# Division of Scientific Services

# QUALITY MANUAL

Index:

## Appendixes

1. Scope

The Department of Emergency Services and Public Protection (DESPP), Division of Scientific Services provides forensic analyses of evidence submitted by Law Enforcement, Judicial Services and State and Federal Agencies. A listing of the type and extent of examinations and testing provided within the Division is provided within GL1.1.

2. Organization

The Division of Scientific Services is an entity of the Connecticut Department of Emergency Services and Public Protection, as illustrated in the Departmental Organizational Chart. The Division's organization is illustrated within its own Organizational Chart.

3. Introduction

The following information, provided in numerical order corresponding with the ASCLD/LAB International Criteria documents (ISO/IEC 17025:2005 and the Supplemental guide) presents the Division's approach to conformance with the individual standard or criteria, with reference to specific operational guidance (SOP) and/or supportive documentation.

4.0 Management Requirements

4.1 Organization

4.1.1 The Division of Scientific Services (DSS) is part of the State of Connecticut Department of Emergency Services and Public Protection (DESPP). The Connecticut DESPP is the legally responsible entity for the Division.

4.1.2 The DSS is authorized by Section 29-7b of the Connecticut General Statues (GL1.2). The responsibility of the DSS is to meet the requirements of the statute while also meeting the needs of its customers, the applicable requirements of ASCLD/LAB International Supplemental document, ISO/IEC 17025:2005, and the requirements of the DNA Quality Assurance Standards (QAS).

4.1.3 The Management System covers work performed by any and all of the Units within the Division of Scientific Services, whether work is being performed at the 278 Colony Street facility, or as a function of off-site, or field-related operations. At this point in time, the Division has no permanent off-site facilities. The Division does utilize a mobile work facility for Computer Crimes Investigations and the Multi-Media Unit.

4.1.4 While the Division of Scientific Services (DSS) is a part of a larger organization active in Law Enforcement and related activities, the relationship of the Division to the parent organization is designed to preclude any undue involvement or influence of Departmental Personnel. The DSS Director reports directly to the Commissioner of the Department of Emergency Services and Public Protection. The Deputy Directors, Assistant Directors, Laboratory Administrative Manager, Quality Section and Division's scientific staff has no reporting responsibility outside this direct chain of command.

4.1.4.1 The Director of the DSS and the Deputy Directors' have responsibilities and authorities as defined within their job descriptions. A copy of job descriptions will be maintained by the Quality Section and is available on the State of CT Department of Administrative Services (DAS) web site.

4.1.4.1.1 The Director has the delegated authority through the Commissioner of the Department of Emergency Services and Public Protection to make and enforce decisions within the Division of Scientific Services as per Connecticut General Statute Section 20-7b (GL1.2).

4.1.5 Division Management Functions and Responsibilities:

a. Ensure there are adequate managerial and technical personnel and support staff to effectively implement, maintain and improve the management system. Such staffing will be suitable to identify and rectify any operational, procedural, managerial or other departures from standard laboratory practice. Management routinely evaluates the staffing levels, and communicates those needs to the Director. Appropriate adjustments are then made through standard Departmental administrative procedures.

b. Ensure that all management and Division personnel are free from any undue internal and/or external inappropriate influences or pressures that may adversely affect the quality of their work. Guidance to ensure that DSS personnel are not subject to such influence is provided and detailed in GL-05 "Ethics."

c. Ensure that the Division of Scientific Services has policies and procedures that address client confidentiality, proprietary rights and the secure storage and where applicable, transmission of electronic data, and that those policies and procedures are followed. General Laboratory SOPs GL-5 "Ethics" and GL-4 "LIMS" address aspects of these issues.

d. Ensure that Division personnel avoid involvement in any activities that might be construed as compromising the forensic defensibility of the Division's analyses, reports or personnel integrity. Guidance in this area is provided in general GL-5; "Ethics".

e. The Division of Scientific Services is one of several Divisions within the Department of Emergency Services and Public Protection.

Division: Defined as all Units and Sections under the direction of the DSS Director.

Section: A sub-set of Units, grouped based on the needs of the Division. Sections are led by the Deputy Directors.

Unit: The individual disciplines and categories of testing within the DSS. Units are under the direction of Assistant Directors and, in general, are led by an FSE2, FSE3, or a Division of State Police Sergeant.

The Division consists of:

Administration:
- Quality Section

Support Services Section:
- Administrative Support Unit
- Case Management Unit (CMU)
- Evidence Receiving Unit (ERU)
- Information Technology Unit (ITU)

Chemical Analysis Section:
- Toxicology Unit (TX)
- Controlled Substance and Breathalyzer Unit (CSBU)
- Chemistry Unit (CH)
  - Arson (AR)
  - Instrumentation (IN)
  - Trace (TR)

Forensic Biology/DNA Section:
- Forensic Biology Unit (FB)
- DNA Unit (DNA)
  - Database (DB)
  - Nuclear
  - Mitochondrial DNA (mtDNA)
- SAKI Coordinator

Identification Section:
- Computer Crimes and Electronic Evidence Unit (CC)
  - Forensic Analysis
  - Investigations
  - ICAC Consultant PSA
  - Judicial Court Services Consultant
- Firearms/Toolmarks Unit (FA)
- Imprints Unit (IM)
- Latent Prints Unit (LP)
- Electronic and Digital Imaging Unit (MMIE)
- Questioned Documents Unit (QD)

DSS Top Management consists of the Director and Deputy Directors. The Quality Manager reports directly to the Director.

Each Deputy Director reports to the Director. The DSS Director represents the Division in the Department of Emergency Services and Public Protection (DESPP), reporting directly to the Commissioner thereof. These relationships are detailed in the Divisional and Departmental Organization Charts.

f. The responsibility and authority of technical personnel who manage, perform or verify analytical work in the Division's disciplines are specified in their specific job descriptions. Interrelationships of personnel are indicated on the organizational chart.

Each subordinate is accountable to one and only one immediate lead or supervisor (however titled) per function, as detailed in the Divisional Organizational Chart.

g. Each Deputy Director is responsible for ensuring the adequate supervision of testing staff, including training of new employees by appropriate personnel. Training guidance is provided in the laboratory general SOP GL-14 "General Training" and in each Unit SOPs as detailed below:

| | |
| --- | --- |
| Electronic Evidence/Computer Crimes: | CC-25 |
| Controlled Substance: | CS-13 |
| Toxicology: | TX-30 |
| DNA and mtDNA | DNA-7 |
| Forensic Biology | FB-26 |
| Chemistry | CH-15 |
| Instrumentation | FLIN-06 |
| Trace | TR-1 |
| Questioned Documents | QD-5 |
| Latent Prints | LP-16 |
| Multimedia | MMIE-26 |
| Firearms/Toolmarks | FA SOP-01 |
| Imprints | IM-14 |
| Evidence Receiving | ER-14 |

h. The individual Deputy Directors have authority to oversee the technical operations of the Units they direct; this is done in concert with the Director. The Deputy Directors ensure that the resources needed for each Unit to perform the needed procedures are provided and that the quality of the analytical testing is maintained. Note that in accordance with the FBI DNA QAS document the DNA Technical Leader oversees the technical operations of the DNA Unit. The TL may be the Deputy Director of the Section (or other title as designated by the Director).

The Director and the Quality Manager have approved a contingency plan for the designation of a Technical Leader in the DNA Section in the event that the position requires refilling for any reason. The intent of this plan is to comply with Section 4.1.6 of the FBI DNA QAS documents. This plan addresses two distinct sets of circumstances; first, the appointment of a current employee that has the required qualifications to be a Technical Leader per the FBI DNA QAS documents and secondly, a plan to address the possibility that no current employee meets the requirements as set forth in the FBI DNA QAS documents. This plan is detailed in GL1.7.

Individuals identified as having technical responsibility for specific Units have appropriate training and experience in the discipline. See GL 1.3.

i. Duties of the Laboratory Quality Assurance Manager include but are not limited to:

Maintain/Update the Quality Manual
Monitor Division practices to verify continuing compliance with policies and procedures related to quality
Evaluate instrument calibrations and maintenance records
Periodically assess the adequacy of report review activities
Ensure appropriate validation of new technical procedures
Assist Investigations of technical problems, propose remedial actions and verify their implementation
Administer proficiency tests and evaluate the results
Select, train and evaluate internal auditors
Schedule and coordinate management system audits
Evaluate results of management system audits
Maintain training records of Division personnel
Recommend training to improve the quality of Division personnel
Propose corrections and improvements to the management system
Review QARs to assure completeness and appropriateness
Document and maintain approval of contract laboratories

j. Key managerial personnel include the Director, the Deputy Directors, the Assistant Directors, and Quality Assurance Manager, FB/DNA Quality Assurance Manager, Laboratory Administrative Manager and other personnel as determined by the Director as needed.

In the absence of the Director a Deputy Director will act as their designee. In the absence of a Deputy Director an Assistant Director will act as their designee. In the absence of the Laboratory Administrative Manager, the Director and/or a Deputy Director will act as their designee. In the absence of the Quality Assurance Manager or FB/DNA Quality Assurance Manager the other will act as their designee. If there is an absence of the above designee, the Director will designate who will take on those duties.

k. The relevance and importance of all DSS personnel in the overall criminal justice system, as well as their contributions to the management system is made clear to all employees during their training and orientation process, as detailed in GL-14, "General Training". This is further emphasized during division wide, sectional and unit meetings.

4.1.6 The Quality Assurance Manager and Forensic Biology/DNA Quality Assurance Manager are appointed by the Director. They work with Deputy Directors, Assistant Directors, the Laboratory Administrative Manager, unit Supervisors/Leads and/or individuals appointed within the Division, to address quality assurance concerns. The management system incorporates a yearly review, the results of which are considered and evaluated by the Director and Deputy Directors, as detailed in GL-8; "Management System".

4.1.7 The Division has a Health and Safety committee, headed by an appointed Health and Safety Officer. The committee is comprised of delegates from Division Units, as detailed in GL-2; "Safety Manual."

4.1.8 The DSS define Key Management as: Employees of the DSS holding a title of Director, Deputy Director, Assistant Director, Laboratory Administrative Manager, Quality Manager, Forensic Biology/DNA Quality Assurance Manager or other personnel, designated by the Director as required. Top Management as: employees holding the title of Director or Deputy Director.

4.2 Management System

4.2.1 The Division of Scientific Services' Management System is organized and communicated through the Standard Operating Procedures, both General and Unit Specific. These SOPs include a Quality Manual with administrative personnel-related directives, general SOPs that are applicable to all Units, Unit specific SOPs and specific work instructions (where applicable). The use of the Quality Manual in conjunction with Unit specific SOPs is meant to ensure the quality of work produced in each Unit. SOP availability is through Qualtrax, as detailed in GL-19 "Document Control".

