DIRECTORATE OF FORENSIC SCIENCE SERVICES

FORENSIC SCIENCE LABORATORIES

QUALITY MANUAL

IN ACCORDANCE: ISO / IEC 17025:2017(E)

सत्यमेव जयते

DFSS

न्यायार्थ विज्ञानम्

FSL QUALITY MANUAL

DIRECTORATE OF FORENSIC SCIENCE SERVICES

MINISTRY OF HOME AFFAIRS, GOVT. OF INDIA

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Foreword

The Directorate of Forensic Science Services (DFSS) is a nodal organization of Ministry of Home Affairs, Govt. of India to propagate and carry out best Forensic Science practices in the country to serve the cause of Criminal Justice Delivery System. The Motto of the Organization is to provide **High Quality, on Time and Credible Forensic Science Services to the Nation.** It has six (6) CFSLs under its administrative control viz. CFSL: Chandigarh, Kolkata, Hyderabad, Pune, Guwahati and Bhopal.

As you are aware that organized and individual based crime and terrorist activities are constantly posing threat to the society and homeland security in the country. The scientific investigations, therefore, require to play a major role to combat the crime. Use of high technology and scientific means by potential criminals make the task of detection more challenging, particularly when the technology is fast changing. DFSS along with its six CFSLs is committed to work dedicatedly to meet such challenges.

For the purpose, Forensic Science Laboratories (FSLs) at central and state level are continuing to provide scientific and technical information services to Criminal Justice Delivery System in the country, but these laboratories lack uniformity in the analysis of exhibits involved in various crime cases. The successful prosecution/conviction of offenders/accused or acquittal of innocent with much more precision hinges on the quality of test reports of crime exhibits. The exhibits of the crime cases need to be examined timely, precisely and accurately as the forensic examination report forms the basis of investigation. Therefore, in order to bring uniformity in the analysis and test report of crime cases, Directorate of Forensic Science Services (DFSS), Ministry of Home Affairs has taken initiative and embarked on the preparation of Quality Manual for quality system of the laboratories as per the new guidelines of ISO/IEC 17025:2017 (E) to bring the uniformity in examination, analysis of exhibits and their reporting.

The team of technical experts of CFSLs under DFSS has prepared a Quality Manual as per the new guidelines of ISO/IEC 17025:2017 (E) for accreditation of Forensic Science Laboratories in the country. This is an excellent comprehensive document which can be used as a main quality system document for accreditation of new laboratory by National Accreditation Board for Testing and Calibration Laboratories (NABL), Quality Council of India (QCI) or updating their existing accredited status as well as documentation of accredited laboratory.

I am sure this would help both Central and State Forensic Science Laboratories to get fully geared up for their accreditation (Quality Control/Quality Assurance protocols) as per the new guidelines of ISO/IEC 17025:2017 (E) through NABL which could increase the credibility of their forensic test results and in turn accord a higher status to this field of science in the eyes of the society. I also wish to place on record our appreciation to the team of experts who have contributed to bring out the document in its present shape.

Dr. S. K. Jain
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INTRODUCTION

This document has been developed with the objective of promoting confidence in the operation of FSLs. This document contains requirements for FSLs to enable them to demonstrate they operate competently and can generate valid results. Central Forensic Science Laboratories that confirm to this document will also operate generally in accordance with the principle of ISO 9001.

This document requires the FSL to plan and implement action to risk and opportunities. Addressing both risk and opportunities establish a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The DFSS is responsible for deciding which risk and opportunities need to be addressed.

The use of this document will facilitate cooperation between central forensic science laboratories and other state FSLs, and assessed in the exchange of information and experience, and in the harmonization of standards and procedures. The acceptance of results between FSLs facilitate if laboratories conform to this document.

In this document, the following ISO/IEC verbal forms are used:

- "shall" indicates a requirement;
- "should" indicates a recommendation;
- "may" indicates a permission;
- "can" indicates a possibility or a capability.

Further details can be found in the ISO/IEC directives, part 2.

For the purposes of research, users are encouraged to share their views on this document and share their priorities for changes to future edition.

1. SCOPE

This Quality Manual (QM) contains the policies and procedures of the Central Forensic Science Laboratory, [FSL] quality management system. The Manual covers the requirements specified in **ISO/IEC 17025:2017(E)** and the accrediting body's supplemental requirements. The Quality Manual is the focal point for the Laboratory's Forensic Quality Assurance Program. The Quality Manual, the Health and Safety Manual, the individual Discipline Procedure Manuals, and the individual Discipline Training Manuals form the Forensic Quality Assurance Program for facilitating accreditation needs for the competence, impartiality and consistent operation of the facilities at FSL.

All scientific employees are responsible for performing work (conducting tests, analyzing crime exhibits/test items that are received for testing/ examining crime scenes) within the policies and procedures of the Laboratory's Forensic Quality Assurance Program.

2. NORMATIVE REFERENCES

The following document(s) is/are referred to in the text in such a way that some or all their content constitute requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

1. International Organization for Standardization (ISO)/International Electro-technical Commission (IEC), ISO/IEC 17025:2017 - General Requirements for the Competence of Testing and Calibration Laboratories.

3. TERMS AND DEFINITIONS

The following list includes definitions of terms used within this manual.

Administrative records	Records, such as case-related conversations, evidence receipts/chains of custody, description of evidence packaging and seals, phone logs, court orders, test reports, and other pertinent information that do not constitute data or information resulting from testing.
Administrative review	Review of case records for uniformity with FSL policy and for editorial correctness.
Acceptance criteria	The expected outcome from a reagent quality control test using known positive and negative standards and controls.
Association	A relationship which is concluded to exist between individuals and/or objects based upon testing.
Audit	A systematic, independent, documented process for obtaining records, statements of fact, or other relevant information and assessing it objectively to determine the extent to which specified requirements are fulfilled.
Calibration	The adjustment of an instrument or piece of equipment to an indicated standard or value to ensure precision and accuracy.
Can	Possibility or capability
Case records /Case File	Administrative records, examination records, and any other applicable technical records, whether electronic or printed, generated or received by FSL pertaining to a case which may be stored in one or more locations.
Category of testing	A specific type of analysis within an accredited discipline of forensic science.
Certified Reference Material	Reference material, accompanied by a certificate, with a value certified by a procedure that establishes traceability to an accurate realization of the unit in which the values are expressed, and for which each certified value is accompanied by uncertainty at a stated confidence level.
Case forwarding agency	Authority or organization that sends the crime case exhibits and receives service from FSL. May also be referred to as client, customer, stakeholder or requestor.
Chain-of-Custody	A process that documents all transfers of evidence over which the Laboratory has control.
Conclusion	A statement in an examination report that summarizes the interpretations of examination results in disciplines with established identification criteria. The term *conclusion* also refers to a judgment made, or decision reached based on the results of analysis/examination.
Contract	An agreement between the laboratory and the case forwarding agency to provide testing and/or crime scene examining services (Searching crime scene for locating corroborating evidentiary clues of forensic importance).
Control sample	A standard of comparison for verifying or checking the finding of an experiment.

Controlled document	A document that is distributed in an organized way (usually electronically) to ensure that the latest approved version is identifiable.
Control	A test performed in parallel with experimental samples and designed to demonstrate that a procedure and laboratory supplies worked correctly.
Corrective action	Action taken to correct departures from approved policies and procedures in the management system and/or technical operations.
Competent	Possessing the requisite knowledge, skills and abilities to perform a job or task.
Crime scene	Scene of an incident prior to establishing whether a crime or other action requiring investigation has taken place or not. The crime scene may include both primary (where the crime occurred and/or where a body is located) and secondary scenes (the area surrounding the primary scene).
Critical equipment	Tools or supplies that require calibration or a performance check prior to use and periodically thereafter. (Measuring devices used by the crime scene unit are not be considered critical).
Critical task	Any task that has a significant effect on the quality of an examination test.
Decision rule	A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
Deviation	A planned departure from a procedure/process that is pre-approved by section management.
Discipline	A major area of testing in forensic science
Document	Information in any medium, including, but not limited to, a paper copy, computer disk or tape, audio or videotape, photograph, overhead transparency, or photographic slide.
Document control	The process or system for ensuring that controlled documents, including revisions, are reviewed, approved, and released by the proper issuing authority and then distributed to personnel performing the prescribed activities. It also includes subsequent document revision along with tracking and controlled release of new versions.
Evidence	Item received or analyzed by FSL for testing /Equivalent to "*test item*" as described in ISO/IEC 17025 / Material, regardless of form, which is received by a laboratory for gleaning information relevant to a criminal investigation through examination by one or more of the laboratory's testing procedures.
Examination	A process that uses approved technical procedures to characterize, quantify, or interpret evidence.
Examination records	The documentation (whether electronic or hard copy) of procedures followed, tests conducted, and standards and controls used to characterize, quantify, or interpret evidence. Records could include diagrams, printouts, photographs, and observations and results of testing and close visual inspection. Examination records are technical records.
Environmental conditions	Any characteristic of a laboratory facility that could reasonably be expected to impact the quality of the laboratory's work product (e.g., lighting, heating, air conditioning, ventilation, plumbing, wiring, adequacy of exhaust

	hoods/bio-safety cabinets, etc.).
Health and Safety Coordinator	An individual (however titled) designated by top management who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the requirements of the safety system are implemented and maintained.
Individual characteristic database	A computerized, searchable collection of information generated from samples of known origin from which individual characteristic information originates (i.e. reference biological specimens, known fingerprints, electronic fingerprint records and test fired ammunition).
Inconsistency	A reported result that differs from the consensus result. Inconsistencies may be classified as administrative, systemic, analytical, or interpretive.
Internal audit	An annual in-house audit that gauges compliance with ISO/IEC 17025 and/or FSL's own policies. Internal audits are conducted by FSL personnel.
Internal Proficiency Test	A proficiency test administrated and reported internally.
Key management	Key management includes top management (Director), and Quality manager and Division Heads. The Director may identify other positions for inclusion as key management.
Manager	A person with the responsibility for directing and controlling an organizational unit or program.
May	Permission
Method	The course of action or technique followed in conducting a specific analysis or comparison leading to analytical results.
Must	A requirement
Nonconformance	Nonconforming work is the result of an act, error, violation of an approved procedure/process, or omission that has affected the accuracy, reliability, and/or integrity of FSL's testing or reports. A nonconformance is not the same as a deviation (see 'deviation').
Non-standard method	A method (not published in international, regional, or national standards or by reputable technical organizations or scientific texts or journals) developed by an organization that has been validated to confirm that the method is fit for the intended use.
Objective	*(1)* A measurable, definable goal that once accomplished furthers the progress of the laboratory. *(2)* Without prejudice or not influenced by feelings or opinions.
Open Proficiency Test	A proficiency test known to the participant as such.
Performance check	A set of operations run to determine if a piece of equipment produces examination results consistent with specified parameters. Performance checks are conducted when new equipment is used with existing technical procedures, equipment is moved to another physical location, or existing equipment is modified or undergoes maintenance that could change its performance.

Policy	A guiding principle, operating practice, or plan of action governing decisions made by FSL
Preventive action	An action intended to eliminate the cause of a potential nonconformance or another undesirable situation.
Procedure	The way an operation is performed; a set of directions for performing an examination or analysis; the actual parameters of the methods used.
Proficiency test	A test to evaluate the capability and performance of technical staff, technical support personnel, and other FSL personnel. In open tests, FSL personnel are aware they are being tested; in blind quality control (QC) tests, they are not.
Proper seal	A seal that prevents loss, cross-transfer, or contamination while ensuring that attempted entry into the container is detectable. A proper seal may include a heat seal, tape seal, or a lock. The initials or other identification of the person affixing the seal shall be placed on the seal or across the seal onto the container when possible.
External proficiency test	A test prepared and provided by a source external to the laboratory, laboratory system, or the laboratory's parent organization. External proficiency tests may be from Approved Proficiency Test Providers or from sources which have not been approved as test providers.
Quality audit	A management tool used to evaluate and confirm activities related to quality. Its primary purpose is to verify compliance with the operational requirements of the quality system.
Quality control check	A procedure used to ensure the continued reliability and accuracy of reagents and equipment.
Quality manual	A document stating the quality policy and describing the various elements of the quality system and quality practices of a business or organization (e.g., this FSL manual).
Reagent	A substance used because of its known chemical or biological activity
Request	A request is the process utilized by a case forwarding agency when seeking analysis by FSL. For example, a submission form or letter accompanying submitted evidence that lists examinations sought by the case forwarding agency is a request.
Re-Examination Report	At the request of the client or due to the inability of the original examiner to testify, a sample is re-analyzed in the same manner (protocol) as reported in the original report.
Reprint Report	Reprint of the original case findings. The Reprint report may have a different Issue date and will have a different notarization date.
Revised Report	Issued when the information in the original report was not correct, when additional testing has been completed, or when the biographical information related to a case has changed or needs to be corrected.
Root cause analysis	A process used to identify the root cause(s) of nonconformance.
Safety manual	A document stating the safety policy and describing the various elements of the safety system of an organization or business.
Sample selection	Selecting items or portions of items to test based upon training, experience,

	and competence and without assumptions about homogeneity.
Sampling	A defined procedure whereby a part of a substance, material, or product is taken as a representative sample of the whole for examination.
Shall	Required
Should	Recommended
Staff member	Any person under the management responsibility of FSL, regardless of his/her classification as civilian, classified, or employee.
Subcontractor	An individual or business that independently performs a service for FSL that FSL is accredited to provide.
Sub-discipline	A specific type of analysis within an accredited discipline of forensic science. (See *category of testing.*)
Supplemental Report	See revised report
Technical review	Review of technical records, reports, and testimony to ensure validity of results, opinions, and interpretations.
Technical records	Accumulations of data and information which result from carrying out tests and which indicate where specified quality or examining parameters were achieved. They may include forms, contracts, work sheets, work notes, test reports, calibration certificates.
Technical staff	Individuals, who conduct and/or direct the analysis of forensic casework samples, investigate crime scenes, interpret data, and/or reach conclusions. Technical staff may also be referred to as *forensic analysts, forensic examiners, supervisors, managers, examiners,* and *investigators.*
Technical support personnel	Individuals who perform casework-related duties at the direction of technical staff but do not issue test reports related to conclusions reached.
Test record	Administrative and technical (examination) records generated during or pertaining to testing performed.
Testing	Using a procedure to determine one or more characteristics of a test item.
Top management	Chief Forensic Scientist/FSL directors are considered top management.
Traceability	The property of a measurement result whereby the result can be related to a reference through a documented, unbroken chain of calibrations, each contributing to the uncertainty of measurement
Uncertainty of measurement	An estimated value, within specified confidence limits, that depicts a value of variability that can be attributed to a quantitative value.
Uncontrolled document	A document that is not a part of an organization's document control system (or a copy of a controlled document provided for informational purposes only).
Validation	The documented process of ensuring a test method is fit for purpose for its intended use and consistently produces reliable results.
Verification	Procedure used to evaluate the validity of a test result or opinion by repeating the comparison between a known and unknown.
Will	A requirement (future tense)

4. GENERAL REQUIREMENTS

4.1 Impartiality

The Central Forensic Science Laboratories are publicly funded Central Government Organization under the Directorate of Forensic Science Services, Ministry of Home Affairs, Govt. of India. The Laboratory provides crime scene examination services and Forensic examination services in the fields of Ballistics, Biology (including DNA), Chemistry (including Narcotics), Explosives, Toxicology, Documents, and Physics (including Audio video, Speaker identification & Computer Forensics).

4.1.1	All activities conducted at FSL are performed in a manner that ensures impartiality of its operations and objectiveness in accordance with requirements of an ISO/IEC 17025:2017 accreditation program and the laboratory's management system documents. Laboratory activities shall be undertaken impartially and are structured and managed to safeguard impartiality.
4.1.2	The Laboratory's objectives are described in the Mission and Operating Statements. FSL management, beginning with the Director, is committed to impartiality in all laboratory activities. All staff members are expected to remain objective, impartial, and independent when:
a.	Working a Crime case examination.
b.	Examining and collecting corroborative/ physical clues/evidences at a Crime scene.
c.	Examiner/ reporting officer testifying as expert witness in Court of Law.
4.1.2.1	**Laboratory Staff members shall avoid:**
a.	Situations giving rise to conflict of interest.
b.	Involvement in activities or association that would diminish confidence in their competence or interfere with their independent exercise of quality work, operational integrity and professional opinion.
4.1.2.2	**The investigation, analysis and other official duties should be free from:**
a.	Bias or preconceived conclusions
b.	Political pressure or other outside influences
c.	Extraneous information
4.1.3	Any conflicts of interest, any attempt to influence or any perceived pressure to investigate, analysis or other duties in prejudiced manner shall be brought to the attention of the Director/ Management immediately.
4.1.3.1	**DFSS/FSL Management System will make every effort to ensure that:**
a.	The quality of FSL's forensic services is not adversely affected due to inappropriate internal and external influences (including commercial, financial and/or political) on the professional judgment of all laboratory management and personnel.
b.	Laboratory Division personnel are never instructed to alter or falsify data.
c.	Personnel involved in dishonest activities shall be subject to discipline according to department policies and procedures.
4.1.3.2	**All members of the Laboratory shall strive to identify risks to independence and impartiality** and
a.	Will not engage in activities that may diminish confidence in FSL's competence, impartiality, judgment, or operational integrity.
b.	Shall never use confidential information for any purpose beyond the scope of employment.

c.	shall be aware of risks to impartiality due to their own personal activities and relationships
d.	Should invariably submit permission for outside employment, including volunteer work to the Director under ethics disclosure.
e.	Must notify FSL management immediately if an entity is attempting to or has exerted influence or pressure on them.
4.1.4	Laboratory personnel shall comply with all relevant rules for ethical conduct that includes Laboratory General Policy #041 Code of Professional Conduct, ISP Regulation 1: Code of Professional Ethics and Rules. Laboratory Personnel are expected to adhere to ethical standards including, but not limited to, the following:
a.	**Objectivity**—Examinations, investigations, reports, testimony, and other communications will be objective, impartial, based on the evidence, and within the staff member's knowledge and area of expertise. Full, clear, and accurate records of examinations and crime scene investigations will be generated and maintained.
	Competency and Proficiency—Technical/ Scientific staff will conduct only those examinations and investigations for which they are qualified by education, training, and demonstrated competency. They will accurately represent their qualifications to others.
	Professionalism—Staff members will uphold the law as well as FSL policies and procedures to the best of their ability and ethical responsibility. Any unethical or illegal conduct. Staff members will report immediately to their Director.
4.1.5	**Laboratory management will ensure that:**
a.	The Code of Ethics is integrated into the professional conduct and Ethics information for Government employees is provided during the new employee training programs.
b.	All staff members annually review the Code of Ethics. Additional ethics training may include the review of other related documents, such as the *Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists.* A record of the review shall be maintained in the quality assurance records.
c.	Appropriate actions are taken if there is a failure to review the document within the time frame allocated. Management is obligated to act if staff violates the Code of Ethics.
d.	At a minimum, the Laboratory shall identify risks to its impartiality annually.
e.	Identification of a risk of impartiality will be brought to the attention to Top Management
4.1.6	Plan to eliminate or minimize the risk will be executed and documented and this will be stored in the quality assurance records.

