and descriptions of the items analyzed.
- Identity of the technical employee(s) performing the examination(s).
- Identity of the technical and administrative reviewers.

Quality records are also maintained, named to facilitate appropriate filing, and are typically stored by subject and/or date. These records include but are not limited to:

- Internal audit reports.
- Management reviews.
- Corrective and preventive actions.
- Proficiency tests.

- Testimony monitoring.
- Training records.

Access to case records stored in an electronic format and the file server and/or are associated with JusticeTrax, or Small Pond is granted through the authority of the Center Director or the DNA & Forensic Biology Director. If access is granted to an approved software vendor, that access will be granted for a single session via an email request to or from a designated staff member for a specified purpose. This access to the system is fulfilled through the LSD&FC ICT department.

8.3 Record Storage

- All records are stored in secure locations. Records may be in a hard copy or electronic format. Hard copies are stored in secure offices and cabinets with limited-access. Electronic copies are stored on secure servers that are password protected. Access to records are controlled by the Center Director.
- All records shall be stored in an environment that will prevent damage, deterioration, and loss. Case files are filed numerically by a unique case identifier. Technical records, such as reagent logs, maintenance or calibration logs, and temperature logs, are stored in an alphabetical order in locations designated by the DNA & Forensic Biology Director or DNA Technical Leader.
- Quality, administrative, and technical records will be kept for at least five years or one full accreditation cycle, whichever is longer. If pertaining to DNA, those same records are kept for at least 5 years. Records are typically scanned into a secure, backed-up electronic system. The electronic versions of these records are maintained indefinitely, unless LSD&FC is otherwise ordered by the customer or by legal requirements. The paper copies of these scanned records may be stored or shredded after the duration of storage. Top management may authorize the disposal of quality and/or technical records in accordance with LSD&FC records retention

policy. When necessary, documents and records will be disposed of by shredding or otherwise disposed of in a manner that ensures the confidentiality of the information.

- Regardless of the format of the record (electronic, paper), LSD&FC will provide the record or copies of the record upon request from its customers.
- All records are held secure and in confidence. Staff members have the responsibility to safeguard all confidential information obtained in their official capacity from unauthorized distribution. Staff members will not access or disclose any confidential information except when disclosure is legally authorized or approved by key management. Staff members are not authorized to disclose any portion of a case record to an unauthorized third party, and they should consult key management for assistance if necessary.

  Electronic records are stored using LIMS or on a file server. Electronic storage systems are backed up in-house and offsite. All electronic records are password protected to prevent unauthorized access or amendment of the records. Changes to records stored in LIMS are tracked through the system's audit log function. The LIMS database is password protected and backup devices are stored in a secure manner. Access to electronic records is limited to those having user names and passwords issued at the direction of the Center Director.

8.4 Evaluating Risks and Opportunities

LSD&FC recognizes the existence of strategic, operational, reporting and compliance risks associated with the operation of a forensic laboratory. Therefore LSD&FC will routinely identify, evaluate, measure and manage risks for improved performance and stakeholder value enhancement. LSD&FC shall exploit and protect the present opportunities in the forensic casework and relationship testing services it offers, constantly explore future innovations while managing risks to meet regulatory requirements, improve management performance and stakeholder confidence.

LSD&FCs' core operational objective is to demonstrate excellence in the DNA forensic and customer services. It will perform DNA testing in the most efficient and reliable way and take advantage of new opportunities that will define the future of the center by 1) managing the downside of all identified risks and 2) focusing on innovation and addition of new forensic services for value creation.

The management of risk and opportunities will be a continuous process at LSD&FC as illustrated below (Figure 3), and this process will be aligned to the business strategy, operating performance, and stakeholder value enhancement, in addition to compliance and prevention, to facilitate process improvement and achieve greater success.