4.2.2 The Quality Assurance program of the Division of Scientific Services is a comprehensive program designed to ensure the delivery of reliable forensic services to the Connecticut and Federal criminal justice systems. To this end, the management of the Division of Scientific Services is committed to supporting a Division wide "Quality Policy" as detailed below:

The Division of Scientific Services will demonstrate professional practice by providing:

a.

- A system to evaluate and demonstrate the technical competency of all analytical employees, ensuring only forensically defensible results are reported. See Unit specific SOPs and GL-14; General Training.
- A system for case review that provides both technical and administrative review of casework documentation. See GL-18; Case Reviews".
- A system for procedural development, modification and validation. See Unit specific SOPs.
- A comprehensive system of quality control, such that all analyses and analytical batches may be individually evaluated for procedural function. See GL-18; "Case Reviews".
- A system for monitoring courtroom testimony of Division employees. See GL-17; Court monitoring.
- A system to deal with problems or discrepancies which may occur during the handling of case materials, evidence analysis, or reporting of results. See GL-9; Quality Action Requests.
- A comprehensive system of reagent and standard validation, such that the analyst has a maximal expectation of procedural function and accuracy. See Unit specific SOPs

b.

- A Standard of Service of forensic analysis and support that is unbiased, scientifically sound, consistent with current accepted Division standards, and may be relied upon by all aspect of the Criminal Justice system.
- A management system that works to support and enhance the quality system of the Division. See GL-7; Audits.

c.

- A mechanism for the continuous review of the management system, with a goal of improvement of the overall effectiveness of the system, thereby enhancing the overall quality of analyses performed and overall customer satisfaction. See GL-8; "Management System".

d.

- A system, which ensures that analytical personnel are familiar with the quality manual and with the quality procedures that are required for the work they perform. See GL-19; Document Control.

e.

- Adherence to ASCLD/LAB International and ISO/IEC 17025:2005 standards and FBI DNA QAS. See GL-7; Audits.

4.2.2.1 The ASCLD/LAB *Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* is used as a reference for ethical and appropriate professional behavior within the Division. See GL 1.4.

4.2.2.2 The ASCLD/LAB *Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* is reviewed annually by all personnel and a record of the review will be maintained for 10 years, as detailed in GL-5; "Ethics."

4.2.3 To continually monitor and improve the Management System, the top management of the Division of Scientific Services uses Audits, QARs, customer feedback and Proficiency testing records to identify areas that need development. Review of these items allows the Director and Deputy Directors to evaluate the Quality System for effectiveness, and to identify potential areas for improvement. A review of the Quality System will be scheduled and used to develop and implement any needed improvements to the system, this is specified in GL-8; "Management System".

4.2.4 The Divisional Mission Statement emphasizes the importance of servicing customer needs and requirements. Statutory and regulatory requirements for analytical work performed in each Unit are addressed in the SOPs for those Units, as noted below:

| | |
| --- | --- |
| Controlled Substance | CS-13 |
| Toxicology | TX-30 |
| DNA | DNA-1, 13.1 |
| Forensic Biology | FB-2 |
| Latent Prints | LP-15 |
| Firearms/Toolmarks | FA-13 |

4.2.5 The Quality Manual ("QM"; GL-01) serves as the central organizing element for the procedural documentation of the Division. The Quality Manual makes reference to specific procedures, and outlines the structure of the documentation used in the quality system.

The Management System for the Division includes documentation that is common to all Sections and those that are specific to the individual Units. Those common to all areas are the Quality Manual, General Laboratory (GL) Standard Operating Procedures (GL-1 thru GL-21).

The Quality Manual is the backbone of the quality system for the Division as a whole; individual Units can adjust their quality system to be more rigorous then the quality manual but not to be less rigorous.

General Laboratory Standard Operating Procedures: these are specific procedures that are followed universally by all Division Units. These include guidance for subjects such as court monitoring, quality action requests and proficiency testing.

The Safety Manual includes guidance for general safety issues that are faced throughout the Division; individual procedures per Unit may require specific safety precautions, which will be exclusive to the procedure.

Documents used within Division Units Include:

SOPs (Standard Operating Procedures): General instructions for the performance of the analytical analysis performed in the various Units.
Work Instructions: Specific instructions for operating equipment or performing tasks specific to the various Units. Note that some Units do not use these; the guidance is directly in the Section or Unit SOPs.
Training SOP: Individual procedures meant for guiding new employees or employees new to the unit through the basics of the analysis.

For issues such as internet use, phone use, dress codes, time off requests and engaging in outside employment Division employees will refer to Departmental guidance such as that given in the pertinent Sections of the A&O manual.

4.2.6 The roles and responsibilities of Management, the Quality Section, and Section Supervisors and Leads including their responsibility for ensuring compliance with the ASCLD/LAB ISO/IEC 17025:2005 International Standard and the FBI Quality Assurance Standards are defined as detailed below:

Director:

Serves as the scientific management and Division representative within the Department of Emergency Services and Public Protection and is responsible for the overall operation of the Division. The Director acts to support the Deputy Directors for both administrative and scientific matters. The Director is responsible for ensuring that work and personnel assignments are structured in such a manner as to allow for efficient operation of the Division. The Director is responsible for establishment and implementation of the Quality Assurance/ Management system of the Division, in association with the Division Quality Manager. The Director and Quality Manager ensure that the Quality System includes all components necessary to comply with ASCLD/LAB International, ISO/IEC 17025:2005 and the FBI Quality Assurance Standards. The Director

works in conjunction with the Deputy Directors, Quality Assurance Manager, FB/DNA Quality Assurance Manager and Section Supervisors/Leads to Monitor the Quality System and make improvements as needed.

Deputy Director:

Deputy Directors direct specific Sections within the Division, as determined to be appropriate by the Director. The Deputy Directors report directly to the Director and are responsible for the overall operation of the Units that make up the Sections, including strategic planning, preparation of budgets, formulation of project goals and objectives, analytical processes, evidence handling, overseeing of grants and security. The Deputy Directors are responsible to support the Quality Assurance/ Management system of the Division, in association with the Quality Assurance Manager and FB/DNA Quality Assurance Manager. As part of this they must ensure that the Quality System includes all components necessary to comply with ASCLD/LAB International and ISO/IEC 17025:2005. The Deputy Directors work in conjunction with the Assistant Directors, Quality Section and Section Supervisors and Leads to Monitor the Quality System and make improvements as needed.

Assistant Director:

Assistant Directors report directly to the Deputy Directors and are responsible for the day to day operations of their respective Sections. The Assistant Directors are responsible for ensuring that work and personnel assignments are structured in such a manner as to allow for efficient operation of the Units. The Assistant Directors are responsible to support the Quality Assurance/ Management system of the Division, in association with the Quality Assurance Manager and FB/DNA Quality Assurance Manager. As part of this they must ensure that the Quality System includes all components to comply with ASCLD/LAB International and ISO/IEC 17025:2005. The Assistant Directors work in conjunction with the Deputy Directors, Quality Section and Unit Supervisors and Leads to Monitor the Quality System and make improvements as needed.

Laboratory Administrative Manager (LAM):

The Laboratory Administrative Manager reports directly to the Director. The LAM is responsible for the oversite of the Administrative Support, Information Technology, Case Management and Evidence Receiving Units. Additionally, they are the liaison with the building maintenance contract company and oversees all related projects. The LAM is responsible for the administration of a comprehensive program to manage the evidence of

criminal and civil cases at the Division. The LAM additionally has responsibility of the oversight of grants, fiscal and security of the laboratory. The LAM is responsible to support the Quality System of the Division, in association with the Quality Manager and Forensic Biology/DNA Quality Manager. As part of this they must ensure that the Quality System includes all components necessary to comply with ASCLD/LAB International and ISO/IEC 17025:2005. The LAM works in conjunction with the Quality Section and Deputy Directors to Monitor the Quality System and make improvements as needed.

Quality Assurance Manager (QM):

The Quality Manager is a central and essential position within the Division; the QM serves to facilitate the implementation of the overall quality system. As such, the Quality Manager is responsible for the monitoring of the Quality System and identifying deviations or potential deviations from the system. The QM will strive to improve the overall Quality System of the Division. The Quality Manager works directly with the Director, Deputy Directors and the FB/DNA Quality Assurance Manager to ensure that the Quality System meets the requirements of ASCLD/LAB International, ISO/IEC 17025:2005 and the FBI DNA Quality Assurance Standards. The Quality Manager is also a source of guidance for Section Supervisors/Leads to aid them in achieving the goals of the quality system. (See 4.1.5, i for specific duties as related to the Management System).

Forensic Biology/DNA Quality Assurance Manager (FB/DNA QM):

The FB/DNA Quality Assurance Manager will work with the Quality Assurance Manager to monitor the Quality System of the Division. The FB/DNA QM assists in identifying deviations and areas for improvement within the system. Together the FB/DNA QM and QM monitor the Quality System to ensure compliance with ASCLD/LAB International, ISO/IEC 17025:2005 and the FBI Quality Assurance Standards. Note: The position referred to as FB/DNA QM has the official state title of Forensic Biology/DNA Quality Assurance Manager; the specialization of this position as defined in the state job title is DNA.

Section Supervisors (FSE3) or Leads (FSE2 or equivalent):

Supervisors or leads directly monitor all aspects of work in their Unit. They must have a thorough understanding of the Quality System as it relates to the work performed in their assigned areas. They must ensure that analysts follow all procedures and quality control measures for the tasks being performed. They ensure that through training, analysts are made aware of the specific quality procedures for the assigned tasks. They (or their designee) document all aspects of training for new employees, including competency testing. They work closely

with the Deputy and Assistant Directors, and the Quality Section to identify what individuals require proficiency testing and in what discipline. The Section Supervisors and/or Leads should have an understanding of the ASCLD/LAB International accreditation process and of the ISO/IEC 17025:2005 standard. DNA Section Supervisors/Leads are also responsible to have an understanding of the FBI DNA Quality Assurance Standards.

4.2.7 Management has ensured that the integrity of the Management System is maintained when changes to that system are planned or implemented by requiring that all changes to the Management System flow through the QM, as specified in GL-19; "Document Control". When a change is required, Qualtrax will be used to ensure the document is reviewed and approved by the responsible parties. When changes are requested, the QM or the FB/DNA QM will review the presented information and analyze it to determine how it could potentially affect all Sections. As part of the review of any such proposed change, the QM will work in coordination with the Deputy Directors, Assistant Directors, Laboratory Administrative Manager or Director, as appropriate. Changes must be such that they maintain the integrity of the Management System so that the system continuously meets the requirements of customers and the criteria set forth by ASCLD/LAB International and ISO/IEC 17025:2005. The Director (or their designee) will approve SOP changes through Qualtrax.

The Quality Manager is responsible to ensure that all changes to the Management System are made available to all employees. Distribution and notification of approved changes will be through Qualtrax.

