Department of Emergency Services and Public Protection
Division of Scientific Services

# QUALITY ASSURANCE MANUAL

Index:

## 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.

Link to the scope of accreditation for the Division:

https://search.anab.org/public/organization_files/State-of-Connecticut-Department-of-Emergency-Services-and-Public-Protection-Division-of-Scientific-Services-Cert-and-Scope-File-02-04-2022_1643994972.pdf

.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 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:

a) International Standard ISO/IEC 17025:2017. This document will be referred to using ([1]).

b) ANAB AR3125 Forensic Science Testing and Calibration Laboratories Accreditation Requirements. This document will be referred to using ([2])

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

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

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

f) 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 and ANAB AR3125 terms and definitions.

## 4 General Requirements

4.1 Impartiality

4.1.1 ([1] 4.1.1)

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

4.1.2 ([1] 4.1.2)

DSS Management is committed to impartiality.

4.1.3 ([1] 4.1.3)

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." ([1] 4.1.3)

4.1.3.1 ([2] 4.1.3.1)

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 the Quality Management Software (QMS).

c) GL-5 "Ethics" provides guidance on follow-up to reported ethics issues as appropriate.

4.1.4 ([1] 4.1.4)

While the Division of Scientific Services (DSS) is a part of a larger organization active in Law Enforcement and related activities, the relationship of the Division to the parent organization is designed to preclude any undue involvement or influence of Departmental Personnel. The DSS Director reports directly to the Commissioner of the Department of Emergency Services and Public Protection. Other Division Managers and the Division's scientific staff have 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 the QMS. A record of the review will be maintained for 10 years, as detailed in GL-5 "Ethics."

4.1.5 ([1] 4.1.5)

The Laboratory will identify risks to its impartiality on an ongoing 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 Division Managers and the Division's scientific staff have 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 ([1] 4.2.1)

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).

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.

All employees of the DSS will adhere to the 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 ([1] 4.2.2)

Generally, the DSS only releases case information (i.e. reports) to the submitting agency and the related GA (Geographical Area) Court. If an agency, requests a copy of another agencies case report the individual needs to obtain permission from the submitting agency. The contract between the DSS and submitting agencies allows for the sharing of case information as intelligence leads with law enforcement agencies. If required to release case-specific information on a large scale for other reasons the Director or their designee will inform the related customers.

The Toxicology Unit will disseminate case reports related to DUIs per General Statutes 248, 14-227a section b), subsection 2).

4.2.3 ([1] 4.2.3)

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

4.2.4 ([1] 4.2.4)

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.

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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 ([1] 5.1)

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 ([1] 5.1)

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 Divisions Organization Chart.

5.2.1 ([2] 5.2.1)

The defined duties of the Director of the DSS can be found in the state job description 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, Scientific Services Administrative Manager (SSAM), Laboratory Information Systems Manager (LISM), 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 the 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 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, ISO/IEC 17025:2017 and the FBI DNA Quality Assurance Standards. 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 monitoring 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. In the absence of an individual with this title, this role may be fulfilled by the DNA technical lead.

Scientific Services Administrative Manager (SSAM):
The Scientific Services Administrative Manager reports directly to the Director. The SSAM 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 SSAM is responsible for the administration of a comprehensive program to manage the evidence of criminal and civil cases at the Division. The SSAM additionally has the responsibility of the oversight of grants, fiscal and security of the laboratory.

Laboratory Information System Manager (LISM):
The Laboratory Information System Manager works closely with the Director, SSAM and other Managers. They will oversee the laboratory information system and develop and implement comprehensive tools to allow for data analysis to be used for objective decision-making and strategic planning.

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/monitoring 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. Support Sections are under the direction of other titled Managers.
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 Assistant Director) and, in general, are led by an FSE3 or FSE2. Support Units are under the direction of Managers, and are led by FSE2, FSE1 or other as needed.

5.3 ([1] 5.3)

DSS covers a range of laboratory activities that are under the laboratory's scope of accreditation. Refer to the current scope of accreditation and accreditation certificate in the QMS in the folder 'Scope of Accreditation – ANAB' 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 (CHEM)
Fire Debris
Gun Shot Residue

**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)



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 ([1] 5.4)

The Management System is designed to ensure that laboratory activities shall be carried out to meet the requirements of ANAB, the laboratory's customers, the FBI QAS for DNA and the ATF MROS for Firearms. Additionally the DSS will meet the needs of the State of Connecticut as defined by state regulations/statutes.

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 in 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 Division may allow periodic telework based on the needs of the Division. In these events the DESPP IT Unit will be consulted to ensure the individual(s) have the current technologies to access needed materials and perform secure remote work. (Refer to GL-23)

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 DSS 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. The Computer Crimes Unit assists in the retrieval of data and/or the telematics system from vehicles. The data/system is turned directly to the law enforcement agency they are assisting on the scene.