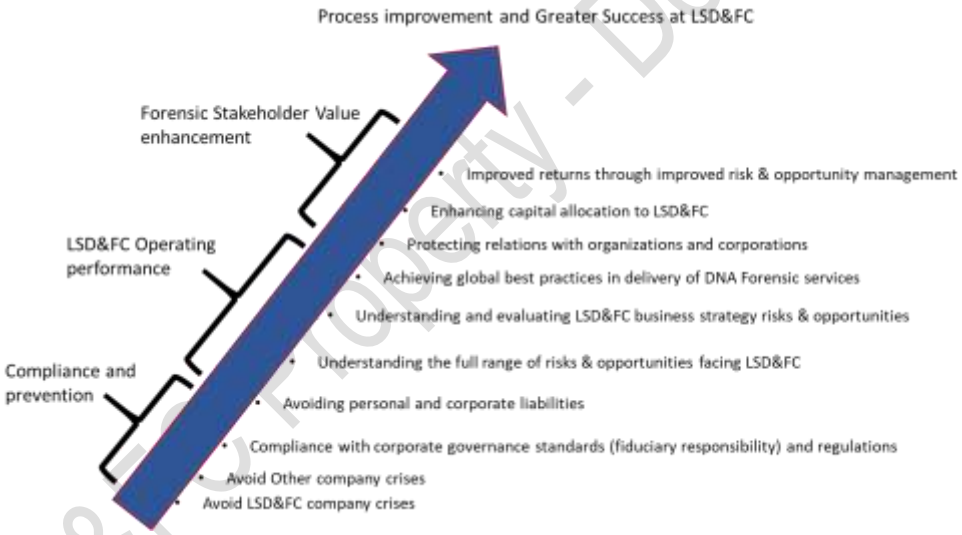

Figure 3: DNA & Forensic Biology Section Risk and Opportunity Management Continuum

LSD&FC recognizes that certain risks present opportunities. It will therefore identify, manage, measure and monitor both risks and opportunities within the existing management structure. This will enable management to have a broader approach to risk rather than focusing exclusively on risk as a threat. The following approach will be used:

1) Effective identification of risks and opportunities, including,

a. Sources of risk
b. Sources of opportunity

2) Effective management of risks and opportunities, including,
   a. Assessing and altering risk appetite
   b. Assessing risks and opportunities
   c. Managing risk
   d. Managing opportunity
   e. Monitoring a management control system to review the strategy, costs and benefits, structure, systems, and appetite for risk.
3) Effective evaluation of risks and opportunities through Return On Investment (ROI) coupled with real options analysis and / or scenario analysis.

LSD&FC will adopt the simultaneous risk and opportunity management process as illustrated below (Figure 4).

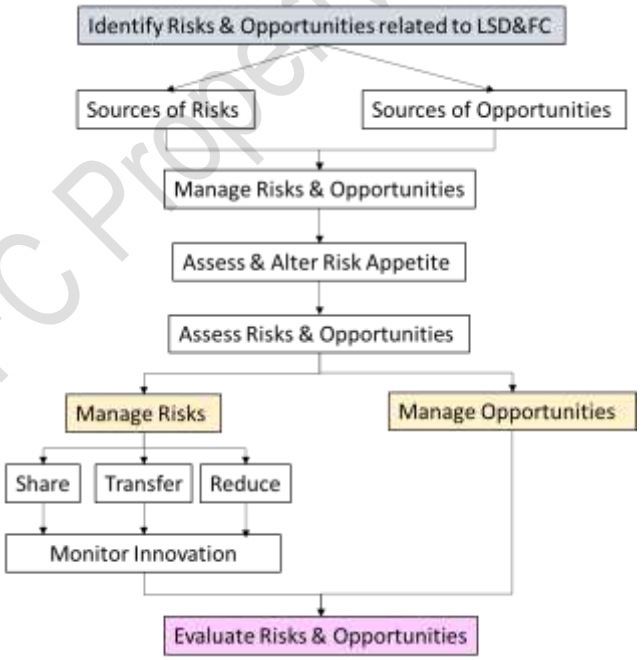

Figure 4: DNA & Forensic Biology Section Risk and Opportunity Process

Sources of Risks

LSD&FC Identifies, and will assess and manage the following risks:

a) Strategic risks: This includes economic, industry, social, political, technological and organizational risks that endanger the achievement of its goals or the existence of the center. LSD&FC's strategic risk assessment will identify the risks associated with specific strategies.

b) Operational risks: This includes financial, human resources, environmental, project, health and safety, reputation, property and innovation risks. LSD&FC strategic risk assessment will identify the risks associated with the business operations and process.

c) Reporting risks: This includes the reliability, accuracy, and timeliness of information systems and the reliability or completeness of information required for internal or external decision making.

d) Compliance risks: This includes dealing with the presence or lack of systems to 1) monitor communication of laws and regulations, internal behavior, codes and contract requirements, and 2) provide information about failure of management, employees, or trading partners to comply with applicable laws, regulations, contracts, and expected behaviors.