Changes to Unit specific documents (SOPs) will flow through the Quality Section. The Quality Assurance Manager or FB/DNA Quality Assurance Manager will work with the Deputy Director, Assistant Director, Laboratory Administrative Manager and/or Section Supervisor or Lead (or Technical Leader in the DNA Section) of the specific area to determine how the change will affect the procedure in question and if the change will still allow the customer's needs to be met. They must also ensure that the change is not contradictory to any components of the Quality Manual. Changes to SOPs are reviewed by the Assistant Director and approved by the Deputy Director and Director, (or designee in cases of emergencies), prior to the change being implemented through Qualtrax. The Assistant Director and Section Supervisor or Lead will ensure that the analysts performing the procedure implement the changes. Changes to Section SOPs will be communicated through Qualtrax.

4.3 Document Control

4.3.1 Control of original Management System documents will be through the Quality Section, as detailed in GL-19; "Document Control". All Management System documents applicable to all Section disciplines will be maintained by the Quality Section through Qualtrax (a Quality Assurance software program). No paper controlled copies will be maintained.

The Quality Section is responsible to maintain all the GL SOPs and Unit specific SOPs through Qualtrax, and to inform all employees when updates are made. Employees will be made aware of changes to procedures (whether General Laboratory SOPs or Section specific SOPs) through Qualtrax notification/email.

4.3.2 Document Approval and Issue

4.3.2.1 Preparation and maintenance of a master list of controlled documents, detailing review and approval prior to issue is described in GL-19; "Document Control." This SOP also describes document control procedures allowing identification of the current revision status and distribution of documents.

4.3.2.2 (a-d) GL-19; "Document Control" addresses the following issues:

a) Distribution of Management System Documents. The SOP specifies that appropriate, authorized editions of essential Division documents are available to analysts and other appropriate personnel, at their workstations. All SOPs are available through Qualtrax.

b) Document Review, the SOP specifies that all management system documents will be reviewed at least annually to ensure that they are still suitable for the task and are compliant to any applicable requirements.

c) Removal of expired, invalid, or obsolete documents. The SOP specifies that the Quality Section will ensure that expired, invalid, or obsolete documents are removed from points of issue or use when appropriate, or when superseded by new documents. SOPs printed from Qualtrax will print with a footer stating that they are not controlled documents. The Qualtrax document tree will be set to allow only the Quality Section and members of management access to out of date procedures.

d) Retention of Copies. The SOP specifies that original copies of management system documents be maintained for a period of not less than 10 years from date of expiration. Documents will be maintained either in paper or electronic form.

4.3.2.3 The identification system for documents is detailed in GL-19 "Document Control" Briefly; the Quality Section will maintain a master list of all Management System documents through Qualtrax. The alpha numeric designation along with the document title will serve as the unique identifier of Division procedures.

4.3.3 Document Changes

4.3.3.1 Document changes are subject to the same review and approval processes as required for the original document issued, as specified in GL-19; "Document Control." The review and approval process is required to include access to pertinent background information.

4.3.3.2 Altered and/or new text is identified in modified documents or attachments, as appropriate, as specified in GL-19; "Document Control".

The Qualtrax "properties" and "history" menu tabs are used to document the changes made to versions of controlled documents. Minor changes (such as those that are typographical, formatting or grammatical in nature) need not specifically identified. Information added to the "Changes Made" field will be detailed enough to allow the user to identify the nature of the changes. Depending on the nature of the change, before an approved new revision of an SOP is "published" or "released" in Qualtrax, an email may be sent by the QM with the changes made to the document in a colored font. This will allow another way for document changes to be reviewed in addition to the Qualtrax notification/email. Qualtrax will be the only location to find a current controlled copy of an SOP.

4.3.3.3 The DSS does not allow for hand written changes to Management System documents, as detailed in GL-19; "Document Control." Changes to Division procedures are documented through the use of Qualtrax.

4.3.3.4 Document changes in computerized documents is detailed in GL-19; "Document Control".

4.4 Review of Requests, Tenders, and Contracts

4.4.1 The Division of Scientific Services Laboratories' procedure for the review of Requests, Tenders and Contracts is detailed in GL-20 "Review of Requests and Tenders" and GL-12; "Evidence Receiving".

GL-20 "Requests and Tenders" contains the wording of the contract with customers submitting evidence and specifies that:

a) Methods to be used are adequately defined, documented, and understood.
b) The Division has the capability and resources to meet the requirements of the contract.
c) The appropriate testing is capable of meeting the customer's requirements.
d) Differences between the request and the contract will be resolved prior to the commencement of casework.
e) Each contract shall be acceptable to both the Division and the customer.
f) Electronic or handwritten signatures are acceptable on DSS reports.

GL-20 "Request of Tenders" also specifies that when a Memorandum of Understanding (MOU) occurs between the DSS and a customer, that MOU will supersede the standard contract.

4.4.2 All pertinent case review documents/documentation are maintained by the Division, as specified in Section-specific SOPs addressing case notes and documentation, as noted below. Pertinent discussions with customers relating to casework are similarly documented and maintained.

| | |
| --- | --- |
| Electronic Evidence/Computer Crimes: | CC-10 |
| Controlled Substance: | CS-1 |
| Toxicology: | TX-5 |
| DNA | DNA-1, 23 |
| Forensic Biology | FB-05 |
| Chemistry | CH-11 |
| Trace | TR-22 |
| Questioned Documents | QD-3 |
| Latent Prints | LP-24 |
| Multimedia | MMIE-27 |
| Firearms/Toolmarks | FA-06 |
| Imprints | IM-3, 13 |
| Instrumentation | FLIN-09 |

4.4.3 Sub-contracting:

In the event the Division of Scientific Services chooses to sub-contract case work the criteria set forth by ASCLD/LAB International documents and the FBI DNA QAS document will be followed. Contracts with sub-contractors will be reviewed annually, if the contract is maintained. Division Units using sub-contractors may include Unit specific requirements in Unit SOPs.

4.4.4 Contract Deviation: If a major deviation from the contract is required on a case, the customer (submitting agency) will be informed prior to performing the deviation, as detailed in GL-20 "Requests and Tenders".

4.4.5 If, during the process of working a case, a change to the contract is required the analyst or their lead/supervisor will contact the submitting agency to discuss the change; such discussion will be noted in the case file (date, person contacted and topics discussed will be included along with the initials of the person that made the contact). The analyst should consider the guidelines in 4.4.4 to determine if the change is sufficient enough to warrant contacting the customer. This process is detailed in GL-20 "Requests and Tenders"

4.5 Subcontracting of Tests: in the event the Division desires to sub-contract case work the Director will approve the contract vendor based on competency of the vendor.

4.5.1

The Quality Section is responsible to identify competent sub-contractors and maintain the records to demonstrate that competency.

> Competent is defined as a laboratory that has gained accreditation through an accrediting body in the specific discipline of work required. Acceptable accrediting bodies include but are not limited to ASCLD/LAB, ANAB, ABFT, FQS, A2LA, and NFSTC, or other laboratories that can demonstrate ISO/IEC 17025:2005 accreditation.

As a need arises the Quality Section will work with the Director, Deputy Directors or Assistant Directors to identify a contract laboratory that best meets the needs of the Division and its customers. If DNA cases are to be sub-contracted, the DNA TL will determine the competency of the contract laboratory based on the guidance of the FBI DNA QAS document.

4.5.2

The Division maintains the right, as defined in our customer contract, to sub-contract work. In the event that there is not a signed customer contract for a case identified to be sub-contracted out, a letter will be sent to the submitting agency informing them of the laboratories' intent to contract out case materials they had submitted. The customer may or may not be contacted on a case by case basis based on the reason for the need to sub-contract the work.

When the work that is being sub-contracted out is based on individual case need; such as testing required that the Division does not perform, the submitting agency will be contacted prior to sending the specific samples to the contract laboratory. When the work being sub-contracted out is based on the needs of the Division, such as for backlog reduction, and the testing being sub-contracted out is within the scope of normal testing the customer will not be informed on an individual case basis; since this is within the definition of the Divisions contract with its customer.

When samples are prepared for submission to a subcontractor, the Division Unit may send a notification stating samples were sent to an approved vendor laboratory.

4.5.3

When case work is sub-contracted, the DSS laboratory has the following options for reporting the findings to the customer:

- Issue the sub-contractors report directly to the submitting agency. The Unit will ensure that an abbreviated case review process occurs and that the report sent to the customer meets all Division requirements. The Unit upon receiving reports back from the contracted laboratory will perform an outsourcing review (see GL-18; "Case Reviews"); this is in place of a standard Technical and Administrative review.
- Issue a DSS laboratory report based on the data generated from the contract laboratory. The data generated from the contracted laboratory will be reviewed for accuracy. A laboratory report will be issued based on the findings of any work performed by the Division and by the data generated by the sub-contracted laboratory. Where applicable, the DSS Section will review sub-contracted work and make interpretations and conclusions based on that work. The laboratory report will clearly state what analysis (however titled) was performed by the contract laboratory; the report will include the name and address of the contract laboratory. The laboratory report will be subjected to

the normal case review process of both a Technical and Administrative review.

The Division of Scientific Services retains responsibility for case reports produced and issued to the client based on work performed in a contract laboratory.

4.5.4

The Quality Section will maintain a list of contract laboratories that have been deemed competent. This information will minimally include the name and contact information of the contracted laboratory, a copy of their accreditation certificate and the scope of the accreditation (or other document demonstrating accreditation in the specific required field).

4.6 Purchasing Services and Supplies

4.6.1 Each Unit selects and purchases services and supplies as detailed in GL-6; "Purchasing." This SOP also addresses receipt and distribution of materials. Storage of reagents and consumable material is detailed in Unit-specific SOPs;

| | |
| --- | --- |
| Controlled Substance: | CS-1 |
| Toxicology: | TX-14 & 19 |
| DNA | DNA-8 |
| mtDNA | mtDNA-01 |
| Forensic Biology | FB-8 to 18, 21 |
| Chemistry | CH-12 |
| Instrumentation | FLIN-8 & 9 |
| Trace | TR-2 & 4 |
| Imprints | IM-2 |

4.6.2 Procedures to ensure suitability of purchased supplies, reagents and consumable materials prior to use, are addressed in GL-6 "Purchasing". Further, Section-specific guidance is maintained in Section Specific SOPs as follows:

| | |
| --- | --- |
| Controlled Substance: | CS-1 |
| Toxicology: | TX-19 |
| DNA | DNA-8 |
| mtDNA | mtDNA-1 |
| Forensic Biology | FB-8 to 18, 21 |

| | |
| --- | --- |
| Chemistry | CH-12 |
| Trace | TR-2 |
| Latent Prints | LP-3 & 4 |
| Firearms/Toolmarks | FA-27, 28 |
| Instrumentation | FLIN-9 |

4.6.3 GL-6 "Purchasing" specifies that documents (SP33's) produced to purchase critical consumables or reagents will be reviewed by and signed or approved electronically by the Director (or their designee if the Director is not present) prior to being sent to fiscal for the purchasing order.

