Department of Emergency Services and Public Protection
Division of Scientific Services

QUALITY ASSURANCE MANUAL

Note on the use of this document: *Italicized* text indicates that this is criteria either from the ANAB AR3125 Forensic Science Testing and Calibration Laboratories Accreditation Requirements document or the ISO/IEC 17025:2017 international standard. The text that follows the criteria is the DSS policy related to the criteria.

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INTRODUCTION

This Quality Assurance Manual defines the Department of Emergency Services and Public Protection (DESPP), Division of Scientific Services (DSS) overall commitment to quality and provides information about the processes that are used to generate quality data, the indicators that continually measure/monitor the systems and the activities which are part of the quality system. The sum total of these activities will provide an accurate assessment of customer satisfaction and provide the foundation for improvement of services to our stake-holders in the State of Connecticut.

Quality Policy Statement
The primary goal of DSS is to provide high quality, forensically defensible analytical services to our customers. The Division Mission Statement emphasizes the importance of servicing customer needs and requirements.

1 Scope

The Department of Emergency Services and Public Protection (DESPP), Division of Scientific Services (DSS) 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 specified in GL1.1.

.1 This Quality Assurance (QA) Manual specifies the general policies of DSS that ensure the quality, administrative and technical operations of the laboratory.

1.2 The quality system and management system will cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

1.3 Knowledge of the contents of this manual is the responsibility of all employees of the Division.

2 Normative References

The documents that guide the management system include:

2.1 International Standard ISO/IEC 17025:2017.

2.2 ANAB AR3125 Forensic Science Testing and Calibration Laboratories Accreditation Requirements.

2.3 Federal Bureau of Investigation (FBI) Quality Assurance Standards (QAS) for Forensic DNA Testing Laboratories and DNA Databasing Laboratories (2011).

2.4 ATF Minimum Required Operating Standards (MROS) Audit for National Integrated Ballistic Information Network Sites (2018).

2.5 ANAB *Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel (GL-1.4)*

2.6 DSS Laboratory Standard Operating Procedures (SOPs), as applicable.

3 Terms and Definitions

3.1 Terms used in this document are aligned with ISO/IEC 17025:2017 terms and definitions.

4 General Requirements

4.1 Impartiality

4.1.1 Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality

Laboratory activities are impartial and are structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management shall be committed to impartiality

DSS Management is committed to impartiality.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

The Laboratory will be responsible for ensuring no commercial, financial, or other pressures compromise impartiality or the quality of work. 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-5 "Ethics."

4.1.3.1 *The management system shall:*
a) have a code of ethics as part of the management's commitment to good professional practice;
b) ensure annual review of the document by all personnel and maintain a record of the review; and
c) ensure appropriate actions are taken when necessary.

The Management System of the DSS includes:

a) GL-5 "Ethics" which includes the commitment of the DSS to good professional practice.
b) GL-5 "Ethics" includes a requirement for annual review of the ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel (refer to GL 1.4.). Documentation is retained within Qualtrax.
c) GL-5 "Ethics" provides guidance on follow-up to reported ethics issues as appropriate.

4.1.4 The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its

personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

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, Quality Section and Division's scientific staff has no reporting responsibility outside this direct chain of command.

Management will 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 GL-5 "Ethics".

Such pressures will be reported to the Director and appropriate responses will be coordinated. If documentation is required, it will be maintained by the Laboratory Director or in the appropriate record with the Quality Section.

DSS personnel are required to read the current, published version of the *ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel* annually. Compliance with this will be documented in Qualtrax. A record of the review will be maintained for 10 years, as detailed in GL-5 "Ethics."

4.1.5 If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

The Laboratory will identify risks to its impartiality on an on-going basis through the review of compliance related issues, the review/creation of Standard Operating Procedures (SOP's), and by monitoring adherence to the Division's Quality Assurance Manuals and Section/Unit SOPs.

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, Quality Section and Division's scientific staff has no reporting responsibility outside this direct chain of command.

If a risk to impartiality is identified, a review will be conducted to ensure that proper corrective action is taken to eliminate or minimize the risk.

4.2 Confidentiality

4.2.1 The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential.

The DSS is authorized by Section 29-7b of the Connecticut General Statutes (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 ANAB Accreditation Requirements, ISO/IEC 17025:2017, and the requirements of the DNA Quality Assurance Standards (QAS).

All employees of the DSS will adhere to confidentiality policy as set forth in GL-5 "Ethics". The DSS will not make public confidential information unless agreed upon by the customer.

4.2.2 When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned will, unless prohibited by law, be notified of the information provided.

Generally the DSS only releases case information (i.e. reports) to the submitting agency and the related GA (Geographical Area) Court. If required to release case specific information the Director or their designee will inform the related customers.

Per state statute 14-227b case reports related to DUI's in the Toxicology unit are also provided directly to the subject.

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) will be confidential between the customer and the laboratory. The provider (source) of this information will be confidential to the laboratory and will not be shared with the customer, unless agreed by the source.

All employees of the DSS will adhere to confidentiality policy as set forth on GL-5 "Ethics".

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

The Division of Scientific Services has policies and procedures that address client/customer confidentiality, proprietary rights and the secure storage and where applicable, transmission of electronic data, and that those policies and procedures are followed.

GL-5 "Ethics" addresses confidentiality and proprietary rights.
GL-4 "LIMS" addresses secure electronic storage of data.
GL-11 "Control of Records" addresses transmission of electronic data.

When the DSS uses contract employees, those employees will adhere to DSS ethics policy. Additionally when the DSS sub-contracts work, the contract will include language on confidentiality.

5 Structural Requirements

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities

The Division of Scientific Services 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. The DSS is authorized by Section 29-7b of the Connecticut General Statues (GL1.2).

5.2 The laboratory shall identify management that has overall responsibility for the laboratory.

DSS Top Management consists of the Director and Deputy Directors. The Director has overall responsibility for the laboratory.

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 29-7b (GL1.2).

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.

5.2.1 There shall be a director, whose duties shall be defined.

The defined duties of the Director of the DSS can be found in the job description maintained by the Quality Section and also available on the State of CT Department of Administrative Services (DAS) web site. Below are summaries of job duties.

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 Assurance Manager (QM). The Director and QM ensure that the Quality System includes all components necessary to comply with ANAB AR3125, ISO/IEC 17025:2017, the FBI Quality Assurance Standards, and the ATF Minimum Required Operating Standards (MROS). The Director works in conjunction with the Deputy Directors (DD), Assistant Director(s) (AD), Assistant Director of the State Forensic Science Laboratory (ADFL), Quality Assurance Manager, FB/DNA Quality Assurance Manager, Section Supervisors and Unit Leads to monitor the Quality System and make improvements as needed.

Deputy Director (section specific):
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 ANAB AR3125 and ISO/IEC 17025:2017. Additionally as applicable they must ensure adherence to the FBI QAS and ATF MROS documents. The Deputy Directors work in conjunction with the Assistant Directors, Quality Section, Section Supervisors and Unit Leads to monitor the Quality System and make improvements as needed.

Assistant Directors (section specific):
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 ANAB AR3125 and ISO/IEC 17025:2017. The Assistant Directors work in conjunction with the Deputy Directors, Quality Section and Section Supervisors and Unit Leads to monitor the Quality System and make improvements as needed.

Assistant Director of the State Forensic Science Laboratory (ADFL):
The Assistant Director reports directly to the Director. The Assistant Director is responsible for the oversight of the Administrative Support, Information Technology, Case Management and Evidence Receiving Units. Additionally, they are the liaison with the building maintenance contract company and oversee all related projects. The Assistant Director is responsible for the administration of a comprehensive program to manage the evidence of criminal and civil cases at the Division. The Assistant Director additionally has responsibility of the oversight of grants, fiscal and security of the laboratory. The Assistant Director is responsible to support the Quality System of the Division, in association with the Quality Assurance Manager and Forensic Biology/DNA Quality Assurance Manager. As part of this they must ensure that the Quality System includes all components necessary to comply with ANAB AR3125 and ISO/IEC 17025:2017. The Assistant Director works in conjunction with the Quality Section, Section Assistant Directors and Deputy Directors to monitor the Quality System and make improvements as needed.

Quality Assurance Manager (QM):
The Quality Assurance Manager reports directly to the Director. The Quality Assurance 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 Assurance 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 Assurance Manager works directly with the Director, Deputy Directors, Assistant Directors and the FB/DNA Quality Assurance Manager to ensure that the Quality System meets the requirements of ANAB AR3125, ISO/IEC 17025:2017, the FBI DNA Quality Assurance Standards and the ATF MROS document. The Quality Assurance Manager is also a source of guidance for Section Supervisors and Unit Leads to aid them in achieving the goals of the quality 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 ANAB AR3125, ISO/IEC 17025:2017 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.

Leadership Associate:
The position of Leadership Associate is used as a transition to a designated Management position. The Leadership Associate will be introduced to many of the general Management duties but the specific duties of this position will be dependent of the final designation class and as such will be determined as needed.

Section Supervisors (FSE3) or Leads (FSE2 or equivalent):
Supervisors or Leads directly monitor all aspects of work in their Unit(s). 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 ANAB AR3125, ISO/IEC 17025:2017 accreditation process and of the standards. DNA Section Supervisors/Leads are also responsible to have an understanding of the FBI DNA Quality Assurance Standards. Supervisors/Leads associated with the Firearms Unit are responsible for understanding and maintaining the ATF MROS standards for the use of NIBIN.

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

Division: Defined as all 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 or Assistant Directors.
Unit: The individual disciplines and components of testing within the DSS. Units are under the direction of Assistant Directors (Deputy Directors in the absence of an AD) and, in general, are led by an FSE3 or FSE2.

5.3 The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.

DSS covers a range of laboratory activities which are under the laboratory's scope of accreditation. The scope of accreditation can be found in GL 1.1. At no time will an employee of the DSS infer accreditation in activities outside of those listed in the DSS Scope of Accreditation.

The Division of Scientific Services consists of:

- **Administration:**
  - Quality Section (QS)
- **Support Services Section:**
  - Administrative Support Unit
  - Case Management Unit (CMU)
  - Evidence Receiving Unit (ERU)
  - Information Technology Unit (ITU)
- **Chemical Analysis Section (CAS):**
  - Toxicology Unit (TX)
    - Breath Alcohol (BA)
  - Controlled Substance Unit (CS)
  - Chemistry Unit (CU)
    - Arson (CH)
    - Instrumentation/GSR (IN)
- **Forensic Biology/DNA Section (FB/DNA):**
  - Forensic Biology Unit (FB)
  - DNA Unit (DNA)
    - Database (DB)
    - Nuclear
- **Identification Section (ID):**
  - Computer Crimes and Electronic Evidence Unit (CC)
    - Forensic Analysis
    - Investigations
  - Firearms Unit (FA)
  - Imprints Unit (IM)
  - Latent Prints Unit (LP)
  - Multimedia Unit (MMIE)
  - Questioned Documents Unit (QD)

The CT Division of Scientific Services is a National DNA Index System (NDIS) participating laboratory and will conform to requirements in the NDIS Operation Procedures Manual and in applicable FBI DNA Quality Assurance Standards (QAS).

The Director and the Quality Assurance Manager have approved a contingency plan for the designation of a Technical Leader in the DNA Unit 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.

The DSS has also developed a contingency plan pursuant to the FBI QAS document to address the event that the number of qualified DNA analysts, employed by the DSS, falls below two (refer to GL-1.8). This plan has been approved by Division Management as appropriate.

The Director and Deputy Director of the Identification Section have approved a contingency plan for the designation of a NIBIN Program Administrator in the event the position requires refilling for any reason. Refer to FA-SOP-22 "NIBIN" for guidance.

5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

NOTE: An example of a regulatory authority is the Federal Bureau of Investigation for laboratories participating in the National DNA Index System (NDIS).

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 Meriden facility, as a function 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 the Computer Crimes Investigations Unit.

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 Division for analysis by this Unit do fall under the DSS accreditation scope of testing.

The Multimedia Unit and Computer Crimes and Electronic Evidence Unit may assist on site in the retrieval of media/data. In general the Multimedia Unit assists in the retrieval of media/data from recording devices. The Unit creates two copies of the "evidence"; one being given to the requesting PD on site and the second being transferred back to the DSS.

Computer Crimes and Multimedia 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.

5.4.1 Laboratories shall conform to requirements in PR 1018 ANAB Policy on Use of ANAB Accreditation Symbol and Claims of Accreditation Status.

The DSS does not currently use accreditation symbols. If the DSS decides to use the ANAB accreditation symbol the ANAB document PR 1018 will be followed.

5.4.2 If a laboratory performs testing or calibration under the authority of a statute, regulation or other legal requirement, the laboratory shall make this readily available.

NOTE: A legal requirement is created, imposed and enforced by a third-party external to the laboratory.

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 ANAB AR3125, ISO/IEC 17025:2017, and the requirements of the FBI DNA Quality Assurance Standards (QAS). Other regulations that are required to be followed by the laboratory include;

CT Public Acts:	14-227
	15-140u
	15-207
	18-83
General Statutes	19a-112a
	19a-112f
	19a-407a
	21a-283
	29-7b
	29-7h
	54-86k
	54-102g to 54-102l

Copies of these public acts are maintained in Qualtrax in the folder labeled ‘Public Acts’.

5.5 The DSS laboratory shall:

a. Define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services.
b. Specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory results.
c. Document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.
(Note c: Documenting procedures to the extent necessary to ensure the consistent application of testing and calibration and the validity of the results includes analysis and data interpretation to arrive at a result, opinion or interpretation.)

a. 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 DSS organizational chart defines the organization and

management structure of the laboratory and the relationships between management, technical operations, quality assurance, and support services. The DSS table of organization is maintained in Qualtrax.

b. The Division's organization is illustrated within its own Organizational Chart. The organization chart identifies management that has overall responsibility for the laboratory. Clear lines of authority and accountability are established between personnel responsible for those assigned to manage and perform or verify work affecting the results of laboratory analysis. Interrelationships of personnel are indicated on the organizational chart.

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.

