

Houston Forensic Science Center
Quality Manual
Quality Division



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Mission Statement—The mission statement of HFSC is to receive, analyze, and preserve physical and digital evidence while adhering to the highest standards of quality, objectivity, and ethics.

Objectives—HFSC’s objectives support its overall mission. Discipline-specific objectives may be stated in section-specific SOPs. HFSC’s objectives are:

- to provide quality analytical examinations
- to provide quality forensic investigations
- to meet or exceed all standards necessary to maintain accreditation
- to monitor and ensure the timely generation of test or investigation reports
- to enhance the scientific capabilities of HFSC

Quality Policy Statement—HFSC is committed to providing the highest quality service available to the general public, law enforcement agencies, forensic laboratories, and members of the criminal justice community. To meet this goal, HFSC established a quality system to ensure it provides accurate, impartial, and relevant reports to law enforcement and criminal justice organizations.



1. Scope

The Houston Forensic Science Center (HFSC) Quality Manual covers the requirements specified in ISO/IEC 17025:2017, ANAB Forensic Science Testing and Calibration Laboratories Accreditation Requirements for competence, impartiality, and consistent operations, and **ANAB Accreditation Requirements for the Management and Operation of Property and Evidence Control Units**. Staff will follow this manual while conducting tests, creating items that are subject to testing and processing crime scenes. Throughout this document, statements that include the words 'shall', 'must' or 'will' are requirements that must be followed by staff. Statements that include the words 'should', 'may' or 'can' are recommendations rather than requirements.

2. References

HFSC staff will follow the requirements set forth in this manual as well as those in the current version of ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories, ANAB AR 3125 (Accreditation Requirements for Forensic Testing and Calibration (2023)), ANAB AR 3181 (Accreditation Requirements for the Management and Operation of Property and Evidence Control Units (2023)), and the current FBI *Quality Assurance Standards for Forensic DNA Testing Laboratories*. Applicable sections are accredited by and follow the requirements of the Texas Forensic Science Commission (TFSC). HFSC will also meet applicable standards published on the Organization of Scientific Area Committees (OSAC) for Forensic Science Registry. If TFSC requirements conflict with OSAC Registry standards, HFSC will follow the TFSC requirements.

HFSC uses the JCGM 200:2012 *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)* for scientific definitions associated with uncertainty of measurement. A copy of this document can be found at www.bipm.org/en/publications/guides/vim.html and in Qualtrax (HFSC's document control and quality management tracking system, however named).

HFSC uses the ANAB symbol in accordance with ANAB's *Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status* (<https://anab.org>).



3. Terms and Definitions

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

administrative records	Records, including evidence receipts/chains of custody, description of evidence packaging and seals, documentation of case related conversations such as emails and phone calls, court orders, subpoenas, reports, and other pertinent information that do not constitute data or information resulting from testing.
administrative review	Review of case records and/or reports for consistency with HFSC policies and procedures and for editorial correctness.
acceptance criteria	<ol style="list-style-type: none">1. The expected outcome from a competency test or an analytical test.2. The expected outcome from a quality control test using known positive and negative standards and controls.
association	A relationship which is concluded to exist between individuals and/or objects based upon testing.
audit	A systematic, independent, documented process for obtaining records, statements of fact, or other relevant information and an objective assessment to determine the extent to which specified requirements are fulfilled.
blind quality control (BQC or blind QC)	Mock cases created in-house and submitted for analysis to mimic normal cases in order to evaluate the entire quality management system, supplement proficiency tests, and bolster analyst testimony.
calibration	The adjustment of an instrument or piece of equipment to an indicated standard or value to ensure precision and accuracy.
can	Possibility or capability
case records	Administrative records, examination records, and any other applicable technical records, whether electronic or printed, generated, or received by HFSC, pertaining to a case.
certified reference material	Reference material, accompanied by a certificate, with a value certified by a procedure that establishes traceability to an accurate realization of the unit in which the values are expressed, and for which each certified value is accompanied by uncertainty at a stated confidence level.
competency	Documentation that a forensic science practitioner has acquired and demonstrated specialized knowledge, skills, and/or abilities (KSAs) in the standard practices necessary to conduct examinations in a discipline or



	category of testing prior to performing independent casework.
conclusion	A statement on a report that summarizes the interpretations of examination results in disciplines with established identification criteria. The term <i>conclusion</i> also refers to a judgment made or decision reached based on the results of analysis/examination.
continuing education	The mechanism through which forensic science practitioners and non-technical staff members increase or update KSAs, reinforce knowledge, or learn of the latest research, developments, or technology related to his or her profession.
controlled document	<ol style="list-style-type: none">1. A document (printed or electronic) that has undergone a formal review and approval process and which is maintained using methods that track revisions and historical evolution of the document.2. A type of quality management system document that contains instructions or procedures that are to be followed to ensure the quality of a product or service.
controls	Material of established origin used to evaluate the performance of a test or comparison, or a test performed to demonstrate that a test method works correctly and to ensure that data are valid. Positive controls confirm that the procedure (methods, reagents, processes, tests, etc.) will produce the expected result. Negative controls confirm that the procedure does not produce an unintended result.
corrective action	<ol style="list-style-type: none">1. A workflow used to document nonconforming work that requires a root cause analysis and includes actions taken to correct departures from approved policies and procedures in the management system and/or technical operations.2. Actions taken to correct nonconforming work and reduce/prevent a recurrence.
corrective seal	A seal placed on evidence by a staff member when the evidence is not sealed per the definition of a seal set forth in this manual.
crime scene	Scene of an incident prior to establishing whether a crime or other action requiring investigation has taken place or not. The crime scene may include both primary (where the crime occurred and/or where a body is located) and secondary scenes (other related areas, regardless of geographic location).
decision rule	A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified



	requirement.
deviation	A planned departure from a procedure/process that is pre-approved by section management.
discipline	A major area of testing in forensic science.
document	Information in any medium, including, but not limited to, a paper copy, computer disk or tape, audio or videotape, photograph, overhead transparency, or photographic slide.
Document control	The process or system for ensuring that controlled documents, including revisions, are reviewed, approved, and released by the proper issuing authority and then distributed to staff members performing the prescribed activities. Includes subsequent document revision along with tracking and controlled release of new versions.
equipment	Instruments, measuring devices, standards, reference materials, reference data, reagents, consumables, or auxiliary apparatuses used for the collection, sampling, or examination of evidence.
evidence	Items collected, received, or created by HFSC which may be tested or analyzed.
evidence storage location	Any physical evidence storage location with a corresponding Porter Lee /JusticeTrax electronic location.
examination	A process that uses approved technical procedures to characterize, quantitate, or interpret evidence.
examination records	The documentation (whether electronic or hard copy) of procedures followed, tests conducted, and standards and controls used to characterize, quantitate, or interpret evidence. Records could include diagrams, printouts, photographs, and observations and results of testing and close visual inspection. Examination records are technical records.
executive management	President/Chief Executive Officer (CEO), Vice President/Chief Operating Officer (COO), Treasurer/Chief Financial Officer (CFO), HFSC General Counsel, and select HFSC directors.
field sampling	The process by which samples are collected prior to submission to the laboratory for testing based on a sampling plan (typically in an SOP). Field sampling is a non-statistical sampling method.
forensic practitioner	An individual employed in a technical section who applies scientific or technical practices to the recognition, collection, analysis, or interpretation of evidence for criminal and civil law or regulatory issues



	and issues test results, provides reports, or provides interpretations, conclusions, or opinions through testimony with respect to such evidence. Forensic practitioners may also be referred to as <i>forensic analysts, forensic scientists, forensic examiners, supervisors, managers, examiners, and investigators.</i>
impartiality	The quality of not being biased or prejudiced; the presence of fairness and objectivity.
individual characteristic database	A computerized, searchable collection of information generated from samples of known origin from which individual characteristic information originates (e.g., reference biological specimens, known fingerprints, electronic fingerprint records, test fired ammunition).
interlaboratory comparisons	Tests performed on the same or similar items by two or more laboratories in accordance with pre-established criteria. Proficiency tests are a type of interlaboratory comparison (see <i>proficiency test</i>).
internal audit	An annual in-house audit that gauges compliance with ISO/IEC 17025 and/or HFSC's own policies. Internal audits are conducted by HFSC staff members.
internal proficiency test	<ol style="list-style-type: none">1. Internally created test samples used to monitor performance by comparison to known results.2. Externally purchased proficiency tests not submitted to the provider by the due date but used by HFSC to monitor performance by comparison to the external provider's results.
intralaboratory comparisons	Tests performed on the same or similar items within the same laboratory in accordance with pre-established criteria. Some HFSC blind quality control samples may serve as a type of intralaboratory comparison (see <i>blind quality control</i>).
laboratory activity	Laboratory activities include but are not limited to: <ol style="list-style-type: none">a. method development, modification, verification, and validation.b. collecting, testing, processing, sampling, creating test items, giving opinions, interpretations, statements of conformity, and operating equipment used in casework.c. reporting, reviewing and authorizing results.
LIMS	<ol style="list-style-type: none">1. Laboratory Information Management System2. A system used by HFSC for the collection, processing, recording, reporting, storage, or retrieval of data, including paper or electronic systems.
management	HFSC's management team consists of section management (section supervisors, technical leads, and



	section managers) and executive management (President/Chief Executive Officer (CEO), Vice President/Chief Operating Officer (COO), Treasurer/Chief Financial Officer (CFO), HFSC General Counsel, and select HFSC directors).
may	Permission
method	A combination of procedural steps used to perform a specific technical process, or series of related processes, that results in the preservation, collection or creation of evidence, analytic results, opinions and interpretations, or comparison results.
misplaced evidence	Any instance when the physical and electronic chain of custody locations do not correspond.
missing evidence	Item(s) that cannot be found during the inventory or audit of an evidence location and after a search of all areas controlled by HFSC where there was any reasonable likelihood the evidence may be located has been conducted.
must	Requirement
nonconformance	An unapproved deviation from a policy, procedure, or process that may affect the accuracy, reliability, and/or integrity of HFSC's testing or reports. A nonconformance is not the same as a deviation (see <i>deviation</i>).
non-standard method	A method (not published in international, regional, or national standards or by reputable technical organizations or scientific texts or journals) developed by an organization that has been validated to confirm that the method is fit for the intended use.
objective	<ol style="list-style-type: none">1. A measurable, definable goal that, once accomplished, furthers the progress of HFSC.2. Without prejudice or not influenced by feelings or opinions.
ownership review	A review conducted by HFSC of vendor laboratory-generated DNA records before HFSC enters the DNA data into the Federal Bureau of Investigation's Combined DNA Index System (CODIS).
performance check	A quality assurance measure to assess the functionality of laboratory equipment that may affect the accuracy and/or validity of forensic, database, known, or casework reference sample analysis.
performance monitoring	Ensuring the validity of results of forensic services provided by HFSC through a combination of external proficiency tests, internal proficiency tests, and/or direct observations.
policy	A guiding principle, operating practice, or plan of action