Sources of Opportunities

LSD&FC will identify opportunities, both as they relate to risk and beyond. Management awareness into these areas will be expanded to provide insights into 1) potential opportunities to leverage and 2) the risks that should be mitigated. LSD&FC recognizes that opportunities may emerge within and outside the organization.

Opportunities within LSD&FC

a) Supply Chain: The way in which LSD&FC's value is created and delivered to the market, can be a source of opportunity and innovation. The LSD&FC structure, partnership with other entities like the Police and non-government organizations, and the operational model for delivering products and services can also represent

opportunities that can be leveraged. For example, LSD&FC may bundle crime scene investigation, serology and DNA testing services to secure above average interests and margins.

b) Product and service offering: LSD&FC will systematically add new products and services to the list of offerings to the Police and criminal investigators. There will also be changes to existing products and services when indicated.
c) Process: Process improvement opportunities will be leveraged to ensure faster, better and less expensive delivery of forensic DNA services.
d) Technology: LSD&FC will constantly update its technology for faster execution of strategies and delivery of services to clients. For example, modern communications technology will be used to speed up planning, exchange of ideas and communication with clients while information technology will be used to improve supply chain management and accounting.
e) New markets: LSD&FC will seek new markets to source products, reagents and equipment as well as new markets to deliver its products and services to new consumer groups.

Opportunities outside LSD&FC

Customers: LSD&FC will be sensitive to customer needs and trends to enable it anticipate changes and through innovation, meet needs before the competition.

Competitors and complementors: LSD&FC will be sensitive and constantly monitor the opportunities seized by the competition as well as those the competition avoided because of real and perceived risks. LSD&FC will assess how it's structure and know-how can be leveraged to deal with the risks that discourages the competition.

Emerging technologies and scientific developments: LSD&FC will evaluate and when appropriate and feasible adopt emerging technologies and new scientific developments that will enhance the forensic services it delivers.

Political, legal and social forces: LSD&FC will seek for opportunities in the political, legal and social landscape in Nigeria. For instance, the law that will require all prison inmates to

provide DNA samples and the interest in using DNA paternity test as the basis for distributing inheritance presents an opportunity for LSD&FC.

8.5 Improvements

LSD&FC is committed to continued improvement of the effectiveness of the Management System through the following:

- encourage all personnel to actively participate in identifying opportunities for improvement. This is achieved through 1) direct solicitation of concerns or opinions of personnel by the Center Director at weekly staff meeting 2) an open-door policy whereby staff is encouraged to communicate any observations that may be detrimental to the quality assurance system to their supervisor, the Quality Manager, Section Director and/or Center Director;
- review of results and recommendations from internal and external audits;
- implement corrective and preventive actions;
- technical and administrative review of case files;
- quality policies;
- review of results and recommendations from management reviews;
- review of proficiency test results;
- review of feedback from customers;
- review of complaints from customers and personnel;
- review of SOPs;
- risk assessment.

8.6 Corrective Actions

- LSD&FC has developed a corrective actions SOP to provide a formalized mechanism for the identification and documentation of issues or non-conforming work requiring corrective actions.

- LSD&FC shall evaluate the effectiveness of any corrective actions and make changes to the management system, if necessary.

- Risks and assessments shall be updated after review of corrective actions at the annual Management Review, if necessary.

- Any personnel who becomes aware that non-conforming, potentially non-conforming, or a technical issue has occurred shall immediately report it to the Quality Manager through the LSD&FC "Incident Report" Form (Form # QAC 024). The Quality Manager shall review the incident form and decide if the incident requires a corrective action. Generally, issues that fall in the incident category without a corrective action are straightforward, uncomplicated issues that are easily resolved.

- Incidents shall be fully documented and the documentation shall be maintained by the Quality Manager. The appropriate procedure for reporting and documenting incidents is detailed in the **LSD&FC Incident Report SOP**.

- Issues, concerns, or non-conforming work that are not closed-out as an incident are handled as a corrective action and are issued a Corrective Action Report (CAR).