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 ([2] 5.4.1)

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

The DSS website states the current ANAB accreditation status in a manner consistent with the PR 1018 guidance document. The website provides a link to the current scope of

accreditation. The ANAB symbol is not used within the website other than as related to the issued scope of accreditation. Link to web site: https://portal.ct.gov/DESPP/Division-of-Scientific-Services/Home

5.4.2 ([2] 5.4.2)

Any event or nonconformity that can substantially affect the integrity of the DSS will be disclosed to ANAB within 30 days of the issue. If the event is identified more than 30 days after the event occurred the information will immediately be disclosed to ANAB.

5.5 ([1] 5.5)

The DSS laboratory shall:

a) The Division of Scientific Services is an entity of the Connecticut Department of Emergency Services and Public Protection. The DSS is one of six division within the DESPP with the DSS Director reporting directly to the Commissioner of the DESPP. 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 the QMS.

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 the QMS, 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-23). 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 (GL) 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.

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.

Documents used within Division Units Include:

a) 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.

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

c) 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.

5.6 ([1] 5.6)

The individual Deputy Directors or Assistant Directors have the authority to oversee the technical operations of the Units they direct; this is done in concert with the Director. The Deputy Directors or Assistant 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 Section Managers, 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 (Quality Action Requests) and monitoring/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" and GL-14.5 "Competency Testing General Guidance".
- A system for case reviews. See GL-18 "Case Reviews".
- A system for procedural development, modification and validation. See GL-22 "Policy on Validations and Performance Checks" and 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 ([1] 5.7)

Laboratory Management shall ensure that:

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, the QMS 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 appropriate Managers, 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 the QMS.

## 6 Resource Requirements

6.1 ([1] 6.1)

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, Scientific Services Administrative Manager, Laboratory Information System 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 ([1] 6.2.1)

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, Section and Unit SOPs when performing laboratory activities.

6.2.2 ([1] 6.2.2)

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 documents 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. Authorization documentation needs to be detailed enough to ensure that an analyst is only authorized in those methods/activities 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.

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.

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| --- | --- |
| Controlled Substance | CS-15 |
| Toxicology | TX-44 |
| Chemistry | CHEM-07 |
| DNA | DNA-1 & 7 |
| Forensic Biology | FB-26 |
| Latent Prints | LP-16 |
| Firearms | FA -01 |
| Imprints | IM-14 |
| Computer Crimes and Electronic Evidence | CC-25 |

| | |
| --- | --- |
| Multimedia | MMIE-26 |

6.2.2.1 ([2] 6.2.2.1)

All Division of Scientific Services technical personnel possess a baccalaureate or advanced degree or meet other educational requirements specified in their job description. GL-15 "Professional Development." Provides guidance on maintaining copies of educational materials and CVs within the QMS. (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 ([2] 6.2.2.2)

All DSS analytical personnel are required to receive appropriate training and demonstrate competency, as per individual Section/Unit SOPs prior to performing casework. The combination of GL-14 "General Training" and Section/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 ([1] 6.2.3)

Each Unit Manager 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 Section/Unit SOPs as detailed below:

| | |
| --- | --- |
| Controlled Substance | CS-15 |
| Toxicology | TX-44 |
| Chemistry | CHEM-07 |
| DNA | DNA-7 |
| Forensic Biology | FB-26 |
| Computer Crimes and Electronic Evidence | CC-25 |
| Latent Prints | LP-16 |

| | |
| --- | --- |
| Multimedia | MMIE-26 |
| Firearms | FA -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 as described in the appropriate training manual.

6.2.3.1 ([2] 6.2.3.1)

All analytical personnel of the DSS are required to receive appropriate training and demonstrate competency, as per individual Section/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).

Section/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 assesses 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 practical competency test(s) in the specified component or parameter of testing and/or discipline. Additionally written or oral assessments may be used. Successful completion of the practical competency test is defined as obtaining the intended results. Successful completion of a written examination is 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 ([2] 6.2.3.2)

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 a 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 ([1] 6.2.4)

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 ([1] 6.2.5)

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

a) Section/Unit specific training procedures detail requirements for demonstration of competency; including requirements for the documentation and maintenance 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 Section/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-14 "General Training" specifies that authorization of personnel is granted by the Director. Generally, this is based on the recommendation by the Deputy or Assistant Director and TL in DNA.

*f)* GL-16 "Proficiency Testing" outlines the method of monitoring analyst competency through the use of periodic proficiency tests, internal tests and observation-based testing. Additionally evidentiary reports are technically and administratively reviewed refer to GL-18 "Case Reviews" and testimony is periodically reviewed refer to GL-17 "Court Monitoring" as part of ongoing competency monitoring.