	governing decisions made by HFSC.
preventive action	An action intended to improve a process or eliminate the cause of a potential nonconformance. Preventive actions may be referred to as process improvements or continuous improvements.
procedure	The way an operation is performed; a set of directions for performing an examination or analysis; the actual parameters of the methods used.
proficiency test	Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons where participants are aware they are being evaluated. Proficiency tests are purchased from external providers. For an interlaboratory comparison to be considered a proficiency test, participants must submit results to the provider by the due date.
quality control check	A procedure used to ensure the continued reliability and accuracy of reagents and equipment.
quality report	A report generated when an incident or corrective action workflow closes, identified by the quality tracking number.
quality tracking number	A number assigned to track nonconforming work designated as either an incident or a corrective action in a Qualtrax nonconformance workflow.
reagent	A substance used because of its known chemical or biological activity. Examples include working solutions, controls, and aliquots of chemical screening reagents.
reference material	Material, sufficiently uniform and stable with respect to one or more specified properties, determined to be fit for its intended use in a measurement or testing process.
Reference standard	Material with a traceable benchmark or level of quality that is used to calibrate equipment measuring values reported in SI units. Examples include NIST traceable weights and thermometers. Reference standard performance is checked before and after any adjustment.
refresher training	Training provided to employees to ensure continued familiarity with sectional procedures.
request	As it applies to forensic services, a request is the process utilized by a stakeholder when seeking analysis by HFSC. For example, a submission form or letter accompanying submitted evidence that lists examinations sought by the stakeholder. Electronic requests can be made through the LIMS.
retraining (post-authorization)	Training provided to an employee (authorized to perform independent casework) when the employee is



	no longer performing casework as expected. Retraining is typically part of a corrective action plan or an HR improvement plan.
review DUIs	Dynamic user interfaces (DUI) in JusticeTrax LIMS used to document and track case record technical reviews, administrative reviews, and batch reviews.
root cause analysis	A process used to identify the root cause(s) of a nonconformance.
safety manual	A document stating the safety policy and describing the various elements of the safety system of an organization or business.
sample selection	The selection of items for testing by forensic practitioners based upon training, experience, and competence and without assumptions about homogeneity.
seal	Evidence that is packaged in a manner that prevents loss, contamination, or deleterious change. When evidence is sealed by HFSC, “sealed” evidence shall be dated and initialed (or signed). If the evidence is taped closed, the date and initials shall cross the tape/evidence barrier; if the evidence is heat-sealed, the date and initials shall cross the seal.
section management	Section supervisors, technical leads, and section managers that are responsible for the day-to-day operation of their technical sections.
shall	Required
should	Recommended
stakeholder	Person or organization who receives a product or service from HFSC. May also be referred to as client, customer, or requestor.
staff member	Any person under the management responsibility of HFSC, regardless of his/her classification as civilian, classified, or employee.
statistical sampling	The selection of a portion of a sample for analysis by a forensic practitioner for the purposes of making an inference regarding the whole population.
subcontractor	An individual or business that independently performs a service for HFSC that HFSC is accredited to provide.
technical review	Review of technical records, reports, and testimony to ensure validity of results, opinions, and interpretations.
technical records	Accumulations of data and information which result from carrying out tests and which indicate where specified quality or process parameters were achieved. May include forms, contracts, worksheets, work notes, reports, calibration certificates, and stakeholders’ notes.



test record	Administrative and technical (examination) records generated during or pertaining to testing performed. May also be referred to as the case record or case file.
testing	Using a procedure to determine one or more characteristics of a test item.
traceability	The property of a measurement result whereby the result can be related to a reference through a documented, unbroken chain of calibrations, each contributing to the uncertainty of measurement.
training	The formal, structured process through which a forensic science practitioner reaches a level of scientific competency after acquiring the KSAs required to conduct specific forensic analyses.
undue influence	An individual's ability to persuade another's decision due to the relationship between the two people. May also be referred to as <i>undue pressure</i> .
uncertainty of measurement	An estimated value, within specified confidence limits, that depicts a value of variability that can be attributed to a quantitative value.
uncontrolled document	A document that is not a part of an organization's document control system, or a copy of a controlled document provided for informational purposes only.
unique identifier	An assigned forensic case number (FCN) or agency case number (ACN) used to identify data, case records and evidence. Prior to February 1, 2014, case records and evidence may have been identified by the forensic case number, agency case number, laboratory number, or other identification system.
validation	The documented process of ensuring a test method is fit for purpose for its intended use and consistently produces reliable results.
verification	<ol style="list-style-type: none">1. A procedure used to evaluate the validity and/or confirm/refute a test result or opinion by conducting an independent examination. May be referred to as a <i>comparative verification</i>.2. A procedure used to ensure an instrument or method performs as expected. Parameters used for verification are typically a subset of parameters used for method validation.
will	Requirement (future tense)



4. General Requirements

4.1. Impartiality

4.1.1. HFSC is a publicly funded local government corporation with a budget adequate to meet the objectives of the laboratory. As an autonomous organization, all activities conducted at HFSC are undertaken in a manner that ensures impartiality of operations and professional integrity during the performance of tasks.

The Quality Division is responsible for the oversight of HFSC's Quality Management System (hereafter referred to as the Quality System) under the direction of the Quality Director. The Quality Division functions independently of operations and reports directly to the CEO. By being independent of operations, HFSC ensures that the Quality System is objective and impartial in all duties, including internal audits, management reviews, and root cause analyses conducted during investigations of nonconforming work.

4.1.2. HFSC management, beginning with the CEO, is committed to impartiality in all laboratory activities. All staff members are expected to remain objective, impartial, and independent when performing laboratory activities, including when testifying in court. Staff members should not be influenced by extraneous information, political pressure, or other internal/external influences. Instances of such should be reported to management.