4.2. Confidentiality

4.2.1	All information obtained or analyzed during the performance of crime scene investigations and laboratory examinations are considered investigatory records of a law enforcement agency/ Hon'ble Courts; such information is confidential and not subject to public disclosure unless required by law. FSL is responsible for the management of all information obtained from case forwarding agencies and the information generated during the crime scene investigation or laboratory examination including paper record, electronic storage, and transmission of results. FSL regards such information as confidential and shall protect and shall not release confidential information to unauthorized personnel.
a.	FSL has a public website where it posts documents including, but not limited to, policies, corrective actions and personnel records such as resume but it does not publicly post case-specific details such as subject names unless required to do so under the terms of the Right to Information Act, 2005.
b.	Each employee is duty-bound to protect confidential information that is obtained in an official capacity, regardless of the source of the information. He is responsible for safeguarding confidential information from unauthorized distribution. Staff members will not

	access or disclose any confidential information regarding investigations or casework to the news media, family members, or others except when legally authorized or approved by the Director. All public and media requests must be directed to the Director, FSL.
4.2.2.	Confidential information shall only be released in accordance with the Laboratory procedures.
a.	Staff members may make case records and copies of case records available to authorized entities only. Authorized entities include, but are not limited to, police officers with a legitimate need for the records, public prosecutor, and those with valid court orders. When needed for official matter, FSL personnel can access the Case File in the Records Management System (RMS) and may release a report on the Court order.
b.	If required by law to release confidential information, FSL will notify the case forwarding agencies of the release. In the case of a request pursuant to the Right to Information Act, FSL will notify the case forwarding agencies the request has been made and provide the opportunity to submit a request to the Court to withhold the information from disclosure. Right to information requests received and processed by FSL are documented in file.
c.	Distribution to unauthorized entities is prohibited and inquiries from unauthorized entities should be referred to the appropriate law enforcement or criminal justice agency.
d.	The Forensic Scientist's Reports shall be maintained in the Examination Case File. Information will be released in written form, to a member of a criminal justice agency who has a need and right to know or with a valid court order. When the information contained in the Case Report is released, a Record of Dissemination shall be completed in the RMS. No Information in electronic or verbal form will be released; except to the Hon'ble Court through MedLEaPR/ ICJS portals. All questions related to release of records should be addressed to the Director.
e.	The written, electronic, or verbal dissemination of confidential information related to a criminal investigation or laboratory examination to persons outside of the criminal justice system (e.g. defense attorneys, news media, victim, family, etc.) is prohibited without written authorization (letter, email, etc.) from the prosecutor of the case or a court order.
4.2.3	Government of India (GoI) rule shall apply on the sharing /non- sharing of information to third party.
4.2.4	Other personnel acting on FSL's behalf, including contractual staff and interns, must keep confidential all information obtained or analyzed during the performance of their work for FSL, except as otherwise required by law.

5. STRUCTURAL REQUIREMENTS	
5.1	**Directorate of Forensic Science Services**, Ministry of Home Affairs (MHA) Government of India with the legal authority to provide forensic services to case forwarding agencies operates six Central Laboratories in Kolkata, Hyderabad, Chandigarh, Bhopal, Guwahati and Pune.
a.	The **Chief Forensic Scientist** serves as the organization head and provides guidance and vision for the entire Directorate and has overall leadership and authority of the Laboratory to include staff, budget, goals, and direction of the Laboratory and is responsible for administering, directing, and implementing the DFSS forensic operations. A full list of duties is available in the position description. The Chief Forensic Scientist reports to the Ministry of Home Affairs, Government of India.
b.	The FSL has an organizational chart demonstrating the management structure and its place within the Ministry of Home Affairs. The organizational chart is maintained by the Quality Manager.
c.	The Laboratory performs forensic testing services in the disciplines of Ballistics, Biology (including DNA), Chemistry (including Narcotics), Explosives, Toxicology, Documents, and Physics (including Audio video, Speaker identification & Computer Forensics) to meet, at a minimum, the requirements of the country to satisfy the needs of the Case forwarding agencies.
d.	The **Director** supervises all Scientific Divisions, the Management and Administration Sections and is responsible for ensuring the division's conformance with accreditation standards. The **Director** exercises full supervisory authority to coordinate and direct the day-to-day multi-discipline forensic investigation, testing, and analysis activities of the Laboratory through Division heads and reporting officers of their respective forensic disciplines. Director is also responsible for assessing and providing recommendations of substantial weight to the Chief Forensic Scientist with regards to laboratory budgeting, staffing, training, and technological needs. The Director reports directly to the Chief Forensic Scientist.
e.	The nominated **Quality Manager** has the authority and obligation to ensure that the requirements of the Forensic Quality Assurance Program are implemented and maintained through scheduling, coordinating, and evaluating all aspects of the quality system including audits. The Quality Manager ensures compliance with ISO/IEC 17025:2017 (E). The Quality Manager is the controller of all quality assurance records and is responsible for assessing and providing recommendations to the Chief Forensic Scientist and Director with regards to laboratory accreditation needs. The Quality Manager reports directly to the Director.
f.	The nominated **Technical Manager** has the obligation to ensure all technical requirements of the Forensic Quality Assurance Program that are implemented and maintained through scheduling, coordinating, and evaluating all technical aspects of the quality system. The Technical Manager ensures technical compliance with ISO/IEC 17025:2017 (E) in case examination reports under the accreditation scope of all divisions. Technical Manager is the controller of all technical crime case records and is responsible for assessing and providing recommendations to the Chief Forensic Scientist and Director with regards to laboratory technical needs. The technical Manager reports directly to the Director.
g.	**Heads of Divisions (Deputy Director & Scientist D or nominated Scientist)** are the human resources and quality assurance interface within the discipline. **Heads of Divisions** are also **Training Manager** of their disciplines. They supervise analytical activities and responsible for evaluating interpersonal skills and tracking performance metrics of direct reports, case management for the disciplines under their supervision, ensuring manuals are reviewed

	according to laboratory standards, tracking and approving purchases within the limits of their authority, ensuring work conditions, equipment, calibrations, measurement-uncertainty, monitoring and documenting appropriate corrective measures in relation to discrepant results. The Heads of Divisions report to the Director and Quality Manager.
h.	**Assistant Director (Scientist-C), Senior Scientific Officer (Scientist-B), Junior Scientific Officer (JSO), Senior Scientific Assistant (SSA)** are technical/scientific human resources and have in turn responsibility for all technical operations in divisions and the resources necessary to ensure quality forensic laboratory operations. They are responsible for technical content of Standard Operating Procedure (SOP), managing the performance of validations, the technical training of new analysts, ensuring quality control measures are being followed, and reviewing and evaluating case work and proficiency testing.
i.	The **Health and Safety Manager** is designated by the Director. The **Health and Safety Manager** oversees the safety program of the Laboratory and ensures that it is always implemented and followed. The Safety Manager provides educational opportunities in the areas of biological/chemical spill control, evacuation procedures, and hepatitis vaccination to laboratory personnel. The Safety Manager may develop a safety committee to assist with the program. The **Security Manager** responsible for security of FSL premises is designated by the Director.
5.2	**Member(s) of top management (Director, Quality Manager and Technical Manager)** are normally available to handle their respective laboratory's affairs. If necessary, Director will nominate a Deputy Director/ Assistant Director in turn of seniority to officiate as director in charge for a tour/leave period. The officiating director assumes those responsibilities given to the director until the director returns to duty. When appropriate, key management will appoint one or more individuals who may act on their behalf. The **Deputy Managers** in the needed areas are to be nominated by the Director.
5.3.	FSL provides a range of forensic services as specified in its ISO/IEC 17025:2017(E) scope of accreditation, includes Seized Narcotic Drugs and Psychotropic Substances (NDPS), Toxicology, Firearms, Crime Scene, Digital and Multimedia Evidence and Forensic Biology. Other departments include Administration. Only the accredited disciplines listed on FSL's scope of accreditation will claim conformity to ISO/IEC 17025:2017(E) accreditation requirements. Policies and procedures demonstrating this conformance can be found in the Discipline SOPs. The proficiency test requirements of the Quality Assurance Standards for Forensic Testing Laboratories will be applied to Forensic analysts and Technical support personnel performing analysis. The Laboratory performs activities under the authority of the Central Statutes and the Indian Laws/ Legal Codes.
5.4	FSL conducts its investigation and testing activities, both at its permanent laboratory facilities and at crime scenes, in accordance with the practices described in this manual to meet accreditation standards and to satisfy the needs of case forwarding agencies. This includes using standardized and validated methods and/or procedures to conduct quality forensic testing and crime investigations in an impartial manner. FSL has a quality management system that provides case forwarding agencies with confidence that it's technical and investigation services are accurate and impartial. FSL considers any recipient of its reports and/or services to be a case forwarding agencies. This includes, but is not limited to, law enforcement agencies, prosecutors, defense attorneys, forensic laboratories, and the public.
5.4.1.	The Laboratory conforms to the requirements in the Accreditation Body Policy on use of the Accreditation symbols and claims of Accreditation statutes.
5.5	The Laboratory Management System specifies the responsibilities and authority of all forensic personnel through position descriptions. The FSL has and maintains its policies and procedures in enough details to assure the

	consistent application of activities and validity of results to include analysis and data interpretation to arrive at a result, opinion or interpretation.
5.5.1	The Laboratory ensures adequate supervision and technical guidance of all employees including those in training. This supervision is performed by individuals familiar with the policies and procedures of the Laboratory and technical guidance performed by individuals familiar with the methods and procedures as well as the purpose and evaluation of the methods and procedures.
5.6.	**FSL Director**, in conjunction with key management, have the authority and resources to carry out their duties, including improvements to the quality system, and are responsible for ensuring that daily technical and/or investigation operations follow accepted policies and procedures. All sections have individuals who are technically responsible and have appropriate training and technical experience in that discipline. The Director has authority to make and enforce quality-related decisions across all divisions, including closing technical sections if quality-related issues arise.
5.6.1	FSL key management is responsible for the following:
a.	Implementing, maintaining and improving the management system.
	Key management will ensure that personnel have the means necessary to follow this quality manual and verify that complaints concerning their respective divisions are evaluated and documented. Key management will also ensure that technical staff members are trained and will monitor casework and other sectional activities to gauge compliance with the quality system.
b.	Identifying departures from the management system or from technical procedures.
c.	Initiating actions to prevent or minimize departures.
d.	Providing reports to management regarding the performance of the management system and any need for improvement.
e.	Ensuring the effectiveness of laboratory activities.
5.7	**Laboratory Division personnel have the authority and resources needed to carry out their duties, including:**
a.	Implementation, improvement, and maintenance of the management system.
b.	Identification of deviations from the management system documents.
c.	Initiation of actions to prevent or minimize such deviations
d.	Reporting to the Laboratory management on the performance of the management system and any need for improvement; and
e.	ensuring the effectiveness of laboratory activities
5.8.	FSL ensures that its management system has effective communication and integrity:
5.8.1	**Communication**
a.	FSL management is responsible for ensuring appropriate communication processes are followed within FSL and communication takes place regarding the effectiveness of the management system.
b.	These communications may take the form of lab-wide or sectional meetings, emails, memos or other written correspondence, formal and informal training sessions, and/or review of FSL policies and procedures. FSL encourages and supports a flow of communication throughout the organization that allows for input from all staff members.
c.	Clear, concise, and professional communications should be a hallmark of forensic science and

	FSL has established procedures for communicating results.
d.	FSL encourages regularly scheduled management and analytical section meetings that uses a documented agenda. These meetings are essential to support the flow of communications, information exchange, creative brainstorming, and the recognition of exceptional performances. Generally, attendance and minutes of meetings should be documented and made available for review.
e.	Division Heads are responsible for communicating to staff when sectional documents, including but not limited to SOPs, worksheets, and checklists, are revised and when new validations are approved for use on casework. These communications must be documented.
f.	Divisional meeting minutes and attendance records may also be used for documentation purposes if the meeting minutes clearly show what was discussed and include names of all parties/ members present during the discussion.
g.	If meeting minutes are used, Division Heads are also responsible for disseminating the information to staff that were not present at the meeting. This also applies if meetings are used for training and educational purposes.
h.	All training materials presented in a section meeting, however named, must also be presented to all staff not present during the meeting. The documentation requirement applies in all these situations.
i.	Requests for a deviation from this Quality Assurance (QA) Manual or a Laboratory Policy shall be made in writing through channels to the Director. The request shall include the reason for the deviation and the alternate approach to be used. The Director shall notify the employee and respective chain of command in writing of his decision. A copy of the deviation request and approval shall be forwarded to the Accreditation and Quality Manager for the QA records.
j.	The requirements in the Laboratory's management system documents shall be followed regardless of where work is conducted by the Laboratory personnel. The integrity of the management system shall be maintained when changes to the management system are planned and implemented.
5.8.2	**Integrity**
	Top management, with assistance from key management, will ensure that the integrity of the management system is maintained when changes to the system are implemented. Changes that may affect FSL's accreditation will be approved by the Quality Division prior to implementation. Management system changes will be communicated to appropriate staff.

6. RESOURCE REQUIREMENTS	
6.1.	**General**
	FSL management ensures necessary resources are available to manage and perform the activities listed on its scope of accreditation. These resources include personnel, facilities, equipment, systems and support services.
6.2.	**Personnel**
6.2.1.	**General Personnel Requirements**
a.	Staffing of the Laboratory Division shall follow the Recruitment Rules as notified in the Gazette of India. It is the need and objective of the Laboratory Division to employ only the highest qualified personnel. Contract employees will be held to the same standards and expectations as employees with respect to competency and proficiency testing.
b.	FSL expects all staff, whether employed by or under contract to FSL, who influence laboratory activities to act impartially, to be competent to perform their duties and to adhere to management system while on duty.
c.	The technical staff of FSL has the responsibility of ensuring that all requirements of the quality system are met and failures to conform to quality standards are minimized, prevented, or eliminated.
d.	Staff should understand the importance and relevance of testing and examination activities and review FSL's mission statement, objectives and quality policy statement yearly.
e.	All personnel must follow this Quality Manual and all applicable sectional procedures. All personnel also have the responsibility and authority to identify opportunities for improvement and to take appropriate measures to implement them.
f.	Technical staff will ensure that reports and case documentation are complete and will advise key management of technical problems or questionable results. Staff will also use validated methods while examining and/or investigating forensic evidence and in meeting the needs of stake-holders.
g.	FSL uses a comprehensive training program, a performance appraisal system, casework review, proficiency testing, method validation, reagent validation, and testimony monitoring to ensure the quality of work produced by staff members.
h.	New technical staff members review the policies, the quality manual, safety manual, section-specific documents, and other policies and documents listed on the On-Boarding Checklist for New Employees during their training program.
6.2.2	**Training and Competency**
	FSL maintains descriptions of job duties, which include competency requirements, for all personnel who influence laboratory activities.
6.2.2.1.	**Educational Requirements**
	The job descriptions, education, and experience requirements (class specifications) for each position are available in Recruitment Rules (RRs). Training, technical knowledge, skills, and experience requirements are documented in Discipline Training Manuals. Transcripts are required to verify completion of coursework to satisfy certain sectional coursework requirements. These transcripts are maintained in the staff members' personal files. Personnel performing specific tasks shall be qualified based on education, training, experience, and/or demonstrated skills, as required. Personnel shall have relevant knowledge of the technology used in their discipline. This knowledge is obtained and enhanced by attending training, seminars,

	webinars, literature review, etc.
6.2.2.2.	**Training Requirements**
	Division heads shall coordinate and oversee the training of Forensic Scientists (FS) within their respective units. The Laboratory Division's documented training program shall be used to train staff in the technical knowledge, skills, and abilities needed to perform their duties and to satisfy competency requirements including testing and examining of evidence. Newly hired Scientists, including contract employees, will complete appropriate training and demonstrate competence before beginning casework. All training programs will include a documented reading of all relevant in-house policies and manuals (including but not limited to administrative policies and procedures, the Health and Safety Manual, the Security Manual, and the Quality Manual). Each technical discipline within FSL has a documented training program. The training programs shall be structured to provide:
a.	The knowledge, skills and abilities necessary for new staff to perform their job duties.
b.	General knowledge of forensic science.
c.	Ethical practices in forensic science.
d.	The application of law to forensic science, criminal law, civil law, and court room testimony.
e.	Provisions for retraining.
f.	Provisions for maintaining skills and expertise.
g.	Criteria for acceptable performance.
6.2.2.3.	**Training program activities will also include, at a minimum:**
a.	A review of relevant written materials, such as journal articles, books, and Division specific SOPs.
b.	Laboratory exercises that demonstrate practical skills.
c.	On-the-job training, such as observing an experienced crime scene investigator as he/she is examining a scene, observing an Expert testimony in the courts.
d.	Training is carried out under the direction of the appropriate key management or a qualified designee. Director/Quality Manager appoints an individual or individuals to oversee the training of new staff members. This trainer is responsible for supervising the staff member throughout the training process.
e.	The Division Head will evaluate the new staff member's credentials and modify the training program if applicable. Previous training records summarizing educational qualifications, relevant courses addended and other supporting documentation shall be maintained for record.
6.2.3.	**Competency**
a.	All technical staff members conducting casework, regardless of academic qualifications or past work experience, must satisfactorily complete a competency test prior to being authorized to perform tests, analyzing crime exhibits/ test items, issue reports, offer opinions or interpretations, perform technical reviews or testify in court. Satisfactorily completing the test(s) means the intended results were achieved. Competency testing is also required for technical staff who cross-train in a new discipline and for technical support personnel. Technical support personnel are those individuals who perform casework-related duties within FSL at the direction of a technical staff member but do not issue reports related to conclusions reached.
b.	Staff must show the ability to convey results and conclusions and the significance of them in an appropriate manner before being declared competent to perform casework