6.2.6 ([1] 6.2.6)

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

6.3 Facilities and environmental conditions

6.3.1 ([1] 6.3.1)

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 ([1] 6.3.2)
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 ([1]6.3.3)

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 ([1]6.3.4)

Measures to control the DSS facility are outlined in GL-3 "Security".

a) 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 the separation of the workspaces. GL-13 "General Evidence Handling" provides guidance on the performance of work on cases with multiple crime scenes.

6.3.4.1 ([2]6.3.4.1)

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 ([1]6.3.5)

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.

6.4 Equipment

6.4.1 ([1]6.4.1)

Division Units are equipped with instrumentation and test equipment required by each Unit's SOPs. Procedural SOPs require and specify instrumental operational parameters. Instrument use, regardless of the operational ownership or control of the instrument, must be in accordance with the laboratory SOP.

6.4.2 ([1]6.4.2)

Laboratory equipment used for the examination of evidence that is housed within the DSS facility's operational areas may only be used by persons authorized by the Director through the Division's established approval process. Appropriate vendors are only authorized to perform service-related operations which do not directly involve evidence. Equipment may not be used for testing purposes by non-DSS entities regardless of their experience. Such restrictions, allow the DSS laboratory to maintain permanent control and ensure proper working conditions of such testing equipment.

Equipment returned to the manufacturer for repair, or that is out of the control of the Division such as for validation services or maintenance performed by a vendor in-house, may require a performance check or calibration (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.

Note: Annual calibration of equipment such as for pipettes, centrifuges or balances when performed on-site does not require a performance check unless the Unit deems this necessary based on how the device is used.

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. In the DNA Unit, the DNA Technical Leader or their designee will initial the documents to demonstrate approval.

6.4.3 ([1]6.4.3)

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, 7 & 8 |
| Toxicology | TX- 42, 43 |
| Fire Debris | CHEM-03 |
| Gun Shot Residue | CHEM-04 |
| DNA | DNA-1 & 9 |
| Forensic Biology | FB-23 |
| Latent Prints | LP-09-12, 25 & 29 |
| Firearms | FA-22, 33 |
| Imprints | IM-05, 11 |
| 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-11 |
| Toxicology | TX-43 |
| DNA | DNA-8 |
| Forensic Biology | FB-8 to 18 & 21 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| 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-11 |
| Toxicology | TX-43 |
| DNA | DNA-8 |
| Forensic Biology | FB-8 to 18, 21 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Latent Prints | LP-3 & 4 |

| | |
| --- | --- |
| Firearms | FA-26 |

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

| | |
| --- | --- |
| Controlled Substance | CS-11 |
| Toxicology | TX-43 |
| DNA | DNA-8 &1 |
| Forensic Biology | FB-8 to 18 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Firearms | FA-26 |
| Latent Prints | LP-3, 4 & 17 |
| Imprints | IM-8 |

6.4.3.1 ([2]6.4.3.1)

The DSS specifies procedures for labeling reagents prepared in the laboratory, in GL-2 "Safety Manual". The records will be retained 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, 11 |
| Toxicology | TX-43 |
| DNA | DNA-8 |
| Forensic Biology | FB-08-10, 12-14, 16, 18, & 21 |
| Latent Prints | LP-3 |
| Firearms | FA-26 |

6.4.3.2 ([2]6.4.3.2)

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 |
| 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 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 ([1]6.4.4)

All equipment shall be checked/calibrated to verify it meets needed specifications before being put into service. This includes new equipment and equipment being returned to service. Refer to GL-21 "General Laboratory Equipment" for calibration/checks of weights and balances. 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, 7, 8 &10 |
| Toxicology | TX- 42 & 43 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| DNA | DNA 1 & 9 |
| Forensic Biology | FB-23 |
| Latent Prints | LP-9-12, 25 & 33 |
| Firearms | FA-22 |
| Imprints | IM-05, 11 |
| Computer Crimes and Electronic Evidence | CC-19-21 & 28 |
| Multimedia | MMIE-14 |

6.4.5 ([1]6.4.5)

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-20 "Review of Requests and Tenders".

Where appropriate DSS Unit SOPs specify that factors that may affect measurement uncertainty are considered in developing testing methods, refer to Unit procedures.

6.4.6 ([1]6.4.5)

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, 7 & 8 |
| Toxicology | TX-43 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| DNA | DNA-1 & 9 |
| Forensic Biology | FB-23 |
| Latent Prints | LP-12 |
| Firearms | FA-22, 33 & 35 |
| Imprints | IM-05, 11 |
| Computer Crimes and Electronic Evidence | CC-19-21 |
| Multimedia | MMIE-14 |

6.4.7 ([1]6.4.7)

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, 7 & 8 |
| Toxicology | TX- 43 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| DNA | DNA-1 & 9 |
| Forensic Biology | FB-23 |
| Latent Prints | LP-12 |
| Firearms | FA-22 |
| Imprints | IM-11 |
| 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 ([2]6.4.7.1)

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

a) Each Unit maintains an equipment list with a reference to calibration requirements. 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 ([1]6.4.8)

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. Note for weights the label will be on the proximal container.