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

c. 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, general SOPs that are applicable to all Sections, Unit SOPs and specific work instructions (where applicable). The use of the Quality Manual in conjunction with Unit SOPs is meant to ensure the quality and validity of work produced in each Unit by ensuring consistent application of laboratory activities. SOP availability is through Qualtrax, as detailed in GL-19 "Document Control".

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-22). The Quality Manual (GL-1) 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 Assurance Manual but not to be less rigorous.

General Laboratory Standard Operating Procedures: these are specific procedures that are followed universally by all Division Sections. 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): Instructions for the performance of the analytical analysis performed in the various Units. Some Sections may have Section SOPs relevant to each Unit within the Section.
Training SOP: Individual procedures meant for guiding new employees or employees new to the Unit through the basics of the analysis.
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.

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.

5.6 The laboratory has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;
b) identification of deviations from the management system or from the procedures for performing laboratory activities;
c) initiation of actions to prevent or minimize such deviations;
d) reporting to laboratory management on the performance of the management system and any need for improvement;
e) ensuring the effectiveness of laboratory activities.

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 DNA TL may be the Deputy Director of the Section (or other title as designated by the Director).

The Quality Assurance Manager and Forensic Biology/DNA Quality Assurance Manager are appointed by the Director. They work with Deputy Directors, Assistant Directors, Section Supervisors, Unit Leads and/or individuals appointed within the Division, to address quality assurance concerns. The DSS will:

a) Ensure there are adequate managerial and technical personnel and support staff to effectively implement, maintain and improve the management system.
b) Ensure 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.

c) Initiate actions to prevent/minimize any deviations.
d) Work to identify needs for improvement to the management system encouraging all staff to report these needs to management.
e) Use auditing, customer surveys, review of QARs and proficiency testing records and other methods to review and ensure the effectiveness of laboratory activities.

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 system to evaluate and demonstrate the technical competency of all analytical employees, ensuring only forensically defensible results are reported. See Unit 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 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 SOPs.
- 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 aspects of the Criminal Justice system.
- A management system that works to support and enhance the quality system of the Division. See GL-7 "Audits".
- 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".

- 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".
- Adherence to ANAB and ISO/IEC 17025:2017 standards, the FBI DNA QAS and the ATF MROS. See GL-7 "Audits".

5.7 Laboratory Management shall ensure that:

a. Communication takes place regarding the effectiveness of the management system and the importance of meeting customer' and other requirements.

b. *DSS management will help ensure the integrity of the management system is maintained when changes to the management system are planned and implemented through open communication with appropriate personnel.*

a. DSS Management will help ensure the effectiveness of the management system and the importance of meeting the customer's needs through appropriate communication processes including emails and meetings. All DSS personnel will familiarize themselves with the DSS Quality Assurance Manual and documentation.

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", GL-4 "LIMS" and GL-11 "Control of Records" address aspects of these issues.

b. 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 Quality Assurance Manager, 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 Quality Assurance Manager 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, 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 ANAB AR3125 and ISO 17025:2017. The Director (or their designee) will approve SOP changes through Qualtrax.

6 Resource Requirements

6.1 General: The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

The Laboratory has available the personnel, facilities, equipment, systems, and support services necessary to manage and perform its laboratory activities.

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

Key managerial personnel include the Director, the Deputy Directors, the Assistant Directors, the Quality Assurance Manager, the FB/DNA Quality Assurance 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 the Director will act as their designee. In the absence of an Assistant Director, the Director 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.

The Quality Assurance Manager and Forensic Biology/DNA Quality Assurance Manager are appointed by the Director. They work with Deputy Directors, Assistant Directors, Section Supervisors, DNA Technical Leader, Unit 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”.

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.”

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

DSS will ensure the competence, impartiality, and compliance to the Management System of personnel employed by or contracted to DSS. All employees are expected to work inside the confines of the Management System and to follow the guidance of all applicable GL and Unit SOPs when performing laboratory activities.

6.2.2 The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

NOTE: See GD 3152 for guidance on the phrase "influence the result of laboratory activities"

The laboratory will document the competence requirements, the duties, and responsibilities of laboratory personnel in job descriptions and training plans/SOPs. Competency requirements will include education, qualification, training, technical knowledge, skills and experience.

Training will be provided as required and relevant authorizations will be documented. DSS has established comprehensive trainee training programs and documents authorizations in the following tasks:

- Development, Modifications, Verification and Validation of Methods
- Performance of laboratory activities (testing, sampling)
- Analysis of results
- Review results
- Authorize results
- Verification of Results
- Technical Reviews
- Express Opinion or Interpretation
- Report Results/Authorize Reports

Note 1: Authorization letters may include all techniques within a discipline, or may include only specific components or parameters of a discipline in cases where an analyst is only trained in portions of that discipline. The letter 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. The DNA Unit will follow the guidance of the current FBI QAS document as to the level of detail required for documentation of authorization.

Note 2: In transitioning to paperless quality system, there is a workflow in Qualtrax "Personnel Authorization" that will be used to document the competency and authorization of personnel. A Manager, Supervisor, or the DNA Technical Leader may start the workflow. The output from this workflow will be a certificate and a letter with details of the authorization. Qualtrax will automatically save the documents in a folder in the document tree designated, "Laboratory Authorizations" that can be accessed by Management. A copy of the certificate will be forwarded to the analyst to file in their training records. No paper memo will be required.

Per GL-14 "General Training" 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.

Chemical Analysis Section	CAS-02
Controlled Substance	CS-13
Toxicology	TX-30
Chemistry	CUTR-01 and CUTR-02
DNA	DNA-1 & 7
Forensic Biology	FB-26
Questioned Documents	QD-5
Latent Prints	LP-16
Multimedia	MMIE-26
Firearms	FA SOP-01
Imprints	IM-14
Computer Crimes and Electronic Evidence	CC-25

6.2.2.1 Personnel who authorize results, opinions and/or interpretations shall meet the minimum educational requirements established in the country in which the laboratory operates (see Annex A).

All Division of Scientific Services technical 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 requirements of the Quality Assurance Standard for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories that is current at the time of qualification in their first DNA authorization).

Technical support personnel must meet the guidelines set forth in the specific job description.

6.2.2.2 The training program for each function influencing the results of laboratory activities, to the extent necessary based on job function, shall include:

a. the knowledge, skills, and abilities needed to perform work;
b. general knowledge of forensic science
c. the application of ethical practices in forensic science
d. criminal law, civil law, and testimony
e. provisions for retraining
f. provisions for maintenance of skills and expertise; and

g. *criteria for acceptable performance*
NOTE 1: Past work experience and training may be substituted for portions of the training program to the extent that it has been demonstrated to be relevant and sufficient. NOTE 2: ISO/IEC 17025:2017, section 7.3 may be applicable to training programs

All DSS analytical personnel are required to receive appropriate training and demonstrate competency, as per individual Unit SOPs prior to performing casework. The combination of GL-14 "General Training" and Unit training programs will include:

a. Assessment of knowledge, skills and abilities needed to perform the work.
b. Introduction to general knowledge of forensic science.
c. The application of ethics in forensic science.
d. Introduction to criminal law, civil law and testimony.
e. Provisions for retraining when need is identified.
f. Provisions for maintenance of skills and expertise.
g. Criteria for acceptable performance.

6.2.3 The laboratory shall ensure that personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

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:

Chemical Analysis Section	CAS-02
Controlled Substance	CS-13
Toxicology	TX-30
Chemistry	CUTR-01 & CUTR-02
DNA	DNA-7
Forensic Biology	FB-26
Computer Crimes and Electronic Evidence	CC-25
Questioned Documents	QD-5
Latent Prints	LP-16
Multimedia	MMIE-26
Firearms	FA SOP-01
Imprints	IM-14
Evidence Receiving	ER-14

These training programs are designed to cover the relevant knowledge and performance elements of each discipline, and ensure the competence of the analyst. Each discipline area has established milestones and expectations for the trainee, and the process will be documented in the appropriate training manual.

6.2.3.1 All personnel who perform testing or calibration shall be competency tested. Testing or calibration includes the review and authorization of results and expressing an opinion or an interpretation. The competency test shall include practical examination(s) that cover the spectrum of anticipated tasks related to the test or calibration. The competency test intended results shall be achieved prior to performing the tasks on a test or calibration item.

NOTE: Competency testing can be conducted for an individual task or a group of tasks covered by a module of a training program

All analytical personnel of the DSS are required to receive appropriate training and demonstrate competency, as per individual Unit SOPs (specified below) prior to performing casework.

GL-14 "General Training" specifies that all employees and/or contract personnel must demonstrate competence in a given component or parameter of a discipline, prior to the performance of casework in that discipline. The scope of the practical examination should cover the spectrum of anticipated activities for that testing (or as is practicable).

Unit training SOPs address:

- 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).

Demonstration of competency will be through the successful completion of both a written or oral examination and a practical competency test in the specified component or parameter of testing and/or discipline. Successful completion of the practical competency test is defined as obtaining the intended results. Successful completion of a written examination will be defined as a grade of 80% or higher, those units using oral examinations will include guidance on the definition of successful completion within Unit SOPs.

6.2.3.2 Personnel who perform technical review of results or testimony, shall meet the competency requirements as specified in 6.2.3.1 for the testing or calibration tasks being reviewed.

Analysts who perform technical reviews of results or testimony will have been deemed competent in the task being reviewed.

For the DNA Unit this will include the method, technology, test kit, platform and interpretation software or as defined in the current FBI QAS documents.

For employees new to a discipline, training SOPs (as noted above) also address the competency tests required of all personnel who generate laboratory reports, perform technical review of results or perform technical review of court testimony.

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).

Refer to GL-18 "Case Reviews" for specific guidance on technical reviews of case analysis. Refer to GL-17 'Court Monitoring' for technical review of testimony.

6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities.

All technical and non-technical personnel have responsibilities and authorities as defined within their job descriptions. Responsibilities and authorities of DSS personnel in relation to laboratory activities are communicated through Management System documents (SOPs). Performance reviews, performed annually or as required, are another way management communicates duties and responsibilities. Additionally, annual performance reviews will ensure that personnel are supervised, performing their duties, and that they are working within the DSS's quality management system.

6.2.5 The laboratory shall have a procedure and retain records for

a. determining and monitoring the competence requirements
b. selection of personnel
c. training of personnel
d. supervision of personnel
e. authorization of personnel
f. monitoring competence of personnel

The DSS maintains personnel training documentation as detailed in GL-11"Control of Records".

a. Unit specific training procedures detail requirements for competency requirements. Unit specific training procedures detail requirements for the documentation of training and competency records.
b. CT DAS Job Descriptions describe minimal qualifications for the selection of personnel per job classification.
c. GL-14 "General Training" and Unit procedures specify training activities for personnel.

d. Supervision of personnel is through those in the position of Forensic Science Examiner 3 (FSE3). FSE3 are supervised by those in the role of Assistant Director or Deputy Director. See section 5.2.1 above. Refer to the current organizational chart.
e. GL-15 "Professional Development" specifies that authorization of personnel is granted by the Director based on recommendation by the Deputy or Assistant Director.
f. GL-16 "Proficiency Testing" outlines the method of monitoring analyst competency through the use of periodic proficiency tests. All evidentiary reports are technically and administratively reviewed. These reviews allow for the monitoring of competency for individual analysts on an on-going basis.

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a. Development, modification, verification and validation of methods
b. Analysis of results, including statements of conformity or opinions and interpretations
c. Report, review and authorization of results
NOTE: Authorization of personnel includes all aspects of testing or calibration including, as applicable, the use of equipment.

GL-14 "General Training" gives guidance on laboratory activities that require authorization.

6.3 Facilities and environmental conditions

6.3.1 The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results.

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

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented.

Current DSS procedures preclude the need to monitor environmental conditions. As new methods are put in place if environmental monitoring is appropriate the DSS will require Unit SOPs to provide guidance on documentation of the specified conditions.

6.3.3 The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

Current DSS procedures preclude the need to monitor environmental conditions. As new methods are put in place if environmental monitoring is appropriate the DSS will require Unit SOPs to provide guidance on the method of monitoring the specified conditions.

6.3.4 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include but not limited to:

a. access to and use of areas affecting laboratory activities
b. prevention of contamination, interference or adverse influences on laboratory activities
c. effective separation between areas with incompatible laboratory activities

a. Measures to control the DSS facility are outlined in GL-3 "Security". This procedure includes guidance on building accessibility (interior and exterior). Security systems are monitored by a contracted vendor.

   Access to all laboratory work areas in the DSS is controlled by proximity card-key systems. These systems restrict the access to essential personnel, as described in GL-3 "Security."

b. The DSS employs measures within the appropriate working areas to prevent cross contamination. This includes partitions on workbenches and separate rooms for incompatible activities. Measures to minimize contamination, interference or adverse influences on laboratory activities are outlined in GL-13 "General Evidence Handling" and in Unit SOPs.

c. When the DSS determines that laboratory activities may be incompatible, attempts will be made to ensure separation of the work spaces. GL-13 "General Evidence Handling" provides guidance on performance of work on cases with multiple crime scenes.

6.3.4.1 There shall be a procedure that addresses security and access to areas where testing and calibration occur.

NOTE: Topics to consider may include, but are not limited to: access to building, access by personnel, access by visitors, security during operational hours and non-operational hours, and devices that grant access.

GL-3 "Security" provides guidance regarding security for the DSS facility including building access for operational and non-operational hours, access to laboratory spaces, visitors, hard keys, and the proximity card key reader system.

6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met.

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. The Computer Crimes Investigations Unit follows the guidance provided by the CT State Police for off site investigations.

6.4 Equipment

6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.

Division Units are equipped with instrumentation and test equipment required by each Unit's 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.

6.4.2 When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met.

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 vendor in-house) shall be checked/calibrated (as appropriate for the device) 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 performance check/calibration will include the examiner's 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.

6.4.3 The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

Unit procedures shall include guidance on the handling, transport, storage, use and maintenance of equipment.