	or to analyze items that could be used for testing.
6.2.3.1.	**Competency will include:**
a.	Examination of unknown samples covering the spectrum of assigned duties and areas within the discipline or category of testing of training.
b.	Writing a test report to demonstrate the individual's ability to properly convey results and/or conclusions and the significance of the results and/or conclusions.
c.	Courtroom testimony training- the testimony requirement can be met through a mock trial or oral examination that gauges the staff member's ability to communicate technical and FSL-specific information.
d.	Exceptions to the above requirements may be granted upon written approval of the Quality Manager.
e.	Non-technical staff members and those who do not analyze evidence or examine items that could be used for testing associated with active cases are not required to undergo mock trial training. However, whenever possible, a mock trial will be conducted before the non-technical staff member testifies in court for the first time.
6.2.3.2.	Personnel who review and authorize results, offer opinions or interpretations, or perform technical reviews of results, must meet the competency requirements specified in 6.2.3.1.
6.2.4.	**FSL Communication**
	FSL communicates to staff their duties, responsibilities, and authorities. Job duties and responsibilities are provided through job descriptions maintained by RRs and as directed by Director. Authorization to perform these duties and responsibilities are given to staff upon fulfilling training requirements and/or competencies.
6.2.5.	**FSLhas documented procedures for the following:**
a.	Competency requirements for technical staff.
b.	Selection of personnel
c.	Training programs include documented competency requirements for each discipline and/or sub-discipline within that Division.
d.	DFSS works to develop job descriptions for technical positions. DFSS is responsible for maintaining records related to job descriptions or postings.
6.2.6	**Staff training**
a.	Key management formulates goals with respect to the continuing education, training, and skills of all laboratory personnel. Identifying training needs, providing this training to personnel, and evaluating the effectiveness of this training is the responsibility of the Discipline Heads. Discipline Heads will provide occasions for each member to attend education courses when such attendance will directly benefit the effectiveness or efficiency of services provided.
b.	The following procedure shall be used to identify training needs and provide training to Laboratory personnel. Each fiscal year (April 1 to March 31), Division Heads shall consult with the Director to identify the relevant training needs within their respective Divisions and submit a list of requested training to the Training Manager. The Training Manager shall formulate the essential training priorities for the Laboratory Division. Training requests should be prepared by supervisory staff and shall be submitted through proper Department channels. Personnel attending external training should submit in writing or give an oral evaluation of the training. The supervisor shall retain any written evaluations in the attendee's personnel files.
c.	The training goals as outlined in each discipline's training manual are evaluated based on the following:
•	Present and perceived workload demands during annual management review to align

	competencies with case forwarding agencies' needs.
•	To promote professional development.
•	To ensure that mandated training is provided.
•	To ensure the best utilization of personnel resources.
d.	The effectiveness of in-house training is evaluated by the trainer and/or Division Head. Effectiveness may be evaluated by how well content meets stated goals or objectives and by the performance of trainees on competency tests and/or proficiency testing.
e.	Technical trainees are responsible for maintaining a training notebook, or equivalent record-keeping system that includes documentation of goals and objectives, exercises, exams, and other documentation supporting their training activities.
f.	Laboratory members are encouraged to improve their knowledge and skills through a variety of educational opportunities such as literature readings, attending conferences, and other professional meetings. Staff members may be allowed to attend training while on duty if funding is available.
g.	Training is documented so that it is clear what tasks were undertaken during the training program. When in training, personnel are permitted to use instruments and equipment while under the supervision of trained and authorized staff members. Copies of the Laboratory Training Record forms and all the remaining records of the training program shall be submitted to the respective Division Head. The training records shall be securely maintained as hardcopies or electronically on a network drive for at least five (5) years after which the file may be disposed with approval of the Laboratory Division Head.
h.	A competency memo will be issued upon completion of a training program that includes the scope of competency and date authorized for casework. Trainees are not allowed to issue independent reports unless they have received authorization to do so.
6.2.7	**Staff supervision**
a.	FSL has Division management, including Division Head, who are responsible for personnel under their direction.
b.	Each staff member is accountable to one and only one immediate Division Head for each forensic discipline in which they work.
c.	Supervising techniques should ensure the quality of the work product meets applicable accreditation standards, stimulate productivity, recognize exemplary performance, and encourage a free exchange of information within FSL.
6.2.8	**Staff authorization**
a.	The Laboratory Division Head authorizes qualified and trained personnel to conduct crime scene investigations, to perform specific tasks such as sampling (examining crime exhibits/ test items) operating specific instruments and equipment, laboratory analysis, and/or evidence handling, conducting technical reviews, issue reports, and/or handle evidence giving opinions, interpreting findings.
b.	Authorization memos are issued upon successful completion of the Division-specific training and a competency test. New memos are issued as the technical staff develops new competencies.
c.	No employee shall perform a procedure in which they have not been trained and authorized to perform.
d.	Authorization memos and supporting documentation are reviewed and approved by the Quality Manager and the Division Head before independent casework begins.
6.2.9	**Monitoring competency**
a.	Competency is monitored annually through programs such as the proficiency testing

	and blind QC programs, continuing education, and testimony monitoring. Critical tasks that require competence include, but are not limited to, collecting evidence samples, performing visual and chemical examinations, operating equipment and instruments, interpreting results, writing reports, testifying in court, and performing technical reviews.
b.	To maintain competency, skills, and expertise, technical staff members are encouraged to participate in continuing education. Section-specific continuing education requirements, such as those for Reporting Officers must be met. Skills and expertise can be maintained by:
•	Attendance at meetings, seminars, and conferences
•	Participation in scientific working groups
•	Review of current and applicable literature
•	Presentation and submittal of content for publication in professional journals
•	Presentations at technical meetings
•	Participation in college-level and other specialized courses
•	Completion of webinars or other online training opportunities.
6.2.10	FSL maintains literature resources or provides Internet access to literature resources such as relevant books, journals, and other literature dealing with each discipline. The technical leader must approve Webinars or other online training opportunities used to meet continuing education requirements.
6.2.11	Statements of qualifications, training certificates or other records of specialized training received, are maintained in staff members' personal files. SOQs are required for all technical staff members at the level of manager and below and should be updated yearly or more frequently if significant changes occur.
6.2.12.	**Authorization**
a.	The Technical Manager and Discipline Scientists have the authority to develop, modify, verify, and validate methods
b.	Forensic Scientists have the authority to perform Testing, analyzing, sampling, examining crime exhibits/ test items, giving opinions, interpretations, statements of conformity, and operating equipment and instruments used in casework as defined in individual's competency memo(s).
c.	Forensic Scientists have the authority to report, review and authorize results as defined in individual's competency memo(s).
6.3.	**Facilities and Environmental Conditions**
6.3.1.	FSL is well equipped with utilities to facilitate performance of all aspects of forensic testing. Comfortable work environment is ensured by providing adequate and appropriate space for its personnel, for storage of record and evidence, supplies, space for equipment and instruments. FSL ensures that neither testing nor test results are at risk of invalidation or diminished quality because of environmental conditions.
6.3.2.	Technical requirements for accommodation and environmental conditions are noted in sectional SOPs. Concerns related to environmental conditions that could affect casework should be brought to the attention of Division Head and should be investigated. If the environment is found to be a threat to reliable testing, conditions should be corrected in a timely fashion. Laboratory operations will be stopped when the detrimental environmental conditions persist that could impact instruments or equipment or cause an increased risk of contamination in the Biology laboratory and jeopardize the results.
6.3.3.	
a.	To maintain the environmental conditions of the Laboratory Division facilities, all

	employees shall maintain the physical appearance of the facility in a clean, safe, and orderly manner.
b.	Each employee is responsible for the appearance of his/her desk, work area, and other areas as assigned and shall maintain the area of responsibility in a safe and orderly manner by applying good housekeeping practices.
c.	Laboratory Services shall facilitate proper performance of the examinations, including but not limited to energy sources, lighting, and environmental conditions. Staff shall ensure that the environmental conditions do not affect the results of work to call into question the reliability of results.
d.	FSL monitors and records environmental conditions when required by relevant specifications, methods and procedures or when the conditions influence the quality of forensic results. If environmental conditions could affect the quality of an examination, the conditions will be recorded in the appropriate case records. Evidentiary items, reagents, DNA extracts, and other biological items are stored properly and separately to ensure their integrity. Dedicated refrigerators and freezers are clearly marked, and temperatures are monitored.
e.	Refrigerators and freezers used for storing evidence, temperature-sensitive chemicals, or critical reagents are checked periodically to ensure they are operating properly. The temperature of each unit should be kept within a range appropriate for the items being stored. Unless otherwise specified within sectional procedure manuals, temperatures should fall within the following parameters: • refrigerators: >0°C to 10°C (>32°F to 50°F) • freezers: ≤0°C (≤32°F) If the temperature of a refrigerator or freezer is out of range, adjustments should be made and the temperature rechecked and readjusted until the reading is in range. If, after adjustment the temperature remains outside the range stated above, the person who identified the problem is responsible for informing Division management. Section management is responsible for arranging any necessary repairs or replacements.
f.	One way to monitor temperatures is to record temperatures in a log that includes the date, temperature, and the recorder's name or initials. Manual recordings should be done at least once each week. All temperature logs and/or temperature reports are kept for one full accreditation cycle.
g.	Thermometers and temperature probes used to measure critical temperatures are verified at least annually against a thermometer traceable to National Standards.
6.3.4.	**Security procedures and facility access.**
a.	Access to and use of laboratory testing areas is limited and controlled. The Director or Security Officer determines the access level. Access levels will be reviewed and updated annually during the internal audit at minimum. The Laboratory will take measures to prevent contamination, interference, or adverse influences on laboratory activities. The Laboratory Management System will review these measures annually during the Annual Management Review.
b.	The Laboratory entrance/exit points and the outer perimeter always have security control. The internal testing areas of the Laboratory has a locking system. Keys for the Laboratory's individual interior forensic discipline laboratories will be issued to individuals by the Director/Security Manager. These items will be accounted for and documented as described in the Key Control Procedure. Non-FSL staff is not allowed unrestricted access to operational areas of FSL. Division head will implement appropriate measures to prevent unauthorized access to computers used for digital evidence examination.

c.	The Laboratory facility has a fire fighting system.
d.	Preventing contamination by maintaining clean work surfaces and examination implements.
e.	Effective separation between neighboring areas in which incompatible activities take place. Incompatible activities are separated by time or space to prevent contamination. Seized drug and toxicology analyses are performed in separate and distinct locations within FSL and instruments are dedicated. Items of evidence that potentially contain trace evidence (e.g., hair, fiber) from subject and victim in the same case are analyzed at different times or in different rooms to prevent cross contamination. Evidentiary and reference DNA samples are also handled at different times or in different locations to prevent cross-contamination.
f.	As much as possible, FSL is maintained in a clean and orderly condition. Each staff member is responsible for keeping his or her area clean. Caretaker services may be used when appropriate.
6.3.4.1.	Evidence storage areas are secured and have limited and controlled access. The storage conditions are designed to prevent loss, deterioration and contamination as well as maintain the integrity and identity of the evidence. Discipline Supervisors/ HoD will implement appropriate measures to prevent unauthorized access e.g. computers used for digital evidence examination.
6.3.5.	FSL does not routinely perform laboratory activities outside its building. However, if FSL needs to perform laboratory activities (such as obtaining reference blood samples at the courthouse) at sites or facilities outside of its permanent control, staff will ensure that the facilities and environmental conditions are suitable. This does not apply to crime scene examinations because those facilities and environmental conditions are beyond FSL's control.
6.3.6	FSL has an individual designated as Health and Safety Manager to oversee its health and safety program. He may be assisted by a safety committee. Please see The FSL *Health and Safety Manual* for additional information. FSL has an individual designated as Security Officer to monitor security control.
6.4.	**Equipment**
6.4.1.	**General**
a.	FSL is furnished with the proper equipment needed for the collection, sampling, examination, and testing activities performed by staff. This includes appropriate analytical instrumentation, measuring equipment, software, measurement standards, reference materials, reference data, reagents, consumables, and auxiliary apparatus necessary to perform these activities. If staff believes equipment is not operating properly, they must notify section management as soon as possible. FSL instruments and equipment will be used for testing purposes only by FSL staff. Non-FSL personnel are not allowed to use instruments or equipment without prior approval from the Director. If equipment is operated outside of the control of laboratory personnel, the equipment will be performance checked, at a minimum, prior to next use by laboratory personnel.
b.	Equipment used by FSL staff for testing is normally owned by FSL. If it is necessary to use equipment for testing that is not owned by FSL, approval must first be obtained from the Director/Technical Manager.
c.	Equipment and instruments are operated only by authorized personnel, or, in the case of trainees or interns, under the direction of authorized personnel. Personnel are typically authorized to operate equipment and instruments through completion of section-specific training programs.

6.4.2	**Equipment Inventory and Records**
6.4.2.1	Equipment which can influence the quality of the crime scene investigation and laboratory analysis shall be uniquely identified. The respective Division Heads and Quality Manager shall maintain an Equipment Inventory List and Maintenance Logs for the equipment for each Laboratory Division facility. All equipment issued to the Divisions, including the unissued equipment, shall be recorded on an Equipment Inventory List by the Division Head, who shall keep a Maintenance Log. All Equipment Inventory Lists shall be reviewed annually to ensure that they are kept up-to-date.
6.4.2.2	Records shall be maintained for each item of equipment which can influence the quality in examination/ analysis of crime exhibits. The record of equipment and/or instrumentation shall include the following, where applicable:
a.	identify the equipment/instrumentation and its software;
b.	name of manufacturer, model, and serial number and/or other unique identification;
c.	performance checks that equipment complies with the specified requirements;
d.	location of or individual assigned to the equipment/instrumentation;
e.	calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
f.	documentation of reference materials, results, acceptance criteria, relevant dates, and period of validity;
g.	the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment; and
h.	Details of any damage, malfunction, modification to, or repair of, the equipment.
6.4.2.3	Each Discipline will have procedures for the safe handling, transport, storage, use and planned maintenance of equipment. Discipline Procedure Manuals/Manufacturer's instruction and maintenance manual will outline any necessary procedures for maintaining measuring equipment to ensure proper functioning and to prevent contamination or deterioration. Laboratory equipment will be used by authorized personnel. Instruction and maintenance manuals will be readily available to the appropriate personnel. If manufacturers' information is not available, Division Head should determine the proper procedures for handling, transport, storage, and maintenance of that equipment. When equipment that is sensitive to movement (e.g. balances) and is used to make critical measurements is moved, a performance check must be conducted. Equipment manuals and SOPs should be stored near the equipment or in a location agreed upon by Division staff.
6.4.3	**Equipment Calibration**
a.	Each section must verify that equipment is calibrated or otherwise checked to ensure it meets specified requirements before being placed into service or returned to service. This includes equipment used for collection and sampling purposes.
b.	Equipment and corresponding software and hardware used for testing, examinations, and sampling must be capable of achieving the accuracy required by SOPs and must comply with specifications relevant to the testing being conducted. Equipment that

	significantly affects the quality of an examination requires regular quality control through internal validation, performance verification, external calibration, and/or intermediate checks.
c.	Section SOPs contain additional details when applicable. General service equipment not used for measurement purposes (i.e., hot plates, stirrers, non-volumetric glassware, cameras, and refrigerators) will be maintained through visual examination, safety checks, and cleaning as necessary.
d.	All equipment used for testing, including equipment for subsidiary measurements, that has a significant effect on the accuracy or validity of the test result is calibrated before being put into service. For measuring devices that have a significant effect on the accuracy or validity of the reported result and the result is a measurement that matters, the calibration is performed by an ISO/IEC 17025–accredited calibration laboratory that can demonstrate traceability to the International System of Units (SI) when possible.
e.	A *measurement that matters* is one that is used, or may reasonably be expected to be used, by a laboratory case forwarding agencies to determine, prosecute, or defend the type or level of criminal charges. All critical weight, critical volume, and critical length measurement devices are certified to NIST standards.
f.	Sectional SOPs contain details for ensuring the calibration of critical equipment. Calibration/performance check records are maintained, preferably in a location near the instrument or equipment. Measuring devices used by the Crime Scene Unit may be checked before being placed into service but are typically not considered critical.
6.4.4	**FSL calibration program**
	The following is a list of critical equipment requiring internal/external calibration: • pipettes • gauge blocks • steel rules (steel rulers) • standard reference weights • balances
6.4.4.1	The vendor conducting the calibration must demonstrate and provide documentation of competence, capability, and traceability. Competence is verified by selecting an ISO/IEC 17025–accredited calibration laboratory. Capability can be determined by reviewing the calibration provider's scope of accreditation, and, in lieu of accreditation, a competent vendor may also be one that provides certificates of traceability to a national standard. For devices that have little to no effect on the overall quality of testing, calibration vendors that can provide traceability to a national Standard will be considered competent. FSL maintains documentation of calibration activities.
6.4.4.2	Equipment calibration procedures are established according to the specific requirements of the test being conducted. Specified requirements for calibrations are listed in sectional SOPs. The interval for checking equipment calibrations will not be less stringent than manufacturers' recommendations. It will be necessary to check equipment calibration after any shutdown, repair and following service or other substantial maintenance. Equipment check documentation is maintained in section logbooks. It is not necessary to check equipment after calibrations are performed on site.
6.4.4.3	When critical equipment requires calibration, the calibration will be performed at least annually by an external vendor unless otherwise specified in sectional SOPs. The frequency of the calibration interval depends on the function of the equipment. Sectional SOPs may include further details regarding specifications and maintenance

	schedules for noncritical and critical equipment.
6.4.4.4	In addition to the annual balance calibration, sectional personnel complete a balance performance check at least monthly. When the use of a balance is infrequent, performance checks are not required each month if the balance is not used monthly. However, a check will be performed prior to each use.
6.4.4.5	Specific time frames for maintenance of equipment and/or instruments used in DNA testing will follow Quality Assurance Standards for Forensic DNA Testing Laboratories guidelines whenever stricter than those stated in this manual
6.4.4.6	When practical, equipment that requires calibration will be labeled with the last calibration date and the date the next calibration is due.
6.4.5.	The equipment will be removed from service if these checks indicate a problem with the ongoing use of the equipment. Volumetric equipment is visually examined and cleaned as necessary. Microscopes and attachments are cleaned and serviced periodically. Fume hoods and super glue chambers that are vented to the fume hood exhaust system are checked annually by an external vendor. See applicable sectional SOPs for additional information. CSU cameras will be handled and maintained in accordance with CSU SOP. Sections that re-use disposable equipment will have a procedure, validation study, carryover study, or some similar document to ensure these items do not contribute to contamination through misuse or re-use. See applicable sectional SOPs for further information. Sections that do not re-use disposable equipment are not required to state this in their sectional SOP.
6.4.6	When intermediate checks are needed to maintain confidence in the calibration of instruments or equipment, the nature and frequency of such checks are specified in applicable section SOPs. Manufacturers' recommendations or specifications will be considered when conducting these checks. Equipment or instruments that fail intermediate checks are removed from service. When appropriate, affected casework is reviewed. These intermediate checks are documented. If an intermediate check is missed, the instrument or equipment must be labeled or marked out of service until it is performance checked prior to use on casework.
6.4.7	If calibration and reference material data include correction factors that differ from those currently in uses, the correction factor will be updated accordingly on section specific worksheets. As an example, if a thermometer has a correction factor of ±2°C after calibration, that correction factor will be incorporated and documented into subsequent temperature readings.
6.4.8.	Results of quality control checks on testing equipment are reviewed to ensure that no unintended adjustments have been made that invalidate test results. When practical, access to equipment operational parameters may be restricted.
6.4.9.	When equipment and its software is significant to the analysis or test performed, FSL maintains the following information:
a.	The identity of equipment and any corresponding forensic software and/or hardware (Digital and Multimedia Evidence only).
b.	The manufacturer's name, type of instrument or equipment (e.g. mass spectrometer, microscope) identification, and serial number or other unique identification. This identification may be in the form of an asset management tag.
c.	Documentation that equipment has been validated or performance checked prior to use.
d.	The section where equipment is assigned.
e.	Calibration records (records shall include dates of calibrations and results), operating