4.6.4 GL-6 "Purchasing" specifies that the Division shall evaluate vendors to determine if they meet the minimum requirements for critical consumables and critical reagents through the use of a questionnaire or through appropriate accreditation documentation. A list of the approved vendors and associated documentation is maintained in Qualtrax.

4.7 Service to the Customer

4.7.1 The Quality System utilized by the Division includes reviews and evaluations of the Division's willingness to cooperate with customers to clarify their requests and monitor the Division's performance relative to the work performed. (GL-8; "Management System" and GL-10; "Customer Inquiries")

4.7.2 The Division seeks feedback from all customers, including but not limited to State and Local Police Departments, Federal Agencies, Chief State Attorney's Office, State Public Defenders Office, our employees and other State agencies. Feedback both positive and negative will be reviewed periodically to continuously improve the Division and the service provided to our customers. Methods to solicit feedback include court monitoring forms, customer surveys and customer inquiry forms, as specified in GL-10; "Customer Inquiries".

4.8 Complaints:
Complaints will be handled as prescribed by GL-10; Customer Inquiries." Complaints are channeled through the Quality Section for review and action.

4.8.1 GL-10; "Customer Inquiries" specifically addresses complaints that may reflect quality issues within the Division.

4.9 Control of Nonconforming Testing Work

4.9.1 Each analytical SOP describes acceptable and unacceptable analytical work, and the criteria for such designation (e.g. instrumental or control material failure). These SOPs including steps to be taken when analytical procedures, and/or analyses fail either as individual samples or when the associated quality control material(s) fail to provide acceptable results. These procedures specify:

a. The responsibility of the individual analyst to inform their supervisor/lead of the issue. The supervisor/lead must inform the Quality Section and Assistant Director, who will then inform the Deputy Director of the issue and work with them (as appropriate) to determine the extent of the non-conformity and how to correct the non-conformity. Existing review/reporting criteria preclude report issuance based on any non-conforming analytical procedure/result. In the DNA Unit the DNA TL will also be included in this process.

b. That the Supervisor/Lead, Assistant Director or Deputy Director working with the QM or FB/DNA QM must determine the significance of the nonconforming work.

c. That the Supervisor/Lead, Assistant Director or Deputy Director and QM or FB/DNA QM will take action to determine if any case results were affected and determine if any remedial action is necessary.

d. That when appropriate, the customer will be notified and any affected reports will be recalled.

e. That if in consequence to the identification of nonconforming work, procedures or processes are halted, (as opposed to merely analysis or batch rejection) the responsibility for resumption of such procedures rests with the Deputy Director (in DNA will be the DNA TL) and Quality Section.

4.9.2 The Division initiates a "Quality Action Request" when non-conformity arises that could recur and/or raises doubt or question about compliance with Division procedures. This process is detailed in GL-9;"Quality Action Requests."

4.10 Improvement

The Division works to continually improve the effectiveness of the management system by the application of the overall quality policy, implementation of routine quality control practices, use of technical and administrative case reviews, and evaluation of annual

audits as a tool to ensure continuous improvement. (GL-8; "Management System"; GL-7; "Audits"; Section SOPs detailing QC criteria)

4.11 Corrective Action

4.11.1 General

The Division of Scientific Services has established policies and procedures to be implemented when nonconforming work or departures from the policies and procedures specified in the Quality Manual and/or the SOPs have been identified, as specified in GL-9; "Quality Action Requests." The implementation of corrective actions starts with the initiation of a QAR as detailed in the SOP noted above.

4.11.2 Root Cause Analysis

When a Corrective Action has been assigned to the QM, FB/DNA QM, Unit Supervisor/Lead (or designee) of a specific Unit, an investigation to determine the root cause or causes and the effect of the discrepancy shall be conducted as per GL-9; "Quality Action Requests."

4.11.3 Selection and Implementation of Corrective Actions

The process of identification and selection of potential corrective actions, is specified to be carried out in such a manner as to select and implement the action(s) most likely to eliminate the problem and to prevent recurrence, and to a degree appropriate to the magnitude and risk of the problem, and be appropriately documented as detailed in GL-9; "Quality Action Requests."

4.11.4 Monitoring of Corrective Actions:

Corrective actions are monitored and recorded to ensure their effectiveness in accordance with GL-9; "Quality Action Requests."

4.11.5 Additional Audits:

When it has been established through the process of a QAR that the nonconformance or procedural departures cast doubt on the Division's compliance with its own policies and procedures, or with ASCLD/LAB, ISO IEC 17025:2005 Standards or the FBI DNA QAS, the Division will ensure that the appropriate areas of activity are audited in accordance with GL-7; "Audits" in a timely manner.

4.12 Preventive Action

4.12.1 When improvement opportunities are identified by any Division personnel, or process (e.g. management review, audit or other means) a Preventive Action/Incident Report will

be initiated through Qualtrax by a member of the Quality Section, as per GL-9; "Quality Action Requests."

4.12.2 Implementation of preventative actions are specified to include appropriate controls to ensure the effectiveness of such preventative actions, as specified in GL-9; "Quality Action Requests."

Incident reports are used as a manner of tracking instances or circumstances that do not rise to the level of a QAR however the Quality Section chooses to assess further or track to ensure there are not trends.

4.13 Control of Records

4.13.1 General

4.13.1.1 The Division has established procedures for record control, including identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records, including reports from internal audits and management reviews as well as records of corrective and preventive actions, as detailed in GL-11; "Control of Records."

GL-11; "Control of Records" gives guidance on Discovery Requests and Freedom of Information Act Requests (FOIA's).

4.13.1.2 GL-11; "Control of Records" specifies that all records are prepared in a legible manner and are stored and retained so as to be readily retrievable. Further, that such record is stored in locations that provide a suitable environment to prevent damage or deterioration and to prevent loss.

4.13.1.3 GL-11; "Control of Records" specifies that all records are stored in a secure manner.

4.13.1.4 GL-11; "Control of Records" and GL-4; "LIMS" specifies that all electronic records are protected, backed-up, and stored in such a manner as to prevent unauthorized access to, or amendment of, these records.

4.13.1.5 If another forensic laboratory requests documents or software from the CT Division of Scientific Services, a representative from that laboratory is to fill out the "Receipt of Laboratory Documents/Software" form found in the General

Laboratory Forms in Qualtrax. The signed form is kept with the Quality Section and only after the signed form is received, is the document or software to be released.

4.13.2 Technical Records

4.13.2.1 GL-11; "Control of Records" specifies that all significant records generated during the course of analysis are maintained within the case file. Further, that records for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty of the test, and to enable the test to be repeated under conditions as close as possible to the original. Also, that case records include the identity of all personnel responsible for the sampling, performance of each test, and of all review processes.

4.13.2.2 GL-11; "Control of Records" specifies that observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task, and that test results are rejected, the reason for the rejection will be recorded.

4.13.2.2.1 GL-11; "Control of Records" specifies that case documentation shall reflect the date(s) of examination.

4.13.2.2.2 Changes to completed examination records, either hard copy or electronic are tracked so that any change is clearly documented as detailed in individual Section SOPs, and GL-11; "Control of Records". The Division defines completed examination records as those submitted for technical review.

4.13.2.3 GL-11; "Control of Records" specifies that when mistakes in records are found, each mistake will be crossed out with a single line and the correct value/change entered alongside. These alterations will be initialed by the individual making the correction. In the case of electronic records, a copy of the original record will be maintained and a new copy will be generated reflecting the correction. Note: it is acceptable to make hand written corrections on printed electronic records, instead of generating a corrected electronic copy.

4.13.2.3.1 GL-11; "Control of Records" specifies that if, during the technical review process, changes are required to the examination worksheets or other case documentation, the change will be initialed by the individual making that change.

4.13.2.4 Each Unit specifies appropriate and required case record documentation in SOPs as detailed below:

| | |
| --- | --- |
| Electronic Evidence/Computer Crimes: | CC-10 |
| Controlled Substance: | CS-1 |
| Toxicology: | TX-5 |
| DNA | DNA-23 |
| Forensic Biology | FB-05 |
| Chemistry | CH-05 |
| Instrumentation | FLIN-10 |
| Trace | TR-22 |
| Questioned Documents | QD-3 |
| Latent Prints | LP-1, 18 |
| Multimedia | MMIE-3 |
| Firearms/Toolmarks | FA-6 |
| Imprints | IM-13 |

4.13.2.5 GL-11; "Control of Records" specifies that case records include sufficient data to facilitate and allow another competent analyst or supervisor/lead to scientifically evaluate the results and how conclusions were made.

4.13.2.5.1 SOP LP-6 in the Latent Print Discipline specifies that conclusions shall meet all applicable requirements in "ASCLD/LAB Latent Print Examination Documentation."

4.13.2.5.2 When instrumental analysis is performed, the routine working parameters of the instrument used will be documented in the appropriate Sectional procedural SOPs. Any significant departure from such parameters shall be documented in case documentation as detailed in individual Unit SOPs.

4.13.2.6 GL-11; "Control of Records" specifies that a unique case identifier and analyst's handwritten initials (or secure electronic equivalent of initials or signature) shall be on each page of their examination documents in the case record.

4.13.2.7 GL-11; "Control of Records" specifies that any documentation in the case jacket prepared by another analyst, or an individual other than the case analyst(s), must have that individuals initials on all such pages.

4.13.2.8 GL-11; "Control of Records" specifies that all administrative document contained in the case jacket will contain the unique case identifier.

4.13.2.9 GL-11; "Control of Records" specifies that when multiple case data is recorded on a single printout (e.g. Toxicology Batch Summary Sheet), the unique case identifier will be appropriately recorded.

4.13.2.10 GL-11; "Control of Records" specifies that when examination records are present on both sides of a single page, both sides of the page will be considered and treated as a separate page.

4.13.2.11 GL-11; "Control of Records" specifies that examination worksheets shall be completed using a permanent form of a writing device. Examples of such devices include, but are not limited to: pens, permanent markers, and laser inkjet printers. However, colored pencils may be used for sketches and drawings.

4.13.2.12 GL-11; "Control of Records" specifies that when an independent check of a critical finding has been performed, that check will be carried out by an individual having expertise in the field, gained through knowledge, training and experience. A record of this review will be made to confirm the critical finding. This record will include, by whom and when the check was performed, and will be maintained in the case jacket.