All equipment shall be calibrated before being put into service. Refer to GL-21 "General Laboratory Equipment" for calibration/checks of weights and balances and other general devices. Calibration of specific instruments is detailed per individual Unit SOPs:

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

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 SOPs:

Controlled Substance	CS-1
Toxicology	TX-14 & 19
DNA	DNA-8
Forensic Biology	FB-8 to 18 & 21
Chemistry	CH-12
Instrumentation	FLIN-8
Imprints	IM-2

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

Controlled Substance	CS-1
Toxicology	TX-19
DNA	DNA-8
Forensic Biology	FB-8 to 18, 21
Chemistry	CH-12
Latent Prints	LP-3 & 4
Firearms	FA-27, 28
Instrumentation	FLIN-8

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

Controlled Substance	CS-3
Toxicology	TX-19

DNA	DNA-8 &1
Forensic Biology	FB-8 to 18, 24
Chemistry	CH-6-2 & 8
Firearms	FA-27 & 28
Latent Prints	LP-3, 4 & 17
Imprints	IM-8

6.4.3.1 In addition to the procedural requirements in ISO/IEC 17025:2017, clause 6.4.3, reagents prepared shall be labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records shall be maintained identifying who made the reagent and the components used in preparation.

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, components used 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
Latent Prints	LP-3
Firearms	FA-26

6.4.3.2 Reference collections shall have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest.

GL-7 "Audits" provides guidance on the auditing of the Firearms and Controlled Substance reference collections. 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. Materials will be handled in a manner to protect the integrity of the characteristics of interest of the reference collection. Refer to Unit SOPs:

Controlled Substance	CS-7 & 11
Toxicology	TX-29
Firearms	FA-36

Specific to the Firearms Unit: 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.

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.

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 vendor in-house) shall be checked/calibrated (as appropriate for the device) before it is returned to service.

Individual Unit instrument specifications require that equipment and associated software is vendor 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-20-29 & 31 -32
Chemistry	CH-3 & 4, 16
Instrumentation	IN 4 & 5
DNA	DNA 1 & 9
Forensic Biology	FB-23 & 24
Latent Prints	LP-9-12, 25 & 33
Firearms	FA-22
Imprints	IM-11
Questioned Documents	QD-21
Computer Crimes and Electronic Evidence	CC-19-22
Multimedia	MMIE-14

All equipment shall be calibrated before being put into service. Refer to GL-21 "General Laboratory Equipment" for calibration/checks of weights and balances. Calibration of specific instruments is detailed per individual Unit SOPs:

Controlled Substances	CS -5, 6, 7 & 8
Toxicology	TX- 20-29 & 31 -32
Chemistry	CH-3 & 4
Instrumentation	IN-4 & 5
DNA	DNA-1 & 9
Forensic Biology	FB-23 & 24
Latent Prints	LP-9-12, 25 & 33
Firearms	FA-22
Imprints	IM-11
Questioned Documents	QD-9
Computer Crimes and Electronic Evidence	CC-19-21 & 28

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

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

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

Controlled Substance	CAS-04
Toxicology	CAS-04
Firearms	FA SOP-13 & 34

6.4.6 Measuring equipment shall be calibrated when:

a. the measurement accuracy or measurement uncertainty affects the validity of the reported results and/or

b. calibration of the equipment is required to establish the metrological traceability of the reported results.

All measuring equipment shall be calibrated before being put into service, as specified in individual Unit SOPs.
Guidance for maintenance and performance checks of some general laboratory equipment can be found in GL-21 "General Laboratory Equipment".

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.

Controlled Substances	CS-5, 6, 7 & 8
Toxicology	TX-14 & 29
Chemistry	CH-3 & 4
Instrumentation	FLIN-4 & 5
DNA	DNA-1 & 9
Forensic Biology	FB-23,24
Latent Prints	LP-12
Firearms	FA-22, 33 & 35
Imprints	IM-11
Questioned Documents	QD-10
Computer Crimes and Electronic Evidence	CC-19-21
Multimedia	MMIE-14

6.4.7 The laboratory shall establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

All equipment shall be calibrated before being put into service, as specified in individual Unit SOPs. Refer to GL-21 "General Laboratory Equipment" for calibration/checks of weights and balances. The schedule for calibration of specific instruments is detailed per individual Unit SOPs.

Controlled Substances	CS -5, 6, 7 & 8
Toxicology	TX- 20-29 & 31 -32
Chemistry	CH-3 & 4
Instrumentation	FLIN-4 & 5
DNA	DNA-1 & 9
Forensic Biology	FB-23 & 24
Latent Prints	LP-12
Firearms	FA-22
Imprints	IM-11
Questioned Documents	QD-9
Computer Crimes and Electronic Evidence	CC-19-21 & 28
Multimedia	MMIE-14

Where 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. Documentation will be maintained by the respective Units. Review of the calibrations programs is minimally through the annual review of the SOPs, or as needed.

6.4.7.1 The program for the calibration of equipment shall include:

a. a list of the equipment requiring calibration
b. specifications for the calibration laboratory
c. specified requirements for the calibration
d. the interval of calibration

Unit procedures shall identify equipment that requires calibration, requirements for the calibration and the schedule or interval of calibration.

a. The Quality Section maintains a schedule of general equipment requiring calibration.
b. GL-6 "Purchasing" gives guidance for identifying the specification of calibration laboratories.
c. Unit specific SOPs specify equipment requirements for calibration as appropriate. Refer to GL-21 "General Laboratory Equipment" for specifications of weights, thermometers, balances and other general equipment.

d. Unit SOPs specify the interval of equipment calibration. Refer to GL-21 "General Laboratory Equipment" for calibration/checks intervals of weights, thermometers, balances and other general equipment.

6.4.8 All equipment requiring calibration or which has a defined period of validity shall be labeled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity.

Where applicable, calibration labels from the calibration laboratory will be placed directly on the calibrated item. This label should identify the expiration date (however annotated) or calibration date range of the calibration. This shall be done in a manner that the user of the device can readily identify the calibration status.

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.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedures.

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.

A QAR may be opened depending on the nature of the issue for documentation purposes and if necessary, corrections or corrective actions will be performed.

Demonstration of appropriate performance such as through the use of a performance check process, following any repair, or adjustment is also required prior to returning the item to service.

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.
NOTE: When evaluating the need for intermediate checks, topics to consider include, but are not limited to: the calibration interval, the use of the equipment, the stability of the equipment, the method specifications, and risk associated with a failed check.

Where appropriate, Unit 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.

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 and other general laboratory equipment refer to GL-21 "General Laboratory Equipment".

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

Controlled Substance	CS-3
Toxicology	TX-19
DNA	DNA-8 &1
Forensic Biology	FB-8 to 18, 24
Chemistry	CH-6-2
Firearms	FA-27 & 28
Latent Prints	LP-3 & 4
Imprints	IM-8

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

Where applicable, Unit SOPs provide guidance on ensuring correction factors or values associated with reference materials are appropriately documented and updated as appropriate to meet the intended use.

6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

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.

GL-4 "LIMS" specifies that the LIMS and LAN systems are maintained to ensure proper function to maintain the integrity of data.

CC SOP-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.

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable;

a. the identity of equipment, including software and firmware version;
b. the manufacturer's name, type identification, and serial number or other unique identification;
c. evidence of verification that equipment conforms with specified requirements;
d. the current location;
e. calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;
f. documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;
g. the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment
h. details of any damage, malfunction, modification to, or repair of, the equipment.

DESPP equipment contains a unique identification number (for high dollar value equipment, this may be a Department asset inventory tag 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.

Each Unit maintains records for equipment and reference materials that influence laboratory activities.

a. Identification of each item of equipment and/or software and firmware versions are maintained as part of Unit Equipment lists. Instrumentation (and related software) and other laboratory equipment used to obtain results for casework is uniquely identified. This may be through the State of Connecticut asset inventory tag, as specified in GL-6 "Purchasing" or other laboratory generated identification as specified in individual Unit SOPs.

b. Manufacturer's name, description and serial number of equipment are maintained as part of Unit Equipment lists.

c. Checks that the equipment complies with specifications (vendor certification) are maintained as per Unit SOPs. Additionally Units maintain validation documentation demonstrating the instrument conforms to the needs of the unit. Guidance for maintenance and performance checks of some general laboratory equipment can be found in GL-21"General Laboratory Equipment".

   Individual Unit instrument specifications require that equipment and associated software is vendor 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-20-29 & 31 -32
Chemistry	CH-3 & 4, 16
Instrumentation	FLIN-4 & 5
DNA	DNA 1 & 9
Forensic Biology	FB-23 & 24
Latent Prints	LP-9-12, 25 & 29
Firearms	FA-22
Imprints	IM-11
Questioned Documents	QD-21
Computer Crimes and Electronic Evidence	CC-19-22
Multimedia	MMIE-14

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

Controlled Substance	CS-1
Toxicology	TX-19
DNA	DNA-8
Forensic Biology	FB-8 to 18 & 21
Chemistry	CH-12
Latent Prints	LP-3 & 4
Firearms	FA-27 & 28
Instrumentation	FLIN-8

Reagents are classified as equipment and as such the DSS specifies procedures for routinely checking the reliability of reagents as detailed in Unit SOPs identified as follows:

Controlled Substance	CS-3
Toxicology	TX-19
DNA	DNA-8 &1
Forensic Biology	FB-8 to 18 & 24
Chemistry	CH-6-2
Firearms	FA-27 & 28
Latent Prints	LP-3 & 4
Imprints	IM-8

d. Current location of the equipment is maintained as part of Unit Equipment lists.

e. Unit SOPs detail calibration specifications including calibration intervals. Each Unit maintains instrument maintenance logs, as detailed in Unit SOPs. Dates of calibrations, results of the calibrations, and adjustments made are documented in

equipment maintenance logs. For reagents, Units maintain reagent logbooks (or other as outlined in Unit SOPs) to record validations and verifications.

When calibrations, 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).

f. Unit SOPs detail the use and documentation of reference materials and record maintenance. These records include the acceptance criteria, results, relevant dates and the period of validity of the reference materials. Guidance for general laboratory equipment can be found in GL-21 "General Laboratory Equipment".

g. Unit SOPs specify equipment maintenance plans as applicable. Maintenance performed is maintained in equipment maintenance logs. Guidance for maintenance and performance checks of some general laboratory equipment can be found in GL-21 "General Laboratory Equipment".

h. Damage, modification or repair to the equipment is documented in equipment maintenance logs.

i. A Qualtrax workflow, "Equipment List" may be used to aid in equipment lists and maintenance reminders.

6.5 Metrological traceability

6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

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.

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.

6.5.1.1 The laboratory shall establish and maintain metrological traceability of its measurement results by utilizing products and services from suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials that are:
a) a National Metrology Institute that is a signatory to the BIPM1 - CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be purchased or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB)2 ; or
b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be purchased listed in a scope of accreditation; or
c) an accredited reference material producer that is accredited to ISO 170343,4 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material to be purchased.

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 the Division purchases reference standards or reference materials the products will be obtained from suppliers that establish/maintain the metrological traceability of the reference standard or reference material.

Refer to GL-6 “Purchasing” for requirements of vendors of calibration services, reference materials and reference standards.

6.5.1.2 In situations where a supplier that meets 6.5.1.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased shall be confirmed. Objective evidence of the confirmation shall be available for review.

Refer to GL-6 “Purchasing” for guidance on assessing supplier competence when no accredited vendor is available.

6.5.1.3 For the purpose of establishing traceability of a measurement, an accredited laboratory may calibrate its own equipment that supports an accredited parameter on the scope if the related requirements in ISO/IEC 17025 and this document are met:
a) the calibration and any check of the calibration status shall be carried out by

appropriately trained, competency tested, and authorized personnel;
b) the calibration method shall be validated or verified prior to use;
c) certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties;
d) the calibration shall be carried out in an appropriate environment;
e) technical records of the calibration shall be established and maintained;
f) the laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts; and
g) a technical review of the technical records including any data transfers and calculations shall be completed by an individual other than the person(s) who performed the work.

Not applicable, the CT DSS does not calibrate its own equipment.

6.5.1.4 If a certified reference material is changed in a way that alters the traceable measurement value, then the equipment used to alter the certified reference material shall be evaluated for applicability of measurement traceability accreditation requirements.

All reference materials shall, where possible, will be traceable to SI Units or to certified reference materials.

Units altering certified reference materials have Unit guidance on requirements to maintain traceability of the reference material and maintenance of related records.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through;

a. calibration provided by a competent laboratory; or
b. certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
c. direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

Measurement Results where applicable are traceable to SI units.

a. GL-6 “Purchasing” provides guidance on the selection and use of appropriate vendors for the calibration of equipment. GL-21 “General Laboratory Equipment” gives guidance on the calibration of some common equipment. Units having specific calibration requirements will address the requirements in Unit SOPs.
b. GL-6 “Purchasing” provides guidance on the selection and use of appropriate vendors for the purchase of certified reference materials with metrological traceability. Each Unit as applicable shall utilize only measurement standards for calibrations or comparisons which can be linked to relevant primary standards of the SI Units of measurement. All reference standards are

calibrated against NIST standards or by a vendor, which can provide traceability to NIST or an equivalent.

c. All reference materials, where possible, shall be traceable to SI Units.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference such as:

a. certified values of certified reference materials provided by a competent producer.
b. results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

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.

6.6 Externally provided products and services

6.6.1 The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

a. are intended for incorporation into the laboratory's own activities;
b. are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
c. are used to support the operation of the laboratory.

Guidance for products purchased for use in case analysis and services purchased (such as equipment calibration and instrument maintenance) is provided in GL-6 "Purchasing". Guidance for use of sub-contracting services for case analysis is provided in GL-20 "Review of Requests and Tenders".

a. Procedures to ensure suitability of purchased supplies, reagents and consumable materials prior to use, are addressed in GL-6 "Purchasing". Further, guidance is maintained in Unit SOPs as follow:

Controlled Substance	CS-1
Toxicology	TX-19
DNA	DNA-8
Forensic Biology	FB-8 to 18 & 21
Chemistry	CH-12
Latent Prints	LP-3 & 4
Firearms	FA-27 & 28
Instrumentation	FLIN-8

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 SOPs:

Controlled Substance	CS-1
Toxicology	TX-14 & 19
DNA	DNA-8
Forensic Biology	FB-8 to 18 & 21
Chemistry	CH-12
Instrumentation	FLIN-8
Imprints	IM-2

b. When case work is to be outsourced the Deputy Director and Director (or designee) will identify the contract laboratory and ensure the suitability of the contract laboratory to provide the needed service. In the case of the DNA Unit the Technical Leader will be responsible to review and approve the suitability of the contract laboratory following the guidance of the FBI DNA QAS document.