6.4.9 ([1]6.4.9)

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 ([1]6.4.10)

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.

Quality control 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, 11 |
| Toxicology | TX-43 |
| DNA | DNA-8 &1 |
| Forensic Biology | FB-8 to 18 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Firearms | FA-26, 33, 35 & 39 |
| Latent Prints | LP-3 & 4 |
| Imprints | IM-8 |

6.4.11 ([1]6.4.11)

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 ([1]6.4.12)

The DSS is a limited access facility. Equipment is maintained in laboratory spaces with access limited through the use of proximity card reader locks. GL-3 "Security" provides guidance on laboratory accessibility.

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 ([1]6.4.13)

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, 7, 8 &10 |
| Toxicology | TX-43 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| DNA | DNA 1 & 9 |
| Forensic Biology | FB-23 |
| Latent Prints | LP-9-12, 25 & 29 |
| Firearms | FA-22 |
| Imprints | IM-11 |
| Computer Crimes and Electronic Evidence | CC-19-21, 30 &36 |
| 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, 11 |
| Toxicology | TX-43 |
| DNA | DNA-8 |
| Forensic Biology | FB-8 to 18 & 21 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Latent Prints | LP-3 & 4 |

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, 11 |
| Toxicology | TX-43 |
| DNA | DNA-8 &1 |
| Forensic Biology | FB-8 to 18, 21 & 22 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| 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 QMS workflow, “Equipment List” may be used to aid in equipment lists and maintenance reminders.

6.5 Metrological traceability

6.5.1 ([1]6.5.1)

Where applicable the Division maintains metrological traceability of measurement results via documented unbroken chain of calibrations. This is done by linking results to appropriate reference materials. Examples include barrel lengths in Firearms linked to calibrated rulers, weights in Controlled Substances linked to calibrated balances and drug concentrations being linked to certified reference materials in Toxicology.

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.

As applicable, Units shall utilize only measurement standards for calibrations or comparisons which can be linked to relevant primary standards of the SI units of measurement.

If the quantitative value of a reference material is changed, then the calibration of the equipment used to alter the reference material impacts the traceability chain; the equipment will be tracked.

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 ([2]6.5.1.1)

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 ([2]6.5.1.2)

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

6.5.1.3 ([2]6.5.1.3)

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

6.5.2 ([1]6.5.2)

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 the traceability of the reference material and maintenance of related records.

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 ([1]6.5.3)

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 Externally provided products and services

6.6.1 ([1]6.6.1)

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 the use of sub-contracting services for case analysis is provided in GL-20 "Review of Requests and Tenders".

a) Procedures to ensure the 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, 3 & 11 |
| Toxicology | TX-43 |
| DNA | DNA-8 |
| Forensic Biology | FB-8 to 18 & 21 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Latent Prints | LP-3 & 4 |
| Firearms | FA-26 |

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, 3 &11 |
| Toxicology | TX-43 |
| DNA | DNA-8 |
| Forensic Biology | FB-8 to 18 & 21 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Imprints | IM-2 |

b) When case work is to be outsourced the Section Manager 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, ANAB, ABFT and A2LA or other laboratories that can demonstrate ISO/IEC 17025 accreditation.

For the Firearms Unit the National NIBIN Correlation and Training Center has been assessed and is considered an acceptable agency to outsource casework.

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 ([1]6.6.2)

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 the QMS. 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.

1. 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, 3 & 11 |
| Toxicology | TX-43 |
| DNA | DNA-8 |
| Forensic Biology | FB-8 to 18 & 21 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Latent Prints | LP-3 & 4 |
| Firearms | FA-26 |
| 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).

2. 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 Managers (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 casework.

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 Manager 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:

1. 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.

2. 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 the QMS. 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 Manager to determine the correct path to rectify the issue.

6.6.3 ([1]6.6.3)

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 ([1]7.1.1)

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 subcontracted 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 subcontracted out is based on individual case needs; 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.

h) Simplified reports will be used where the dates of laboratory activities will be available upon request but not on the 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 ([1]7.1.2)

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 ([1]7.1.3)

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

7.1.4 ([1]7.1.4)

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 Manager will determine if the deviation request is appropriate.

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

7.1.5 ([1]7.1.5)

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 ([1]7.1.6)

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, the 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 to warrant contacting the customer.

7.1.7 ([1]7.1.7)

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"). Refer to "GL-4 Security" for guidance on customer's request to witness/observe laboratory activities related to a specific case.