	acceptance criteria for use in case work, and the due date of the next calibration.
f.	Reference material documentation, including results of testing, acceptance criteria, relevant dates, and expiration/re-testing dates.
g.	Documentation of maintenance plan and maintenance activities, as appropriate.
h.	Equipment records including records of malfunction, damage, modification, repair, adjustments and repairs. Maintenance, repairs, and performance verifications are recorded in instrument logbooks (maintained by each section) or an electronic equivalent as soon as possible after completion.
6.4.10.	Equipment that does not meet quality control criteria and that is not immediately repaired must be taken out of service. The equipment is labeled or marked to indicate that it is out of service until it has been repaired and shown by calibration or performance check to perform correctly. The instrument/equipment maintenance record is updated to show the date and reason it was removed from service. If appropriate, FSL will examine the effect of the defect on previously conducted tests and will institute any necessary corrective action.
6.4.11.	**Reagents**
	Reagents of superior quality shall be used to ensure the validity and reliability of the testing conclusions reported by FSL. Reagents prepared in-house are labeled with the identity of the reagent, concentration (if applicable), date of preparation or lot number, and, as applicable. Reagents will be prepared by authorized personnel and each Discipline will maintain records that will identify the identity of the preparer, the components used in preparation, who performed the quality control check and the results of the quality control check. When necessary, sectional SOPs contain further instructions related to special storage conditions and hazard warnings. Sectional SOPs will specify the frequency of reliability testing for reagents. Reagents will be tested before use or, if appropriate, concurrent with the test. Reagents not meeting quality control criteria are removed from use and affected casework, if any, is reviewed.
6.4.12.	**Reference Collections**
	Disciplines utilizing Reference collections of data or items/materials encountered in casework that are maintained for identification, comparison, or interpretation purposes (e.g. mass spectral libraries, drug samples, firearms, bullets, cartridges, DNA profiles, frequency databases) will document, uniquely identify and properly control the reference collection to protect the characteristics of interest. If the item is collected from casework, documentation of this must be included as part of the case record.
6.5.	**Metrological Traceability**
6.5.1.	Disciplines with factors contributing to measurement uncertainty will establish and maintain traceability by means of an unbroken chain of calibrations or comparisons linking the calibration standards to the relevant primary standards of the SI units of measurement to ensure the validity of results. *NOTE: In ISO/IEC 17025:2017, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty."*
6.5.2	Measuring equipment and/or reference standards shall be traceable to International System of Units (SI) of measurement. Suppliers of external calibration services shall be accredited to ISO/IEC 17025, with scope of accreditation covering the calibration requested. The calibration certificates provided shall contain the measurement results in SI units, measurement of uncertainty, evidence of ISO 17025:2017 (E)

	accreditation and traceability to National Standard.
6.5.2.1.	**Reference Standards and Materials**
	Reference standard refers to a traceable benchmark or level of quality that is used to calibrate equipment measuring values reported in SI units. Examples include NIST-traceable weights and thermometers. Reference standards are not to be used as both calibrators and controls unless it is shown their performance as a reference will not be invalidated. Reference standard performance is checked before and after any adjustment. *Reference material* is certified by a technically valid procedure and typically accompanied by a traceability certificate issued by a certifying body. Reference materials are traceable to SI units of measurement or to certified reference materials when applicable. Internal reference materials are checked as far as is technically and economically practical. If it is not possible or appropriate to trace reported results to SI units, FSL will ensure the reliability of reported results, when practical, using certified reference materials. Certificates of analysis provided by manufacturers are maintained in a designated location. A certificate of analysis received with a drug or other standard will generally serve to establish the initial quality of that standard. Reference material should not be stored with evidence samples.
a.	Certified reference materials shall be from a reference material producer accredited to ISO 17034, where available. If there is no certified reference material (CRM) supplier meeting the requirements stated above, FSL will confirm competency, measurement capability, and measurement traceability for the product being purchased. Documentation of confirmation will be maintained.
b.	When traceability of measurement to SI units is not possible, the FSL shall ensure metrological traceability to an appropriate reference.
6.5.2.2.	FSL does not perform calibration services.
6.5.2.3.	Only calibrated and traceable critical equipment will be used when altering the traceability measurement value of a certified reference material. For example, if a certified drug standard of a specific concentration is used for quantitative measurements and requires dilution; a calibrated pipette will be used.
6.5.2.4	Reference standards are not to be used as both calibrators and controls unless it is shown that their performance as a reference will not be invalidated. The performance of reference standards is checked before and after any adjustment.
6.5.3	**Handling, Transporting and Storing Reference Standards and Reference Materials**
	Reference standards and reference materials must be handled, transported, stored, and used according to manufacturers' instructions or approved section-specific policies to protect the integrity of the materials and to address any unique safety concerns for staff members handling the items. Reference standards and reference materials are handled, transported, and stored in a manner that prevents loss, damage, contamination, or deterioration.
6.6.	**Externally Provided products and Services**

6.6.1.	FSL ensures the suitability of externally provided products and services affecting laboratory activities when they are:
a.	Intended for incorporation into FSL's activities.
b.	Provided, in part or in full, directly to the case forwarding agencies as received.
c.	Used in support of FSL operations.
	NOTE: Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.
6.6.2.	**FSL Procurement Procedures for products and Services**
a.	Central Government purchasing guidelines govern the procurement of products and services for the Laboratory. The Purchasing Procedure (GFR) describes the selection and purchase of supplies and services.
b.	A description of the supplies, equipment, and/or services to be purchased, as well as product specifications and competency requirements, shall be described in the Statement of Justification and/or the supporting documentation.
c.	Sectional SOPs identify the characteristics of a reagent or critical supply (e.g., 95% ethanol) if the characteristic is relevant and critical to accurate testing procedure. Whenever practical, FSL will buy critical supplies and services from businesses that are accredited to ensure that their products will not negatively impact the quality of forensic analyses.
6.6.3	An approved vendor list for critical services and supplies that affect the quality of testing shall be maintained. To add a vendor to the approved list, a vendor evaluation form must be approved by the Director and then submitted to the Quality Manager. Whenever possible, approved vendors will have appropriate ISO certification. Approved vendors may also be those who supply certificates of analysis for reagents or standards, ship supplies in a timely manner, and provide the supplies at an acceptable cost. Historical data may be used to confirm the reliability of a supplier's products or services.
a.	When supplies and equipment are received, the staff receiving the item(s) shall document the inspection of the item(s) to ensure that they meet specifications and quantity described in the Statement of Justification. This quality control check can be done by comparing the packing slip and the purchase order request against what was actually received to ensure all are in agreement.
b.	The incoming item(s) shall not be used until conformance with specification has been verified. Any order discrepancies shall be brought to the attention of a Division Head or Director who will work with the Administration to resolve the matter. Each Discipline will maintain records of these actions taken to verify compliance.

7.	**Process Requirements**
7.1.	**Review of Requests, Tenders, and Contracts**
7.1.1.	The Division Head shall ensure that the Laboratory has the capability and resources for the services offered.
7.1.1.1	**Crime Scene Investigations**
a.	A request for crime scene investigation services by a criminal justice agency serves as a "contract" for service.
b.	The Division Head shall review the request for the work to be conducted and shall ensure that the Laboratory Division has the capabilities, including appropriate procedures and equipment, to meet the needs of the requesting agency
c.	Requests for crime scene examination services are reviewed to ensure the safety of the crime scene investigators and the ability of the Laboratory to complete the requested services.
d.	When necessary, personnel will clarify the needs of the case forwarding agencies, determine the probative nature and value crime scene, and define or discuss testing or investigation methods with the case forwarding agencies before the crime scene investigation begins.
7.1.2	**Laboratory Services**
	Case forwarding agencies may submit requests for testing to FSL. Prior to testing, FSL reviews all requests. The Division SOP provides evidence intake procedures. The forwarding agency shall indicate, on the Request for Laboratory Examination Form/forwarding letter, the type of evidence submitted, and examination(s) requested. Evidence Clerks or Receptionist(s) shall ensure that the Laboratory offers the appropriate test method for the customer's request prior to accepting the evidence. Any differences between the requested services shall be resolved before the Laboratory accepts the evidence.
7.1.3	Requests for analysis and for evidence investigations are reviewed to ensure that:
a.	FSL has the capabilities and resources to meet the case forwarding agency request.
b.	FSL's testing methods can meet the case forwarding agency requirements.
c.	Requests are reviewed by scientific staff to ensure that accurate submission information is included, and evidence is appropriately sealed.
d.	Technical aspects of the review, such as the methods to be used, are completed by scientific staff in the appropriate section. When necessary, personnel will clarify the needs of the case forwarding agency, determine the probative nature and value of the evidence and/or crime scene, and define or discuss testing or investigation methods with the case forwarding agency before casework or the crime scene investigation begins.
e.	FSL informs case forwarding agencies before deviating from an agreed-upon request for analysis. Personnel in sections should contact the case forwarding agencies in advance if the requested analysis could realistically result in destruction of the evidence (e.g., cell phones or firearms).
7.1.4	FSL strives to maintain good working relationships with case forwarding agencies. Maintaining these relationships may require:
a.	Asking for clarification if the request is unclear.
b.	Maintaining appropriate contact with the case forwarding agencies during lengthy examinations.
c.	Maintaining confidentiality.
d.	Seeking feedback from case forwarding agencies.
e.	Providing explanations or interpretations of reports.

7.1.5	The Laboratory will use test methods, including sampling, that are appropriate for the analysis and which meet the needs of the customer/ forwarding agency. Unless otherwise specified, the case forwarding agency agrees to allow FSL to use the scientific knowledge and expertise of its staff members to choose and apply appropriate testing and analytical methods, including sampling, of the evidence. If a request is received that cannot be fulfilled by FSL, then the case forwarding agencies is notified.
7.1.6	FSL will decline the case when requested methods are inappropriate or out of date.
7.1.6.1	The Laboratory reserves the right to decline acceptance or not conduct analysis of evidence deemed unsuitable, insufficient in quantity/quality, or of limited value. Discrepancies in case-related information may result in FSL's refusal to accept or analyze the evidence in question.
7.1.6.2	If a minor discrepancy between the submission information and the evidence received is discovered during the review of a request, it will be noted in the case record and may also be included in reports issued by FSL.
7.1.6.2.1	If significant discrepancies are noted, FSL will provide a report.
7.1.6.2.2	**Examples of discrepancies that may result in a report to the case forwarding agencies indicating the evidence has been rejected for analysis include:**
a.	Inconsistent subject name (including when the name is not the same on all documentation or evidence items and when the evidence and submission information do not match) when the evidence is associated with particular individual (such as in biology or toxicology).
b.	Conflicts between dates of birth on the evidence item and the submission form, when the evidence is associated with particular individual.
c.	Inconsistent case identifiers on evidence and submission form.
d.	Absence of pertinent information (subject name and case forwarding agency/ case identifier) on evidence labels.
e.	Compromised evidence (e.g., a leaking or cracked container or one with indication of tampering). If FSL finds compromised evidence (e.g. dropped evidence, broken blood tube/ glass slide) or other circumstance arises that compromises the original evidence and requires consumption of the evidence or use of a reserved portion (e.g. second blood tube in alcohol analysis), the laboratory will stop the analysis. In both instances, a request to consume will be communicated to the submitting agency in a report. The communication will include the reason why analysis was not completed or conducted. Testing will not resume until permission is obtained. The permission to consume must be documented in the case record. FSL may need specific information from the case forwarding agencies to fulfill a request for analysis. In such circumstances, FSL will contact the case forwarding agencies to obtain the needed information. If, after five business days, the case forwarding agency has not responded, FSL can close the request. The Division must notify the case forwarding agency that the request was closed then notify other FSL disciplines that have open requests on the same evidence. All requests where work has not yet started will be administratively closed until further information is received from the case forwarding agencies.
f.	Inconsistent descriptions on evidence received, including those on a submission form and in evidence documentation.
g.	When evidence is rejected for analysis, the reason for the refusal will be photographed whenever applicable (e.g. discrepancies between documentation and evidence items, improper seals, compromised evidence) or documented in writing.

h.	If FSL receives evidence in an insufficient quantity to complete testing & require adequate sample for additional testing, the laboratory will not proceed with analysis without obtaining permission from the submitting agency or a consumption order.
7.1.7	If evidence is accepted but not analyzed, the Report will include remarks that an item of evidence was not analyzed.
7.1.8	A copy of the Request for Laboratory Examination Form shall be maintained in the technical record. Pertinent discussion and communication regarding the customer's request shall be documented in the technical record. Records of pertinent discussions with a case forwarding agency about its' requirements or the results of the work are maintained in a communication log or equivalent record.
7.1.9	By submitting evidence to the Laboratory, the customer(s) agrees to allow the Laboratory to select the test methods to be used to analyze the evidence. Staff members are available to assist case forwarding agencies regarding evidence submission. If technical questions arise during the submission process, the staff member receiving the evidence will contact the appropriate technical staff member or Division Head for assistance. Depending on the caseload of the Laboratory and the needs of the customer, the customer may be requested to submit the evidence to a competent outside laboratory for analysis. FSL will not forward evidence to other laboratories and shall not request other forensic laboratories on behalf of the case forwarding agency.
7.1.10	Laboratory staff shall determine the test method to be performed, the scope of analysis, and the items to be analyzed according to Laboratory guidelines. The Laboratory acknowledges that each case is unique and shall conduct the most appropriate analysis possible. The Laboratory may conduct testing beyond the type of forensic examinations requested.
7.1.11	Under normal circumstances, individuals who are not staff members are not allowed to observe testing. This policy helps to ensure confidentiality of case information, limits potential for contamination, and ensures security of evidence and case records. Observing testing is not synonymous with touring the laboratory. Tours that are scheduled in advance, guided by FSL staff and brief in nature may be allowed in laboratories except for Biology. Tours through the Biology/DNA lab spaces are not allowed due to contamination concerns. Special arrangements (e.g., outside normal working hours) may be made to comply with court-ordered observations. Other special arrangement may be approved by FSL Director. Division Head or Laboratory Director shall be consulted for further instructions.
7.2.	**Selection, Verification and Validation of Methods**
7.2.1.	**Selection and Verification of Methods**
7.2.1.1.	The Laboratory will use scientifically valid methods and procedures for all tests performed to fit for the purposes required/requested by the case forwarding agency. As critical component in ensuring validity Discipline Procedure Manuals will include methods and procedures for all testing performed in that specific discipline to include sampling, handling, preparation of evidence to be tested, and, where appropriate, an estimation of the measurement of uncertainty with statistical techniques for analysis of test data.
	All Test Methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, for statistical rarity calculations, prior to comparison to a

	known item(s).
	FSL does not perform calibration services.
7.2.1.2.	Discipline Procedure Manuals will describe the method by which comparison of an unknown to a known are evaluated.
7.2.1.3.	Discipline Procedure Manuals will include or reference instructions on the use and operation of all equipment and instruments used by that specific discipline. Discipline Procedure Manuals will describe the handling and preparation of evidence for testing. Each discipline will maintain and keep up to date all equipment and instrument instructions; standards; manuals and reference information relative to testing performed.
7.2.1.4.	In most instances, the case forwarding agency does not specify the method to be used. FSL will determine the most appropriate method or methods of analysis based on the information provided by the case forwarding agency. Methods used by the Laboratory will either be validated laboratory-developed methods or published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or specified by the manufacturer of the equipment. Technical Managers will ensure that all methods operate properly before using them for testing and Division Head will approve the use of the method.
	Control samples or replicate testing will be used with infrequently performed test methods to show the tests are giving appropriate results. Sectional SOPs will identify infrequently performed tests or analyses, if any.
7.2.1.5.	Methods validated outside of the Laboratory will be evaluated prior to implementation. This will include reliability testing by the discipline through documented in-house performance verification. This verification will be documented and maintained in the discipline records for future reference. If the issuing body revises the method Division will repeat the performance check to ensure the revised method works in-house.
7.2.1.6.	The Division Head will coordinate the introduction of any new test methods used in the Discipline and will consult with the Quality Manager and the appropriate Technical Manager during the development of the new method. The new method will be documented, validated, approved, and communicated to the discipline prior to use in casework.
7.2.1.7.	Any significant deviations from test methods will be documented in the case record, technically justified and documented through the technical case review process. If it is necessary to employ non-standard methods, approval will be obtained from the Technical Manager prior to use. The nonstandard method will be validated prior to use on evidence items
7.2.2.	**Validation of Methods**
7.2.2.1.	Validations will be performed on all new technical methods or procedures to assess the procedure's ability to produce high-quality, reliable results. All validations are completed by authorized personnel. Disciplines will maintain a record of the validation to include the procedure used, requirements, determination of the performance characteristics of the method, results obtained, and a statement of validity of the method detailing as to whether the method is fit for the intended use.
7.2.2.1.1.	When new test methods are validated by FSL, the validation will include:
a.	Data interpretation.
b.	Data required to report test results, opinions, or interpretations.
c.	Identification of the limitations of the test method, reported test results, opinions and interpretations.
7.2.2.1.2	During validation, known samples representative of those encountered in casework are examined to determine if the procedure generates acceptable results. The performance

	characteristics evaluated during the method validation can include, but are not limited to:
a.	measurement range
b.	accuracy
c.	measurement uncertainty of results
d.	limit of detection
e.	limit of quantification
f.	selectivity of the method
g.	linearity
h.	repeatability or reproducibility
i.	robustness against external influences or cross-sensitivity against interference from the matrix of the sample
j.	and bias
7.2.2.3	The performance characteristics assessed (e.g., uncertainty, detection limits, selectivity of the method, linearity) shall be relevant to the customers' needs and consistent with specified requirements *NOTE: Performance characteristics can include, but are not limited to, measurement range, accuracy, and measurement uncertainty of the results, limit of detection, limit of qualification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interferences from the matrix of the sample or test object, and bias.*
7.2.2.4	FSL retains the following records of validation:
7.2.2.4.1	Digital and Multimedia Evidence sections can use published validation studies from reputable scientific, law enforcement, or educational organizations in lieu of an internal validation. In these circumstances, these forensic tools are performance verified prior to use in casework. There may be time-sensitive instances in which technical sections, such as Digital and Multimedia Evidence, may need to deviate from validated procedures. In extraordinary cases in which evidence might be compromised if analysis is not attempted in a timely fashion, methods may be employed without prior validation or performance verification if the examiner uses due caution to maintain the integrity of the evidence. Supervisory approval is required in these situations and the circumstances of the case and the analytical processes employed must be fully documented in the case record. These reports will not contain an accreditation statement or the logo of an accrediting body.
7.2.2.4.2	When changes are made to a validated method, the influence of the changes will be determined. If the changes are found to affect the original validation, a new method validation shall be performed. The new validation shall encompass, at a minimum, the specific areas affected by the changes to the method.
7.2.2.4.3	The data used to determine the influence of the changes is considered part of the validation study.
7.2.2.4.4	When method development, modification, verification, or validation is required, it shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources.
7.2.2.4.5	When the validation is completed, a copy of the Method Validation Report shall be forwarded prior to implementation "through channels" to the Division Commander for approval. The Method Validation Report shall include the following sections:
a.	**Introduction** – State the purpose and a brief description of the method validated or the change(s) to an existing validated method.