Suitability of a contract laboratory 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 accreditation.

c. Guidance to ensure that products and services used in support of DSS operations are suitable for the needs of the DSS is provided in GL-6 "Purchasing" and in Unit SOPS as listed above.

6.6.2 The laboratory shall have a procedure and retain records for:

a. defining, reviewing and approving the laboratory's requirements for externally provided products and services;
b. defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
c. ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
d. taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

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).

a. GL-6 "Purchasing" specifies that the Division shall evaluate vendors to determine if they meet the minimum requirements for critical consumables and critical reagents. Additionally this SOP requires maintaining records of the evaluation.

b. GL-6 "Purchasing" specifies criteria to evaluate suppliers of products and services. This includes the acceptance of suppliers accredited to ISO 17025 or 17034 (with appropriate scope of accreditation) or through evaluation using questionnaire GL-6.1. A list of the approved vendors and associated documentation is maintained in Qualtrax. GL-6 "Purchasing" also provides guidance on re-evaluation of suppliers.

c. The DSS ensures that externally provided products and services are appropriate for the needs of the DSS prior to use or prior to providing the product to the customer.

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

Controlled Substance	CS-1
Toxicology	TX-19
DNA	DNA-8
Forensic Biology	FB-8 to 18 & 21
Chemistry	CH-12
Latent Prints	LP-3 & 4
Firearms	FA-27 & 28
Instrumentation	FLIN-8
Imprints	IM-2

Unit Quality Control procedures detail the analysis process for quality control data, and include the appropriate actions to be taken in the event that expected results/parameters are not met (including action to be taken to correct the problem and to prevent an incorrect result from being reported).

ii. Services:
The Quality Section is responsible to ensure that calibration services for general equipment meet the needs of the DSS based on the scope of accreditation of the service provider. Refer to GL-21 "General Laboratory Equipment" and GL-6 "Purchasing".

Section Deputy Directors (or their designees) are responsible to ensure that services (such as calibration, repair and performance checks) to unit specific equipment are performed by vendors that meet the needs of the DSS prior to using the supplier. Refer to GL-6 "Purchasing". Unit SOPs provide guidance on performance checks or other quality controls required after services and prior to use for case work.

Unit Quality Control procedures detail the analysis process for quality control 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).

In the event the Division of Scientific Services chooses to sub-contract case work the criteria set forth in the ANAB accreditation document and the FBI DNA QAS document will be followed as appropriate. Contracts with sub-contractors for DNA related analysis will be reviewed annually, if the contract is maintained. Division Units using sub-contractors may include Unit specific requirements in Unit SOPs.

When casework is outsourced the Section Deputy Director and the Director will ensure that the contracted company meets the needs of the DSS and the guidance of its accrediting body. The DSS retains responsibility for case reports produced and issued to the client based on work performed in a contract laboratory.

When case work is sub-contracted, the DSS 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 if any work was performed by the Division. Where

applicable, the DSS Unit 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. Unit SOPs detail when a report will be necessary and when a letter or notification will suffice.

d. GL-6 "Purchasing" gives guidance on the evaluation/re-evaluation of vendors. The Quality Section maintains a list of approved vendors through Qualtrax. Vendors no longer found to be appropriate for use will be removed from this list. Units obtaining unsatisfactory services or supplies from an authorized vendor will work with the Section Deputy Director to determine the correct path to rectify the issue.

6.6.3 The laboratory shall communicate its requirements to external providers for:

a. the products and services to be provided;
b. the acceptance criteria
c. competence, including any required qualification of personnel
d. activities that the laboratory, or its customer, intends to perform at the external provider's premises.

Requirements of purchased products and services are communicated to the supplier through purchasing requests or in the case of some calibrations through requests for quotes.

a. GL-6 "Purchasing" specifies that when purchasing critical items or services the unit will provide exact specifications deemed critical to the item or service. When a calibration service is required to an exact standard or specification the Quality Section (or their designee) communicates the specifications to the approved vendor.
b. Acceptance criteria for provided products and services are communicated to the vendor through purchasing documents or other communications such as email notification.
c. When a service is to be supplied that requires that the personnel performing the service has specific qualifications this will be communicated to the vendor prior to the service being performed.
d. The DSS will communicate needed requirements to external providers when work such as repairs or calibrations are to be performed off site. This may include guidance on calibration cycles to be defined on calibration certificates, or other general information.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

a. the requirements are adequately defined, documented and understood;

b. the laboratory has the capability and resources to meet the requirements;

c. where external providers are used, the vendor must be accepted by the laboratory and the laboratory will advise the customer of the specific laboratory activities to be performed by the external providers and gain the customer's approval.

d. the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

The Division of Scientific Services 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 "Review of 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 Division reserves the right to use contract laboratories to perform case analysis, the contract on the evidence receipt acts as notification of this to the customer.

   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 Division's 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 subcontract 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 Division's contract with its customer.
d. The appropriate testing is capable of meeting the customer's requirements.

Additionally the contract states:

e. Differences between the request and the contract will be resolved prior to the commencement of casework.
f. Each contract shall be acceptable to both the Division and the customer.
g. Electronic or handwritten signatures are acceptable on DSS reports.

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

7.1.2 The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

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

7.1.3 When the customer requests a statement of conformity to a specification or standard for the test, the specification or standard and the decision rule shall be clearly defined.

The DSS has no requirements with customers to provide a statement of conformity to specific specifications.

7.1.4 Any difference between the request and the contract shall be resolved before laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

GL-20 "Review of Requests and Tenders" contains the wording of the contract with customers submitting evidence and specifies that: Differences between the request and the contract will be resolved prior to the commencement of casework. Additionally GL-20 "Review of Requests and Tenders" provides guidance on documentation of deviation requests. The DSS will ensure that deviations requested by the customer will not impact the integrity of the casework. Analysts receiving requests for deviations will bring these to the Unit Lead. The Unit Supervisor and Assistant Director or Deputy Director will determine if the deviation request is appropriate.

Deviations of any kind, administrative or technical will be entered in the Qualtrax Workflow, "Deviation Request". This request will go through review by the Unit Supervisor (or TL in DNA), Assistant Director (or Supervisor), Deputy Director, Quality Assurance Manager, and to the Director for approval. All reviews and approvals will be documented in Qualtrax. If necessary, external files (i.e. memos) can be uploaded to the workflow. Any user is able to use this workflow to submit a deviation request.

7.1.5 The customer shall be informed of any deviation from the contract.

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 "Review of Requests and Tenders".

Guidance on what constitutes a major deviation is provided in GL-20 "Review of Requests and Tenders".

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

If, during the process of working a case, a change to the contract is required, the analyst or their 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 and Unit Supervisor should consider the guidelines detailed in GL-20 "Review of Requests and Tenders" to determine if the change is sufficient enough to warrant contacting the customer.

7.1.7 The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

The Case Management Section works closely with customers when clarification of customer's requests is required.

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").

7.1.8 Records of reviews, including any significant changes, shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

If, during the process of working a case, a change to the contract is required the analyst or their Lead or 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). This process is detailed in GL-20 "Review of Requests and Tenders".

7.1.9 The extent of database searches shall be communicated to customers and updated as needed.

NOTE 1: "extent" will be specific to the database but may include aspects of the scope or range of the search (e.g., local, state, national, international), the frequency of the search or if the customer is required to make a request to elevate the scope of the search or to have a search performed.
NOTE 2: This may be communicated on a case-by-case basis, in the report, or in a general customer communication

Unit procedures define guidance on communication to customers pursuant to database searches. Operational SOPs for the individual characteristic databases utilized by Division Units are as follows:

NIBIN: (Firearms)	FA-21, 22 & 32
CODIS: (DNA)	DNA-10 to DNA-16
AFIS: (Latent Prints)	LP-11, LP-30 & LP-32

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

The procedural SOPs for each Unit in the Division, when appropriate, specify the use of appropriate methods and procedures for sample selection, 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.

Measurement Uncertainty and/or Statistical techniques SOPs:

Controlled Substance	CAS-04
Toxicology	CAS-04
Firearms	FA SOP-13 & 34
Statistical Analysis SOPs:	
DNA	DNA SOPs- 5, 21, 25, 31, 32 & 33

7.2.1.1.1 The laboratory shall use appropriate methods and procedures for all associated data analysis and interpretation

The DSS uses methods appropriate to the discipline; these include procedures for data analysis and interpretation. See Unit SOPs.

7.2.1.1.2 All test methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s).

NOTE 1: Characteristics include, but are not limited to, alleles in a DNA profile, friction ridge detail in a latent print, striation detail on a bullet, features of handwriting, or criteria for evaluation of mass spectrometry fragments and ratios in a seized drug sample or a toxicology sample extract.
NOTE 2: This requirement is not focused on the process of assessing an unknown in order to identify the test item that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known prior to the assessment of the unknown.

Unit SOPs provide guidance on the assessment of unknown items and specifically the identification of characteristics suitable for comparison to known materials. Additionally where appropriate, the statistical evaluation of the characteristics. These evaluations will be made prior to the comparison to the known.

7.2.1.1.3 For laboratories whose scope of accreditation includes calibration:
a) measuring instrument calibration methods shall assess accuracy (bias and precision) of the instrument across a range of values that meets the needs of the customer; and
b) the source of material(s) used to calibrate a measuring instrument shall be different from that used to adjust a measuring instrument and that used to verify calibration status.
NOTE1 a): "needs of the customer" include regulatory or statutory limits
NOTE b): Preference should be given to material(s) from different manufacturers, followed by different lot numbers of material from the same manufacturer.

The scope of accreditation for the DSS does not include calibration.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel.

GL-19 "Document Control" 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.

GL-19 "Document Control" 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.

7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

GL-19 "Document Control" addresses the 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. The Director may authorize other users access to these documents based on needs of the Division.

7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.

As specified in GL-20 "Review of 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.

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

Each Unit validates all methods prior to use, per Unit SOPs. Documentation of the validation process, including a consideration regarding the method as being "fit for purpose" is specified in the validation documentation. 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.

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. The completed form will be maintained with the validation documentation.

Each Unit will maintain the validation documentation for a minimum of the life of the procedure plus 10 years.

For overview of the Division's Validation Policy, refer to GL-22 "Policy on Validation and Performance Checks". Unit SOP guidance details the method development/validation and documentation process as noted below:

Computer Crimes and Electronic Evidence	CC-20, 28 & 36
Controlled Substance	CS-10
DNA	DNA-1

Forensic Biology	FB-25
Chemistry	CH-16 &17
Latent Prints	LP-12 & 17
Imprints	IM-15
Questioned Documents	QD-21
Firearms	FA-37
Multimedia	MM-29

In the event that a method is revised by an issuing body and the DSS adopts the revision a verification will be performed to ensure that the required performance can be reached.

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan shall be approved and authorized.

For overview of the Division's Validation Policy, refer to GL 22 "Policy on Validation and Performance Checks".

- 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 and approved as development dictates.
- If the plan is updated all involved personnel will be informed.

7.2.1.7 Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

Administrative or Technical deviations will be entered in the Qualtrax Workflow, "Deviation Request". The proposed procedure will contain the technical justification for the deviation. This request will go through review by the Unit Supervisor (or TL in the DNA Unit), Assistant Director, Deputy Director, Quality Assurance Manager, and to the Director for approval. All reviews and approvals will be documented in Qualtrax. If necessary, external files (i.e. memos) can be uploaded to the workflow. Any user is able to use this workflow to submit a deviation request.

Any significant deviation from accepted procedures must be documented and approved by the Director and appropriate managers. A notification of the deviation to the customer will be made. Significant deviations require the acceptance by the customer. The decision on whether a deviation is considered significant will be decided between appropriate Managers and the Quality Assurance Manager.

7.2.2 Validation of methods

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

In the event the DSS requires the development of a non-standard method (i.e. a method used outside its intended scope, laboratory developed methods) all requirements for a validated method, as specified by laboratory procedure, must be fulfilled by the non-standard method prior to use.

Refer to GL-22 'Policy on Validation and Performance Checks'.

7.2.2.1.1 The laboratory shall have a procedure for method validation that:
a) includes the associated data analysis and interpretation;
b) establishes the data required to report a result, opinion, or interpretation; and
c) identifies limitations of the method, reported results, opinions, and interpretations.

For overview of the Division's Validation Policy, refer to GL 22 "Policy on Validation and Performance Checks". This includes guidance on:

a. Data interpretation.
b. Data required for reporting results including where appropriate, opinions and interpretations.
c. Identification of method limitations.

GL-22 "Policy on Validation and Performance Checks" includes guidance on data interpretation requirements, establishing reporting requirements and the identification of method limitations. Units may have additional SOP guidance detailing the method development/validation and documentation process, as noted below:

Computer Crimes and Electronic Evidence	CC-20, 28 & 36
Controlled Substance	CS-10
Toxicology	TX-
DNA	DNA-1
Forensic Biology	FB-25
Chemistry	CH-16 &17
Latent Prints	LP-12 & 17
Imprints	IM-15
Questioned Documents	QD-21
Firearms	FA-37
Multimedia	MM-29

7.2.2.2 When changes are made to a validated method, the influence of such changes shall be relevant to the customer's needs and consistent with specified requirements.

NOTE: Changes to associated data analysis and interpretation are considered changes to a validated method.

When changes are made to validated methods the change will be assessed to assure that the change will be consistent with the need of the customer. Refer to GL-22 "Policy on Validation and Performance Checks".

7.2.2.2.1 The associated data interpretation is considered part of a validated method. When changes are made such changes shall be relevant to the customer's needs and consistent with specified requirements.

GL-22 "Policy on Validation and Performance Checks" states that data interpretation will be included when changes to validated methods are planned.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

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.

7.2.2.4 The laboratory shall retain the following records of validation:

a. the validation procedure used;
b. specification of the requirements;
c. determination of the performance characteristics of the method;
d. results obtained;
e. a statement on the validity of the method, detailing its fitness for the intended use.