7.1.8 ([1]7.1.8)

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, the 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 ([1]7.1.9)

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 & LP-39 |

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 ([1]7.2.1.1)

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.

7.2.1.1.1 ([2]7.2.1.1.1)

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

7.2.1.1.2 ([2]7.2.1.1.2)

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

7.2.1.1.3 ([2]7.2.1.1.3)

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

7.2.1.2 ([1]7.2.1.2)

GL-19 “Document Control” specifies that:

. All SOPs are available through the QMS.
. 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.
. Appropriate, authorized editions of essential Division documents are available to analysts and other appropriate personnel, at their workstations.

7.2.1.3 ([1]7.2.1.3)

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 the QMS will print with a footer stating that they are not controlled documents. The QMS document tree will be set to allow only the Quality Section, members of Management and those assigned to Case 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 ([1]7.2.1.4)

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 Unit Manager and/or Director for use in the specific Unit.

7.2.1.5 ([1]7.2.1.5)

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 Unit Managers and/or Director for use in the specific Unit. In the DNA Unit, the DNA TL will approve validations.

As part of the validation process a 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:

| | |
| --- | --- |
| Controlled Substance | CS-10 |
| DNA | DNA-1 |
| Forensic Biology | FB-25 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Latent Prints | LP-12 & 17 |
| Imprints | IM-15 |

| | |
| --- | --- |
| Firearms | FA-37 |
| Computer Crimes and Electronic Evidence | CC-20, 28 & 36 |
| 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 ([1]7.2.1.6)

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 ([1]7.2.1.7)

Administrative or Technical deviations will be entered in the QMS 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), Unit Manager(s), Quality Assurance Manager, and to the Director for approval. All reviews and approvals will be documented in the QMS. If necessary, external files (i.e. memos) can be uploaded to the workflow. Any QMS 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 the appropriate Managers and the Quality Assurance Manager.

7.2.2.1 ([1]7.2.2.1)

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 ([2]7.2.2.1.1)

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

a) Use of a validation plan.

b) Data interpretation.

c) Data/acceptance criteria required for reporting results including where appropriate, opinions and interpretations.

d) Identification of method limitations.

Units may have additional SOP guidance detailing the method development/validation and documentation process, as noted below:

| | |
| --- | --- |
| Controlled Substance | CS-10 |
| DNA | DNA-1 |
| Forensic Biology | FB-25 |
| Chemistry | CHEM-01 |
| Latent Prints | LP-12 & 17 |
| Imprints | IM-15 |
| Firearms | FA-37 |
| Computer Crimes and Electronic Evidence | CC-20, 28 & 36 |
| Multimedia | MM-29 |

7.2.2.2 ([1]7.2.2.2)

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 ([2]7.2.2.2.1)

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 ([1]7.2.2.2)

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 ([1]7.2.2.4)

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 ([1]7.3.1)

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 the QMS.

7.3.2 ([1]7.3.2 & [2]7.3.2.b).1)

Individual Unit SOPs contain guidance on sampling (sample selection):

a) Selection of samples.
b) General guidance on the sampling plan as applicable.
   Units within the DSS use sample selection. Results of testing apply only to the items tested.
c) Sample preparation for subsequent testing.

7.3.3 ([1]7.3.3)

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 the 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 ([1]7.4.1)

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 ([2]7.4.1.1)

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.
- Reference materials (e.g. buccal swabs) shall be collected from all laboratory personnel and certain visitors. These are added to an internal DNA reference database. See GL 3 'Security' for guidance on buccal swabs for visitors.
- These provisions shall include the collection of reference materials (e.g. buccal swabs) from all 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 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 LIMS-plus 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 Unit Manager(s) 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 & LP-39 |

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 ([1]7.4.2)

GL-4 “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 that 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 ([2]7.4.2.1)

GL-14 “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 ([1]7.4.3)

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 the 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.

| | |
| --- | --- |
| Controlled Substance | CS-1 |
| Toxicology | TX-5 |
| DNA | DNA-1 & 23 |
| Forensic Biology | FB-05 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Latent Prints | LP-1, 2, 24 & 26 |
| Firearms | FA-06 |
| Imprints | IM-3 &13 |
| Computer Crimes and Electronic Evidence | CC-10 |
| Multimedia | MMIE-27 |

7.4.4 ([1]7.4.4)

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 ([1]7.5.1)

GL-11 "Control of Records" specifies that:

- All significant records generated during 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 ([2]7.5.1.1)

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

| | |
| --- | --- |
| Controlled Substance | CS-1 |
| Toxicology | TX-5 |
| DNA | DNA-23 |
| Forensic Biology | FB-05 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| Latent Prints | LP-1 &18 |
| Firearms | FA-6 |
| Imprints | IM-13 |
| Computer Crimes and Electronic Evidence | CC-10 |
| Multimedia | MMIE-3 |