b.	**Method** – Include instructions for performing the method validated or changes to existing validated method including reagents, reference materials, quality control samples, instruments and equipment, and its performance or acceptance requirements.
c.	**Validation Process** – Describe how the validation was performed including determination of the performance characteristics of the method.
d.	**Results** – Summarize in text, tables, or graphs, the data collected during validation process. Discuss the meaning of the data and results in relation to the method validation. When applicable, determine the uncertainty of measurement.
e.	**Conclusion** – Summarize the results of the validation and include a statement on the validity of the method, detailing its fitness for the intended use.
f.	**References** – List any publication used in the development of the method or its validation.
7.2.2.5	Relevant management system documents such as the Training Manual, Procedures Manual, and/or Test Methods shall be updated to reflect new or changed methods and/or equipment. Staff shall be notified when a new or revised method is approved for use.
7.3.	**Sampling**
7.3.1.	The Laboratory will have a documented sampling plan for disciplines that take a representative sample of a substance or material for testing and report on the whole substance or material. The sampling plan will be available at the location where sampling is undertaken and will address the factors to be controlled to ensure the validity of the testing.
7.3.2.	When a sampling method is utilized, the procedure(s) must include:
a.	The selection of samples or sites.
b.	The sampling plans.
c.	How the sample is prepared from the received evidence to produce the item used for subsequent testing.
7.3.2.1.	The sampling method will also:
a.	Include an evaluation of the selected population for homogeneity.
b.	Ensure the population has a reasonable expectation of homogeneity before using the sampling plan.
c.	Make use of probability and provide an opinion or interpretation with a minimum confidence level of 95.45% (often referred to as approximately 95%).
d.	Ensure each item selected meets the sampling plan level of confidence to be tested completely.
e.	Provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity.
7.3.3.	The technical record shall include:
a.	Reference to the sampling method used.
b.	The date and time of sampling.
c.	Data to identify and describe the sample (e.g. number, amount, name).
d.	The identification of staff performing sampling.
e.	The identification of equipment used.
f.	Environmental or transport conditions.

g.	Diagrams or other equivalent means to identify the sampling location, when appropriate
h.	Deviations, additions to or exclusions from the sampling method and sampling plan.
7.4.	**Handling of Evidence Items**
7.4.1.	Procedures for the transportation, receipt, handling, storage, and retention of evidence items will be outlined in the Discipline SOP to ensure the integrity of the evidence and protect the interests of the Laboratory and the submitting agency.
a.	Procedures for protecting the integrity of all evidence and avoiding deterioration, contamination, loss, or damage to the evidence during handling, transporting, storing, and examination are found in the Evidence Policies in Discipline SOPs.
b.	Items received at the Laboratory are evidence. The Procedure for Evidence Management in Discipline Manual provides a course of action for meeting the standard.
c.	Evidence received at the Laboratory will be assigned a unique identifier comprised of the Laboratory case number. Item number as provided in the forwarding note of the submitting agency is preferred if it maintains the uniqueness of the evidence.
d.	Upon submission, evidence packaging is inspected to ensure that it is appropriate for the type of evidence it contains. In general, the staff member receiving the submitted evidence will ensure that the item is properly sealed. Evidence seals are inspected to ensure they protect evidence from loss, cross-transfer, contamination, or deleterious change.
e.	While in the care, collection, custody, and control of FSL, all evidence items are handled in a way that protects the integrity of the evidence and prevents loss, contamination, or deleterious change.
f.	Exceptions may be made for large or bulky items at the crime scene that do not easily lend themselves to sealing.
7.4.1.1	**Multi-Discipline Evidence Workflow**
	Case forwarding agencies may request that an item of evidence be analyzed by multiple disciplines. When this happens, the usual multi-discipline workflow is Biology followed by either Firearms or Computer Forensics (depending on the type of evidence). However, this flow may vary based on the type of evidence and the circumstances of the investigation. Requests for analysis of seized drug evidence that also includes requests for other disciplines are handled on a case by case basis by Division management. All technical staff, as well as those involved in case assignment activities, are responsible for reviewing requests to ensure that multidiscipline requests are processed in the correct order. The case record must clearly indicate those situations where section management was consulted for guidance on the flow of analysis.
7.4.1.2	**Evidence Received in an Unsealed Condition**
	Before evidence is accepted, the outer container must be inspected for a proper seal. If evidence is not properly sealed upon acceptance, the investigation agency may place a corrected seal over the original seal to ensure it meets FSL's expectations before it is delivered for analysis. A corrected seal is a proper seal placed on the evidence by forwarding agency when the evidence is observed to have a seal but does not meet the description of a proper seal set forth in Discipline SOP. This correction will be documented in the chain of custody comments for that specific item.
	Evidence will be rejected if its identity is compromised or if the requested testing is fundamentally inappropriate for the evidence submitted. If evidence is rejected due to a missing seal or is not packaged, Laboratory Division will photograph the condition of the evidence. The evidence will remain in the custody of the case forwarding agency

	until it is properly sealed/ packaged. Division will give notification to the case forwarding agency that the evidence was not properly sealed/packaged and therefore not accepted by FSL. If evidence is not sealed and/or not packaged and was inadvertently accepted from the case forwarding agency, Division will photograph the condition of the evidence, remediate the seal, and upload the photographic documentation into the case record. The evidence will be assigned to the appropriate Analyst and will proceed with analysis.
7.4.1.3	**Off-Site Evidence Collection**
	When evidence is collected off-site by FSL team, the evidence is packaged in separate containers to prevent loss, cross-transfer, contamination, and/or deleterious change, whether sealed or unsealed, during transport to FSL or an evidence storage facility. Evidence collected from an off-site location by FSL team is identified, packaged, and entered into the evidence management system as soon as practical
7.4.1.4	**On-site Evidence collection**
	Generally, no evidence is collected at FSL. Exceptions may include collection of blood samples at the directions of the Court. A certified or trained laboratory/clinical technician are engaged for drawing blood samples from the subjects on case to case basis. The evidence is packaged in separate containers to prevent loss, cross-transfer, contamination, and/or deleterious change, whether sealed or unsealed. Evidence collected on-site by FSL is identified, packaged, and entered into the evidence management system as soon as practical.
7.4.1.5	The following are requirements for all items of evidence received by FSL:
a.	Evidence is stored, handled, and prepared in a manner that prevents loss, contamination, degradation, and damage. Generally, this means examiners will open and examine only one evidence item at a time. However, the nature of some analyses (such as Firearms, Latent Prints, Digital and Multimedia Evidence) requires the comparison of multiple items at one time. Whether one or multiple items are opened at a given time, evidence will be protected as stated above.
b.	In some disciplines, evidentiary and reference samples must be handled at different times or in different locations to prevent cross-contamination.
c.	All evidence stored by FSL will be properly sealed. All seals placed on evidence by FSL staff must include the initials or signature of the individual placing the seal on the item.
d.	Evidence must be received by FSL in a condition that ensures evidence is protected from loss, cross-contamination, and/or deleterious change**.** If this requirement is not met, the evidence may be rejected by FSL.
e.	After evidence has been examined, analyzed at FSL, it will be re-sealed as soon as practicable.
f.	All evidence in the process of examination is maintained in a secured, limited-access area under proper seal.
g.	Proper security may be achieved by storing evidence in refrigerators or freezers, vaults, rooms, or locked cabinets.
h.	Access is limited to personnel authorized by the Division Head.
7.4.1.6	For situations in which there is an expectation of frequent or multiple analyses of an item or during the process of examination of the item, the evidence item may be stored unsealed in a secure, limited-access area, if the integrity of the item is maintained. During the process of examination, if a technical staff member needs to leave for a short time, such as for a break, the evidence may be left unattended in an area with limited access.

	Unless there is a justifiable expectation of frequent analyses or examinations, evidence is maintained in a secured limited-access area under proper seal.
7.4.1.7	A chain of custody is maintained for evidence submitted to FSL. These chains are records of the submission of evidence to FSL as well as all internal transfers. The chains of custody include the date of receipt or transfer and a description or unique identifier of the evidence. Staff members are responsible for ensuring evidence items have appropriate item descriptions recorded in case file.
7.4.1.8	When evidence is subdivided in FSL, sub-items are tracked through the chain of custody to the same extent that original evidence items are tracked. In some instances, subdivided items are packaged in a container with the original "parent" item. These items may be identified as "packaged with parent" in case file. A chain of custody for the parent item will also apply to the "child" item packaged with the parent.
7.4.1.9	Each person acknowledges by signature, initials, at the time of submission or transfer, when evidence transfers from person to person or to a storage location.
7.4.1.10	Generally, evidence is returned to the case forwarding agency after completion of analysis. Exceptions are specified in sectional SOPs. FSL reports include a statement regarding the disposition of evidence. Evidence that is not in the care, custody or control of FSL will not be retrieved by FSL for the sole purpose of transporting that evidence to court.
7.4.1.11	FSL notifies case forwarding agencies when items of evidence are to be collected. If these items are retained by FSL, they will be preserved in a manner conducive to future testing.
7.4.2.	Evidence received for examination is uniquely identified. This unique identification is retained throughout the life of the evidence item in FSL and is used during evidence transfers to, within, and from FSL. All evidence items received (this includes items received but not tested) are identified and tracked manually. This system allows for, transfer of evidence within FSL, and receipt and return of evidence.
7.4.2.1.	Individual evidence items or containers must be marked with a unique identifier. An item designator will be used with the unique case number to distinguish items within a case. If it is not possible to mark the evidence or if marking it could affect the integrity of the item, then the proximal container will be labeled.
7.4.3.	If, at the time of inventory, the condition of the evidence is not as expected or specified by the case forwarding agency, if clarification regarding the condition of the evidence is needed, or when additional information is needed, the case forwarding agency will be consulted. This communication is documented within the case record. In some instances, the case forwarding agency may require evidence to be tested even though specified conditions were not met. In these situations, FSL will include a disclaimer in the laboratory report that clearly indicates which results are affected.
7.4.4.	If evidence must be stored under specified environmental conditions, those conditions will be maintained, monitored, and recorded.
7.5.	**Technical Records**
7.5.1.	All Analysts will keep notes which adequately document the basis for any findings concerning evidence analyzed and tests performed in every case for which they have evidentiary analysis responsibilities.
a.	The start and end date of the analysis will be documented for each case in the file. The start date is the date analysis or evidence examination begins. The end date is the date the analyst finalizes the case sending it for technical and/or administrative review.
b.	Analysts will document original observations, data and enough information to establish

	an audit trail and issue a report.
c.	All records will indicate the identity of the personnel that performed each aspect of the case by documenting in the examination notes.
d.	The analyst's name or initials along with the Laboratory's unique case number will be present on every page of the case examination records.
e.	It is the responsibility of all analysts to prepare a report which contains the results and conclusions of analyses performed for every case for which they have evidentiary analysis responsibilities. When technical records are prepared by an individual other than the analyst who interprets the findings, the individual's handwritten initials will be on each page of the documentation representing his/her work.
f.	Case records contain enough information to facilitate, if possible, the identification of the factors affecting uncertainty and to enable any test to be repeated under conditions as close as possible to those of the original.
g.	Equipment, instrumentation, or forensic software used during analysis that has a significant influence on the results of the test/examination shall be recorded in the case record.
h.	Instrument operating parameters are recorded in the case record or in a retrievable form that is available for review.
i.	For each page of the examination documentation, a numbering system will be used which indicates the total number of pages used.
j.	When a critical finding is independently checked by a second individual, it will be conducted by someone authorized to perform independent checks in that category of testing. This check will be documented in the case record to indicate that the finding was checked, agreed to, by whom, and when. This independent check should not be confused with a technical review. Further information related to independent checks may be found in applicable sectional SOPs.
7.5.1.1.	Technical records are of enough detail to reproduce or allow the review of examination or investigation results. The following constitutes a technical record of analysis performed and, when applicable, will be maintained in the case record file:
	Administrative documentation
•	Submission forms/requests for analysis
•	Evidence inventory and description
•	Chains of custody
•	Communication logs
•	Report(s) of analysis
•	Documentation of technical and administrative review
•	Quality Incident/Corrective Action Reports
•	Administrative documents, FIRs, MLRs supplied by the case forwarding agency
	Examination documentation
•	Raw data
•	Photographs
•	worksheets
•	case associated notes
•	notes regarding analysis
•	graphs and chromatograms
•	standards and controls
•	other documents produced and used to reach a conclusion
7.5.1.2	Administrative and examination documents must be uniquely identified by either the

	assigned forensic case number or the requesting agency identifier (agency case number). Examination documentation must also have the initials or name of the examiner, on each page.
7.5.1.2.1	Examination records that bear the unique identifier and initials on an original record may be copied for filing in multiple places without the necessity of placing original identifiers on each copy. If the staff member's initials are visible in a photograph, then it is not necessary to add handwritten initials. If electronic records are printed, the unique identifier will be on each page of the printed documentation. When electronic records are viewed on a computer, the unique identifier will be visible on the screen.
7.5.1.2.2	Pages of internally generated examination or investigation records are numbered using a system that indicates the total number of pages. This applies to hardcopy records, including those that are scanned into an electronic record keeping system. Records analyzed in an electronic system and maintained only in an electronic system are not subject to this requirement. When examination records are recorded on both sides of a page, each side is treated (identified and initialed) as a separate page.
7.5.1.3	Abbreviations, acronyms, and symbols are acceptable in examination records if the meanings are readily comprehensible to a reviewer and the meaning of the abbreviation or symbol is documented in the sectional SOP. Abbreviations that are common in a discipline and understood by anyone in that discipline do not have to be listed in a table of abbreviations. Examples include, but are not limited to, chemical element symbols and standard units of measure.
7.5.1.4	Examination documentation is of enough detail to support the conclusions. Documentation is such that in the absence of the examiner or test report, another competent examiner could evaluate what was done and interpret the data. This includes the identity of instruments used and the personnel conducting the analysis.
7.5.1.5	Case records on paper must be legible and recorded using ink. This requirement does not apply to administrative documents submitted by the case forwarding agency. Exceptions may be made if environmental conditions prevent the use of ink. Pencil may be used if appropriate for making diagrams or tracings. While original notes may be recopied, all original notes must be maintained as a permanent component of the case record unless captured electronically and the electronic copy has been found to be legible and accurate.
7.5.1.6	Observations, data, calculations, and other examination documentation are recorded at the time they are collected or made and are uniquely identified (forensic case number, agency case number/laboratory number). It should be clear from the case record, all stages of analysis/examination and the date each stage was performed. Records should show the date images such as chromatograms and photographs were collected. When a test result or observation is rejected, the reason for the rejection, the identity of the individual(s) rejecting the result or observation, and the date shall be recorded.
7.5.1.7	The Crime Scene Team, Digital Forensics, ballistics division must keep all photographic images, regardless of photographic quality, taken during the examination process. These images are considered examination documentation that could be used in lieu of the evidence. The images must be included in the case record and stored in an approved FSL repository.
7.5.1.7.1	The Biology, Seized Drugs and Toxicology laboratories do not typically use photographs in lieu of the actual evidence items. Therefore, when a photograph is taken that is of poor photographic quality (e.g. blurry, the entire item was not captured in the image frame), it will not be considered part of the case record. However, the blurry or otherwise unusable photograph must be preserved in an approved FSL repository Therefore, no photograph, regardless of photographic quality, may be deleted unless

	that photograph has been added to an approved repository and the staff member has verified the image uploaded to the repository correctly. The images in this repository must have, at a minimum, the forensic or agency case number that the photograph is associated with.
7.5.1.7.2	If duplicate photographs (e.g. multiple good quality photographs of the same item) are captured, it is only necessary to upload one of the photographs to the case record. The additional duplicate photographs shall be retained in the same manner as mentioned above.
7.5.1.7.3	When the Crime Scene team examines the scenes, the examined physical evidence and copy of relevant scene photographs captured must be returned to the agency and a CD/DVD copy of the photographs must be kept in the case folder/record. The return of the items must be documented on the chain of custody.
7.5.1.7.4	If a situation arises in which evidence can be recorded or collected only by photography, then the photograph is treated as evidence. These photographs will be tracked with a chain of custody.
7.5.1.8	FSL does not perform calibration services. Data related to repairs, preventive maintenance and external calibrations of testing equipment is maintained as described in section SOPs.
7.5.2.	Changes and alterations made prior to technical/administrative review will be initialed by the person making the change. When striking out information in a case record, a single line is drawn through the error and initialed. Mistakes are not erased, made illegible, or deleted. Erasures on crime scene sketches are not considered mistakes and are not subject to these requirements. These requirements do not apply to changes and alterations made on administrative documents provided to FSL by the case forwarding agency. Changes and alterations made to the case record after the technical/administrative review process has started must be dated and initialed.
a.	In the case of electronic records, equivalent measures are taken to preserve original data. Any changes made to completed examination records generated and/or maintained in an electronic form are tracked, which means enough information is provided to determine what was changed and who made the change.
7.5.3	FSL does not consider test reports to be examination documentation. Therefore, drafts of test reports do not have to be maintained.
7.6.	**Evaluation of Measurement Uncertainty**
7.6.1.	Uncertainty of Measurement (UM) shall be evaluated, or estimated when applicable, for all reported quantitative results. The purpose of calculating the UM is to ensure that quantitative results provided to case forwarding agencies can be understood within the context of accuracy and precision of the methods used. An estimation of uncertainty is determined for quantitative measurements when these numerical values are listed on the test report and there is a reasonable expectation that a case forwarding agency will use these results to determine, prosecute, or defend the type or level of criminal charge. Estimation of UM is not required for qualitative tests. Examples of measurements that require an estimation of uncertainty include the barrel length of a long gun, overall length of a long gun, controlled substance weights, and blood alcohol values. Uncertainty is reported using the same units as the measurement it supports.
7.6.1.1.	The following records shall be maintained for each evaluation and estimation of measurement uncertainty:
a.	The specific measuring device or instrument used for a reported test result to be included in or evaluated against the estimation of measurement uncertainty for that test

	method.
b.	The process of rounding the expanded uncertainty.
c.	The coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%).
d.	The schedule to review and/or recalculate the measurement uncertainty.
7.6.2.	FSL does not perform calibration services.
7.6.3.	When estimating uncertainty, all uncertainty components important to the given situation (those that could contribute more than 10% to total UM) will be considered.
	If the nature of the test precludes rigorous, metrological, and statistically valid calculation of uncertainty, then FSL will at least attempt to identify the components of uncertainty and make a reasonable estimation. Reasonable estimates will be based upon knowledge of the performance of the method and on the measurement scope and will make use of any previous experience and validation data. The form of reporting of the result will not give a wrong impression of the uncertainty.
7.6.3.1.	Measurement uncertainty will be evaluated, or estimated when applicable, for all reported quantitative results.
7.6.4.	Sections must maintain records of their UM estimations. These records will include:
a.	Statement defining the measurement.
b.	Statement of how traceability is established for the measurement.
c.	The equipment (e.g. measuring device(s) or instrument(s)) used.
d.	All uncertainty components considered.
e.	All uncertainty components of significance, including those that arise from sampling, and how they were evaluated.
f.	Data used to estimate repeatability, intermediate precision, and/or reproducibility.
g.	All calculations performed
h.	The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.
7.7.	**Ensuring the Validity of Results**
7.7.1.	The Laboratory will monitor the validity of testing using quality control procedures. Each Discipline Procedure Manual will outline the quality control procedures for that specific Discipline. The following are examples of quality control procedures:
a.	Use of certified reference material and/or internal quality control using secondary reference material.
b.	Use of alternative instrumentation that has been calibrated to provide traceable results.
c.	Functional check(s) of measuring and testing equipment.
d.	Use of positive and negative controls
e.	Participation in proficiency testing programs
f.	Replicate tests using the same or different methods.
g.	Retesting of items.
h.	Correlation of results for different characteristics of an item.
i.	Review of reported results.
7.7.1.1	The following are requirements for the technical, administrative and testimony review processes:
a.	Chains of custody must be reviewed during the technical or the administrative review to ensure all transfers were captured and are accurate. Technical and administrative reviews may be conducted by the same person. Technical staff may not conduct a technical or administrative review on their own work product.
b.	Evidence submitted to FSL for analysis should not be returned to the case forwarding agency until after the technical and administrative reviews are completed.