GL-22 "Policy on Validation and Performance Checks" provides guidance on records to be retained for validations performed.

GL-11 "Control of Records" states that validation records will be maintained for a minimum of ten years. This is to include the validation procedure/plan, specification of validation requirements, performance characteristics of the method, the data/results obtained and the documentation stating the method is fit for use.

7.3 *Sampling*

7.3.1 The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

The CT Division of Scientific Services performs sample selection. Where applicable, each DSS Unit defines and describes its sampling (sample selection) procedures in Unit SOPs. Such processes address the factors to be controlled to ensure the validity of the test results.

All Unit procedures are available through Qualtrax.

7.3.2 The sampling method shall describe:
a) the selection of samples or sites;
b) the sampling plan;
c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration.
NOTE 1: when received into the laboratory, further handling can be required as specified in 7.4.
NOTE 2: The intent of ISO/IEC 17025 is that the activity of sampling occurs prior to the item being submitted to the laboratory. A laboratory can choose to perform further sampling after receipt of the item, in which case the requirements for sampling are applicable.

The CT Division of Scientific Services performs sample selection.

Individual Unit SOPs contain guidance on sampling (sample selection):
a) Selection of samples.
b) General guidance on the sampling plan as applicable.
c) Sample preparation for subsequent testing.

7.3.2.b).1 Statistical sampling at a stated level of confidence shall be used if an inference will be made to report on the whole population.

Units within the DSS use sample selection. Results of testing apply only to the items tested.

7.3.3 The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:
a) reference to the sampling method used;
b) date and time of sampling;
c) data to identify and describe the sample (e.g. number, amount, name);
d) identification of the personnel performing sampling;
e) identification of the equipment used;
f) environmental or transport conditions;
g) diagrams or other equivalent means to identify the sampling location, when appropriate;
h) deviations, additions to or exclusions from the sampling method and sampling plan.

The CT Division of Scientific Services performs sample selection.

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

a) Reference to method.
b) Date sample taken.
c) Description of sample.
d) Name of person performing the work.
e) Identification of equipment used.
f) Environmental or transport conditions.
g) Diagrams or equivalent to document location sample was obtained.
h) Information on deviations from the SOP pertaining to sample selection.

7.4 Handling of test or calibration items

7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.

GL-13 "General Evidence Handling" provides guidance on evidence handling to preserve evidence integrity.

The procedural SOPs for each Unit in the Division, when appropriate, specify the use of appropriate methods and procedures for sample selection, handling, transport, preparation, and storage of items to be tested.

7.4.1.1 For all test items received except known origin individual characteristic database samples, the procedure shall:

a) address requirements for storage, packaging, and sealing of items to:
1. protect the integrity of all items; and
2. require items to be re-sealed as soon as practicable;
b) address measures to be taken to secure unattended items;
c) require chain-of-custody for:
1. all items received; and
2. items that are collected or created and preserved for future testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, trace evidence, DNA extracts);
d) require chain-of-custody to securely and accurately identify:
1. the individual(s) or location(s) receiving or transferring the item(s); and
2. the item(s) being transferred; and
3. the chronological order of all transfers, minimally including the date;
e) require communication to the customer regarding the disposition of all items received; and
f) address communication to the customer regarding items collected or created and preserved for future testing.

NOTE 1: c) An item being tracked could contain multiple components and be tracked as one item.
NOTE 2: d)1) Documentation of internal transfers does not need to include use of personal storage locations.

The DSS addresses the overall handling of test materials in GL-13 "General Evidence Handling" and each DSS Unit has 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).

a. GL-13 "General Evidence Handling" relates to all items submitted to the DSS as evidence.

   GL-13 "General Evidence Handling" and Unit SOPs give guidance on storage, packaging and sealing evidence to 1) protect the integrity of all items received through at minimum ensuring a proper seal and proper storage and 2) to require items to be re-sealed as soon as practical after access.

   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.

b. GL-13 "General Evidence Handling" provides guidance on securing unattended evidence.

c. GL-13 "General Evidence Handling" provides guidance on maintaining the chain of custody for 1) all items of evidence received and 2) for all items collected or created (may be designated as sub-items) and preserved for further testing; (including but may not be limited to ESDA lifts, latent print lifts, DNA extractions, and test-fired ammunition).
   - 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.

d. GL-13 "General Evidence Handling" provides guidance on the use of JusticeTrax to maintain chain of custody for all items of evidence, including securely and accurately documenting 1) the individual(s) or locations(s) receiving the items, 2) the item(s) transferred, and 3) the chronological order of all transfers.
   - Unit SOPs provide guidance on appropriate handling of characteristic database samples.

Individual characteristic database samples:

- are treated as reference materials
- are not treated as evidence
- will be uniquely identified
- will be protected from loss, cross transfer, contamination and/or deleterious change

Unit analytical SOPs specify that access to samples comprising individual characteristic databases will be restricted to those persons authorized by the Deputy Director and/or Director.

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

NIBIN: (Firearms)	FA-21, 22 & 32
CODIS: (DNA)	DNA-10 to DNA-16
AFIS: (Latent Prints)	LP-11, LP-30 & LP-32

e. GL-13 "General Evidence Handling" and Unit SOPs provide guidance on the notification of customers regarding the disposition of all items of evidence. This will generally be through the DSS report(s).

f. GL-13 "General Evidence Handling" and Unit SOPs provide guidance on the notification of customers regarding all items collected or created which are preserved for further testing.

7.4.2 *The laboratory shall have a system for the unambiguous identification of test items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.*

GL-14 "LIMS" and GL-13 "General Evidence Handling" provide guidance on the identification and labeling of test items. Each item, and when necessary, sub-item(s) require(s) a unique label which remains as a permanently affixed identifier and is used in all aspects of the testing/examination process. All sub-items (when generated) are tracked in LIMS in the same manner as original evidence items.

7.4.2.1 The system used to identify items shall cover all items received.

GL-4 "LIMS" specifies the unique numbering identification system used for all cases and related items of evidence received by the DSS.

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.

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. When there is doubt about the suitability of an item for testing, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

Upon review of submitted evidence, if the submission(s) do not conform to the description provided on the Request for Analysis (RFA) form, the customer will be notified, and the case file will be appropriately documented. If the discrepancy is such that it causes doubt as to the suitability of the item for the testing requested, work will be suspended until the discrepancy is clarified by the submitting agency.

Note that minor variations between the RFA and items submitted do not warrant customer notification. Analysts are to refer to their Unit Lead or Supervisor if questioning appropriateness of the description.

Each DSS Unit requires (as detailed in Unit 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. If the customer still requires testing, the related report will include a disclaimer indicating which results could be affected by the deviation.

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

Computer Crimes and Electronic Evidence	CC-10
Controlled Substance	CS-1
Toxicology	TX-5
DNA	DNA-1 & 23
Forensic Biology	FB-05
Chemistry	CH-11
Questioned Documents	QD-3
Latent Prints	LP-1, 2, 24 & 26
Multimedia	MMIE-27

Firearms	FA-06
Imprints	IM-3 &13
Instrumentation	FLIN-09

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

DSS Unit SOPs where appropriate, address specific requirements for the 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.

7.5 Technical Records

7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

NOTE: Options for recording observations include, but are not limited to: written notes, photography, drawing, photocopying, or scanning.

GL-11 "Control of Records" specifies that:

- All significant records generated during the course of analysis are maintained within the case file; including the use and performance of appropriate controls and standards as specified in all procedural SOPs in each Unit.
- 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.
- Case records include the identity of all personnel responsible for the sampling, performance of each test, and of all review processes.
- Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.
- If test results are rejected, the reason for the rejection will be recorded.
- Case documentation shall reflect the date(s) of examination, identifiable to the specific task.

7.5.1.1 Define the technical record(s) to be retained if all related technical records are not maintained.

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

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

7.5.1.2 Where abbreviations or symbols specific to the forensic service provider are used, the meaning of the abbreviations or symbols shall be defined.

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 Unit SOPs, as detailed below:

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

7.5.1.3 Technical records to support a report shall be such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data.

GL-11 "Control of Records" specifies that case records include sufficient data to facilitate and allow another competent analyst, Supervisor or Lead to scientifically evaluate the results and how conclusions were made.

7.5.1.4 Records shall be created and maintained in a permanent manner.

NOTE: For example, technical records originally captured in pencil (e.g., a rough sketch) can be maintained in a permanent manner by photocopying, scanning, or taking a photo.

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.

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

7.5.1.5 If an observation, data, or calculation is rejected, the reason, the identity of the individual(s) taking the action and the date shall be recorded in the technical record.

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 if test results are rejected, the reason for the rejection, the initials of the person taking the action and the date will be recorded and maintained in the technical record.

7.5.1.6 If an adjustment or repair is performed due to a calibration that does not meet specifications, pre and post adjustment/repair data shall be retained.

NOTE: See related clause ISO/IEC 17025:2017, 7.8.4.1.d)

As appropriate individual Unit SOPs provide guidance on maintaining records for calibrations that do not meet Unit specifications. Additionally Unit SOPs state that when adjustments or repairs are made both pre and post repair/adjustment records will be maintained.

7.5.2 The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations. Please note that contemporaneous revisions are not considered amendments.

NOTE: Contemporaneous revisions are not considered amendments.

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

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 and dated 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.

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 and dated by the individual making that change.

7.6 Evaluation of measurement uncertainty

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

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

All DSS Units shall utilize 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.

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

Controlled Substance	CAS-04
Toxicology	CAS-04
Firearms	FA SOP-13 & 34

7.6.1.1 The method of analysis for evaluation of measurement uncertainty shall:

- *a. require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method.*
- *b. include the process of rounding the expanded uncertainty;*
- *c. require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (~95%); and*
- *d. specify the schedule to review and/or recalculate the measurement uncertainty.*

As applicable each DSS Unit specifies that factors that may affect measurement uncertainty are considered in developing testing methods and procedures. Unit procedures:

a. Require that the device used to obtain reported results will be included in the development of the measurement uncertainty or that the device will be assessed against the measurement uncertainty for the procedure.

b. Include guidance on the process of rounding the expanded uncertainty.
c. Require a coverage probability of 95.45%.
d. Specify that the measurement uncertainty will be re-calculated or reviewed annually.

Unit procedures addressing uncertainty:

Controlled Substance	CAS-04
Toxicology	CAS-04
Firearms	FA SOP-13 & 34

7.6.2 A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.

Not applicable, the CT DSS does not perform calibration of its equipment.

7.6.3 A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

The CT DSS requires evaluation of the measurement of uncertainty when reporting quantitative results. Units reporting measurement uncertainty calculate the value based on method evaluation as per Unit SOPs.

7.6.3.1 Measurement uncertainty shall be evaluated, or estimated when applicable for all reported quantitative results.

NOTE: An item descriptor that includes a number is not considered a result. This difference should be clear to the reader of the report.

The CT DSS requires evaluation of the measurement of uncertainty when reporting quantitative results. This includes weights of drug evidence, quantitative results of drugs in blood in toxicology and barrel length in firearms. Other areas may be included as needed.

7.6.4 The following records shall be maintained for each evaluation and estimation of measurement uncertainty:
a. statement defining the measurand;
b. statement of how traceability is established for the measurement;
c. the equipment used;
d. all uncertainty components considered;
e. all uncertainty components of significance and how they were evaluated;
f. data used to estimate repeatability, intermediate precision, and/or reproducibility;
g. all calculations performed; and

h. the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

GL-11 "Control of Records" specifics that, documentation related to the calculation of the uncertainty of measurement will be maintained for 10 years.
Unit procedures addressing uncertainty address the retention of all data/documentation used in developing procedural uncertainty. Documentation to be maintained includes:

a. documentation defining the measurand;
b. documentation on how traceability is established for the measurement;
c. documentation on the equipment used;
d. all uncertainty components considered;
e. all uncertainty components of significance and how they were evaluated;
f. data used to estimate repeatability, intermediate precision, and/or reproducibility;
g. all calculations performed; and
h. the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

Refer to unit procedures:

Controlled Substance	CAS-04
Toxicology	CAS-04
Firearms	FA SOP-13 & 34

7.7 Ensuring the validity of results

7.7.1 The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not limited to:

a. use of reference materials or quality control materials;
b. use of alternative instrument that has been calibrated to provide traceable results;
c. functional checks of measuring and testing equipment;
d. use of check or working standards with control charts, where applicable;
e. intermediate checks on measuring equipment;
f. replicate tests or calibrations using the same or different methods;
g. retesting or recalibration of retained items;
g.1 when a verification of a result is carried out;
a. it shall be conducted by an individual who is currently authorized to perform the testing.
b. a record of the verification shall be made and the record shall identify who performed the verification, when it was performed, and the result of the verification;
c. and the resolution of any discrepancy shall be recorded.
NOTE 1: a) See requirements of 6.2.6 in ISO/IEC 17025:2017.

NOTE 2: b) Verification may be recorded for each result verified or as a summary for all results verified.

h. correlation of results for different characteristics of an item;
i. review of reported results;
j. intralaboratory comparisons;
k. testing of blind sample(s;)
l. there shall be a procedure for the technical review of technical records, including reports, and testimony. The procedure shall;

1. Require the individual performing the technical review to have been competency tested to perform the testing or calibration work that is being reviewed.
2. Preclude an individual from technically reviewing their own work;
3. Define the method to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review;
4. Define the method to be used to ensure testimony in each discipline is reviewed;
5. Define the method to be used to conduct and record the review;
6. Ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record.
7. Ensure conformance with methods and applicable management system documents; and
8. Describe a course of action to be taken if a discrepancy is found.

NOTE 1: An individual conducting the technical review need not be an employee of the forensic service provider, currently proficiency tested or currently performing the work.
NOTE 2: An individual who performs a verification can also perform a technical review.
NOTE 3: The frequency may vary for different disciplines

The DSS monitors the reliability of test results through multiple measures including technical review of cases, internal audits and proficiency testing of analysts. Technical review of cases is required in all disciplines.