7.5.1.2 ([2]7.5.1.2)

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 retained either as a list available within the Section or in individual Unit SOPs, as detailed below:

| | |
| --- | --- |
| Toxicology | TX-19 |
| Controlled Substances | CS-1 |
| Fire Debris | CHEM-03 |

| | |
|---|---|
| GSR | CHEM-02 |
| DNA | DNA -1 |
| Forensic Biology | FB-04 |
| Latent Prints | LP-5 |
| Firearms | FA-7 |
| Computer Crimes and Electronic Evidence | CC-26 |
| Multimedia | MMIE-25 |

7.5.1.3 ([2]7.5.1.3)

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 ([2]7.5.1.4)

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 ([2]7.5.1.5)

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 ([2]7.5.1.6)

The Division is not a calibration laboratory.

7.5.2 ([1]7.5.2)

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 handwritten 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 ([1]7.6.1)

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.

7.6.1.1 ([2]7.6.1.1)

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 the schedule in which the measurement uncertainty will be re-calculated or reviewed. This will be no less than every 5 years or when either new equipment is used for the task or new employees are authorized in the related tasks.

See Unit procedures addressing uncertainty.

7.6.2 ([1]7.6.2)

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

7.6.3 ([1]7.6.3)

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

7.6.3.1 ([2]7.6.3.1)

The CT DSS requires evaluation of the measurement of uncertainty when reporting quantitative results. This includes weights of drugs in Controlled Substances, volatiles in blood or urine in Toxicology and barrel length in Firearms. Other areas may be included as needed.

7.6.4 ([2]7.6.4)

GL-11 "Control of Records" specifics that, documentation related to the calculation of the uncertainty of measurement will be retained 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.

7.7 Ensuring the validity of results

7.7.1 ([1]7.7.7 & [2] 7.7.1 g).1.& [2] 7.7.1 l).1)

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, internal test or observation-based test.

a) Specific quality control procedures are maintained in each Unit for monitoring the validity of tests and calibration procedures. Methods define the required control materials to be used. This may include the 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, 7 & 8 |
| Toxicology | TX-43 |
| Fire Debris | CHEM-03 |
| GSR | CHEM-02 |
| DNA | DNA 1 & 9 |
| Forensic Biology | FB-23 |
| Latent Prints | LP-09-12, 25 & 28 |
| Firearms | FA-22, 33 & 35 |
| Imprints | IM-11 |
| Computer Crimes and Electronic Evidence | CC-19-21 |
| Multimedia | MMIE-14 |

d) Unit SOPs provide guidance on monitoring the validity of tests and calibration 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.

When a unit uses verification, the verification shall:

a. Be performed by an 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.

   The DSS differentiates technical Review/Reviewers and 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.

   Where 100% technical review is not performed the Unit Manager(s) and Director will determine the number of cases per year that require technical review to ensure a representative number of cases are reviewed. The Unit Manger(s) will be responsible to ensure the appropriate number of cases are reviewed.

When reporting for canceled requests, where items may have been sampled but no analytical testing was performed, units may only require an administrative review.

4. Define that court testimony will minimally be reviewed annually, when practicable, 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 ([1]7.7.2)

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 ([2]7.7.2.1)

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.

7.7.3 ([1]7.7.3)

Proficiency tests, internal tests, and observation-based tests are used to monitor analyst and unit performance. Data from this monitoring may be used to make improvements to DSS procedures. GL-16 “Proficiency Testing” gives guidance on monitoring test results and the actions to take when reported results are not consistent with those expected by the test provider/preparer to prevent incorrect results from being reported.

7.7.4 ([2]7.7.4)

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 a 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 Manager(s) or their designee to plan the event.

7.7.5 ([2]7.7.5)

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

a) Ensure that the 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) Not applicable, the DSS is not a calibration laboratory.

f) Require notification to ANAB when results obtained for a monitoring activity are not as expected. Notification will be within 30 days of the results being known to the DSS.

7.7.6 ([2]7.7.6)

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 a sampling of the various components or parameters of testing in which they perform analysis, within 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 ([2]7.7.7)

The DSS will:

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

c) The DSS will authorize the test provider to release test results to ANAB.

d) 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 following the current process for ANAB.

7.7.8 ([2]7.7.8)

GL-16 "Proficiency Testing" specifies that the Quality Section shall retain 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 ([1]7.8.1.1)

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 ([2]7.8.1.1.1)

GL-18 “Case Reviews” specifies that analysts shall review their own work/technical records prior to submitting it for technical review. The review will be documented by updating the milestone in LIMS-plus to draft complete.

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 ([1]7.8.1.2)

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 the methodology employed.