4.1.3. HFSC demonstrates a commitment to impartiality by operating as a local government corporation with oversight from a Board of Directors, working with staff to recognize bias and risks to impartiality, and by fostering an environment of open communication without fear of reprimand.

HFSC recognizes that there are risks to the impartiality of its forensic services. Staff must consult with law enforcement, prosecutors, and defense attorneys in the normal course of their duties, and these entities may have differing priorities than those of staff. If HFSC staff encounter instances where they feel pressured to act in a manner that contradicts HFSC policies, they shall notify section management, HFSC's legal counsel, the Quality Division, or a member of HFSC's executive management team.

Management shall be responsible for ensuring that reported risks to impartiality are resolved and documented as appropriate.

- Staff members are expected to adhere to ethical standards set forth in the HFSC Code of Ethics.

4.1.3.1. Executive management will ensure that:

- a. the HFSC Code of Ethics is integrated into the professional conduct of personnel.
- b. Staff shall review of the HFSC Code of Ethics annually.
 - The Quality Division may sponsor additional staff training addressing current events, trends and/or issued related to forensic science.



New hires, including independent contractors who perform technical work at HFSC, shall complete a documented review of the HFSC Code of Ethics within the calendar year. When applicable, new forensic practitioners should also review any additional training provided by HFSC during that calendar year (e.g., watch the videotape of the training if one exists and complete any related tests in Qualtrax).

- c. if instances of professional misconduct, professional negligence, or other unethical behavior are identified, appropriate actions are taken. Management is obligated to act if staff violate the HFSC Code of Ethics.

4.1.4. HFSC utilizes a variety of tools and programs to evaluate and reduce potential risks to impartiality and professional integrity. One or more of the following tools shall be used on at least an annual basis to evaluate risks to impartiality: management meetings, staff meetings, and staff training. HFSC also has several programs in place to monitor for risks to impartiality, including annual ethics training, in-person testimony reviews, transcript reviews, internal audits, post-mortem reviews, blind QC testing, and blind verifications.

HFSC's executive management strives to foster a culture that encourages staff to report instances of undue influence, whether perceived or real, or whether from internal or external sources to an appropriate authority. Appropriate authorities include the executive management team, HFSC's legal counsel, Human Resources (HR), section management, or the Quality Division. If staff feel that all internal reporting mechanisms have been exhausted, instances of undue influence may be reported to HFSC's Board of Directors or the Texas Forensic Science Commission without fear of adverse employment consequences. See HFSC's Code of Ethics for additional information.

4.1.5. If a risk to impartiality and/or professional integrity is identified, HFSC will work to eliminate or minimize the risk. Mechanisms for minimizing risks are incorporated into all levels of the organization and include annual ethics training and adherence to the ISO/IEC 17025 standard, this Quality Manual, HFSC corporate policies, and sectional procedures.

4.2. Confidentiality

4.2.1. HFSC is responsible for the management of all information obtained from stakeholders and created as part of its business operations. HFSC considers such information proprietary and confidential. HFSC does not release confidential information to unauthorized personnel. HFSC utilizes a public facing site accessible to stakeholders for posting documents such as standard operating procedures, training manuals, Quality reports, and accreditation information. HFSC does not publicly release case-specific details such as subject names unless required to do so under the terms of the Texas Public Information Act.

All staff members have an obligation to safeguard confidential information that is obtained in an official capacity and are responsible for safeguarding confidential information from unauthorized distribution. Staff members will not disclose any confidential or case-related information except when legally authorized or approved by



management. Staff may not release case-related information directly to the news media, family members, or others without the permission of management. All public information requests must be directed to HFSC's Public Information Officer, and all media requests must be directed to HFSC's CEO or designee.

- 4.2.2. If required by law to release confidential information, HFSC will notify the stakeholder of the release, only if there is reason to believe that the requested information may be excepted from disclosure. In the case of a request pursuant to the Texas Public Information Act, HFSC will notify the stakeholder that a request has been made and provide the opportunity to submit a request to the Texas Attorney General to withhold the information from disclosure if there is reason to believe the information may be excepted from disclosure. Public information requests received and processed by HFSC are documented in Qualtrax.

Staff members may make case records and copies of case records available to authorized entities only. Authorized entities include, but are not limited to, police officers, prosecutors, attorneys of record, and individuals with valid court orders or subpoenas. Requests for release of records should be directed to Client Services/Case Management (CS/CM). See Client Services & Case Management Division Standard Operating Procedures. If CS/CM or other staff members receive requests for information and it is not apparent whether the requester is entitled to the information, the request should be forwarded to HFSC's Public Information Officer or legal counsel. See section 7.8.1 for information regarding release of verbal results prior to issuing a laboratory report.

- 4.2.3. If HFSC obtains information about a stakeholder from an outside source (e.g., complainant, regulator), the information will be considered confidential and will not be shared with anyone other than the stakeholder. HFSC will not identify the source during discussions with the stakeholder unless the source of the information has agreed to be named. However, if the information obtained relates to a criminal case and is potentially impeachable or exculpatory, HFSC is obligated by law to disclose this information to the assigned prosecutor's office, pursuant to *Brady v. Maryland* and the Michael Morton Act. Before disclosing this information to the prosecutor's office, HFSC will inform the outside source and the stakeholder.
- 4.2.4. Other personnel acting on HFSC's behalf, including subcontractors, independent contractors, and interns, must keep confidential all information obtained or created during the performance of their work for HFSC, except as otherwise required by law.



5. Structural Requirements

- 5.1. HFSC is a publicly funded local government corporation with the legal authority to perform forensic laboratory activities and evidence tasks for stakeholders.
- 5.2. HFSC's overall management structure is delineated in an organizational chart maintained by HR.