- GL-18 “Case Reviews” provides guidance in the performance of technical reviews.
- GL-7 “Audits” includes guidance on reviewing case files as part of the annual audit.
- GL-16 “Proficiency Testing” requires that each analyst be challenged each year in each discipline in which they perform testing by at least one proficiency test.

a) Specific quality control procedures are maintained in each Unit for monitoring the validity of tests and calibrations procedures. Methods define the required control materials to be used. This may include use of reference materials and procedural blanks.

b) Units may use various analytical techniques in analyzing case materials; an example of this would be a screening and confirmatory test method. Unit SOPs provide guidance on specific testing.

c) All equipment shall be calibrated before being put into service, as specified in individual Unit procedures. Guidance for maintenance and performance checks of some general laboratory equipment can be found in GL-21"General Laboratory Equipment".

The need for periodic calibration/checks of specific instruments is detailed per individual Unit SOPs. Unit procedures addressing checks of equipment are as follows:

Controlled Substances	CS-5, 6, 7 & 8
Toxicology	TX-14 & 29
Chemistry	CH-3 & 4
Instrumentation	FLIN-4 & 5
DNA	DNA 1 & 9
Forensic Biology	FB-23 &24
Latent Prints	LP-09-12, 25 & 28
Firearms	FA-22, 33 & 35
Imprints	IM-11
Questioned Documents	QD-10
Computer Crimes and Electronic Evidence	CC-19-21
Multimedia	MMIE-14

d) Unit SOPs provide guidance on monitoring the validity of tests and calibrations procedures. Where appropriate 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).

e) Where appropriate, Unit 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. Guidance for maintenance and performance checks of some general laboratory equipment can be found in GL-21 "General Laboratory Equipment".

f) Where appropriate replicate testing may be used as a quality control measure. Unit procedures provide guidance on the use of replicate testing.

g) Where appropriate Units may retest retained items as a quality control measure.

g) 1. When a unit uses verification the verification shall a) be performed by a analyst authorized in the method, b) be documented including who performed the verification, when the verification was performed, and the result of the verification and c) include the

resolution of any discrepancy identified; the resolution of the discrepancy will be documented.

h) Units may use various analytical techniques in analyzing case materials, these techniques may be based on differing characteristics of the sample. Unit procedures will define the correlation requirements between the techniques.

i) GL-18 "Case Reviews" provides guidance in the performance of technical and administrative reviews. Unit SOPs may include further guidance based on case review needs of the unit.

j) Intra-laboratory testing may occur as a quality control measure. When a unit uses intra-laboratory testing they will maintain the documentation of the testing.

k) The DSS does not participate in blind testing.

l) The technical review of examination documentation and reports is detailed in GL-18 "Case Reviews". The technical review of court testimony is detailed in GL-17 "Court Monitoring". These procedures specify:

1. Technical reviews must be performed by an individual that has been competency tested in the testing being reviewed.
    a. The DSS differentiates
        i. Technical Review/Reviewers
        ii. Batch technical Review/Reviewers

        See GL-18 "Case Reviews" for this distinction.
2. Technical reviews cannot be performed by the individual that performed the work.
3. Define the number of cases to be technically reviewed.
    a. Where 100% technical review is not performed the Deputy Director and Director will determine the number of cases per year that require technical review to ensure a representative number of cases are reviewed. The Deputy Director or their designee will be responsible to ensure the appropriate number of cases are reviewed.
4. Define that court testimony will minimally be reviewed annually for each discipline in which testimony is presented.
5. Guidance on the performance and documentation of technical reviews both for casework and testimony.
6. That the technical reviewer will ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record.
7. Technical reviewers will ensure conformance with DSS analytical and management system procedures.

8. The course of action to occur when a discrepancy is identified.

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:
a. participation in proficiency testing (external testing)
b. participation in interlaboratory comparisons other than proficiency testing.

The DSS participates in proficiency testing as defined in GL-16 "Proficiency Testing" as a method of monitoring performance. The Quality Section plans proficiency testing events and maintains a schedule of this testing. The proficiency program is reviewed annually as part of the Management System Review.

7.7.2.1 The process for monitoring performance by comparison with results of other forensic service providers shall at a minimum:
a. ensure successful completion of at least one proficiency test for each discipline prior to accreditation being granted in that discipline; and
b. ensure each location on the scope of accreditation successfully completes, per calendar year, at least one proficiency test for each discipline in which accredited services are provided, with authorized release of the test results to ANAB for the test provider.

Guidance on the Proficiency testing program is included in GL-16 "Proficiency Testing".
a) When applying for accreditation in a new discipline at least one proficiency test will be successfully completed.
b) The proficiency test schedule will ensure that for each discipline a minimum of one external proficiency test, for all accredited services will be completed successfully annually. Authorization will be provided to the test provider to release the test results to ANAB.

7.7.3 Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

Proficiency tests are used to monitor analyst and unit performance. Data from proficiency testing may be used to make improvements to DSS procedures. GL-16 "Proficiency Testing" gives guidance on monitoring proficiency test results and the actions to take when reported results are not consistent with those expected by the test provider to prevent incorrect results from being reported.

7.7.4 The performance of personnel shall be monitored. This monitoring shall ensure that all personnel who perform testing or calibration shall successfully complete at least one intralaboratory comparison, interlaboratory comparison or proficiency test per calendar year in each discipline on the scope of accreditation in which the individual conducts work. In the event that the

preceding options are not available or appropriate, observation-based performance monitoring is acceptable.
NOTE 1: The monitoring should be varied over time to cover all aspects of assigned job functions but does not have to include all aspects of the work performed each time.
NOTE 2: Solely performing verifications (7.7.1.g).1) or solely reviewing and authorizing results (7.8.1.1) are considered to be testing or calibration and are subject to these requirements.
NOTE 3: Accreditation occurs in the discipline of Toxicology in both Calibration and Testing. The above requirements apply to the Testing scope of accreditation and Calibration scope of accreditation separately.
NOTE 4: For performance monitoring conducted at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.

Analysts (however titled) will be challenged at minimum, annually in each discipline in which they perform testing; this may be through an internal or external test. Additionally, attempts will be made to challenge analysts in the various components or parameters of testing in which they perform analysis, within the 4 year accreditation cycle. All analysts will be provided with at least 1 external proficiency test in their discipline of testing in the 4 year accreditation cycle.

In the event that proficiency test is not available in a given component or parameter of testing observation based monitoring can be performed. In this event the Quality Section will work with the Section Deputy Director or their designee to plan the event.

7.7.5 The process for monitoring of performance by intralaboratory comparison, interlaboratory comparison, proficiency testing or observation-based testing shall at a minimum:
a) ensure that results are not known or readily available to the participant being monitored;
b) ensure use of approved methods;
c) establish criteria for determining successful completion prior to the monitoring activity;
d) require a mechanism to ensure the quality of intralaboratory comparisons, interlaboratory comparisons and observation-based monitoring prior to the monitoring activity; and
e) for calibration laboratories, require intralaboratory comparisons, interlaboratory comparisons and proficiency tests to be performed using an item that was calibrated by the person performing the comparison or test.

The monitoring program (including intra-laboratory, inter-laboratory, proficiency testing and observational-based testing) will:

a. Ensure that results of test materials are not readily known to the test taker.
b. Ensure that approved methods are used.
c. Establish the criteria for successful completion prior to the monitoring activity.
d. Require a mechanism for ensuring the quality of the intra-laboratory or inter-laboratory comparison materials and of observation-based activities.
e. The DSS is not a calibration laboratory.

7.7.6 There shall be a plan that will:
a. demonstrate conformance with the requirements in 7.7.2.1b and 7.7.4; and

b. ensure inclusion of a representative sample of the components/parameters and equipment/technologies within each discipline listed on the scope of accreditation.

The monitoring program (including intra-laboratory, inter-laboratory, proficiency testing and observational-based testing) plan will:

a. Ensure that for each discipline a minimum of one external proficiency test per discipline for all accredited services will be completed successfully annually. Authorization will be provided to the test provider to release the test results to ANAB.

   Analysts (however titled) will be challenged at minimum, annually in each discipline in which they perform testing; this may be through an internal or external test. Additionally, attempts will be made to challenge analysts in the various components or parameters of testing in which they perform analysis, within the 4 year accreditation cycle. All analysts will be provided with at least 1 external proficiency test in their discipline of testing in the 4 year accreditation cycle

   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 Databasing Laboratories. Further specified is that all DNA proficiency tests shall be reviewed by the DNA Technical Leader. The Quality Section shall maintain proficiency test case files and answers.

b. Where it is impossible to include every aspect of every component or parameter of testing in the monitoring program the Quality Section will make every effort to ensure inclusion of a representative sample of components/parameters, methods, and key equipment/technologies within each discipline during the accreditation cycle.

7.7.7 To satisfy the proficiency test requirements above, the laboratory shall;
a. where available and appropriate for the work conducted, use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLA and has the applicable proficiency test(s) on its scope of accreditation, or
b. where not available or not appropriate for the work conducted, gain approval from ANAB for alternative means by which the laboratory's performance can be assessed; and
c. submit results to the proficiency test provider, if applicable, on or before the agreed upon due date.

a. The DSS will use proficiency testing programs when available, which are accredited to ISO-IEC 17043 by an accreditation body that is a signatory to the APLAC MRA or IAAC MLA and whose scope is appropriate.

b. When there is not an accredited proficiency test provider available (or not appropriate) the Quality Section will gain approval from ANAB to assess the laboratory's performance in another manner.

c. The DSS will submit results to the test providers on or before the date assigned by the test provider**.**

7.7.8 The following records shall be maintained for all intralaboratory comparisons, interlaboratory comparisons, proficiency tests and observation-based monitoring:
a. disciplines monitored;
b. design of the monitoring activity;
c. expected results;
d. location, when more than one location is associated with a single accreditation certificate;
e. records submitted to a proficiency test provider, when applicable;
f. appropriate technical records;
g. evaluation of results and action taken for unexpected results; and
h. feedback on individual performance provided to the participant.

NOTE: f) See requirements of 7.5 in ISO/IEC 17025:2017 and this document.

GL-16 "Proficiency Testing" specifies that the Quality Section shall maintain records of monitoring activities (proficiency testing/intra-laboratory testing/observation based assessments), including as a minimum:

a. The discipline/analyst monitored
b. Design of the monitoring activity (Proficiency test/intra-laboratory/observation)
c. Expected result
d. Location – not applicable
e. Records submitted to the test provider
f. Retention of the appropriate technical records as maintained in the case file
g. Results of testing (evaluation); including actions taken for unexpected results
h. Feedback provided to the participant

Proficiency case files including the results of observation based monitoring will be maintained by the Quality Section.

7.8 Reporting of results

7.8.1 General

7.8.1.1 The results shall be reviewed and authorized prior to release.

GL-18 "Case Reviews" specifies that the authorizer of results is the individual producing the results. GL-18 "Case Reviews" also specifies that the authorizer is responsible to

review their own results prior to the release of the results for review (technical or administrative).

7.8.1.1.1 The authorizer of results shall review the technical record and document the review.

GL-18 "Case Reviews" specifies that analysts shall review their own work/technical records prior to submitting it for technical review. Review will be indicated by initialing the page(s) of the technical records.

In Units where one person may perform sample preparation and a second performs the analysis and analyzes the data the person analyzing the data is the authorizer of the result.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report, and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

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 reports and/or the case file shall include all information requested by the customer, as necessary for the interpretation of the test results, including methodology employed.

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. Where simplified reports have been approved Unit SOPs provide guidance as to the needed information.

GL-11 "Control of Records" defines issued reports as technical records.

7.8.1.2.1The results shall be provided in a written report or through electronic access.

NOTE: The reporting of results does not include testing of known origin samples for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.

As detailed in GL-11 "Control of Records", DSS Units will generate test reports on all case materials analyzed in the Division as detailed in individual Unit SOPs.

7.8.1.2.2 There shall be a procedure for reporting of results that:
a) identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for partial work performed;

b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement;
c) requires communicating the reason(s) in the report when the reported results are inconclusive; and
d) requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics).

NOTE: b) Associations for multiple results may be qualified by a single statistic or qualitative statement if the statistics are identical or, where applicable, meet or exceed a defined minimum threshold.

Reports issued by Units within the DSS will:

a.

- Include results for all items analyzed.
- Clearly annotate items received for analysis where analysis was not performed.
- Include information on any items collected or created that are to be preserved for possible further testing.
- Include information for partial testing, when testing is canceled prior to completion.

b.

- Clearly qualify the significance of associations reported; this may be through a statistic or a qualifying statement.

c.

- Clearly communicate the reason when an inconclusive result is reported.

d.

- Require that initial database entries are reported.

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

Unit SOPs provide guidance on meeting the above criteria, where appropriate.

As detailed in GL-11 “Control of Records”, DSS Units will generate test reports on all case materials analyzed 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 before being 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.

7.8.1.2.3 The documented process for reporting of results of calibration shall:
a) identify what information will be reported in the calibration certificate; and
b) require the issuance of an endorsed calibration certificate if requested by the customer.

The DSS does not issue calibration reports.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in this document as a requirement for a report that is not being reported, shall be readily available.

When testing is performed a written report will be released. If a simplified version of a report is desired for a specific reason, it must be agreed with the customer in writing. The agreement will detail what parts of the required test report are simplified. The case record must maintain all normal report requirements.

7.8.1.3.1 When results are reported in a simplified way, the agreement with the customer shall specify which information in 7.8.2 through 7.8.7 of ISO/IEC 17025:2017 will not be included in a written report or through electronic access. The requirements 7.8.2 through 7.8.7 in this document are applicable even if the forensic service provider reports results in a simplified way.

When an agreement is reached to issue simplified reports the agreement with the customer shall specify which information will not be included in the report. Documentation of the agreement will be added to the case when the agreement is case specific, or will be on file with the Quality Section when the agreement relates to a range of test reports.