Simplified reporting may be used in the case of specific agreements 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.

7.8.1.2.1 ([2]7.8.1.1.2.1)

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 ([2]7.8.1.2.2)

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 ([2]7.8.1.2.3)

The DSS does not issue calibration reports.

7.8.1.3 ([1]7.8.1.3)

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([2]7.8.1.3.1)

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 ([1]7.8.2.1)

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 only apply to outsourced work.

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 the 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 (this is generally not applicable).

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 ([1]7.8.2.2)

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 ([1]7.8.3.1 & [2]7.8.3.1.c.1 )

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:

a. It is relevant to the validity or application of test results

b. A customer's instruction so requires, or

c. The measurement uncertainty affects conformity to a specification limit

d. 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; see exception below.

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 ([2]7.8.3.1.1)

State Statute 14-227a requires truncating blood alcohol results to 2 decimal points. Due to the requirements of this statute ethanol will be reported in 2 ways. The primary reported value will be to 2 decimal places to meet the state statute. Additionally the value will be reported to 3 decimal places to appropriately apply the uncertainty of the method.

The justification for reporting an ethanol result to three decimal places is to allow for an accurate representation of the uncertainty value. Applying the method uncertainty to a 2 decimal place value would cause an uncertainty of 0.00g% to be reported for many cases which is not accurate. The other option would be to falsely round the uncertainty of up to 0.01g% which would not be scientifically valid.

Refer to Unit specific procedures.

7.8.3.2 ([1]7.8.3.2)

Currently there are no examples of sampling activities that effect the interpretation of test results and therefor sampling is not addressed on DSS reports.

7.8.4 ([1]7.8.4.1, [1]7.8.4.2, [1]7.8.4.3, [1]7.8.4.4 & [2]7.8.4.1.1)

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

7.8.5 ([1]7.8.5)

When sampling activities are necessary for the interpretation of results Unit procedures provide guidance on reporting the information related to sampling/sample selection. Based on the type of sampling performed at the DSS, records of these activities are included as part of the case record and are not required on the case report. These include, when appropriate:

a) Date of sampling/sample selection

b) Unique identification of the item/material sampled

c) Location of sampling including diagrams, sketches or photographs were needed

d) A reference to the sampling plan and sample method

d)1 Not Applicable –statistical sampling is not used.

e) Details of environmental conditions that could affect the interpretation of the results.

f) Information required to evaluate the measurement uncertainty for subsequent testing; this is not applicable for the DSS.

7.8.6.1 ([1]7.8.6.1)

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 ([1]7.8.6.2)

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 ([1]7.8.7.1)

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 ([1]7.8.7.2)

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 ([1]7.8.7.3)

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 LIMS-plus or similar method.

7.8.8 Amended Reports

7.8.8.1 ([1]7.8.8.1)

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

The initial original report and the amended report referencing the original report will be maintained in the case file. A cover letter may be generated to aid in explaining the amended report. The Unit Manager 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 ([1]7.8.8.2)

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

7.8.8.3 ([1]7.8.8.3)

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

7.9 Complaints

7.9.1 ([1]7.9.1)

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 ([1]7.9.2)

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 Manager or other appointed individual(s) to address the complaint.

7.9.3 ([1]7.9.3)

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 ([1]7.9.4)

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 others as designated by the Director) will be responsible to validate the complaint.

7.9.5 ([1]7.9.5)

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 ([1]7.9.6)

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 ([1]7.9.7)

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 ([1]7.10.1)

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 Unit Manager (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 Unit Manager (or their designee) to assess the significance of the non-conformity. The Unit Manager (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, Unit Manager 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 Unit Manager (the DNA TL in the DNA Unit) and Quality Section.

7.10.2 ([1]7.10.2)

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

When non-conformity events are singular events (non-systemic) an incident report or corrective action workflow may be initiated through the QMS. The type of QAR will be dependent on the nature of the event. All records will be maintained by the QMS 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 ([1]7.10.3)

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 the QMS.

7.11 Control of data and information management

7.11.1 ([1]7.11.1)

The DSS uses a Laboratory Information Management System (LIMS-plus) and Quality Management Software for document management (QMS) to assure all employees have access to needed procedures and case information needed to perform normal laboratory activities.

Note: The use of the name Qualtrax in DSS documents refers to the document/quality management software in use regardless of the brand name. The name may be replaced over time in DSS procedures with a general term of QMS or Quality Management Software. Qualtrax, Quality Management Software or QMS are equivalent.

7.11.2 ([1]7.11.2)

GL-4 "LIMS' provides guidance on LIMS-plus. When updates (to newer versions) to LIMS-plus 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 Unit Manager.

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 methods; 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 ([2]7.11.2.1)

DSS developed software that is to be used for case work will be validated and the records of the validation will be maintained. GL-22 "Policy on Validation and Performance Checks" provides guidance on validation of software and retention of related records.