4.13.2.13 GL-11; "Control of Records" specifies that any non-common abbreviations or symbols specific to a DSS Unit that are used in the examination worksheets will be maintained either as a list available within the Section or in individual Section SOPs, as detailed below:

| | |
| --- | --- |
| Electronic Evidence/Computer Crimes: | CC-26 |
| Toxicology: | TX-19 |
| DNA | DNA -1 |
| Forensic Biology | FB-04 |
| Chemistry | CH-2 |
| Trace | TR-20 |
| Latent Prints | LP-5 |
| Multimedia | MMIE-25 |
| Firearms/Toolmarks | FA-7 |
| Instrumentation | FLIN-12 |

4.14 Internal Audits:

The Division of Scientific Services is committed to provide auditing training for its members with the intent of providing the best quality management system and ensuring compliance with ASCLD/LAB ISO 17025:2005 requirements and the FBI DNA QAS.

4.14.1 GL-7; "Audits" specifies the process by which each of the Division Sections and Units will conduct internal audits. This process is used to verify that all Division operations are complying with the Management System and the ASCLD/LAB International Standard and the FBI DNA Quality Assurance Standards. These internal audits address all elements of the Management System. The Quality Manager is responsible for planning and organizing these audits according to schedule, and as requested by management. Note: The DNA internal audit will be scheduled and performed by the DNA technical leader with a designated audit team as required by the QAS document.
These audits will be conducted by trained and qualified personnel who are, whenever resources permit, independent of the activity being audited. All internal laboratory audits are reviewed by the Director and Quality Manager.

4.14.1.1 GL-7; "Audits" specifies that audits will be conducted at least annually.

4.14.1.2 GL-7; "Audits" specifies that audits are documented and will be retained for at least one ASCLD/LAB-International cycle of accreditation.

4.14.2 GL-7; "Audits" specifies that when internal audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of test results, the Division will initiate, in a timely manner, a QAR. In addition, effected customers will be notified in writing if investigations show that the laboratory results may have been affected.

4.14.3 GL-7; "Audits" specifies that the audit records will be maintained as noted in 4.14.1.2, above.

4.14.4 GL-7; "Audits" specifies that audit activities shall verify and record the implementation and effectiveness of any corrective action taken.

4.14.5 GL-7; "Audits" specifies that DSS will submit an Annual Accreditation Audit Report to ASCLD/LAB International (if required) within 30 calendar days of the date of the laboratories accreditation anniversary date.

4.15 Management Reviews

4.15.1 GL-8; "Management System" specifies that Top Management will conduct a System Review on a defined schedule to ensure the suitability and effectiveness of the Quality System and any introduced changes to that system or overall Division operation. As a function of this review process, changes and or improvements may be introduced to the Division system.

This management review will take into account the following areas:

- the suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcome of recent internal and external audits
- corrective and preventive actions
- assessments by external bodies
- the results of inter-laboratory comparisons or proficiency tests
- changes in the volume and type of the work
- customer feedback
- complaints
- recommendations for improvement
- other factors, e.g. quality control activities, resources and staff training

4.15.1.1 GL-8; "Management System" specifies that management reviews will be conducted at least once annually. The review process is ongoing as documented through regular Quality Section and management meetings.

4.15.1.2 GL-8; "Management System" specifies that management reviews will be documented, and that documentation produced from management reviews will be retained for at least one ASCLD/LAB International cycle of accreditation.

4.15.2 GL-8; "Management System" specifies that records of findings and actions that arise from management reviews will be maintained, and that any remedial actions are implemented within a timely manner.

5 Technical Requirements

5.1 General

5.1.1 Procedural Correctness and Reliability Factors include but are not limited to:

Human factors
Accommodation and environmental conditions
Test and calibration methods and method validation
Equipment
Measurement traceability
Sampling
Handling of test and calibration items

5.1.2 Each DSS Unit specifies that factors that may affect measurement uncertainty, (as noted in 5.1.1) are considered, as applicable, in developing testing methods and procedures, training and qualification of personnel, and in equipment selection and calibration, as detailed in Section-specific SOPs, identified as follows:

| | |
| --- | --- |
| Controlled Substance: | CS-2 & 5 |
| Toxicology: | TX-19, 21, 21A, 22,23,25,26 & 28 |
| Firearms/Toolmarks | FA SOP-13 & 34 |

5.1.3 The DSS specifies procedures for routinely checking the reliability of their reagents as detailed in Section specific SOPs identified as follows:

| | |
| --- | --- |
| Controlled Substance: | CS-3 |
| Toxicology: | TX-19 |
| DNA | DNA-8 &1 |
| mtDNA | mtDNA 1 |
| Forensic Biology | FB-8 to 18, 24 |
| Chemistry | CH-13 |
| Firearms | DD-2, 3, 4 FA-27 & 28 |
| Trace | TR-2 |
| Latent Prints | LP-3 & 4 |
| Imprints | IM-8 |

5.1.3.1 The DSS specifies procedures for labeling reagents prepared in the laboratory, in GL-2 Safety Manual. The records will be maintained identifying the reagent preparer, and that it was tested and worked as expected to check the reliability of the reagent, as detailed below:

| | |
| --- | --- |
| Controlled Substance: | CS-3 |
| Toxicology: | TX-19 |
| DNA | DNA-8 |
| Forensic Biology | FB-08-10, 12-14, 16,18,21 |
| Chemistry | CH-13 |
| Trace | TR-2 |
| Latent Prints | LP-3 |
| Firearms | FA-27 |

5.2 Personnel

5.2.1 All analytical personnel of DSS are required to receive appropriate training and demonstrate competency, as per individual Unit SOPs (specified below) prior to performing casework. These SOPs further specify that individual employees will, during their training process, receive appropriate supervision when performing analytical tasks, and those personnel will be qualified for the tasks assigned through education training experience and/or demonstrated skill.

| | |
| --- | --- |
| Electronic Evidence/Computer Crimes: | CC-25 |
| Controlled Substance: | CS-13 |
| Toxicology: | TX-30 |
| DNA | DNA-1 & 7 |
| mtDNA | mtDNA-1 and DNA-7 |
| Forensic Biology | FB-26 |
| Chemistry | CH-15 |
| Trace | TR-1 |
| Questioned Documents | QD-5 |
| Latent Prints | LP-16 |
| Multimedia | MMIE-26 |
| Firearms/Toolmarks | FA SOP-01 |
| Imprints | IM-14 |
| Instrumentation | FLIN-6 |

5.2.1.1 Each laboratory Unit maintains SOPs (specified below) which detail the training processes and requirements in the individual Sections. These SOPs additionally address procedures for retraining, and maintenance of skill and expertise.

| | |
| --- | --- |
| Electronic Evidence/Computer Crimes: | CC-25 |
| Controlled Substance: | CS-13 |

| | |
| --- | --- |
| Toxicology: | TX-30 |
| DNA | DNA-7 &1 |
| mtDNA | mtDNA-1 and DNA-7 |
| Forensic Biology | FB-26 |
| Chemistry | CH-13 |
| Trace | TR-1 |
| Questioned Documents | QD-5 |
| Latent Prints | LP-16 |
| Multimedia | MMIE-26 |
| Firearms/Toolmarks | FA-SOP-01 |
| Imprints | IM-14 |
| Instrumentation | FLIN-6 |

5.2.1.2 Training SOPs (as noted in 5.2.1.1, above) also address presentation of evidence in a legal setting (e.g. deposition, courtroom testimony).

5.2.1.3 Training GL-14 "General Training" address the application of ethical practices in forensic science, a general knowledge of forensic science and criminal and civil law procedures pertinent to the Division.

5.2.2 The need for training/retraining of personnel is expected to be identified as a function of the routine quality control/quality assurance program of the Division, including case technical reviews, and evaluation of proficiency testing programs, as well as the annual audit program. The specific consideration for training needs, and evaluation of training effectiveness is address in GL-14; "General Training."

5.2.3 GL-14; "General Training" specifies that all employees, and/or contract personnel must demonstrate competence in a given category of testing prior to the performance of casework in that category of testing. This is based on the DSS accreditation Scope of Testing document.

5.2.4 GL-15; "Professional Development" specifies that job descriptions for each specific position are maintained by the Quality Section.

GL-15; "Professional Development" specifies that the documentation of management authorization to perform casework within a discipline, is maintained in each analysts Professional Development file. The date of competency will be clearly defined in the competency documentation.

Note: Authorization letters may include all techniques within a discipline, or may include only specific sub-disciplines in cases where an analyst is only trained in portions of a discipline. The letters needs to be detailed enough to ensure that an analyst is only authorized in those methods they are competent in, but they need not be so detailed as to list each technique individually within the discipline.

5.2.5 Analysts (however titled) may have the opportunity to give presentations at organized meetings. Analysts (however named) may have the opportunity to author or coauthor publications. These presentations and publications will be pre-approved by the Director and documented on form: "Presentation/Publication Approval" found in the "General Laboratory Forms" folder in Qualtrax. The form will be kept with the Quality Section.

5.2.6 Technical Personnel Qualifications

5.2.6.1 Education

5.2.6.1.1 - .5 All Division of Scientific Services professional personnel possess a baccalaureate or advanced degree or meet other educational requirements specified in their job description per GL-15; "Professional Development." (Note; DNA analysts are required to meet the education requirement of the Quality Assurance Standard for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories). Technical support personnel must meet the guidelines set forth in the specific job description.

5.2.6.2 Competency Testing

5.2.6.2.1 GL-14; "General Training" specifies that all employees, and/or contract personnel must demonstrate competence in a given discipline and category of testing, prior to the performance of casework in that discipline. Demonstration of competency will be through the completion of a competency test in the specified category of testing and/or discipline.

5.2.6.2.2 Training SOPs (as noted in 5.2.1.1, above) also address the competency tests required of all personnel who generate laboratory reports, including:

- The examination of sufficient unknown samples to cover the anticipated spectrum of assigned duties.
- A written report to demonstrate the individual's ability to convey results and the significance of the results.

- A written or oral examination, which assess the individual's knowledge of the discipline.
- Analysts will only be authorized to perform technical reviews after gaining experience through the completion of a specified number of cases within a discipline (this number will be Unit specific).

5.2.7 The Division maintains appropriate reference books and journals in each discipline, including Internet access.

5.3 Accommodation and Environmental Conditions

5.3.1 DSS Facilities have adequate lighting and environmental conditions to facilitate correct performance of test and examination equipment. Monitoring of procedural controls is expected to identify any environmental factor affecting an analytical process.

5.3.2 The Division of Scientific Services (DSS) Units monitor environmental conditions critical to the integrity of the testing results. Unit SOPs detail specific parameters monitored and maintenance of records.

5.3.3 The DSS employ measures within the appropriate working areas to prevent cross-contamination. This includes partitions on workbenches and separate rooms for incompatible activities.

5.3.4 Access to all lab areas in the DSS labs is controlled by key and/or card-key systems. These systems restrict the access to essential personnel, as described in GL-3; "Security."