7.8.2 Common requirements for reports

7.8.2.1 Each report shall include at least the following information, unless the laboratory has a valid reason for not doing so, thereby minimizing any possibility of misunderstanding or misuse.
a. a title.
b. the name and address of the laboratory.
c. the location of performance of the laboratory activities including when performed at a customer facility of off-site, or in associated mobile facilities.
d. unique identification that all its components recognized as a portion of a complete report and a clear identification of the end.
e. the name and contact information of the customer.
f. identification of the method used.
g. a description, unambiguous identification, and when necessary, the condition of the item.

h. the date of receipt for the test or calibration item(s) and the date of sampling, where this is critical to the validity and application of the results.
i. the date(s) of performance for the laboratory activity.
j. the date of issue of the report.
k. reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results.
l. a statement to the effect that the results relate only to the items tested, calibrated or sampled.
m. the results with, where appropriate, the units of measurement.
n. additions to, deviations, or exclusions from the method.
o. identification of the person(s) authorizing the report.
p. clear identification when results are from external providers.

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:

a. Title
b. Name and address of the Division.
c. Location of laboratory activities if other than the DSS facility – this will generally be not applicable.
d. Unique identifier (DSS case number) allowing the identification of all parts/pages of the report to be identified to the report.
e. Name and address/contact information of the submitting agency and the submitting agency case number.
f. Methods used in analysis of the case materials.
g. Evidence description, with item identification and where applicable the condition of the item.
h. Date of case receipt to the Division; and where critical to the validity of the testing the date of sampling. This will often be noted as the 'Date of Request' on case reports.
i. Date of performance of laboratory activity; this will be defined as the date range from the date the request was received to the date of the final report. Specific dates of testing will be captured within the case file.
j. Date of report issued (in general this will be the date of administrative review). Units using another milestone to define the date of issue on the report will define this within their Unit SOP.
k. Reference to a sampling plan if applicable and if relevant to the validity of the results.
l. Items analyzed with a statement to the effect that the results only relate to the items tested.
m. Results with appropriate units of measure if applicable.
n. Notation of any deviations/exclusions from the method when applicable.
o. Name and title of the authorizer of the report (i.e., this is the analyst except in Toxicology; refer to GL-18 "Case Reviews" for guidance). Additionally the name and

title of the Technical Reviewer may be on the report. Signatures of the analyst and technical reviewer may be handwritten or electronic.

p. Clear identification of external testing agency when testing has been outsourced.
q. For Units including names on reports only initials will be included for sexual assault victims and domestic violence cases.

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. Modifications to letterhead formatting must be through pre-approval.

7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage, (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

The DSS is the responsible party for all information reported as having been performed by an employee of the DSS. When data is provided by the submitting agency, that is included in the report, the information shall be clearly identified as being from the submitting agency.

Unless the DSS is responsible for the evidence sampling, DSS reports will have the statement (or similar) that the 'results reported relate to the evidence as received by the DSS'.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements above in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a. information on specific test conditions, such as environmental conditions;

b. where relevant, a statement of conformity with requirements;

c. where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand when:

- *it is relevant to the validity or application of test results*
- *a customer's instruction so requires, or*
- *the measurement uncertainty affects conformity to a specification limit;*

c.1 The measurement uncertainty shall:

a) be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;

b) include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;

c) be in the format of $y \pm U$;

d) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and
e) be reported to the same level of significance (i.e., same number of decimal places or digits) as the measurement result.

NOTE 1: a) A legal requirement is created, imposed, and enforced by a third-party external to the laboratory agency.
NOTE 2: c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.
NOTE 3: e) Reducing or simplifying a fraction is not a change in level of significance.

d. where appropriate, opinions and interpretations.
e. additional information that may be required by specific methods, authorities, customers or groups of customers.

DSS reports will additionally (when applicable) contain:

a. Information on environmental or other specific testing conditions if the conditions are needed for the interpretation of the results – (not normally applicable).
b. A statement of conformity to requirements – (not normally applicable).
c. The measurement uncertainty, in the same units as the measurand. Measurement uncertainty is required when any of the following are true:
   - it is relevant to the validity or application of test results
   - a customer's instruction so requires, or
   - the measurement uncertainty affects conformity to a specification limit

c.1 Measurement uncertainty shall:
   - be included in the report when it impacts the evaluation of a specification limit by a regulatory body (a statute, a law or other legal requirement)
   - be in the format of 'y +/- U'
   - be limited to at most 2 significant digits, unless documented rational for reporting additional significant digits
   - be reported to the same level of significance as the measurement results

d. Unit SOPs for reporting specify that when opinions or interpretations are included in case findings, 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.
e. Other information as required by the method, the customer(s), or other authorities.

7.8.3.1.1 If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, the forensic service provider shall:
a. have objective evidence of the regulation, statute, case law or other legal requirement; and
b. have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

The CT Division of Scientific Services currently has no regulatory or other legal requirements prohibiting the inclusion of, or requiring a specific format of, the measurement uncertainty.

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

The DSS does not performing sampling. Sample selection is used.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 In addition to the requirements listed above, calibration certificates shall include the following:

a. the measurement uncertainty of the measurement results presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

a).1 The measurement uncertainty shall:

a) include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, and the coverage probability;

b) be in the format of y ± U; AR 3125 ISO/IEC 17025:2017 Forensic Science Testing & Calibration Laboratories Accreditation Requirements Effective: 2019/04/29 Page 17 of 19

c) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and

d) be reported to the same level of significance (i.e., same number of decimal places or digits) as the measurement result.

b. the conditions (e.g. environmental under which the calibrations were made that have an influence on the measurement results;

c. a statement identifying how the measurements are metrologically traceable;

d. the results before and after any adjustment or repair, if available;

e. where relevant, a statement of conformity with requirements or specifications;

f. where appropriate, opinions and interpretations.

The CT Division of Scientific Services does not issue calibration certificates.

7.8.4.1.1 If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a calibration result or prohibits including measurement uncertainty, the forensic service provider shall;

a. have objective evidence of the regulation, statute, case law or other legal requirement; and

b. have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.

The CT Division of Scientific Services does not issue calibration certificates.

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

The CT Division of Scientific Services does not issue calibration certificates.

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

The CT Division of Scientific Services does not issue calibration certificates.

7.8.4.4 If applicable, a label (in addition to the calibration certificate) attached to a calibrated item shall not give the impression that the item itself is approved and shall include:
a) the name of the accredited calibration laboratory or its accreditation certificate number;
b) the unambiguous identification of the item calibrated;
c) the date of the current calibration; and
d) cross reference to the calibration certificate issued in respect to the calibration.

The CT Division of Scientific Services does not issue calibration certificates.

7.8.5 Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:
a) the date of sampling;
b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);
c) the location of sampling, including any diagrams, sketches or photographs;
d) a reference to the sampling plan and sampling method;
d).1 If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.
e) details of any environmental conditions during sampling that affect the interpretation of the results;
f) information required to evaluate measurement uncertainty for subsequent testing or calibration.

The CT Division of Scientific Services does not use sampling plans; sample selection is employed for case analysis.

7.8.6 Reporting statements of conformity
7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as statistical assumptions) associated with the decision rule employed, and apply the decision rule.

The CT Division of Scientific Services does not perform analysis in which conformity to a specification or standard is required. Not applicable.

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a. to which results the statement of conformity applies;
b. which specifications, standards or parts thereof are met or not met;
c. the decision rule applied (unless it is inherent in the requested spec. or standard).

The CT Division of Scientific Services does not perform analysis in which conformity to a specification or standard is required. Not applicable.

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

Only authorized examiners may author laboratory reports. Unit 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.

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

Unit SOPs for reporting specify that when opinions or interpretations are included in case finding, the interpretation or opinion shall be based on results obtained through testing performed and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.

Communications with customers regarding opinions and interpretations, verbal or electronic, will be maintained with the case documentation. This may be through a case file notation, electronic notation in JusticeTrax or similar method.

7.8.8 Amendments to reports

7.8.8.1 When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

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 (i.e. when the case demographic information is corrected such as a submitting agency case number). The change in the report will be identified so the reader knows the change (i.e. **bold font or similar**).

The initial original report and the revised/amended report referencing the original report will be maintained in the case file. A cover letter may be generated to aid in explaining the revised or amended report. The Assistant Director or Deputy Director will decide if a cover letter is necessary.

Reports, which are generated to add additional information due to additional work being performed on the case, will be clearly marked as "Supplemental Reports" and refer to the previous report. The original report will be left in the case file.

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which include "Amended Report" or equivalent wording.

Reports which have been issued but that require a correction will be clearly marked as "Revised Report" or "Amended Report".

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Revised/Amended reports shall be uniquely identified and contain a reference to the original report it replaces.

7.9 Complaints

7.9.1 The laboratory shall have a documented process to receive, evaluate and make decisions on complaints.

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

7.9.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and if so deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.

Complaints will be handled as prescribed by GL-10 "Customer Inquiries". Customers or other interested parties should be directed to the Quality Section regarding the handling/processing of complaints.
All complaints will be assessed to determine the area(s) the complaint relates to. The Quality Section will inform the Director of all complaints. The Quality Section will work with the appropriate Assistant Director, Deputy Director or other appointed individual(s) to address the complaint.

7.9.3 The process for handling complaints shall include at least the following elements and methods:

a. description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
b. tracking and recording complaints, including actions undertaken to resolve them;
c. ensuring that any appropriate action is taken.

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

a. The process for receiving complaints, validating, investigating and responding to complaints.
b. The recording, tracking and resolution of complaints.
c. The evaluation of the action taken; ensuring the effectiveness of the action.

7.9.4 The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

Complaints will be handled as prescribed by GL-10 "Customer Inquiries". Complaints are channeled through the Quality Section for review and action. The Quality Assurance Manager (or other as designated by the Director) will be responsible to validate the complaint.

7.9.5 Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

Complaints received, when appropriate, will be acknowledged to the person(s) making the complaint. Updates and/or the outcome of the investigation will be reported to the person(s) making the complaint (when appropriate).

7.9.6 The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individuals not involved in the original laboratory activities in question.

In general those investigating and reviewing complaints will not be directly involved in the complaint. The outcome of the investigation regarding complaints will be reported to the person(s) making the complaint (when appropriate) after appropriate review/approval by the Director (or their designee).

7.9.7 *Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.*
The outcome of the investigation regarding complaints will be reported to the person(s) making the complaint (when appropriate) after appropriate review/approval by the Director (or their designee). This may be a written report if appropriate or may be through electronic or verbal communication.

7.10 Nonconforming work

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer. The procedure shall ensure that:
a. the responsibilities and authorities for the management of nonconforming work are defined;
b. actions (including halting or repeating of work) are based upon the risk levels established by the laboratory.
c. an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
d. a decision is taken on the acceptability of the nonconforming work;
e. where necessary, the customer is notified and work is recalled;
f. the responsibility for authorizing the resumption of work is defined.

Analytical SOPs describe acceptable and unacceptable analytical work, and the criteria for such designation (e.g. instrumental or control material failure). These SOPs include steps to be taken when analytical procedures, and/or analyses fail; producing non-conforming work, either as individual samples or when the associated quality control material(s) fail to provide acceptable results. These procedures specify:

a. That it is the responsibility of the individual analyst to inform their Supervisor or Lead of the issue. The Supervisor or Lead must inform the Quality Section and Assistant Director and/or Deputy Director (and TL in the DNA Unit), 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.

b. That the Unit Supervisor will work with the Assistant or Deputy Director (or their designee) to assess the significance of the non-conformity. The Assistant Director or Deputy Director (or their designee) will work with the Quality Section to determine the appropriate action (QAR or other) based on the risk associated with the issue.

c. That the evaluation will include the significance of the event and assessment of the impact (if any) on previous work.

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

f. 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 (the DNA TL in the DNA Unit) and Quality Section.

7.10.2 The laboratory shall retain records of nonconforming work and actions specified above in 7.10.1; b. to f.

When non-conformity events raise to a 'Quality Action Request' the records of the non-conformity will minimally be retained within Qualtrax. These events can be from case work analysis (including database analysis), proficiency tests, testimony, audits and other laboratory activities.

When non-conformity events are 'one-off' (non-systemic) an incident report or corrective action workflow may be initiated through Qualtrax. The type of QAR will be dependent on the nature of the event. All records will be maintained by Qualtrax and the Quality Section.

When non-conformity events are minor (such as a failed batch, minor instrument issues etc.) the record of the event will be maintained within the unit.

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.

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." Quality Action Requests are maintained by the Quality Section through Qualtrax.

7.11 Control of data and information management

7.11.1 The laboratory shall have access to the data and information needed to perform laboratory activities.

The DSS uses a Laboratory Information Management System (JusticeTrax) and a Document Management System (Qualtrax) to assure all employees have access to needed procedures and case information needed to perform normal laboratory activities.

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

GL-4 "LIMS' provides guidance on JusticeTrax. When updates (to newer versions) to JusticeTrax are required the version will be authorized and validated prior to full implementation.

Updates to LIMS will be authorized by the Director and maintained by the LIMS Administrator. Implementation or update of unit specific software will be authorized by the Assistant or Deputy Director.

GL-22 "Policy on Validation and Performance Checks" provides guidance on upgrades to software. Authorizations may be in the form of email or other written method; this will be maintained by the unit making the change. Similarly any off the shelf software implemented (or updated) will be authorized and validated prior to implementation.

7.11.2.1 There shall be a plan for validation of computer software developed by the user and records of the validation shall be maintained.

GL-22 "Policy on Validation and Performance Checks" provides guidance on validation of software.

Individual Unit instrument specifications require that equipment and associated software is vendor 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- 20-29 & 31 -32
Chemistry	CH-3, 4 & 16
Instrumentation	FLIN 4 & 5
DNA	DNA 1 & 9
Forensic Biology	FB-23 & 24
Latent Prints	LP-11, 12 & 33
Firearms	FA-22
Imprints	IM-11 &15
Questioned Documents	QD-21
Computer Crimes and Electronic Evidence	CC-19-21 & 28
Multimedia	MMIE-14

7.11.3 The laboratory information management system(s) shall:
a. be protected from unauthorized access;
b. be safeguarded against tampering and loss;
c. be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
d. be maintained in a manner that ensures the integrity of the data and information;
e. include recording system failures and the appropriate immediate and corrective actions.