c.	The Laboratory will perform technical review on 100% of scientific examination documentation and test reports prior to release. Verifications are performed as specified in Discipline Procedure Manuals. The technical review process ensures that conclusions of technical staff are reasonable, within the constraints of validated scientific knowledge, and supported by examination records, notes, and/or diagrams. Technical reviews are conducted on all reports or records that contain analytical results, conclusions, or associations.
d.	Technical reviews will be conducted by a qualified competency tested analyst who has extensive knowledge of the Discipline through casework, supervision, training and/or regular casework review. The reviewer will have knowledge of the Laboratory's technical procedures. A memo will be approved by the Director to authorize an analyst as competent to perform technical reviews. Technical reviews are not conducted by the author or coauthors of the examination records or test report under review.
e.	In most instances, the technical review is completed before the test report is released. A record of the review is made to indicate that the conclusion has been checked and agreed to, by whom, and when.
f.	All changes made to administrative and technical records because of verification, technical review or administrative review must be tracked in the case and/or the batch record. Section management will determine what tracking method is used. When non-electronic forms such as worksheets or checklists are used, these must be added to the case and/or the batch record.
g.	Each case record is technically reviewed to include a review of all examination documentation and the test report to ensure:
•	Conformance with Laboratory and Discipline procedures
•	Data supports the results and/or conclusions (including calculations for accuracy)
•	Accuracy of the test report
•	Associations are properly qualified in the test report
•	Test report contains all required information.
7.7.1.2	The Discipline Head, Technical Manager will resolve any differences in opinion between the case analyst and the reviewer.
7.7.1.3	To ensure the quality of forensic results, FSL may subject completed casework to secondary review.
7.7.1.3.1	**Administrative Reviews**
	An administrative review of the case record is conducted prior to the release of the test report. The review is documented in the case record and is conducted by someone other than the author of the report. Administrative reviews are performed on 100% of completed casework.
	The administrative review includes:
a.	Review of the test report for spelling and grammatical accuracy.
b.	Review of all administrative records to ensure that the assigned case number is on each page.
c.	Review of all examination records to ensure that the unique case identifier and technical staff member initials or signature are on each page.
d.	Review of the report to ensure that all key information is included.
e.	The administrative reviewer will review the Request for Laboratory Services Form, the test report, bench notes and all additional case documents, to ensure agreement with the following areas:
f.	Requesting agency
g.	Agency case number

h.	Laboratory case number
i.	Officer's name
j.	Agency item numbers and descriptions.
7.7.1.3.2	**Testimony Reviews**
	The Laboratory will monitor the testimony of all testifying personnel. Each testifying individual will have an evaluation of their testimony at least once per calendar year. Court monitoring provides constructive feedback both positive and any needed improvement. This may be accomplished through one of the following methods:
a.	Communication by Laboratory Management with a Court Officer
b.	Review of court transcripts (if available) by a technically competent analyst.
c.	The Witness Evaluation Forms are used to obtain testimony feedback. The form should be returned directly to the Laboratory's Quality Manager. The Quality Manager will review the form and provide a copy to the Division Head. The Division Head will provide the testimony feedback to the Reporting Officer.
d.	Testimony evaluations are conducted by individuals deemed technically competent in that area of expertise based on training, experience, and competency
e.	The completed evaluation form must be reviewed with and signed by the witness, the reviewer and the witness's supervisor or Technical Manager. The witness should be given appropriate feedback, positive and negative, noting any area needing improvement.
f.	If the evaluation indicates the possibility of a serious problem (either with the witness or with a procedure) or the overall presentation is unacceptable, then key management (for example, the Director, or division Head) will act to remediate the problem. Recommendations for remediation may include, but are not limited to, communications training, remedial technical training, additional mock court training, or a review of technical procedures or methods. The actions taken must be documented through the Quality Manager.
g.	Testimony monitoring records must be kept for at least one accreditation cycle or five years, whichever is longer.
7.7.2	FSL maintains a documented proficiency testing program. The proficiency of all technical staff is tested to the extent of their casework authorizations. The proficiency program is a reliable means of verifying that FSL's technical procedures are valid and that the quality of each technical staff member's work is maintained. The purpose of proficiency tests is to demonstrate the ongoing competence of FSL and/or that of its technical staff and to identify areas or skill sets for which additional training or more stringent quality control may be necessary. Proficiency samples are external. External tests are examinations prepared by, provided by, and reported to sources outside FSL. The proficiency tests are open in nature, meaning staffs are aware they are participating in a proficiency exam
a.	FSL's proficiency program meets at least the minimum requirements set by its accrediting body.
b.	Each Discipline of the Laboratory will participate in proficiency testing. The Quality Manager will coordinate the ordering and submission of proficiency tests for the Laboratory. Approved providers will be used when available. Approved providers are those that operate in accordance with the ISO/IEC 17043 standard. **Mostly proficiency tests samples provided by other Central and State Laboratories are administered.**
c.	At least one external proficiency test will be successfully completed each year for each discipline of forensic science the Laboratory provides service in and will release the

	results to accrediting body
d.	Each analyst performing casework will successfully complete at least one internal or external proficiency test per calendar year in his/her forensic science discipline.
e.	Laboratory members will perform proficiency tests by utilizing the same test methods, technical review, verification, and administrative review procedures as are normally applied to casework. Each proficiency test will have a case file.
f.	All proficiency test documentation is maintained in the quality assurance records. Proficiency test results are evaluated based on the discipline. Blood alcohol results must fall within two standard deviations of the grand mean reported by the provider with the reported uncertainty of measurement range considered, if applicable. Controlled substances, firearm, serial number restoration, tool mark, crime scene, footwear, and biological screening results must be consistent with the reported result by the provider. Should any variations of results arise within these categories of testing, the Division Head and Quality Manager will evaluate on a case by case basis. DNA profile typing data must have no analytical errors. Results and conclusions reported must be consistent with the DNA section standard operating procedures and interpretation guidelines.
g.	The nominated Proficiency Test Manager shall have a documented schedule for proficiency testing which shall be followed through Technical Manager. During the accreditation cycle, a representative sample of the components/parameters, methods, and key equipment/technologies within each discipline listed on the scope of accreditation shall be included on the proficiency testing program.
h.	Technical review, verification, and administrative review policies will be followed as they are in casework. Should consultation be required, the one or more individuals with whom the proficiency is discussed may not perform a technical or administrative review of the test. Consultation may not be with individuals who have knowledge regarding the test beyond the information that is available from the individual performing the test in question.
i.	The Technical Manager will maintain the proficiency testing records and proficiency testing program records to include:
•	Proficiency test number
•	Discipline
•	Location where the test was completed
•	How samples were obtained or analysed
•	Expected results
•	Identity of the person taking the test
•	Originals or copies of all data and notes supporting the conclusion (full details of the analyses/examinations undertaken, and the results and conclusions obtained)
•	Evaluation of the results with any discrepancies from expected results noted
•	An indication that the performance was reviewed, and feedback provided to the analyst
•	Details of the corrective actions taken (when necessary); and
•	Records submitted to the proficiency test provider, when applicable

j.	**Evaluating proficiency tests**
➢	The results of the proficiency test shall be reviewed by the respective Division Head and feedback communicated to the Quality manager via the consolidated Proficiency Test Report Form signed by Technical Manager. Proficiency tests are evaluated both in terms of conformance to the expected results and the quality of supporting documentation. Successfully completing a proficiency test means either obtaining the expected results or completing appropriate corrective actions. Discrepancies between the reported results and the expected results will be evaluated by section management or a technically competent staff member to determine if the results are consistent with FSL's policies and procedures. If the results are not consistent and these discrepancies are significant, the test is deemed "unsatisfactory" and corrective action is initiated. Significant discrepancies are those that raise an immediate concern regarding the quality of FSL's work product. Examples include erroneous identifications or false-positive findings. Management has the authority to implement corrective action policies for less significant occurrences, such as missed identifications or false-negative results.
➢	Some external proficiency tests, such as those in the Cyber Forensics/ Digital/ Multimedia Evidence (CDME) area, may not mimic routine casework. For instance, CDME staff are routinely asked to image/extract derivative data but do not routinely interpret the extracted information. Current proficiency tests provide the extracted derivative data and test the staff member on interpretation of the data. FSL considers interpretation of the derivative data to be investigative in nature, not forensic.
➢	Proficiency test records will be retained for at least one full accreditation cycle or five years, whichever is longer.
7.7.3.	Quality control data is: i) analyzed ii) used to control and if applicable iii) improve FSL activities. If the results of data analysis are outside predefined criteria, action is taken to correct the problem and to prevent incorrect results from being reported. Examination results will not be released if quality control data are outside of defined criteria. Further detailed information can be found in applicable sectional SOPs.
7.8.	**Reporting of Results**
7.8.1.	**General**
	The Crime Scene Investigation Report (CSI) report is called an Incident Report and the Laboratory Analysis report is called a Forensic Examination Report.
	Testing results are provided to case forwarding agencies in written electronic format and include information requested by the case forwarding agency, information necessary for the interpretation of the results, and all information required by the method used. Preliminary verbal results cannot be provided to the customer prior to a written report being completed.
	An accrediting body's symbol is used on laboratory reports issued by accredited disciplines of FSL. Accredited disciplines may also include an accreditation statement on their reports. The symbol and/or statement will be approved by the Quality Manager before being added to report templates.
7.8.1.2	FSL testing results and discrepancies (e.g. broken blood tubes, mishandling of evidence) that arise during analysis are reported accurately, clearly, unambiguously and objectively.
	The assigned Reporting Officer is responsible for the accuracy and completeness of the test report. These reports contain the conclusions and opinions that address the purpose for which analytical work is undertaken and should be formatted to minimize the

	possibility of misunderstanding or misuse. Supporting information that is not included in the report is readily available in the case record.
	Historical reports may be stored electronically or in paper case records.
	Reports will be provided to the case forwarding agency once technical and administrative review milestones are met.
	If FSL receives a written request from case forwarding agency to terminate analysis before the work is completed, a report will be issued indicating this. The written request, which may be submitted by email, will become part of the case record. Results of work that has been completed must be included in the report, but no additional analysis will be done. If all analytical work is completed before the request is received, a full test report will be written and issued to the case forwarding agency.
	Written reports are signed by the authorizer of the results. By signing the report, the authorizer is documenting that they have reviewed the report. The authorizer of the report shall also review the technical record. By signing the report, the authorizer is acknowledging that he/she has also reviewed the technical record.
	Report will be provided only on the written request of the forwarding authority to an authorized messenger. In extraordinary circumstances (Court's Direction) with the written approval from the Director, reports may be dispatched by Speed Post / Insured Parcel.
	Under no circumstances the technical results are released prior to issuing a written report.
	The analyst will document in the Case Record file: the release of Report including the Exhibits /Remnants returned, the name and contact number of the person to whom and when the Report was provided to.
7.8.2	**Common Requirements for Reports (test, calibration or sampling)**
	Discipline Procedure Manuals shall identify what will be reported for all items received by an analyst for analysis, including items on which no work was performed, items collected or analyzed and preserved for future testing, and for all (partial and complete work performed).
➢	The following supporting information, where applicable, will be included in reports:
a.	Items of evidence, including items not tested, as per sectional SOPs
b.	Significance of associations whether by a statistical or qualitative statement, wherever applicable.
c.	Clearly communicate reasons when the reported results indicate that no definitive conclusion can be reached.
➢	The following must either be included on reports (those followed by "required on report") or included in the case record if they are not part of the report:
a.	Title (required on report).
b.	Name and address of the laboratory (required on report).
c.	Location where the activities were performed, if different from above (required on report).
d.	Unique identifier shall be present on each page and each page shall be recognized as part of the test report, a clear identification of the end of the report (e.g. page X of Y) (required on report).
e.	Name and contact information of the case forwarding agency.
f.	Identification of the method used (required on report)
g.	Description, identification, and when necessary, the condition of the items (required on report).
h.	Date of receipt of evidence and the date of sampling, where sampling is critical to the

	validity and application of the results.
i.	Date the testing was performed.
j.	Date the report was issued (required on report).
k.	Sampling plan, if relevant to the validity of the results (required on report).
l.	Statement that the results relate only to the items tested.
m.	Where appropriate, units of measurements (required on report).
n.	Deviations from the test method (required on report).
o.	Identification of the person authorizing the report (required on report).
7.8.2.2	Test reports are formatted to minimize the possibility of misunderstanding or misuse. FSL is responsible for all information provided in its reports, except for information provided by the case forwarding agency (such as names, agency case numbers, etc.). Data regarding evidence items (such as weights or volumes) provided by the case forwarding agency must be clearly identified. Information provided by the case forwarding agency that can affect the validity of the results shall be clearly marked. FSL is usually responsible for sampling the evidence but, in cases in which it is not responsible, the report will state the results apply to the sample as it was received.
7.8.3.	**Specific Requirements for Test Reports**
7.8.3.1.	Where necessary for the interpretation of results, include the following:
a.	Information on the specific test conditions, such as environmental conditions.
b.	Statement of compliance/noncompliance with requirements and/or specifications.
c.	Information on uncertainty when it is relevant to the validity or application of the test results, when a case forwarding agency requests the information, or when the uncertainty affects compliance to a specification limit.
•	**The measurement of uncertainty shall**
a.	Be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by the regulatory body, a statute, case law, or other legal requirement.
b.	Include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability.
c.	Be in the form of y±U.
d.	Be limited to at most two significant digits, unless there is documented rationale for reporting additional significant digits.
e.	Be reported to the same level of significance as the measurement itself.
f.	Opinions and interpretation, if appropriate.
g.	Additional information that may be required by specific methods.
7.8.3.1.1.	FSL is not prohibited from including measurement uncertainty in Reports. FSL will follow statute requirements for reporting when applicable (e.g. reporting cocaine hydrochloride vs. cocaine base).
7.8.3.2	When FSL is responsible for the sampling, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.
7.8.4.	Specific requirements for calibration certificates: Wherever the report includes the measurement uncertainty *the provisions of ISO/IEC/17025/2017(E) clause 7.8.4.1 a-f* will apply.
7.8.5.	**Reporting Sampling – Specific Requirements** Discipline Manuals will define how the Laboratory meets the requirements of this standard if necessary for the interpretation of results. However, test reports containing results of sampling shall include the following when necessary:
a.	Date of sampling.
b.	Unambiguous identification of the substance sampled location of sampling, including

	photographs, if applicable.
c.	The location of sampling, including any diagrams, sketches, or photographs.
d.	Reference to the sampling plan and procedures used.
e.	The report, wherever applicable, shall include confidence levels and corresponding inferences regarding the population.
f.	Details of any environmental conditions during sampling that might affect the interpretation of the test results.
g.	Information required for evaluating measurement uncertainty for subsequent testing.
7.8.6.	**Reporting Statements of Conformity**
	The Laboratory does not provide statements of conformity.
7.8.7.	**Reporting Opinions and Interpretations**
7.8.7.1	When opinions or interpretations are included in test reports, they will be provided by technical staff those who have completed appropriate training and are authorized to express opinions and interpretations.
7.8.7.2	Opinions and interpretations are clearly marked as such when included in the test report.
7.8.8	**Amendments to Reports**
7.8.8.1	If errors or omissions are noted on test reports after they have been issued, then an amended report is required. An amended report will clearly communicate the reason for the amendment.
	Amendments that change the technical findings will be tracked as incidents or corrective actions, depending on the risk associated with the technical change.
	Examples of technical findings include but are not limited to:
	A seized drug report where an incorrect drug or weight was listed.
	A report where a false positive or false negative was listed.
	A toxicology report where an incorrect drug or alcohol concentration was listed.
	A DNA report where incorrect statistics were listed.
7.8.8.2	Amended reports will be clearly identified and will contain a reference to the original report that it is replacing.
7.8.8.3	If necessary to issue a completely new report, the report shall be uniquely identified by the new Analysis Start and End Dates and Reporting Date and will state "This amended report serves to replace the report issued on date."
7.9.	**Complaints**
7.9.1	FSL has a documented procedure for receiving, evaluating and resolving complaints. Complaints can be submitted to Director FSL.
7.9.1	All complaints received from an employee, customer, or other parties concerning the quality management system shall be investigated using the following procedure.
7.9.2	In the event an employee identifies a potential quality management system deficiency or a concern about the quality of the crime scene investigations, laboratory analysis, or evidence storage areas, the employee shall advise supervisory staff of the concerns or issues. Quality management system concerns, or complaints received by the supervisors shall be made in writing, and submitted through channels, to the Accreditation and Quality Manager, who shall acknowledge its receipt and, if necessary, provide progress reports.
7.9.3	In the event an employee receives a written quality complaint from a customer or other party, the employee shall forward the complaint through channels to the Accreditation and Quality Manager. If a verbal complaint is received from a customer or other party, the employee shall fully describe the complaint in an email, including the name and

	contact information of the complainant, through channels to the Accreditation and Quality Manager who, whenever possible, shall acknowledge its receipt and, if necessary, provide progress reports.
7.9.4	The Accreditation and Quality Manager shall ensure all complaints received are investigated, verifying all necessary information to validate the complaint, and determine the appropriate actions to be taken in response to the complaint. The complaint investigation and decisions shall not involve individuals in the original activities in question. The Accreditation and Quality Manager shall, if necessary, implement a corrective action
7.9.5	Regardless of the severity of the concern, the Accreditation and Quality Manager shall prepare a written summary, including actions undertaken to resolve the complaint, to the Division Commander for each complaint received. After the Division Commander's review, the Accreditation and Quality Manager shall ensure, whenever possible, the complainant is advised of the outcome of the complaint.
7.9.6	The records of the complaint, investigation, response, and communications shall be maintained for a minimum of five years.
7.9.7	The procedure for the complaints process shall be made available to any interested party upon request. The complaint investigation and resolution shall not result in any discriminatory actions.
7.10.	**Nonconforming Work**
7.10.1.	FSL has a procedure to address any laboratory activities that do not conform to its own procedures or the agreed requirements of case forwarding agencies. Nonconforming work is the result of an act, error, violation of an approved procedure/process, or omission that has affected the accuracy, reliability, and/or integrity of FSL's testing or reports. Nonconforming work includes mistakes as well as unapproved departures from approved procedures. Non-conformances, whether involving the management system or technical work, may be identified through internal audits, assessments, management reviews.
7.10.2	Non-conformances may be reported to the Quality Manager in several ways including, but not limited to: • email • meeting request • phone conversation • in person
	The appropriate Discipline Head and/or Technical Manager will be notified of the nonconformity as soon as possible via Quality Review Form.
	An evaluation of the significance/risk of the nonconformity will occur to determine whether it has an impact on the analysis of reported results. The evaluation may determine the nonconformance is a one-time occurrence that does not have a significant impact on the validity of results. This evaluation will be documented.
	The Quality Manager will review the Quality Review to determine if a root cause analysis needs to occur. If the evaluation process determines there is a potential problem in relation to the validity of results, the nonconformance will proceed through the corrective action process.
	Any corrective action needed will be taken along with a decision about the acceptability of the nonconforming work.
	The agency is notified, when appropriate (if nonconforming work affects reported

	results and when evidence needs to be recalled for additional testing because of nonconforming work), of the nonconformity.
	If the decision was made to halt work based on the significance of the nonconformance, the Director/Quality manager is responsible for authorizing the resumption of work.
	The Laboratory retains records of nonconforming work and actions in the quality assurance records.
7.10.3	Corrective action is implemented when the evaluation indicates that nonconformity could reoccur or when there is doubt about compliance with the Laboratory's Forensic Quality Assurance Program.
7.11.	**Control of Data and Information Management**
7.11.1	FSL maintains and manages case related information through an Integrated Criminal Justice System.
7.11.2	The Administrator will ensure the proper functioning of interfaces within ICJS by the laboratory.
7.11.3	The Laboratory does not develop its own computer software. Commercial off-the-shelf software in general use within its designed application range will be considered sufficiently validated. This includes word processing, database, or instrument-associated software.
7.11.4	When computers or automated equipment are used for casework, Discipline Heads will ensure that procedures are established and implemented for protecting the integrity and confidentiality of data and computers and automated equipment are properly maintained to ensure the integrity of data.
7.11.5	Manual calculations and data transfers are checked during technical and/or administrative review and the review is conducted by a person other than the person who performed the calculation(s) or the data transfers.