The COO and directors (Quality, Crime Scene) have authority over their respective divisions and are responsible for ensuring conformance with accreditation standards. See Terms and Definitions for further information on executive management.

Members of executive management are usually available 24/7 to handle their respective division's affairs. If necessary, they will designate an acting division director to act in their capacity for a given period. The acting division director assumes those responsibilities given to the division director until the director returns to duty.

Regardless of job title, each division is headed by a staff member with authority to make decisions and coordinate administrative, technical and/or investigative activities within the division.

The individuals referenced above have authority to make and enforce decisions within their respective divisions, including closing technical sections if concerns of a technical or quality nature arise. The Quality Director has authority to make and enforce quality-related decisions across all divisions, including closing technical sections for quality-related reasons.

When appropriate, section management will designate one or more individuals who may act on their behalf.

5.2.1. HFSC's CEO, the highest-ranking official at HFSC, is responsible for the overall operations at HFSC.

- 5.3. HFSC provides a range of forensic services as specified in its ISO/IEC 17025 scope of accreditation, including Seized Drugs, Toxicology, Firearms, Latent Prints, Crime Scene, Multimedia (referred to on HFSC's Scope of Accreditation as 'Digital and Video/Imaging Technology and Analysis') and Forensic Biology. Other HFSC divisions and departments include HR, Quality, Information Technology (IT), Finance, Research and Development (R&D), Logistics and Equipment, Communications/Public Information, Client Services/Case Management (CS/CM), and Lean Six Sigma (LSS) Development Group. Only the accredited disciplines listed on HFSC's scope of accreditation will claim conformity to ISO/IEC 17025 accreditation requirements.

CS/CM conducts evidence handling tasks in accordance with ANAB AR 3181.

- 5.4. HFSC's forensic services are primarily conducted at its permanent facility (500 Jefferson St in Houston, Texas). Most vehicle processing by CSU is conducted at the vehicle examination building (VEB), located at 1300 Dart St in Houston, Texas. All staff who work at the VEB maintain



an office at 500 Jefferson St. HFSC also provides field sampling to the greater Houston area by sections with field sampling on their scope of accreditation. All forensic services provided by HFSC follow the requirements set forth in this manual and are designed to fulfill the needs of HFSC's stakeholders. HFSC stakeholders include, but are not limited to, law enforcement agencies, prosecutors, defense attorneys, forensic laboratories, and the public.

HFSC's quality system incorporates the requirements of its regulatory bodies, ANAB and TFSC, as well other regulatory authorities including the Drug Enforcement Administration (DEA), the Federal Bureau of Investigations (FBI) and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF).

HFSC's Forensic Biology section, as a National DNA Index System (NDIS) participating laboratory, will conform to the requirements stated in the NDIS Operational Procedures Manual and FBI Quality Assurance Standards (QAS), as applicable.

5.4.1. HFSC uses the ANAB accreditation symbol in accordance with ANAB's *Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status*.

5.4.2. Certain HFSC disciplines are also accredited by and follow the requirements of the TFSC (<https://www.txcourts.gov/fsc/>). For accrediting body disclosure requirements, refer to section 8.7.

5.5. HFSC is an autonomous organization with a president/CEO who reports to a Board of Directors appointed by the Mayor of the City of Houston. The organization and management structure of HFSC is outlined in the organizational chart maintained by HR. Descriptions of position responsibilities (job duties/descriptions) are also maintained by HR.

HFSC maintains its policies and procedures as controlled documents to ensure consistent application of all laboratory activities and the validity of testing and processing results. Staff members will follow HFSC's quality system and administrative policies in the daily operations of HFSC.

5.6. Executive management, in conjunction with section management, have the authority and resources to carry out their duties, including improvements to the quality system, and are responsible for ensuring that all laboratory activities and property evidence tasks follow accepted policies and procedures. All sections have individuals who are responsible and have appropriate training and experience in that discipline. All staff are responsible for adhering to HFSC's quality system. The Quality Division, under the direction of the Quality Director, is responsible for:

- a. implementing, maintaining, and improving the management system, see section 8.

HFSC management will ensure that personnel have the means necessary to follow this Quality Manual and verify that complaints concerning their respective divisions are evaluated and documented. Section managers will also ensure that forensic practitioners are trained and will monitor casework and other sectional activities to gauge compliance with the quality system.



- b. identifying departures from the quality system or from technical procedures, see sections 7.10 and 8.7.
- c. initiating actions to prevent or minimize departures, see sections 7.7 and 8.5.
- d. providing reports to management regarding the performance and improvements to the quality system. Management reviews are authored by the Quality Division, see sections 8.8 and 8.9.
- e. ensuring the effectiveness of laboratory activities, see section 8.9.

5.7. HFSC ensures that its management system has effective communication and integrity:

a. Communication

HFSC management is responsible for ensuring appropriate communication processes are followed within HFSC and that communication takes place regarding the effectiveness of the management system. These communications may take the form of company-wide or sectional meetings, emails, memos, or other written or recorded correspondences, formal and informal training sessions, the HFSC intranet, internal and external newsletters, and/or review of HFSC policies and procedures.

Section management or designee should document attendance at section meetings; however, management shall ensure that the topics discussed are made available for review. This includes any discussion regarding controlled documents (see section 8.3.2), as well as any training materials presented in a section meeting, however named.

Staff members not in attendance (not present) at section and company meetings are responsible for following up and reading the section minutes and/or watching the meeting videos.

b. Integrity

HFSC management will ensure that the integrity of the quality system is maintained when changes to the system are implemented. Changes that may affect HFSC's accreditation will be approved by the Quality Division prior to implementation. Quality system changes will be communicated to appropriate staff.