GL-4 "LIMS" provides guidance on use and security of the LIMS and LAN systems. Guidance includes:

a. Protection from unauthorized access.
b. Safeguarding the LIMS system from loss or tampering.
c. Proper use of the systems.
d. Use, maintenance, and backup of the LIMS and LAN to ensure the integrity of the data maintained.
e. Requirement to document system failures and initiate corrective actions as appropriate.

7.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable accreditation requirements.

The servers for the LIMS and LAN systems are maintained at DESPP headquarters. There is a designated system administrator and LAN administrator. In the function of System or LIMS administrator the individuals report to the Director or their designee.

7.11.5 The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

The LIMS administrator maintains the LIMS user guide.

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

NOTE: This requirement does not apply if the calculation or data transfer is secure and not subject to human error.

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

7.11.6.1 The technical record shall indicate the check was performed and who performed the check. When possible, this check shall not be conducted by the person who performed the calculation or the data transfers.

NOTE: This check may be part of a technical review.

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

8. Management system requirements

8.1 Options

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.

For accreditation purposes, the CT Division of Scientific Services falls under Option A for Management system requirements.

8.1.2 As a minimum, the management system of the laboratory shall address the following:

a. management system documentation;
b. control of management system documents;
c. control of records;
d. actions to address risks and opportunities;
e. improvement;
f. corrective actions;
g. internal audits;
h. management reviews.

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 SOPs and specific work instructions (where applicable). The use of the Quality Manual in conjunction with Unit 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".

Minimally the Management System includes:

a. Documentation provided as General and Unit procedures.
b. 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. No paper controlled copies will be maintained.
c. 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".
d. 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.

e. 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.
f. 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."
g. 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 ANAB accreditation requirements and the FBI DNA Quality Assurance Standards.
h. 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".

8.2 Management system documentation

8.2.1 Laboratory management shall establish, document, and maintain policies and objectives for the fulfillment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

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 SOPs and specific work instructions (where applicable). The use of the Quality Manual in conjunction with Unit 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".

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, 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 ANAB AR 3125 and ISO/IEC 17025:2017. The Director (or their designee) will approve SOP changes through Qualtrax.

The Quality Assurance 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 and Section 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, and/or Section Supervisor or Lead (or Technical Leader in the DNA Unit) 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 finally the Director, (or designee in cases of emergencies), prior to the change being published through Qualtrax. The Assistant Director and Section Supervisor or Lead will ensure that the analysts performing the procedure implement the changes. Changes to SOPs will be communicated through Qualtrax.

8.2.1.1 The following words (to include forms of the same word) used in ISO/IEC 17025:2017 or in this document require addressing the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify

When the following words are used in DSS SOPs, the requirement will be addressed in writing; agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, specify.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.

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".

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

- A system to evaluate and demonstrate the technical competency of all analytical employees, ensuring only forensically defensible results are reported. See Unit SOPs and GL-14 "General Training".
- A system for case review that provides both technical and administrative reviews of casework documentation. See GL-18 "Case Reviews".

- A system for procedural development, modification and validation. See Unit 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 SOPs.
- 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 aspects of the Criminal Justice system.
- A management system that works to support and enhance the Quality System of the Division. See GL-7 "Audits".
- 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".
- A system, which ensures that analytical personnel are familiar with the Quality Assurance Manual and with the quality procedures that are required for the work they perform. See GL-19 "Document Control".
- Adherence to ANAB accreditation standards and ISO/IEC 17025:2005 standards, ATF MROS standards and the FBI DNA QAS documents.

8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

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".

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".

8.2.4 All documentation, processes systems, records, related to the fulfillment of the requirements of this document shall be included in, referenced from, or linked to the management system.

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-22).

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.
Training SOP: Individual procedures meant for guiding new employees or employees new to the unit through the basics of the analysis.
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.

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.

8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

Gl-19 "Document Control" 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.

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 procedure also describes document control procedures allowing identification of the current revision status and distribution of documents.

8.3 Control of management system documents

8.3.1 The laboratory shall control the documents that relate to the fulfillment of this document.

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 Sections will be maintained by the Quality Section through Qualtrax. No paper controlled copies will be maintained.

The Quality Section is responsible to maintain all the GL SOPs and Unit 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, Section SOPs or Unit SOPs) through Qualtrax notification/email.

8.3.2 The laboratory shall ensure that:
a. documents are approved for adequacy prior to issue by authorized personnel;
b. documents are periodically reviewed, and updated as necessary;
c. changes and the current revision status of documents are identified;
d. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
e. documents are uniquely identified;
f. the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

GL-19 "Document Control" addresses the following:

a. The Document Control procedure specifies that appropriate, authorized editions of essential Division documents are available to analysts and other appropriate personnel. All DSS procedures require the Director's (or designee when not available) approval prior to being published for use.

- General Laboratory procedures may be reviewed by the Quality Section, Assistant Directors and Deputy Directors for adequacy/appropriateness prior to review and approval by the Director. SOPs are published after the Director documents approval in Qualtrax.
- Unit procedures are reviewed by personnel per the needs of the Unit prior to being forwarded for review and approval by the Assistant Director, Deputy Director and Director. SOPs are published after the Director documents approval in Qualtrax.

b. The Document Control procedure 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. 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.

c. Qualtrax allows for viewing of current procedures with a tracked changes feature to allow the user to readily identify updates. Identification of the current revision and effective date is also viewed within Qualtrax.

d. The Document Control Procedure 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. Qualtrax is the only location to find a current controlled copy of an SOP.

e. The Document Control Procedure specifies that all Management System Documents will be uniquely identified. The alpha numeric designation along with the document title will serve as the unique identifier of Division procedures. Each page of the controlled document will have a designator, except when the controlled document is an external document such as an instrument manual.

- When a controlled document is software or a manufacturer's manual, the original will be maintained in the Unit that uses the document. This will be notated in the Management System Document list. (Example: Computer Crimes will maintain the software used for their imaging process).

Note: There will be occasions when "hard" copies (paper or CD) of software are not available (i.e. the purchase of the document is such that a copy is available only in the cloud or electronic manuals saved on a Division server). For these cases the Section will record the title, version, date in service and other pertinent information on the section instrument/software list.

f. 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.

8.4 Control of records

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfillment of the requirements in this document.

The Division has established procedures for record control, including identification, collection, indexing, access, filing, storage, maintenance, and disposal of quality and technical records. Guidance is provided in GL-11 "Control of Records" including that for:

- Case files including technical records
- Proficiency testing records
- Corrective Actions
- Audits (internal and external)
- Management System Reviews
- Training Records
- Continuing education records
- Court monitoring records

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

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.

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

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.

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.

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, backup, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

GL-11 "Control of Records" specifies that:

- All records contain 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.
    - When multiple case data is recorded on a single printout (e.g. Toxicology or DNA Batch worksheets), the unique case identifier will be appropriately recorded.
- Administrative documents in a case file require the associated case number and the initials of the person adding the document (this need not be the analyst).
- All records will be maintained within the DSS facility.
- Records will be stored in a secure location that provides a suitable environment to prevent damage, deterioration, and loss.
- Electronic records shall be backed-up and/or stored in a manner that prevents unauthorized access or amendment.
- All records are maintained/archived within the DSS facility
- Access to or retrieval of records is based on the needs of the DSS.
- All records are retained based on the State record retention policy.
- Record disposal is scheduled through the Division Record Management Liaison.

8.5 Actions to address risk and opportunities

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:
a. give assurance that the management system achieves its intended results;
b. enhance opportunities to achieve the purpose and objectives of the laboratory;
c. prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
d. achieve improvement.

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. Additionally risk assessment is used to identify opportunities for improvement.

8.5.1.1 Risks and opportunities related to health and safety shall be considered.

GL-2 "Safety Manual" gives guidance on health and safety.

8.5.2 The laboratory shall plan:
a. actions to address these risks and opportunities;
b. how to:
- integrate and implement these actions into its management system;
- evaluate the effectiveness of these actions.

When a risk or opportunity is identified Management will determine the appropriate method to address the issue; this may include the use of a Quality Action Request (Corrective Action, Incident Report or Preventative Action).

Plans to address identified risks or opportunities (Quality Action Request or other) will include how to integrate the changes and how to evaluate the effectiveness of the actions taken.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

Management will address risks and opportunities in a manner that is proportional to the impact of the identified issue.

8.6 Improvement

8.6.1 The laboratory shall identify and select opportunities for improvement and implement any necessary actions.

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, as per GL-9 "Quality Action Requests."

8.6.2 The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service.

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 Defender's 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" and GL-17 "Court Monitoring".

8.7 Corrective Actions

8.7.1 When nonconformity occurs, the laboratory shall:
a. react to the nonconformity and, as applicable;
- take action to control and correct it;
- address the consequences;
b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
- reviewing and analyzing the nonconformity;
- determining the causes of the nonconformity;
- determining if similar nonconformities exist, or could potentially occur;
c. implement any action needed;
d. review the effectiveness of any corrective action taken;
e. update risks and opportunities determined during planning, if necessary;
f. make changes to the management system, if necessary.
g. The process for corrective action shall establish a reasonable timeframe for completion for each corrective action.

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". The implementation of corrective actions starts with the initiation of a QAR as detailed in the SOP noted above. This includes:

a. Reaction to the event to control and correct it including addressing any consequences of the event.
b. Evaluate the need for action to ensure that the cause of the non-conformity is eliminated to prevent re-occurrence. This can include reviewing/analyzing the non-conformity, determining the cause and determining if similar events exist or could potentially occur.
c. Implementation of needed action(s).
d. Review of effectiveness of the remediation/corrective actions taken.
e. Where applicable, review and update risks or opportunities identified.
f. Where applicable, update any needed SOPs or other Management System components.
g. Establishment of a reasonable time frame to complete corrective actions.

When a Corrective Action has been assigned to the QM, FB/DNA QM, AD, DD, Section Supervisor or Unit Lead (or designee), 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."

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

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."

8.7.3 The laboratory shall retain records as evidence of:
a. the nature of the nonconformities, cause(s) and any subsequent actions taken;
b. the results of any corrective action.

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

8.8 Internal Audits

8.8.1 The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:
a) conforms to:
- the laboratory's own requirements for its management system, including the laboratory activities;
- the applicable accreditation standards.
8.8.1.a).1 internal audits shall provide information on whether the management system conforms to the accreditation requirements.
b) is effectively implemented and maintained.

The DSS performs annual audits including audits to its own Management System, laboratory activities, and adherence to appropriate accreditation standards. Guidance for annual audits can be found in GL-7 "Audits", GL-8 "Management System" and in DNA SOP-1 "General Procedures".

8.8.1.1 Internal audits shall be conducted at least annually, as well as prior to the initial accreditation assessment.

Guidance for the scheduling of annual audits can be found in GL-7 "Audits', GL-8 "Management System" and in DNA SOP-1 "General Procedures". Internal Audits will be performed annually, except for DNA QAS internal audits which will be performed only in years that external audits are not scheduled.

When accredited to new accreditation standards an internal audit will occur prior to the initial accreditation to those standards.

8.8.2 The laboratory shall:
a. plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into

consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;
b. define the audit criteria and scope for each audit;
b).1 Internal audits shall include direct observation of a sample of accredited services within each discipline.
c. ensure that the results of the audits are reported to relevant management;
d. implement appropriate correction and corrective actions without undue delay;
e. retain records as evidence of the implementation of the audit programme and the audit results.

GL-7 "Audits" provides general guidance on performing audits. This procedure includes:

a. Guidance on planning, implementing and maintaining the audit program. Additionally this procedure establishes the frequency of audits, methods, and responsibilities for audits based on the audit performed and the needs of the Division.
b. Guidance on establishing an audit scope as part of the audit plan.
   - Guidance that internal audits will include a component of direct observation of a sample of accredited services for each discipline.
c. Guidance on reporting of results to the Director.
d. Guidance on follow up on identified issues through Quality Action Requests.
e. Guidance on retaining the audit documentation.

8.9 Management reviews

8.9.1 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this document.

GL-8 "Management System" establishes that a review of the management system will be performed annually to ensure its continued suitability; including adherence to ANAB AR3125, ISO/IEC 17025:2005 standards and FBI DNA QAS.

8.9.1.1 Management reviews shall be conducted at least annually, as well as prior to the initial accreditation assessment.

GL-8 "Management System" establishes that a review of the management system will be performed annually and prior to initial accreditation to new standards.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:
a. changes in internal and external issues that are relevant to the laboratory;
b. fulfilment objectives;
c. suitability of policies and procedures;
d. status of actions from previous management reviews;
e. outcome of recent internal audits;
f. corrective actions;

g. assessments by external bodies;
h. changes in the volume and type of the work or in the range of laboratory activities;
i. customer and personnel feedback;
j. complaints;
k. effectiveness of any implemented improvements;
l. adequacy of resources;
m. results of risk identification;
n. outcomes of the assurance of the validity of results; and
o. other relevant factors, such as monitoring activities and training.

GL-8 "Management System" gives guidance on information to be covered as part of the annual review including:

a. Changes internal or external that are relevant to the DSS.
b. Determination of fulfillment of DSS objectives.
c. Suitability of DSS policies and procedures.
d. Status of previous management system reviews.
e. Status of the internal audit, outcome and status of any identified issues.
f. Review of corrective actions.
g. Review of any external assessments.
h. Changes in laboratory activities (case volume, type of requests).
i. Review of annual surveys and any customer/employee feedback.
j. Review of internal and external complaints received.
k. Review of implemented improvements for effectiveness.
l. Adequacy of resources.
m. Review of any risks identified; results of follow through.
n. Review of activities that monitor the validity of results including results of proficiency testing, and intra-laboratory testing.
o. Other relevant factors as determined by the Director.

8.9.3 The outputs from the management review shall record all decisions and actions related to at least;
a. the effectiveness for the management system and its processes;
b. improvement of the laboratory activities related to the fulfillment of the requirements of this document;
c. provision of required resources;
d. any need for change.

GL-8 "Management System" gives guidance on records maintenance for the annual review including:

a. Determination of the effectiveness of the Management System and its processes.
b. Identification of need for improvement to assure adherence to the ANAB Accreditation Requirements, ISO/IEC 17025:2005 standards, ATF MROS and FBI DNA QAS.

c. Provisions for identified required resources.
d. Identification of any changes required.