8	**Management System Requirements**
8.1	**General**
8.1.1	FSL has a management system that is established, documented, implemented and maintained in a manner that supports and demonstrates compliance to the standards set forth in ISO/IEC 17025 and Calibration Laboratories Accreditation Requirements FSL operates its management system in accordance with Option A of ISO/IEC 17025 clause 8.1.2
8.1.2	**Option A**
	- As a minimum, the management system of the laboratory shall address the following: - Management system documentation - Control of management system documents - Control of records - Actions to address risks and opportunities\improvement - Improvement - Corrective actions - Internal audits - Management reviews
8.1.3	**Option B**
	FSL has established and maintain a management system, in accordance with the requirements of ISO 9001, and that can support and demonstrate the consistent fulfilment of the requirements of clause 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.
8.2.	**Management System Documentation (Option A)**
8.2.1.	The Laboratory Division management and supervisory staff shall establish, document, and maintain policies and objectives for fulfillment of the ISO/IEC 17025 standard. The policy and objectives shall address the competence, impartiality, and consistent operation of the Laboratory Division. They shall ensure the policies and objectives are acknowledged and implemented by all personnel in the Laboratory Division. The quality system is a mechanism to ensure that FSL's investigation activities, examinations, documentation, and testimony remain accurate, impartial, and ethical.
.2.2.	The documents of the Forensic Quality Assurance Program are reviewed and updated as necessary to improve the effectiveness of the program. All personnel are required to familiarize themselves with the Quality Assurance Manual, Health and Safety Manual, the Discipline Procedure Manuals, and procedures specific to the scope of their responsibility.
	FSL's mission statement, objectives, and quality policy statement is reviewed annually, and revised if necessary. Management provides evidence of their commitment to the development, implementation, and continual improvement of the effectiveness of the Laboratory Management System through discussions at regular supervisor meetings, monthly laboratory staff meetings, and discipline meetings.
	Mission Statement—'High quality and credible forensic services' to justice delivery system.
	Objectives—FSL's objectives support its overall mission. Discipline-specific objectives may be stated in section-specific SOPs. FSL's objectives are • To provide quality analytical examinations. • To provide quality forensic investigations. • To meet or exceed all standards necessary to maintain accreditation

	• To monitor and ensure the timely generation of test or investigation reports • To enhance the scientific capabilities of FSL. ***Forensic Awareness programs*** ***Specialized training programs for Forensic Scientists, Police and Judiciary***
	Quality Policy Statement—FSL is committed to provide the highest quality service available to the public, law enforcement agencies, forensic laboratories, and members of the criminal justice community. To meet this goal, FSL established a quality system to ensure it provides accurate, impartial, and relevant reports to law enforcement and criminal justice organizations.
8.2.3	Top management, with the assistance of key management, review the development, implementation, improvement, and continued effectiveness of the quality system. These reviews may include a review of the internal audit(s), communications from case forwarding agencies, proficiency testing results, corrective actions, preventive actions, incident reports, and testimony monitoring.
8.2.4	The Forensic Quality Assurance Program is comprised of the Laboratory Quality Assurance Manual, Discipline Procedure Manuals, Discipline Training Manuals, and Health and Safety Manual. The authority to approve and revise Forensic Quality Assurance Program documentation is defined as follows:
	Laboratory policy is set forth in this Quality Assurance Manual. The Quality Assurance Manual is approved by the Director. Any revisions to the Laboratory Quality Assurance Manual are approved by the Director or designee.
	Laboratory technical procedures are found in each Discipline's Procedure Manuals and/or Discipline Work Instructions. The Procedure Manuals and Work Instructions are written by technically competent analysts and approved by the Discipline Supervisors and/or the Technical Manager. Any revisions to the Procedure Manuals and Work Instructions are approved by the Discipline Supervisors and/or the Technical Manager under intimation to Quality Manager/Director.
	Laboratory training procedures are found in each Discipline Training Manual. The Training Manuals are approved by the Discipline's Supervisor and/or the Technical Manager. Any revisions to the Training Manuals are approved by the Discipline's Supervisor and/or the Technical Manager.
	Each new Laboratory employee will complete the New Employee Training Program. The New Employee Training Program is approved by the Quality Manager and any revisions are approved by the Quality Manager.
	The Health and Safety Manual is approved by the concerned Manager. Any revisions to the Health and Safety Manual are approved by the Technical Manager under intimation to Quality Manager/Director.
8.2.5	All documents in the Forensic Quality Assurance Program are always authorized and available to laboratory personnel through the Laboratory's internal network drive.
	The Quality Manager will ensure that FSL is following the guidelines set forth in this manual by:
	• updating the quality manual and proposing corrections and improvements to the • system
	• developing quality system policies and procedures in coordination with technical staff
	• addressing quality concerns or complaint
	• monitoring and reviewing forensic practices that affect the quality of examination and/or investigation results, including instrument calibration and maintenance, use of reagents and standards, performing case reviews, taking corrective/preventive

	actions, providing technical training as necessary.
	• scheduling, monitoring, and/or conducting division audits to verify compliance with policies and procedures, proficiency testing, and testimony monitoring
	• maintaining quality system records and archives
8.3.	**Control of Management System Documents (Option A)**
8.3.1	All documents that comprise the Forensic Quality Assurance Program are controlled and maintained according to the Controlled Documents Procedure (Appendix B) by the Quality Manager. The term *document* may mean a paper or electronic file that includes regulations, standards, other normative documents, test methods, drawings, software, specifications, instructions, and manuals. All key functionaries will review revisions to the *Quality Manual,* the *Health and Safety Manual,* and the *FSL Security Manual*. Technical sectional procedure manuals are reviewed by those individuals assigned to technical positions within that section. These reviews are documented.
8.3.2.	All documents in the Forensic Quality Assurance Program are reviewed and approved by the appropriate person prior to issue. The Quality Manager will maintain a master-controlled documents list according to the **Controlled Documents Procedure**. This list identifies the current revision of all controlled documents to preclude the use of invalid and/or obsolete documents. The Controlled Documents Procedure ensures that all documents in the Forensic Quality Assurance Program are periodically reviewed and revised when necessary to ensure compliance, are current versions and invalid and/or obsolete documents are promptly archived to assure against unintended use, and once obsolete are suitably marked and retained. All documents in the Forensic Quality Assurance Program are uniquely identified. Each document contains the date issued, issuing authority, revision identification, and page numbering system. Changes will be identified in the Revision History of each document as outlined in the Controlled Documents Procedure. The Laboratory does not allow the amendment of controlled documents by hand. Manuals are changed/ updated via document revisions only.
8.3.3	Management system documents generated internally are identified by:
	title
	issue date
	page number
	total number of pages or a mark to signify the end of the document
	issuing authority
	Technical procedure manuals are formatted with headers and/or footers that contain required information. Forms are formatted in a way that is practical and applicable to that task. Procedures are posted in an electronic format and are the controlling documents followed by staff members.
8.3.4	Controlled documents are uncontrolled when printed. Staff members are responsible for ensuring they are utilizing the most current version when using a printed document. Any uncontrolled document that is not current shall be shredded or clearly marked to indicate that it is no longer in use. Obsolete documents, such as complete SOPs, are marked to ensure that they are not confused with current versions.
8.4	**Control of Records (Option A)**
8.4.1	The Laboratory will maintain quality and technical records. Records will be stored in the quality assurance records, Discipline records and/or hard copy case records. Examples of the quality assurance records include but are not limited to information from assessments, management reviews, corrective and preventive actions taken, and training /continuing education records.

8.4.2	Records are legible, in a readily retrievable format, and are stored in secure locations. They may be maintained in hard copy or electronic format. Paper files are stored in limited-access areas in FSL offices/Divisions. Paper-based case files may also be stored in the custody of a FSL staff member.
	Records shall be stored in an environment designed to prevent damage, deterioration, and loss. Case files stored on-site are grouped by section and may be filed numerically by unique case identifier. Technical records, such as reagent logs, maintenance or calibration logs, and temperature logs, are stored in an orderly fashion in locations designated by the Division management. Quality, administrative, and technical records will be kept for at least five years or one full accreditation cycle, whichever is longer.
	Case Records A case record is maintained for each request for analysis and crime scene investigation accepted by FSL. Case records are identified by an assigned forensic case number or the requesting agency identifier (agency 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 deviations
	identifiers and descriptions of the items analyzed
	identity of the technical staff performing the examination(s)
	identity of the technical and administrative reviewers
	Quality Incident and/or Corrective Action Reports
	Field notes, laboratory case notes, reports, and other related records (i.e. technical records) are investigatory records of a law enforcement agency. Investigatory records of law enforcement agencies are confidential and not subject to public disclosure without due course of law.
	Quality Records Quality records are also maintained and are 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
8.5.	**Actions to Address Risk and Opportunities (Option A)**
8.5.1	The Laboratory Division shall consider risks and opportunities associated with crime scene, laboratory, and evidence handling activities in order to:
a.	Give assurance that the management system achieves its intended results
b.	Enhance opportunities to achieve the purpose and objectives of the Laboratory Division
c.	Prevent, or reduce, undesired impacts and potential failures in Laboratory Division activities
d.	Achieve improvement.
8.5.2	The Laboratory Division shall plan actions to address these risks and opportunities, integrate and implement these actions into the management system, and evaluate the

	effectiveness of these actions.
8.5.3	Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of crime scene and laboratory results. *NOTE: Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.*
8.6.	**Improvements (Option A)**
8.6.1	Laboratory Management will proactively identify areas of needed improvement or potential sources of nonconformities. When identified, action plans will be developed, implemented, and monitored. Documentation will be maintained in the quality assurance records.
8.6.2	The Laboratory shall seek feedback from our customers through periodic surveys. The feedback shall be analyzed and used to improve the management system, crime scene and laboratory activities, and customer service. *NOTE: Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.*
8.7.	**Corrective Actions (Option A)**
8.7.1	Non-conforming work (departures from Laboratory's Forensic Quality Assurance Program) may be identified and brought to the attention of management through a variety of avenues including, but not limited to, technical and administrative case review, proficiency testing, annual internal audits, etc. The Director and Quality Manager shall be notified through channels of the potential need to implement a corrective action. The Discipline Head, Technical Manager, and/or the Quality Manager will initiate the corrective action process with a root cause analysis to ensure that the cause, rather than just a symptom, of the non-conformance will be prevented from occurring again. The root cause analysis should take into consideration all possible sources of nonconforming work to include an evaluation of the methods, procedures, equipment, supplies, training, work environment, customer agency needs, etc. Upon completion of the root cause analysis, the Discipline Head and/or Technical Manager will meet with the Quality Manager and discuss their findings. If needed, the Discipline Head and/or Technical Manager and Quality Manager will select the corrective action and implement to address the problem and prevent reoccurrence of the nonconformity.
a.	It is the responsibility of the Quality Manager, with assistance from the Discipline Head, Technical Lead, and/or the Technical Manager, to verify and monitor the effectiveness and implementation of the corrective action plan.
b.	A general timeline will be maintained at the beginning of each corrective action report by the Discipline Supervisor, Technical Lead, and/or by the Technical Manager to provide the Quality Manager with the information necessary to perform this function.
c.	**FSL's corrective action procedure includes:**
•	Determining the risk associated with the nonconformance
•	Case forwarding agency notification
•	Implementing an action plan
•	Closing corrective actions
•	Monitoring the effectiveness of the corrective actions taken.
d.	A Summary of Corrective Action Report Form will be completed by the Quality Manager when a Corrective Action is finalized, and the Form will be uploaded to the

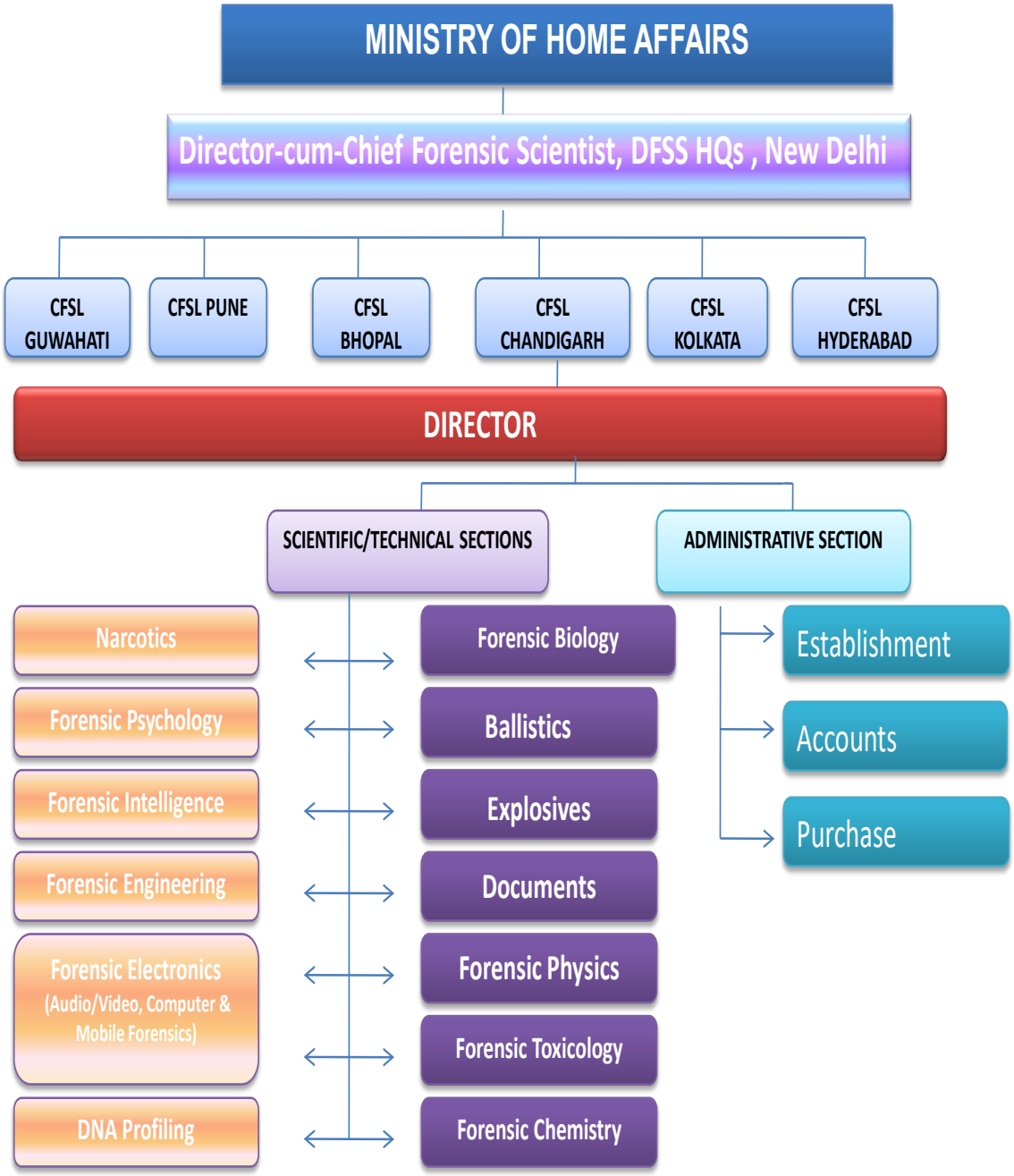
	Laboratory's website.
e.	The Laboratory will perform an audit of the appropriate areas, as soon as possible, when nonconformities could affect the Laboratory's compliance with the Forensic Quality Assurance Program, International Standard 17025 Implemented corrective actions will be appropriate to the magnitude and risk of the problem.
f.	The corrective action process will be documented on the Corrective Action Report Form. This documentation will be maintained by the Quality Manager.
g.	Corrective action records are maintained in the quality assurance records.
h.	If the nonconforming work is determined to have no impact on the quality of or presents no risk to the work product, it will be closed as 'no action needed'.
i.	Evaluate the need for action to address the cause of the nonconformance and take actions to prevent or reduce recurrence by reviewing and analyzing the nonconformity and determining if other instances of similar nonconforming work exist.
j.	Corrective actions are used to address non-conformances that have a significant impact on the quality of our work product and require root cause analysis to determine the actions needed to prevent recurrence.
k.	**Examples of Corrective Actions After Root Cause Analysis**
	Depending upon the nature of the problem or error, appropriate corrective actions may include the following:
•	If the error is determined to be in the method, the method may be removed from use on casework, modified, or moderated by additional controls as necessary. Other cases in which the same method was used may be reviewed.
•	If the error is determined to be caused by an instrument or other equipment used in the test, the error will be corrected and documented. Other cases in which the same instrument or equipment was used may be Re-evaluated and appropriate action taken.
•	If the error rests with a staff member, it will be determined if the error was the result of inadequate or inappropriate training or is an isolated incident and not likely to recur. If the original training is found to be inadequate, appropriate additional training or evaluation will be completed. If the original training is determined to be adequate, the review will attempt to identify the specific cause of the problem or error.
•	If the error is determined to be administrative or clerical in nature, the documentation and review process will be studied and revised, if appropriate, to minimize recurrence of this error.
8.7.2	Corrective actions will be of the appropriate degree and magnitude to correct the problem, reduce the risk and create a long-term resolution to prevent recurrence.
a.	Implement any actions needed to ensure that the issue is resolved, and the chance of recurrence is eliminated or reduced. Actions will also be taken to address the consequence of the nonconforming work, including issuing amended reports and notifying case forwarding agencies, if appropriate.
b.	Monitor non-conformances to determine if the corrective action was effective.
c.	Additional actions will be taken as necessary to prevent recurrence. The evaluation of the effectiveness of corrective actions may be reviewed during the annual management review. Management has the authority to request and/or conduct a follow-up audit if the corrective action casts doubt on FSL's compliance with its own policies, procedures, or with accreditation standards. Additional follow-up audits will be conducted as necessary.
d.	Take appropriate action to address any risks or opportunities identified during an investigation of nonconforming work.