6. Resource Requirements

6.1. General

HFSC management ensures necessary resources are available to manage and perform the activities and tasks listed on HFSC's scope(s) of accreditation. These resources include personnel, facilities, equipment, and support systems and services.

6.2. Personnel

6.2.1. General Personnel Requirements

HFSC expects all staff, whether employed by or under contract to HFSC, who influence laboratory activities to act impartially, be competent to perform their duties, and adhere to HFSC's management system while on duty.



HFSC forensic practitioners are responsible for ensuring that all requirements of the quality system are met and failures to conform to quality standards are minimized, prevented, or eliminated (see section 7.10). All personnel must follow this Quality Manual and all applicable sectional procedures. All personnel also have the responsibility and authority to recognize opportunities for improvement and to take appropriate measures to implement them (see section 8.6). Forensic practitioners will ensure that laboratory reports and case documentation are complete and will advise section management of technical problems or questionable results. Staff will also use validated methods while examining and/or investigating forensic evidence and in meeting the needs of stakeholders.

All HFSC employees are responsible for reviewing and complying with HFSC corporate policies, the Quality Manual, the safety manual, the security manual, and section-specific documents. The manuals and policies are maintained in Qualtrax.

Texas Forensic Science Commission (TFSC) Licensing

Per Texas Administrative Code Chapter 651, starting January 1, 2019, the following disciplines are subject to licensure by TFSC: Seized Drugs, Toxicology, Forensic Biology and Firearms/Toolmarks. Refer to TFSC's website for continuing education and biennial licensing renewal requirements. HFSC's policy regarding licensing, *Required Professional Licensure*, is maintained in Qualtrax.

6.2.2. Training

HFSC has documented competency requirements for each forensic service that can influence results, including educational requirements, when applicable (see section 6.2.2.1), training (see section 6.2.2.2), and technical knowledge, skills, and abilities (see section 6.2.2.2). Job qualifications are listed in job postings which are maintained by HR and available upon request.

6.2.2.1. Educational Requirements

Forensic practitioners in the Seized Drugs, Firearms, Toxicology and Forensic Biology disciplines are required to meet the educational requirements specified in §651.207 of the Texas Administrative Code related or be able to obtain a waiver from TFSC. Specifically:

- Forensic Firearms examiners, Seized Drugs practitioners, and Toxicology practitioners must have a baccalaureate or advanced degree in a chemical, physical, biological science, chemical engineering, or forensic science from an accredited university.
- Forensic Biology practitioners must have a baccalaureate or advanced degree in a chemical, physical, biological science, or forensic science from an accredited university.

DNA forensic practitioners must also meet the educational requirements of the FBI QAS for Forensic DNA Testing Laboratories.



The CEO, COO, and technical management positions must meet the minimum educational requirements stated in the job posting or job description.

Section management is responsible for ensuring that all forensic practitioner trainees who will issue laboratory reports containing opinions or interpretations, and whose job duties include creating items of evidence in Firearms, Multimedia, Latent Prints and Crime Scene meet the educational requirements stated in the job announcement. If experience can be used in lieu of an educational requirement, that must be specified in the job announcement.

Technicians working in technical support positions in any discipline will meet the educational requirements specified in the job posting or job description for their position.

Transcripts are required to verify completion of coursework to satisfy certain sectional coursework requirements. These transcripts are maintained in the forensic practitioners' quality files.

6.2.2.2. Training Requirements

HFSC has a documented training program that provides knowledge and skills needed to perform specific forensic techniques, including testing and processing of evidence. Newly hired forensic practitioners, including contract employees and staff performing accessioning activities, will complete appropriate training and demonstrate competence before beginning casework.

Each technical discipline within HFSC has a documented training program to the extent necessary based on the job function, which shall include:

- a. the KSAs necessary for new staff to perform their job duties.
- b. general knowledge of forensic science.
- c. ethical practices in forensic science.
- d. the application of forensic science to court proceedings, including criminal law, civil law, and testimony.
- e. provisions for retraining.
- f. provisions for maintaining skills and expertise.
- g. acceptance criteria for written or oral exams as specified in section training programs.

See the CS/CM training manual for the evidence specialist training program and competency requirements.

Technical sections have also incorporated the training requirements specified in ASTM Standard E2917.

Training program activities will also include, at a minimum:

- a review of relevant written materials, such as journal articles, books, and section specific SOPs.



- laboratory exercises (practice samples/scenes) that demonstrate practical skills.
- discipline-specific written, practical, and/or oral examinations that demonstrate understanding of the scientific subject matter and associated laboratory activities.
- direct observation/training, such as observing an experienced crime scene investigator process a scene.

Section management designates an individual or individuals to oversee the training of new staff members. This trainer is responsible for supervising the staff member throughout the training process.

Section management will evaluate the new forensic practitioner's credentials and may modify the training program if applicable. Previous training records summarizing court qualifications, courses taken, and other supporting documentation should support training program modifications when practical. Staff must exhibit the ability to convey results and conclusions and their significance in an appropriate manner before being declared competent to perform casework or to create items that could be used for testing.

Upon the successful completion of their training program, forensic practitioners shall submit a Training Evaluation Form to section management and the Quality Division.

If section management and/or the Quality Division determines that an authorized employee requires retraining, section management shall develop a retraining plan. The plan will be communicated to and agreed upon with the employee. The plan shall include competency requirements and acceptance criteria for successful completion. Section management will issue a re-authorization memo that will be in effect once signed by the Quality Division. When retraining is part of a corrective action in response to a nonconformance, it will be documented through a Nonconformance workflow, see sections 7.10.1 and 8.7.1.