- A Corrective Action Report is a synopsis of an issue or concern requiring corrective action. The CAR shall include the following:

  - Review and analysis of the issue or non-conforming work;
  - Root cause analysis;

- Determination if similar issues or non-conformities exist; or could potentially occur;
- Remedial actions;
- Effectiveness of any corrective actions taken;

The request shall be documented on the LSD&FC "Corrective Action Report" Form (Form # QAC 008). A CAR can be issued for any of the following circumstances:

- Areas of non-compliance with ISO/IEC 17025 and/or A2LA Supplemental Requirements, LSD&FC Quality Manual and Policies, section-specific SOPs and other LSD&FC SOPs;
- Technical concerns, casework and/or proficiency test errors
- Other instances deemed appropriate by the Quality Manager

A CAR may originate as a result of any of the following:

- An internal or external audit;
- Notification to the Quality Manager through an Incident Report Form of non-conforming, potentially non-conforming or technical issue;
- Information the Quality Manager is given or obtains through the normal course of his/her duties;
- A customer's or personnel complaint.

Handling of non-conforming work is described in Section 9.6.4 and in further details in the **LSD&FC SOP Titled Non-Conformities and Corrective actions**.

8.7 Internal Audits

LSD&FC has established a procedure by which the internal quality system and technical activities' audits are conducted. This information is described in detail in the LSD&FC SOP titled "Audits and Assessments".

8.7.1 Policy

LSD&FC shall conduct systematic internal audits to:

- Monitor and determine compliance with the requirements of its quality system and accreditation standards
- Evaluate the technical activities and work product of employees

8.7.2 General Information

The Quality Manager or designee is responsible for coordinating all internal audits. The Quality Manager shall ensure that internal audits are performed by trained and qualified personnel and that at least one person independent of the section being audited participate in the audit.

Audits shall be conducted annually according to an established schedule.

The auditors shall use the *A2LA C025 Checklist: ISO/IEC 17025:2017 Laboratory Accreditation Program* and the *A2LA C221 (2017) -Specific Checklist: Forensic Examination Accreditation Program Testing-Testing*. A modified version of this form may be used if an audit covers a specific criteria or section. Auditors shall not be restricted to items on the checklist and shall investigate any uncovered issue affecting quality.

The audit will cover all quality records generated since the previous audit.

Auditors shall verify the effectiveness of corrective and preventive actions implemented since the previous audit.

The director of the section being audited will be notified in writing of the upcoming audit. The written notification will include the scope of the audit and the number of cases to be reviewed per analyst.

At the conclusion of the audit, the Quality Manager shall submit a memorandum to the Center Director summarizing the audit and any corrective or preventive action requests resulting from the audit. Corrective Action Requests may be issued to correct deficiencies noted in the audit. Preventive Action Requests may be issued to address and document possible areas of improvement or areas where potential non-conformities may occur. A copy of the memo shall be forwarded to the Section Director.

8.8 Management Reviews

LSD&FC is committed to ensuring the continuing suitability, adequacy and effectiveness of its management system and operational activities. Furthermore, LSD&FC is committed to introducing any necessary changes and improvements to its management system and operational activities. This commitment will be demonstrated through management reviews.

8.8.1 Policy

LSD&FC top management shall conduct, at least annually, a management review of its quality management system and operational activities. This planned review will serve as the basis for complying with accreditation requirements but does not preclude top management from reviewing the Center's Activities throughout the year.

Top Management is defined as:

- The Center Director
- The Business Manager
- The ICT Director
- Section Director(s)
- Section Quality Manager(s)
- Section Technical Leader(s)

The Center Director shall select a date and inform top management, at least two weeks in advance, of the management review and shall lead this review.

The Management Review shall address, but not be limited to, the following:

- suitability of policies and procedures;
- fulfilment of overall objectives of the management system;
- outcome of internal audit(s) and external assessments performed during the year;
- corrective and preventive actions undertaken during the year;
- incident reports;
- status of actions from previous management reviews;
- feedback from customers;
- complaints from customers and employees;
- recommendations for improvements and effectiveness of any implemented improvements;
- adequacy of resources;
- changes in volume and type of work;
- personnel training;
- outcomes of the assurance of the validity of results;
- results of risks identification and opportunities for improvement;

- review of subcontractors;
- health and safety program.

8.8.2 Documentation and Communication

Management reviews shall be documented, and the documentation shall be retained for at least five years.

Documentation shall include decisions and actions in relation to:

- findings;
- effectiveness of the management system;
- recommendations for improvement, including provision of required resources;
- any need for change.

A plan and schedule will be established and implemented to address any findings.

Pertinent information from management reviews will be communicated by section directors to personnel under their supervision.

Procedure Review, Sign Off & Effective Date

By: Annette Alchin, M.S.
Name: Annette Alchin, M.S.
Title: Quality Manager

By:
Name: Richard I. Somiari, PhD
Title: Center Director