7.11.3 ([1]7.11.3)

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 ([1]7.11.4)

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 ([1]7.11.5)

The LIMS user guide is available as part of the 'Help' function embedded in the LIMS-plus software.

7.11.6 ([1] 7.11.6)

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

7.11.6.1 ([2] 7.11.6.1)

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 ([1]8.1.1)

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

8.1.2 ([1]8.1.2)

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 the QMS, 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 the QMS. 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 other Managers, as detailed in GL-8 "Management System".

8.2 Management System Documentation

8.2.1 ([1]8.2.1)

The Division of Scientific Services' Management System is organized and communicated through the Standard Operating Procedures, both General and Unit specific. These SOPs include a Quality Manual with administrative personnel-related directives, general SOPs that are applicable to all Units, Unit 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 the QMS, 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, the QMS 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 Managers, 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 the QMS.

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 the QMS.

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 Unit Managers 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 and approved by the appropriate Managers and finally the Director, (or designee in cases of emergencies), prior to the change being published through the QMS. The Unit Managers and Section Supervisor or Lead will ensure that

the analysts performing the procedure implement the changes. Changes to SOPs will be communicated through the QMS.

8.2.1.1 ([2]8.2.1.1)

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

8.2.2 ([1]8.2.2)

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 ([1]8.2.3)

The Management System incorporates a yearly review, the results of which are considered and evaluated by the Director and other Managers, 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 Managers 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 ([1]8.2.4)

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-23).

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 than 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.

8.2.5 ([1]8.2.5)

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 the QMS.

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 ([1]8.3.1)

Control of original Management System documents will be through the Quality Section, as detailed in GL-19 “Document Control”. All Management System documents applicable to all Sections will be maintained by the Quality Section through the QMS. No paper-controlled copies will be maintained.

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

8.3.2 ([1]8.3.2)
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 and Managers for adequacy/appropriateness prior to review and approval by the Director. SOPs are published after the Director documents approval in the QMS.

Unit procedures are reviewed by personnel per the needs of the Unit prior to being forwarded for review and approval by the Unit Manager(s) and Director. SOPs are published after the Director documents approval in the QMS.

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) The QMS 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 the QMS.

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 the QMS. The QMS 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 alphanumeric 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 the QMS will print with a footer stating that they are not controlled documents. The QMS 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 ([1]8.4.1)

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" for:

- Case documentation including technical records
- Proficiency testing records (to include internal tests and observation-based tests)
- 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 (FOIAs).

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, such records are 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 or other agency 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 the QMS. This must be approved by the Director prior to providing the

documents. The signed form is maintained electronically with the Quality Section and only after the signed form is received, is the document or software to be released. This is for requests not related to FOIA's or Discoveries.

8.4.2 ([1]8.4.2)

GL-11 "Control of Records" specifies that:

- The DSS Case Number, or other unique case identifier, are on each page of the examination documents in the case record.
- When data from multiple cases is recorded on a single printout (e.g. Toxicology or DNA Batch worksheets), the unique case identifier will be appropriately recorded.
- All administrative documents in the case file contain the DSS Case Number or other unique case identifier. In the event administrative documents are added to a file once the case is completed, the initials of the person placing administrative documents within the file should be on the documents; this individual is also responsible to ensure the case number is on the document(s).
- · All records will be maintained within the DSS facility or within a facility approved per the State Library
- · 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.
- · 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 under the guidance of the State Library.
- · Record disposal is scheduled through the Division Record Management Liaison.



8.5 Actions to address risk and opportunities

8.5.1 ([1]8.5.1)

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 ([2]8.5.1.1)

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

8.5.2 ([1]8.5.2)

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 ([1]8.5.3)

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 ([1]8.6.1)

When improvement opportunities are identified by any Division personnel or process (e.g. management review, audit or other means) a Preventive Action/Incident Report will be initiated, as per GL-9 “Quality Action Requests.”

8.6.2 ([1]8.6.2)

The Division seeks feedback from all customers, including but not limited to State and Local Police Departments, Federal Agencies, Chief State Attorney’s Office, State Public 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 ([1]8.7.1)

The Division initiates a “Quality Action Request” when a 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 the 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 ([1]8.7.2)

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 ([1]8.7.3)

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 ([1]8.8.1) ([2]8.8.1. a).1)

The DSS performs annual audits including audits to its own Management System, laboratory activities, and adherence to appropriate accreditation standards; ISO 17025:2017 and the AR 3125). 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 ([2]8.8.1.1)

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 ([1]8.8.2)

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 portion 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 ([1]8.9.1)

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([2]8.9.1.1)

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 ([1]8.9.2)

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 ([1]8.9.3)

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 the 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.