6.2.3. Competency

Staff authorized to perform laboratory activities or evidence tasks are deemed competent and are responsible for understanding the risk of departing from processes and/or procedures. All forensic practitioners conducting casework regardless of academic qualifications or past work experience, must satisfactorily complete a competency test prior to being authorized to perform independent casework issue laboratory reports, offer opinions or interpretations, perform technical reviews, or testify in court. Satisfactorily completing the test(s) means the intended results were achieved. Competency testing is also required for forensic practitioners who cross-train in a new discipline.

6.2.3.1. Competency for forensic practitioners is established through the successful completion of the following activities. Successful completion of each component shall be documented.



- a practical examination (may be referred to as a competency test) that covers the spectrum of anticipated work to be performed.
- writing a report, if applicable, to demonstrate the individual's ability to properly convey results and/or conclusions and the significance of the results and/or conclusions.
- a written or oral examination to assess the individual's knowledge of the anticipated work or task being performed. In situations where only an oral exam is given, documentation that reflects the topics discussed or questions asked during the oral exam must be maintained.
- courtroom testimony evaluation of a mock trial that gauges the staff member's ability to communicate technical and HFSC-specific information. This requirement applies to all forensic practitioners, regardless of whether they are required to be licensed by the TFSC.

A Quality Division team member, as well as HFSC's legal counsel, should be invited to observe mock trials.

There may be other means of meeting the testimony requirement, such as a courtroom testimony class that includes a mock trial. However, a class that does not include a mock trial does not meet this requirement. Consult the Quality Division for approval of other methods.

Mock trials are not required for non-technical staff members or staff who are licensed by TFSC as technicians. However, whenever possible, a mock trial will be conducted if these staff members are compelled to testify.

HFSC may provide additional training to forensic practitioners already authorized to perform casework. Examples include technical reviewer training, learning new analytical techniques or utilizing new technologies. Section management will ensure that staff complete a practical examination (competency test) and are issued authorization memos prior to performing casework. This type of training does not require staff to fulfill all the requirements specified in sections 6.2.2.2 and 6.2.3.1.

Exceptions to the competency test requirements may be granted upon written approval by the Quality Division. Example: for personnel involved in a validation, section management may allow the validation to serve as the demonstration of competency. Documentation must be available to indicate that involvement in the validation was representative of the extent to which the individual will use the method in casework.

If a forensic practitioner neither performs casework nor completes a proficiency test in a discipline for a period of 12 months or longer (the time may be less than 12 months based upon the discretion of the section manager and/or executive management), he or she must successfully complete a competency test prior to resuming casework in that discipline or analytical workflow. The competency test must include a practical examination and written report, if applicable. This documentation must be reviewed and approved by the Quality Division.



If a forensic practitioner transfers from one discipline to another and does not complete a proficiency test in the discipline they transferred from within 12 months, they will no longer be authorized in the discipline from which they transferred.

6.2.3.2. Forensic practitioners who perform technical reviews of results or evaluate testimony must meet the competency requirements specified in section 6.2.3.1 for the testing being reviewed.

Competency tests for technical reviews cover the task(s) that the review is encompassing. The following are examples of how competency can be demonstrated:

- technical reviews of mock case record(s).
- technical reviews of real case record(s) that are then technically reviewed by an already authorized individual.

Competency for testimony evaluation can be demonstrated through the following:

- authorized to perform casework in the task covered by the testimony.
- authorized to technically review tasks covered by the testimony.

If not authorized to perform casework or technical reviews, testimony evaluation competency tests shall include the evaluation of real or mock testimony. The practice evaluation will be reviewed by an individual who is already deemed technically competent in that discipline. Section management will determine how many practice evaluations are needed before the individual is authorized to evaluate testimony. The authorization must be approved by the Quality Division.

6.2.4. HFSC communicates to staff their duties, responsibilities, and authorities. Job duties and responsibilities are provided through job descriptions maintained by HR and as directed by section management. Authorization to perform these duties and responsibilities is given to staff upon fulfilling training requirements and/or competencies (see section 6.2.5.e).

6.2.5. HFSC has documented procedures and retains records for the following:

- a. Establishing/determining competency requirements for forensic practitioners and evidence specialists.

Sectional training programs include documented competency requirements for each discipline and/or subdiscipline within that section.

- b. Selection of Staff Members

Section management works with HR to develop job descriptions for positions. These job descriptions shall include the educational requirements listed in section 6.2.2.1. of this manual. HR is responsible for maintaining records related to job descriptions or postings.

- c. Staff training

Each section has a training manual(s). Training records shall be documented to the same extent as technical case record documents. See section 7.5.1 for details. Further details may be found in sectional training manuals.



The effectiveness of in-house training is evaluated by the trainer and/or section management. Effectiveness may be evaluated by how well content meets training requirements or objectives and by the performance of trainees on quizzes, competency tests, oral examinations, and/or mock casework.

Staff members are encouraged to join professional organizations and may attend conferences and seminars if funding is available.

Training is documented so that it is clear what tasks were undertaken during the training program. When in training, staff members are permitted to use equipment while under the direction of trained and authorized forensic practitioners. Trainees are not allowed to issue laboratory reports on casework unless authorized to do so (see sections 6.2.5.e and 6.2.6).

Training records are maintained in accordance with the HFSC Record Retention Policy and Record Retention Schedule.

d. Staff supervision

HFSC has section management, including supervisors, managers and/or technical leaders within each technical discipline, who are responsible for personnel under their direction. See the HFSC Organization Chart for more information regarding the chain of command.