5.3.4.1 The GL-3; "Security" specifies that

a. Access to the operational areas of the DSS facility is controlled and limited. Operational area is defined as any area used in the analysis or storage of case materials. Only visitors for the purpose of building maintenance, instrument maintenance/calibration, and accreditation assessment are allowed access to operational areas of the DSS facility. Access limitation of interns will be determined on a case by case basis and Section need by Director.

For DNA consumption cases where there is a request for an observation, those participating in the observation will do so via the use of a camera system set up for this purpose.

Access to areas such as the classrooms, do not require escorted access. Use of classrooms by outside agents must be pre-approved by the Director or their designee. No tours will be given of the DSS facility without prior approval by the Director or their designee.

b. All exterior entrance/exit points have adequate security control.
c. Internal areas requiring limited/controlled access have a lock system
d. Key and proximity card distribution and accountability is documented and distribution limited to individuals designated by the Director or the Laboratory Administrative Manager or appropriate Deputy Director.
e. The DSS facility is monitored during vacant hours by an intrusion alarm system.
f. Evidence storage areas are secured to prevent theft or other interference, and are in limited, controlled access locations. Storage conditions in such areas are such as to prevent loss, deterioration and contamination, and to maintain the integrity and identity of the evidence, both before and after examinations have been performed.
g. A fire alarm system, compliant with applicable state and local codes, is maintained by the DSS facility.
h. Background checks are required on all employees, interns and contract employees who will be working in or on the DSS facility. For information on obtaining a background check for a non-DESPP employees performing work in the DSS facility see GL-3 Security.

5.3.5 Each Unit lead/supervisor is responsible for the housekeeping in their Section, as detailed in GL-2; "Safety." All limited access areas are cleaned and maintained by DSS staff or by contracted cleaning staff. All public access and common areas of DSS are cleaned by a contracted company. Additional outside vendors are hired when necessary for specific house cleaning needs (e.g. cleaning the indoor firing range).

5.3.6 The DSS safety program is detailed in GL-2; "Safety". The Division has a designated safety officer and safety committee, which oversees all aspects of the safety program.

5.4 Test and Calibration Methods and Method Validation

5.4.1 General

The procedural SOPs for each Unit in the Division, when appropriate, specify the use of appropriate methods and procedures for sampling, handling, transport, preparation, and storage of items to be tested. Each Unit as appropriate includes in its procedures, provision of estimation of measurement uncertainty, as well as statistical techniques for

analysis of test data.

Each Unit has, as appropriate, current and readily available instruction on the use and operation of all relevant equipment. Any significant deviation from accepted procedures must be documented and approved by the Director and/or Deputy Director (TL in DNA) of the Section and the customer.

5.4.2 Selection of Methods

As specified in GL-20; "Requests and Tenders" each Unit shall, as a function of the contractual agreement with the customer, specify and use appropriate procedures which meet the needs of the customer and which are appropriate for the examination/testing required.
As specified in GL-19; "Document Control" each Unit may only use procedures that have been validated and are approved by the Deputy Director and/or Director for use in the specific Unit. In the DNA Unit, the DNA TL will approve validations. Each Unit has a specific SOP detailing the method development/validation and documentation process, as noted below:

| | |
| --- | --- |
| Electronic Evidence/Computer Crimes: | CC-20, 28 & 36 |
| Controlled Substance: | CS-10 |
| Toxicology: | TX-10 |
| DNA | DNA-1 |
| mtDNA | mtDNA-1 |
| Forensic Biology | FB-25 |
| Chemistry | CH-16 and 17 |
| Trace | TR-21 |
| Latent Prints | LP-17 |
| Imprints | IM-15 |
| Questioned Documents | QD-21 |
| Firearms/Toolmarks | FA-37 |
| Multi-Media | MM-29 |

As specified in GL-20; "Requests and Tenders", each Unit shall inform a customer when the method proposed by the customer is considered to be inappropriate or out of date.

5.4.2.1 Individual Unit validation procedures (as noted in 5.4.2, above) specify that new laboratory procedures demonstrate reliability and performance characteristic of the analysis, and that appropriate documentation be maintained.

5.4.3. Unit-developed and validated methods will only be utilized for casework by properly qualified personnel, as documented per GL-15 "Professional Development". During the validation process, the validation plan must be updated as development dictates. If the plan is updated all involved personnel will be informed.

As specified in GL-19;"Document Control" SOPs reflecting updates, modifications or new procedures will be communicated to appropriate employees by the QM, FB/DNA QM, Deputy Director or Supervisor/Lead. Qualtrax will be used as the mechanism to notify employees that a new revision of a procedure has been issued.

5.4.4 If a case requires use of a non-standard method, the customer will be contacted, and the agreement regarding use of such a method will be noted in the case file, as detailed in GL-20; "Requests and Tenders." All requirements for a validated method as specified by laboratory SOPs must be fulfilled by the non-standard method prior to use.

5.4.5. Validation of Methods

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

a. Validation plans will be written and approved prior to implementation. In general the Unit Lead or their designee will develop the plan. Once a plan is developed it will be approved prior to implementing the plan.
b. The plan will be approved by the Section Deputy Director and/or the Director. For the DNA Unit the DNA Technical Leader will review and approve the plan.
c. When implementing a validation plan, if a change to the plan is required, the change plan will be updated and approved by the Deputy Director (or DNA TL if in DNA).

5.4.5.2 Each Unit validates all methods prior to use, per Unit specific SOPs (noted in 5.4.2, above). Documentation of the validation process, including a consideration regarding the method as being "fit for purpose" is specified in the validation documentation. Each Unit will maintain the validation documentation for a minimum of the life of the procedure plus 10 years.

5.4.5.3 Validation methods will include, as appropriate, consideration of range and accuracy, uncertainty, detection limit, linearity, and robustness against external influences, and/or matrix effects (as appropriate to the method being validated). Method validation is driven, at least in part, by a consideration of customer needs.

5.4.5.4 Prior to implementation, validated methods will be verified using in-house documented performance characteristics. See Unit specific SOPs for validation as noted in Section 5.4.2 above.

5.4.5.5 At the completion of a validation, General Laboratory Form "Laboratory Method Validation Summary Form" will be filled out to ensure all necessary information is captured. This form can be found in the "General Laboratory Forms" folder in Qualtrax.

5.4.5.6 Please refer to GL-1.8 "Guidance Document for Validation and Performance Checks" for further details.

5.4.6 Estimation of Uncertainty of Measurement: DSS Units which include the estimation of measurement uncertainty as part of their reporting process will conform to the most current, published ASCLD/LAB policy on Estimation of Uncertainty of Measurement (See GL 1.5), as specified in individual Section SOPs.

5.4.6.1 All DSS Units shall utilize method/sample-specific procedures to estimate the uncertainty of measurement where applicable. As appropriate, analytical procedures which require consideration of uncertainty address that process on a method-specific basis for each individual Unit.

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| --- | --- |
| Controlled Substances | CS-2 and CS-5 |
| Chemistry | CH-21 |
| Firearms | FA-13 & 34 |
| Toxicology | TX-19, 21, 21A, 22, 23, 25, 26, 28, 31, 32, 33,35, 36 |

5.4.6.2 As addressed in specific analytical SOPs, the process of determination of uncertainty will include an attempt at identifying all significant factors contributing to the uncertainty of a particular measurement, to provide a reasonable estimation of the confidence interval. The particular format for reporting uncertainty (confidence interval) is addressed on a procedure-specific basis, as noted above. A reasonable estimation can be based, for example on previous experience and validation data.

5.4.6.3 As addressed in specific analytical SOPs, the process of determination of uncertainty will include an attempt at identifying all significant factors contributing to the uncertainty of a particular measurement, to provide a reasonable estimation of the confidence interval.

5.4.7 Control of Data

5.4.7.1 Technical reviews of all case calculations and data transfers, and the documentation thereof is detailed in GL-18; "Case Reviews".

5.4.7.2 The DSS does not utilize user-developed software. Procedures for protection of data, including integrity and confidentiality of data entry, collection, storage transmission, and data processing are detailed in GL-4; "LIMS". This SOP further specifies that computer and related automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test data.

5.4.7.2.1 SOP CC-19; "QC Protocol – Forensic Computer" specifies that the Division of Scientific Services takes measures to prevent unauthorized access to computer systems used for examining digital evidence.

5.5 Equipment

5.5.1 Division Units are equipped with instrumentation and test equipment required by each Units SOPs. All procedural SOPs require and specify instrumental operational parameters. All instrument use, regardless of the operational ownership or control of the instrument, must be in accordance with the laboratory SOP. See Section 5.5.9 below, for guidance on instrumentation that is temporarily out of control of the DSS.

5.5.2 Guidance for maintenance and performance checks of some general laboratory equipment can be found in GL-21.

Individual Unit instrument specifications require that equipment and associated software is vender certified/qualified and validation is complete before being placed into service. Calibration procedures and schedules are specified in individual Unit SOPs.

| | |
| --- | --- |
| Controlled Substances | CS-5, 6, 7, 8 &10 |
| Toxicology | TX-10, 20-29 & 31 -32 |

| | |
| --- | --- |
| Chemistry | CH-3 & 4, 16 |
| Instrumentation | IN 4 & 5 |
| Trace | TR 3, 4 & 21 |
| DNA | DNA 1 & 9 |
| mtDNA | mtDNA 1 & 12 |
| Forensic Biology | FB-23 & 24 |
| Latent Prints | LP-11 & 25 |
| Firearms | FA-22 |
| Imprints | IM-11 |
| Questioned Documents | QD-21 |
| Computer Crimes | CC-19-22 |
| Multi-Media | MMIE-14 |

5.5.3 Competency with specific equipment is documented in each analysts training records. Authorization documentation is maintained in individual analysts Professional Development files, as detailed in GL-15; "Professional Development". All SOPs (General and Unit specific) including those containing current instructions on the use and maintenance of equipment are available to all DSS employees through Qualtrax as detailed in GL-19; "Document Control".

5.5.4 Instrumentation (and related software) and other laboratory equipment used to obtain results for casework will be uniquely identified. This may be through the State of Connecticut Bar Code label, as specified in GL-6; "Purchasing" or other laboratory generated identification as specified in individual Unit SOPs.

5.5.5 Each Unit maintains a master list of equipment; this list includes the following:

ID of each item of equipment and/or software
Manufacturer's name, description and serial number
Checks that the equipment complies with specs – see vender certification
Current location
Each Laboratory maintains instrument maintenance logs, as detailed in Section-specific SOPs.
Maintenance Logs detail the following:
Dates and copies of validation documentation
Maintenance plan and maintenance
Damage, modification or repair to the equipment

A Qualtrax workflow may be used to aid in equipment lists and maintenance reminders.