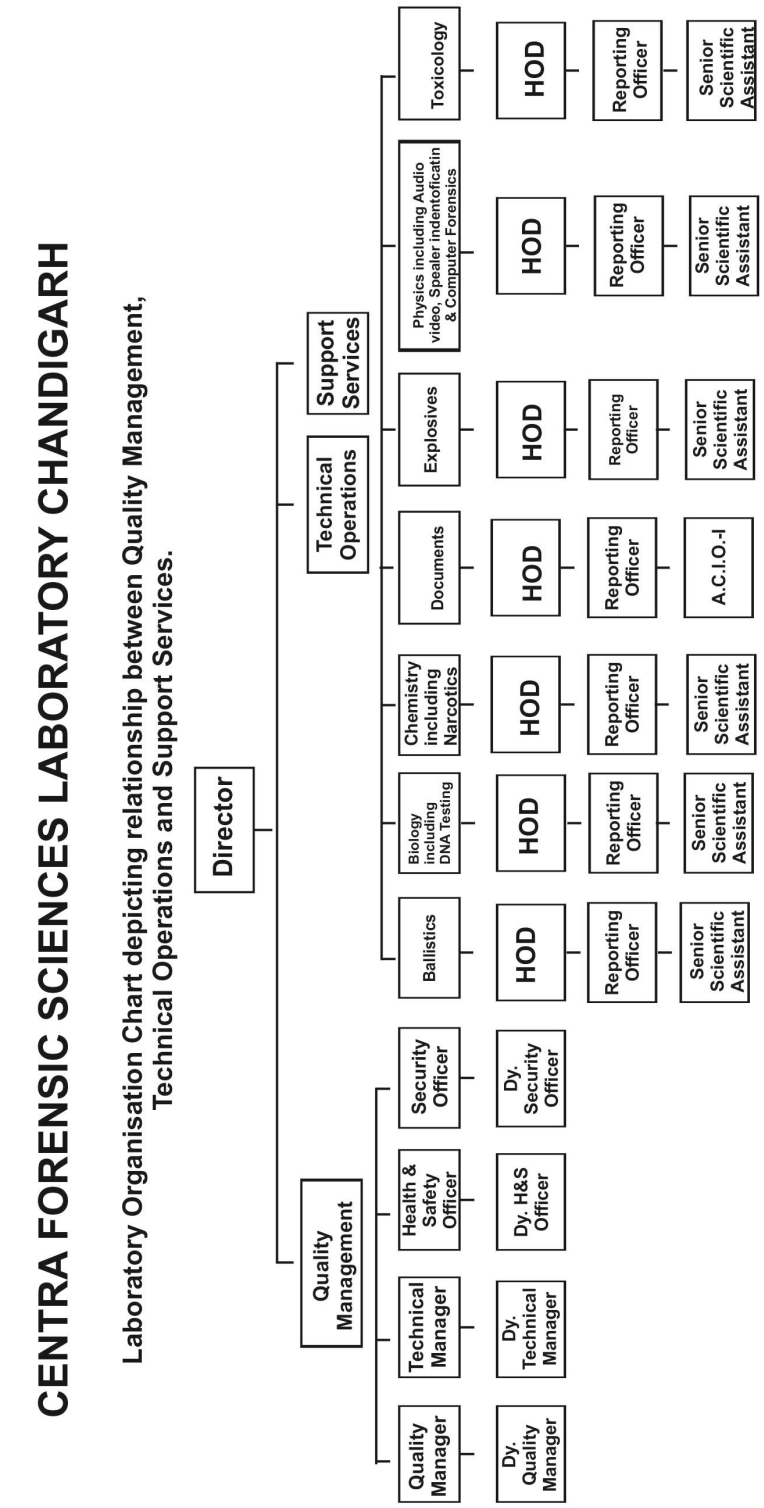
e.	Take appropriate actions to address deficiencies in the management system, if necessary.
f.	Address nonconforming work in a timely manner.
8.7.3	**Corrective actions are classified by the following class levels:**
	***Class I* errors** are those that have an immediate impact on the quality of FSL's work product. Class I non-conformances include those instances where the reliability of the tests performed, or the report is questionable. Examples include, but are not limited to, false identifications, false-positive results, contamination that results in the entire evidence sample being compromised and chain of custody errors that are systemic.
	***Class II* errors** may affect the quality of the work but are not serious enough to cause immediate concern for the overall quality of FSL's work product. Class II non-conformances include missed identifications and false-negative results. This class includes errors that are likely to continue unless appropriate corrective action is taken. Even though corrective action is necessary, the reliability of results is not in question.
	***Class III* errors** are inconsistencies having minimal effect or significance on quality, are unlikely to recur, are not systemic, and do not affect the fundamental reliability of FSL's work product. Class III non-conformances include administrative or transcription errors. If the same error occurs routinely for the same staff member or under the same circumstances, then the error may be elevated in class.
8.7.4	**Closing Corrective Actions** The Director/Quality Manager is responsible for following up and closing out the corrective action process. Closing a corrective action means that no additional action, except for monitoring the effectiveness of the corrective action, is planned. The Director/Quality Manager may reopen a corrective action if the nonconformance recurs or if it is later determined that further action is needed.
8.8.	**Internal Audits (Option A)**
8.8.1	The Laboratory will conduct internal audits on a predetermined schedule. The Quality Manager will plan and organize the laboratory audit. The Laboratory will document whether the management system conforms to the requirements of ISO/IEC 17025:2017 (E) in addition to its own laboratory requirements. The Laboratory will provide information on whether the management system is effectively implemented and maintained. Laboratory members will be trained and instructed about their audit responsibilities by the Quality Manager or designee and will assist in the audits as requested.
	Internal audits will be conducted at least annually at the direction of the Quality Manager. Prior to each audit, the Quality Manager/Director will select an audit team. This team will include a lead auditor (typically Quality Manager) and team members who will be assigned a specific discipline to audit. Each of these team members will have or will have had audit training. This documented training may be provided by external sources or conducted in-house. Audit documents, including criteria to be assessed, will be provided to the auditors.
8.8.2	The planning and scope shall take into consideration the work performed and areas to be audited, as well as results of the previous audits. The annual internal audit shall include direct observations of the work conducted.

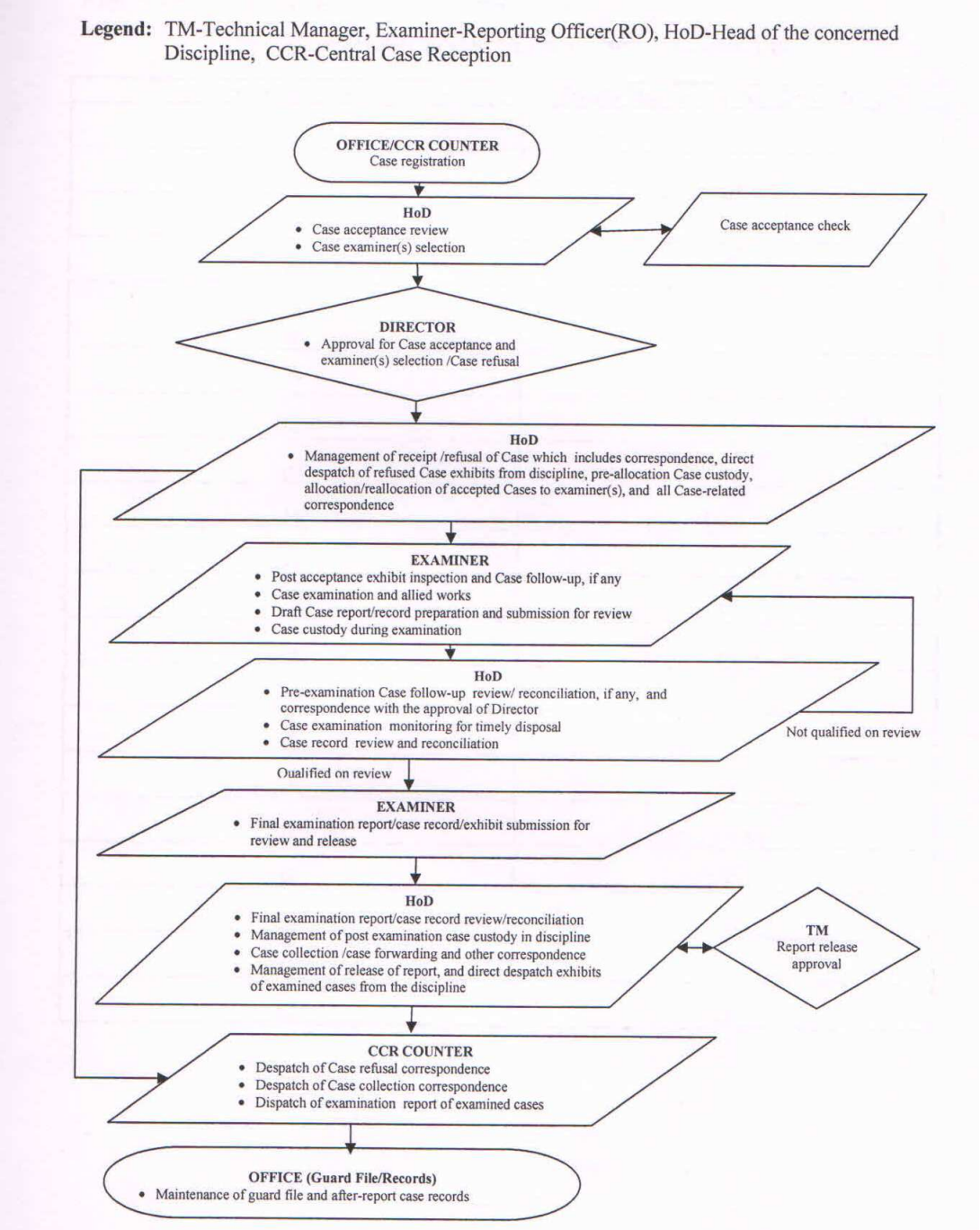
a.	Internal audits will include direct observation of a sample of accredited services within each discipline.
b.	Checklists or other records shall be produced by the internal auditors. A summary report shall be prepared by the Accreditation and Quality Manager and reviewed by the Division Commander.
c.	Any non-conformance found during the internal audits shall be documented and the appropriate correction and/or corrective action implemented including a time line for completion. Opportunities for improvement should be identified and implemented.
d.	Internal audit documentation shall be maintained for a minimum of five years.

8.9.	**Management Reviews (Option A)**
8.9.1	A management review shall be conducted annually to ensure continuing suitability, adequacy, and effectiveness of the policies, procedures, and objectives related to the fulfilment of the ISO/IEC 17025 standard and accreditation body requirements.
8.9.2	The following procedures shall be used to conduct the annual management review of the Laboratory. At a minimum, the Director, Division Heads and Quality Manager shall annually review the management system operations. A management review shall include, at a minimum, the following topics:
a.	changes in internal and external issues that are relevant to the Laboratory Division
b.	fulfilment of objectives (Mission & Operating Statements)
c.	suitability of policies and procedures
d.	status of actions from previous management reviews
e.	outcomes of recent internal audits
f.	corrective actions
g.	assessments by external bodies
h.	Changes in the volume and type of the work are in range of laboratory activities
i.	Customer and personnel feedback
j.	Complaints
k.	Effectiveness of any implemented improvements
l.	Adequacy of resources
m.	Results of risk identification
n.	Outcomes of the assurance of the validity of results
o.	Other relevant factors, such as monitoring activities and training.
8.9.3	Documentation from a management review shall include decisions and actions related to at least the following:
a.	The effectiveness of management system and its processes;
b.	Improvement of the Laboratory Division activities related to the fulfilment of the ISO/IEC 17025 standard and accrediting body's requirements

c.	Provision of required resources
d.	Any need for changes.
8.9.4	The Director shall ensure action items from the management review are completed in an appropriate time.
8.9.5	Records of the management review shall be maintained on the network drive for a minimum of five years.


MINISTRY OF HOME AFFAIRS
Director-cum-Chief Forensic Scientist, DFSS HQs , New Delhi
CFSL GUWAHATI
CFSL PUNE
CFSL BHOPAL
CFSL CHANDIGARH
CFSL KOLKATA
CFSL HYDERABAD
DIRECTOR
SCIENTIFIC/TECHNICAL SECTIONS
ADMINISTRATIVE SECTION
Narcotics
Forensic Psychology
Forensic Intelligence
Forensic Engineering
Forensic Electronics (Audio/Video, Computer & Mobile Forensics)
DNA Profiling
Forensic Biology
Ballistics
Explosives
Documents
Forensic Physics
Forensic Toxicology
Forensic Chemistry
Establishment
Accounts
Purchase


CENTRA FORENSIC SCIENCES LABORATORY CHANDIGARH
Laboratory Organisation Chart depicting relationship between Quality Management, Technical Operations and Support Services.
Director
Quality Management
Technical Operations
Support Services
Quality Manager
Dy. Quality Manager
Technical Manager
Dy. Technical Manager
Health & Safety Officer
Dy. H&S Officer
Security Officer
Dy. Security Officer
Ballistics
Biology including DNA Testing
Chemistry including Narcotics
Documents
Explosives
Physics including Audio video, Spealer indentoficatin & Computer Forensics
Toxicology
HOD
Reporting Officer
Senior Scientific Assistant
A.C.I.O.-I


Legend: TM-Technical Manager, Examiner-Reporting Officer(RO), HoD-Head of the concerned Discipline, CCR-Central Case Reception
OFFICE/CCR COUNTER
Case registration
HoD
Case acceptance review
Case examiner(s) selection
Case acceptance check
DIRECTOR
Approval for Case acceptance and examiner(s) selection /Case refusal
HoD
Management of receipt /refusal of Case which includes correspondence, direct despatch of refused Case exhibits from discipline, pre-allocation Case custody, allocation/reallocation of accepted Cases to examiner(s), and all Case-related correspondence
EXAMINER
Post acceptance exhibit inspection and Case follow-up, if any
Case examination and allied works
Draft Case report/record preparation and submission for review
Case custody during examination
HoD
Pre-examination Case follow-up review/ reconciliation, if any, and correspondence with the approval of Director
Case examination monitoring for timely disposal
Case record review and reconciliation
Not qualified on review
Qualified on review
EXAMINER
Final examination report/case record/exhibit submission for review and release
HoD
Final examination report/case record review/reconciliation
Management of post examination case custody in discipline
Case collection /case forwarding and other correspondence
Management of release of report, and direct despatch exhibits of examined cases from the discipline
TM
Report release approval
CCR COUNTER
Despatch of Case refusal correspondence
Despatch of Case collection correspondence
Dispatch of examination report of examined cases
OFFICE (Guard File/Records)
Maintenance of guard file and after-report case records

Annexure -A
(Informative)
Metrological traceability

A.1 General

This annex provides additional information on metrological traceability, which is an important concept to ensure comparability of measurement results both nationally and internationally.

A.2 Establishing metrological traceability

A.2.1 Metrological traceability is established by considering, and then ensuring, the following:

a) the specification of the measurand (quantity to be measured);

b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards);

c) that measurement uncertainty for each step in the traceability chain is evaluated according to agreed methods;

d) that each step of the chain is performed in accordance with appropriate methods, with the measurement results and with associated, recorded measurement uncertainties;

e) that the laboratories performing one or more steps in the chain supply evidence for their technical competence.

A.2.2 The systematic measurement error (sometimes called "bias") of the calibrated equipment is considered to disseminate metrological traceability to measurement results in the laboratory. There are several mechanisms available to consider the systematic measurement errors in the dissemination of measurement metrological traceability.

A.2.3 Measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:

— the use of an appropriate decision rule to establish conformity;

— the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.

The technical basis for this approach is that the declared conformance to a specification defines a range of measurement values, within which the true value is expected to lie, at a specified level of confidence, which considers both any bias from the true value, as well as the measurement uncertainty.

EXAMPLE The use of OIML R 111 class weights to calibrate a balance.

A.3 Demonstrating metrological traceability

A.3.1 Laboratories are responsible for establishing metrological traceability in accordance with this document. Calibration results from laboratories conforming to this document provide metrological traceability. Certified values of certified reference materials from reference material producers conforming to ISO 17034 provide metrological traceability. There are various ways to demonstrate conformity with this document: third party recognition (such as an accreditation body), external assessment by customers or self-assessment. Internationally accepted paths include, but are not limited to, the following:

a) Calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service.

b) Calibration and measurement capabilities that have been accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited laboratories are publicly available from their respective accreditation bodies.

A.3.2 The Joint BIPM, OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.

Annexure -B
(Informative)
Management system options

B.1 Growth in the use of management systems generally has increased the need to ensure that laboratories can operate a management system that is seen as conforming to ISO 9001, as well as to this document. As a result, this document provides two options for the requirements related to the implementation of a management system.

B.2 Option A (see 8.1.2) lists the minimum requirements for implementation of a management system in a laboratory. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system. Laboratories that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.

B.3 Option B (see 8.1.3) allows laboratories to establish and maintain a management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7. Laboratories that implement Option B of Clause 8 will therefore also operate in accordance with ISO 9001. Conformity of the management system within which the laboratory operates to the requirements of ISO 9001 does not demonstrate the competence of the laboratory to produce technically valid data and results. This is accomplished through compliance with Clauses 4 to 7.

B.4 Both options are intended to achieve the same result in the performance of the management system and compliance with Clauses 4 to 7.

NOTE Documents, data and records are components of documented information as used in ISO 9001 and other management system standards. Control of documents is covered in 8.3. The control of records is covered in 8.4 and 7.5. The control of data related to the laboratory activities is covered in 7.11.

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