5.5.6 The proper handling, use, storage and scheduled maintenance of measuring equipment is specified or referenced in each Units procedural SOP in which the use of such equipment is specified. Guidance for maintenance and performance checks of some general laboratory equipment can be found in GL-21.

| | |
| --- | --- |
| Controlled Substances | CS-5,6,7 and 8 |
| Toxicology | TX-14 and 29 |
| Chemistry | CH-3 and 4 |
| Instrumentation | IN 4 and 5 |
| Trace | TR 3 and 4 |
| DNA | DNA 1 and 9 |
| mtDNA | mtDNA 1 and 12 |
| Forensic Biology | FB-23,24 |
| Latent Prints | LP-09, 10, 11 & 25 |
| Firearms | FA-22, 33 & 35 |
| Imprints | IM-11 |
| Questioned Documents | QD-10 |
| Computer Crimes | CC-19-21 |
| Multi-Media | MMIE-14 |

5.5.7 Any equipment suspected of malfunctioning or of giving incorrect results shall be removed from service and labeled as "out-of-service" (or similar language) and any possible impact on previous tests will be considered, and appropriate remediation initiated. Demonstration of appropriate performance following any repair, or adjustment is also specified.

5.5.8 All DESPP equipment contains a unique identification number (for high dollar value equipment, this may be a Department bar code that is as part of the inventory control procedures). Instrument-specific records detailing maintenance, repair and functional parameters (including calibration documentation as appropriate) are kept by each analytical instrument, as specified in individual Unit SOPs.

When preventative maintenance or verifications are to occur on an annual basis, the laboratory will make every effort to ensure the action occurs on or about the anniversary date (+/-30 working days).

5.5.9 Any equipment returned to the manufacturer for repair, or that is out of the control of the Division for any reason (such as validation services or maintenance performed by a vender in-house) shall be checked/calibrated (as appropriate) before it is returned to service. All repairs must be documented in the instrument maintenance log as specified in individual Unit SOPs. The documentation for the check/calibration will include the examiners name, the date, the findings (data if applicable) and a statement that the device

is demonstrably fit for purpose. Note in the DNA Unit the DNA Technical Leader or their designee will initial the documents to demonstrate approval.

5.5.10 When appropriate, Unit specific procedures define any equipment that may require periodic checks to verify proper working conditions. These checks may be periodic performance checks, day of use, weekly, monthly or checks as otherwise defined by the procedures.

5.5.11 No current instrumentation utilizes correction factors.

5.5.12 Analytical instrumentation is maintained in limited-access facilities. Evaluation of control material during routine test evaluation ensures that no inappropriate adjustment affecting calibration and/or test results has been made.

5.6 Measurement Traceability:

The DSS will conform to the most current ASCLD/LAB *Policy on Measurement Traceability* (See GL-1.6) as specified in individual Unit SOPs.

5.6.1 General

All equipment shall be calibrated before being put into service, as specified in individual laboratory Section SOPs. Calibration of specific instruments is detailed per individual Unit SOPs; refer to GL-21 for calibration/checks of weights and balances.

| | |
| --- | --- |
| Controlled Substances | CS -5, 6, 7 & 8 |
| Toxicology | TX- 20-29 & 31 -32 |
| Chemistry | CH-3 & 4 |
| Instrumentation | IN-4 & 5 |
| Trace | TR-3 & 4 |
| DNA | DNA-1 & 9 |
| mtDNA | mtDNA-1 & 12 |
| Forensic Biology | FB-23 & 24 |
| Latent Prints | LP-09, 11 & 25 |
| Firearms | FA-22 |
| Imprints | IM-11 |
| Questioned Documents | QD-9 |
| Computer Crimes | CC-19-21 & 28 |
| Multi-Media | MMIE-14 |

5.6.1.1 Evaluation of instrumental calibration is detailed, (e.g. following instrumental shut down or post-service) on a per-instrument or instrument type (e.g. GCMS) in individual Unit SOPs (see above).

5.6.2 Specific Requirements

5.6.2.1 Calibration

5.6.2.1.1 All equipment calibrations shall whenever possible be traceable to the International System of Units (SI) either through the use of suitable standards or the use of ISO or equivalent certified laboratories or companies, as specified in Unit SOPs.

Each Unit shall utilize only measurement standards for calibrations or comparisons which can be linked to relevant primary standards of the SI Units of measurement.

When the Division utilizes external calibration services, only facilities that can demonstrate competence, measurement capability and traceability will be employed. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

When calibrations are scheduled to occur annually the Division defines compliance as having the event occur +/-30 working days of the due date.

5.6.2.1.2 If certain calibrations cannot be made in SI Units, certified reference materials provided by a competent supplier shall be used to give a reliable physical or chemical characterization as described in individual Unit SOPs.

5.6.2.2 Testing

5.6.2.2.1 Each Unit is responsible to ensure that testing equipment and protocols are "fit for purpose" (provide an uncertainty level appropriate to the testing required) as per the customer contract, as specified in GL-12 "Evidence Receiving."

5.6.2.2.2 If certain calibrations cannot be made in SI Units, certified reference materials provided by a competent supplier shall be used to give a reliable physical or chemical characterization as described in individual Unit SOPs.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

All reference standards are calibrated against NIST standards or by a vendor, which can provide traceability to NIST or an equivalent. Reference standards are not adjusted or modified.

5.6.3.2 Reference Materials.

All reference materials shall, where possible, be traceable to SI Units or to certified reference materials. Internal reference materials shall be produced and checked as far as is technically and economically practicable as detailed in individual Unit SOPs.

5.6.3.2.1 Reference collections of data or items/materials maintained for comparison or interpretation purposes are to be fully documented, identified and controlled, see appropriate Unit SOPs.

5.6.3.3 Intermediate Checks

QC checks for the integrity of standards and reference materials are defined, as appropriate for each calibration, in the specific SOP associated with that procedure. For weights, Units may refer to GL-21.

5.6.3.4 Transport and Storage

Procedures for the safe handling, transport, storage and use of reference standards and materials are detailed in Unit-specific SOPs.

5.7 Sampling

5.7.1 Where applicable, each DSS Unit defines and describes its sampling protocols in Unit specific SOPs. Such sampling processes address the factors to be controlled to ensure the validity of the test results.

5.7.2 Individual Unit sampling SOPs specify that any deviations from the

sampling procedure (plan) required by the customer shall be noted on the appropriate worksheet in the case file.

5.7.3 Each DSS Unit, when appropriate, specifies procedures for recording relevant sampling data. Such protocols specify that all information on the sampling procedure (including pertinent diagrams for location of sampling) shall be documented on case worksheet(s).

5.8 Handling of Test and Calibration Items

5.8.1 The DSS addresses the overall handling of test materials in GL-13; "General Evidence Handling" and each DSS Unit has specific SOPs addressing transportation, receipt, handling, protection, storage, retention, and/or disposal of test items. These SOPs include provisions to protect the integrity of each item and the interests of the lab and the customer. These provisions shall include the collection of reference materials (e.g. Buccal Swabs) from laboratory personnel or visitors (e.g. observers, vendors, or other individuals who may be allowed into laboratory areas).

5.8.1.1 Chain of custody (COC) for all test and sample materials received by the Division is documented as detailed in GL-4; "LIMS". This electronic capture of COC information includes each person taking possession of an item of evidence, or the location of that item, the date of receipt or transfer and the description and unique barcode identifier/case number of the item.

5.8.1.1.1 All sub-items (when generated) are tracked in LIMS in the same manner as original evidence items, as per 5.8.1.1 above.

5.8.1.1.2 Evidence accepted by, and stored in the Division Units will be properly sealed when not in the analytical process, as detailed in GL- 12; "Evidence Receiving".

5.8.2 Each DSS Unit has a specific system for the identification of test items, as detailed in GL-13; "General Evidence Handling". Each item and, when necessary, sub-item(s) acquire(s) a unique label which remains as a permanently affixed identifier and is used in all aspects of the testing/examination process.

5.8.3 Each DSS Unit requires (as detailed in Unit-specific SOPs) documentation of any departure of samples or test materials from procedural specification(s). If the departure is of sufficient magnitude as to potentially affect the suitability of the item for testing, the customer will be notified for further instruction, and the information detailed in the case file. Further, if the submission(s) do not conform to the description provided, the customer will be notified, and the case file will be appropriately documented.

5.8.4 Each DSS Unit has a specific SOP requirement for the appropriate storage conditions for samples and test materials. These procedures ensure the proper storage, handling, and preparation of submitted items. Storage facility conditions are monitored and recorded as appropriate.

5.8.4.1 GL-13; "General Evidence Handling" specifies that any evidence not in the process of examination will be maintained in a secured, limited-access storage area.

5.8.4.2 GL-13; "General Evidence Handling" specifies that all unattended evidence (in the process of examination, e.g. assigned to an examiner) shall be stored in a secure evidence storage area or locked in a personal locker.

5.8.4.2.1 GL-13; "General Evidence Handling" specifies that the process of examination cannot be "open ended," and that there shall be a reasonable end point to the process of analysis, determined on a case-specific basis.

5.8.4.3 GL-13; "General Evidence Handling" specifies that each item of evidence shall be marked with the unique case number and any appropriate further identification (e.g. sub-item number). If the evidence does not lend itself to marking, its proximate container or ID tag shall be marked as noted above.

5.8.4.4 Digital files, photographs, or photographic negatives of images from evidence, such as latent prints and impressions, are treated as evidence, when the evidence itself is not recoverable as specified in Unit SOPs.

5.8.4.5 The DSS has a Computer Crimes Investigations Unit; the work performed at crime scenes as State Police Officers for this Unit does not fall under laboratory accreditation scope of testing. Case materials delivered to the laboratory, for analysis by this Unit does fall under laboratory accreditation scope of testing. Forensic Science Examiners may however assist the State Police Officers at scenes (previewing).

The Multi-Media Unit utilizes a van equipped with audio and video equipment to go to scenes to retrieve video or audio footage per request of local and state police departments. In general, two copies of the "evidence" is created; one being given to the requesting PD on site and the 2nd being transferred back to the DSS.

Computer Crimes and Multi-Media Unit procedures outline methods used to prevent loss, cross transfer, contamination and deleterious change of evidence transported from a crime scene to the DSS facility.

5.8.4.6 Operational SOPs for the individual characteristic databases utilized by Division Units are as follows:

NIBIN: (Firearms/Toolmarks) FA-21, 22, 32 & QR FA7
CODIS: (DNA) DNA-10 to DNA-16
AFIS: (Latent Prints) LP-11

5.8.4.6.1 Individual characteristic database samples are treated as reference materials by the DSS.

5.8.4.6.1a Individual characteristic database samples for the DSS are not treated as evidence.

5.8.4.6.1b Individual characteristic database samples for the DSS shall meet criteria as specified in 5.8.4.6.2 to 5.8.4.6.4 below.

5.8.4.6.2 Unit specific analytical SOPs (as noted in 5.8.4.6, above) specify that samples comprising individual characteristic databases will be uniquely identified.

5.8.4.6.3 Unit specific analytical SOPs (as noted in 5.8.4.6, above) specify that samples comprising individual characteristic databases will be protected from loss, cross transfer, contamination and/or deleterious change.

5.8.4.6.4 Unit specific analytical SOPs (as noted in 5.8.4.6, above) specify that access to samples comprising individual characteristic databases will be restricted to those persons authorized by the Deputy Director and/or Director.

Specific to the Firearms Section: Firearms that make up the reference collection cannot be signed out of the Unit to any outside agency including to State Police personnel without the written permission from the Director. If at any time an item from the Firearms Reference Collection must be removed from the DSS building, written authorization must be obtained from the Director. The make, model and serial number of the item(s) must be included as part of the authorization.

5.9 Assuring the Quality of Test Results

5.9.1 Specific quality control procedures are maintained in each Unit for monitoring the validity of tests and calibrations procedures. These procedures further specify which data will be recorded and tracked for the purpose of trend evaluation, and the statistical evaluations to which the data may be subjected, and the monitoring plan. The QC procedures detail the basis for evaluation (e.g. use of CRM or secondary reference materials; proficiency-testing programs, replicate tests or calibrations, retesting retained items and/or correlation of results).

5.9.1.1 Documentation in the case record of the use and performance of appropriate controls and standards is specified in all procedural SOPs in each Unit.

5.9.2 Unit specific QC procedures detail the analysis process for QC data, and include the appropriate actions to be taken in the event of failed parameters (including action to be taken to correct the problem and to prevent an incorrect result from being reported).

5.9.3 The DSS participates in a program of external proficiency testing, as specified in GL-16; "Proficiency Testing".

5.9.3.1 GL-16; "Proficiency Testing" specifies that the laboratory will utilize its own approved and documented test procedures for the analysis of proficiency testing material, including both normal technical and administrative review practices.

5.9.3.2 GL-16; "Proficiency Testing" Specifies that the DSS uses proficiency testing programs when available, which comply with the ASCLD/LAB Proficiency Review Program.

5.9.3.3 GL-16; "Proficiency Testing" Specifies that each analyst (however named) shall successfully complete one external or internal proficiency test per calendar year in his/her forensic science discipline(s).

5.9.3.3.1 GL-16; "Proficiency Testing" specifies that, where applicable, all DNA analysts shall comply with proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Data basing Laboratories. Further specified is that all DNA proficiency tests shall be reviewed by the DNA technical leader. The laboratory Quality Section shall maintain proficiency test case files and answers.

5.9.3.3.2 Analysts (however named) will be challenged at minimum, annually in each discipline in which they perform testing; this may be through an internal or external test. Additionally, analysts will be challenged in the various categories of testing in

which they perform analysis, within the 4 year accreditation cycle. All analysts will be provided with at least 1 proficiency test in their categories of testing in the 4 year accreditation cycle.

5.9.3.4 At a minimum, and as required, all DSS Units shall annually participate in at least one external proficiency test for each discipline of forensic science in which it provides services. ASCLD/LAB approved test providers shall be used where available. For discipline(s) /categories of testing where there is not an ASCLD/LAB approved test provider available, the laboratory quality Section shall locate and use a source of an external test for the discipline(s). Internal proficiency tests may be developed by the Quality Section for categories of testing where an external provider cannot be identified.

5.9.3.5 GL-16; "Proficiency Testing" specifies that the Quality Section shall maintain records of proficiency testing, including as a minimum:

Test set identifier
Sample source
Analyst
Analysis and completion dates
All analytical and associated data
Findings
Any discrepancies noted
Documentation of review and feedback for analyst
Start and end date of analysis as specified in GL-11 (Section D.6)
Corrective and/or remedial action (if appropriate)

Proficiency case files will be maintained by the Quality Section.

5.9.3.6 GL-16; "Proficiency Testing" specifies that the DSS shall retain proficiency test records for a period of ten years.

5.9.3 The technical review of examination documentation and reports is detailed in GL-18; "Case Reviews".

5.9.4.1 GL-18; "Case Reviews" specifies that technical reviews shall include appropriate review to ensure:

- Conformance with proper technical policies and procedures
- Accuracy of test reports and that the data supports the conclusions on the reports
- That where performed, associations are properly qualified
- That the test report contains all the required information.

5.9.4.2 GL-18; "Case Reviews" specifies that all technical reviews shall be conducted by individuals having expertise gained through knowledge, training, and experience in the discipline being reviewed.

5.9.4.3 Technical reviews of examination data or test report shall not be conducted by the author or co-authors of report or examination data, as specified in GL-18; "Case Reviews".

5.9.5 Administrative review of case files prior to report release is detailed in GL-18; "Case Reviews".

5.9.5.1 Administrative reviews will include at a minimum:

- A review of the test report for spelling and grammatical errors
- A review of all administrative and examination documentation records to ensure that the records contain the laboratory case number.
- A review of the test report to ensure that all key information has been included in the report.

It is recognized that individual Units may combine the responsibilities for the Technical and Administrative review based on the Unit's personnel requirements. Such combined functionality is detailed in Unit SOPs.

5.9.6 GL-17; "Court Monitoring" specifies that the DSS shall have a policy whereby the testimony of all testifying personnel is monitored on an annual basis, including feedback and remedial action as appropriate.

5.9.7 GL-17; "Court Monitoring" specifies that all court-monitoring records shall be retained for 10 years. Court monitoring records are maintained by the Quality Section.

5.10 Reporting the Results

5.10.1 General

Each DSS Unit has an SOP detailing that reporting of results from that Unit shall be reported accurately, clearly, unambiguously and objectively, in accordance with test-specific instructions.

Each DSS Unit reporting SOP specifies that case files will contain all relevant information required by ASCLD/LAB International and ISO/IEC 17025:2005 and the FBI DNA QAS. Further, that reports and/or the case file shall include all information

requested by the customer, and necessary for the interpretation of the test results, including methodology employed. Also specified is that simplified reporting may be used in the case of specific agreement with customers, as long as the case file contains all pertinent and relevant information, as required by ASCLD/LAB International and ISO/IEC 17025:2005.

5.10.1.1 As detailed in GL-11 "Control of Records"; DSS Units will generate test reports on all case materials tested in the Division as detailed in individual Unit SOPs with the following possible exceptions:

- Evidence which is designated by the submitting agency or court to be no longer required. In such cases the evidence will be returned to the submitting agency and the reason for not analyzing the case will be documented in the case file. If work had been performed a report will be generated only on the testing performed when notified of the cancelation.

- Evidence received by the Division that prior to the start of analysis is determined to be unacceptable for analysis. In such cases, the submitting agency must be contacted and the reason must be documented in the case file.

5.10.2 Each DSS Unit has an SOP detailing that reports will be issued on all cases analyzed by the DSS. The reports will accurately and clearly represent the results obtained through the analysis performed. The reports will include the following (the reason for any deviations must be documented in the case file):

Title
Name and address of the Division
Name and address of the submitting agency
Laboratory case number
Submitting Agency Case Number
Methods used in analysis of the case materials
Evidence description
Date of case receipt to the Division
Items analyzed (with a reference to a sampling plan if applicable) with a statement to the effect that the results only relate to the items tested
Results with appropriate Units of measure if applicable
Name and title of the analyst(s) and co-signer (technical reviewer)
Signatures of the analyst(s) and technical reviewer may be hand written or electronic.

For Units including names on reports only initials will be included for sexual assault victims.

When testing has been initiated but then canceled, by the submitting agency, prior to completion, a report is required, the report will be based on only the work performed to that point.

5.10.3 Test Reports

5.10.3.1 Where applicable, Unit SOPs on reporting specify that reports shall include:

Deviations from standard procedures
Statement of measurement uncertainty as appropriate
Opinions and interpretations as appropriate
Any other information that may be required by the Customer or State Regulations

5.10.3.2 Unit reporting SOPs specify that case files will include (when necessary for the interpretation of results):

date of sampling
unambiguous ID of the item, material or substance tested or sampled
location of sampling, including any diagrams, sketches or photographs
reference to the sampling plan used
details of environmental conditions (if potentially affecting test result interpretation)
details of sampling method(s), and/or technique(s)

5.10.3.3 GL-11; "Control of Records" details the procedures for controlling the release of case report information.

5.10.3.4 GL-18; "Case Reviews" specifies that any Division personnel who issue findings, write reports and/or provide testimony based on another person's work shall complete and document the review of all relevant pages in the case record.

5.10.3.5 Unit-specific SOPs for disciplines reporting "associations" and/or the significance of associations specify that the Unit shall identify and qualify the significance of all associations in the report.

5.10.3.6 Where appropriate, Unit specific SOPs detail that when comparative examinations, result in the elimination of an individual or object, the report shall clearly communicate the elimination.

5.10.3.7 Unit -specific SOPs for reporting specify that reasons for an "inconclusive" test finding or result shall be documented in the report.

5.10.4 The DSS does not issue Calibration Certificates.

5.10.5 Unit specific SOPs for reporting specify that when opinions or interpretations are included in case finding, the basis of the interpretation or opinion shall be clearly designated as such in the case report and the basis of such opinions documented in the case file.

5.10.6 When case work is subcontracted, the results generated by the subcontractor will be clearly indicated in the case report. Subcontracted work does not include work that generates a calibration certificate.

5.10.7 GL-11; "Control of Records" specifies that any transmission of test results by means other than a written report will be performed in compliance with 5.4.7 above.

5.10.8 All laboratory report formats, presented on DSS letterhead (or equivalent as formatted in LIMS), and containing the analyst(s) hand written or electronic signature, are designed to accommodate each type of test, and to minimize the possibility of misunderstanding or misuse.

5.10.9. If necessary, all DSS Units shall issue amended reports in the same format as the original:

- Reports, which are generated to add additional information due to additional work being performed on the case, will be clearly marked as "Supplemental Reports". The original report will be left in the case file.
- Reports which have been issued but that require a correction will be clearly marked as "Revised Reports" or "Amended Report". Revised or amended reports will be issued in cases where required information was omitted from the original report, when the case demographic information is corrected (such as a submitting agency case number), information was incorrect and the correct information is added. The initial original report and the revised/amended report will be maintained in the case file.

Such Supplemental/Revised Reports will be issued in compliance with individual Unit reporting SOPs.

Note: General Laboratory and Unit SOPs may refer to the term Section to mean Unit and Unit to mean Section. This will be updated as new versions of procedures are required. Changes do not need to be made specifically to address this issue.

Note: General Laboratory and Unit SOPs may use the term supervisor to mean the lead within a Section whether titled as FSE2, FSE 3 or Principal Chemist. As SOP updates are made this may be changed to lead/supervisor or supervisor/lead or similar.