Each staff member is accountable to one and only one immediate manager or supervisor for each forensic discipline in which they work.

e. Staff authorization

Technical Section Management and the Quality Division authorize forensic practitioners to perform specific laboratory activities such as field sampling, creating test items, testing, issuing reports, giving opinions, interpreting findings, conducting technical reviews, and operating specific equipment. Authorization memos are issued upon successful completion of the section-specific training manual and a competency test. New memos are issued as forensic practitioners develop new competencies. Forensic practitioners can perform technical reviews and specific tasks that lead to the creation of items that could be used for testing if these tasks are included in the written authorization memo(s). All work authorization memos and supporting documentation (including practical exams, competency test results, mock trials, training logs, and tests) are reviewed and approved by the Quality Division and section management and/or technical leaders before independent casework begins.

CS/CM and the Quality Division authorize evidence specialists to perform property and evidence handling tasks.

f. Monitoring competency

Competency is monitored through programs such as proficiency testing, blind QC testing, continuing education, testimony monitoring, and direct observations.



To promote continued competency, skills, and expertise, forensic practitioners are required to complete a total of 16 hours of continuing education and/or professional development per calendar year (or per performance review period as defined in section goals). This continuing education requirement complies with ASTM Standard E2917. Documentation of the total number of hours for continuing education and professional development training will be maintained in Qualtrax. Forensic-specific continuing education requirements, such as those for DNA forensic practitioners and CODIS administrators, must be met. Continuing education credits can be maintained through:

- attendance at meetings, seminars, and conferences.
- participation in scientific working groups.
- review of current and applicable literature.
- submittal of content for publication in professional journals.
- presentations at technical meetings.
- participation in college-level and other specialized courses.
- completion of webinars or other online training opportunities.

HFSC maintains literature resources or provides internet access to literature resources such as relevant books, journals, and other literature pertaining to each discipline. The DNA Technical Leader must approve webinars or other online training opportunities used to meet DNA continuing education requirements.

Statements of qualifications (SOQ), training certificates or other records of specialized training received, are maintained in staff members' electronic quality files. SOQs are required for all staff working in technical sections, laboratory support personnel, and staff performing accessioning activities, and should be updated yearly or more frequently if significant changes occur.

6.2.6. Authorization

HFSC authorizes forensic practitioners to perform laboratory activities, including but not limited to:

- a. method development, modification, verification, and validation.

Staff are authorized to participate in method development, modification, verification, and validation within their discipline once they are authorized to perform independent casework. Section management may authorize other HFSC employees, such as interns or trainees, to participate as needed.

- b. testing, processing, sampling, creating test items, giving opinions, interpretations, statements of conformity, and operating equipment used in casework.
- c. reporting, reviewing and authorizing results.

Authorization memos are:

- signed or initialed and dated by section management.



- signed or initialed and dated by the trainee, thereby acknowledging their understanding of their competencies and authorization to perform specified duties.
- signed or initialed and dated by a representative of the Quality Division, who will be the final signatory on the memo.
- in effect on the date the authorization is signed by the Quality Division representative.
- are maintained in Qualtrax and are uploaded by Quality Division personnel. See section 6.2.5.e for additional information.

Before forensic practitioners can begin casework, they must be authorized by HFSC and receive notification of their licensure by TFSC, if licensure is required for that discipline.

See the CS/CM training manual for the evidence specialist training program authorization requirements.

6.3. Facilities and Environmental Conditions

6.3.1. HFSC ensures that the environmental conditions are suitable for laboratory activities and do not adversely affect the validity of results. See HFSC's Safety Manual and Procedure Guide for 500 Jefferson 18th Floor Laboratory Systems for additional information.

6.3.2. Technical requirements for accommodations and environmental conditions are noted in sectional SOPs. Concerns related to environmental conditions that could affect casework should be brought to the attention of section management and/or the facilities and logistics coordinator. If the environment is found to be a threat to reliable testing, conditions should be corrected in a timely fashion. Laboratory operations may be ceased in high temperature situations that could impact equipment or cause an increased risk of contamination in the Forensic Biology laboratory.

6.3.3. HFSC monitors and records environmental conditions when required for evidence storage, technical methods, or when the conditions influence the quality of forensic results. Evidentiary items, reagents, DNA extracts, and other biological items are stored properly and separately to ensure their integrity. Dedicated refrigerators and freezers are clearly marked, and temperatures are monitored.

Refrigerators and freezers used for storing evidence, temperature-sensitive chemicals, or critical reagents are checked periodically to ensure they are operating properly. The temperature of each unit should be kept within a range appropriate for the items being stored. Unless otherwise specified within sectional procedure manuals, temperatures should fall within the following parameters:

- refrigerators: $>0^{\circ}\text{C}$ to 10°C ($>32^{\circ}\text{F}$ to 50°F)
- freezers: $\leq 0^{\circ}\text{C}$ ($\leq 32^{\circ}\text{F}$)

If the temperature of a refrigerator or freezer is out of range, adjustments should be made and the temperature rechecked and readjusted until the reading is in range. If, after



adjustment the temperature remains outside the range stated above, the person who identified the problem is responsible for informing section management. Section management is responsible for arranging any necessary repairs or replacements.

One way to monitor temperatures is to record temperatures in a log that includes the date, temperature, and the recorder's name or initials. Manual recordings should be done at least once each week. Another way to monitor and record temperature is by using a temperature monitoring system, such as DicksonOne. The temperature monitoring system transmits temperature readings wirelessly to a secure website, which is monitored and controlled by designated forensic practitioners and the Logistics and Equipment Division. When the temperature monitoring system is used, it is not necessary for personnel to record temperature readings manually. All temperature logs and/or temperature reports are maintained per HFSC's Records Retention Policy.

Thermometers and temperature probes used to record critical temperatures as required in sectional SOPs are verified at least annually against a National Institute of Standards and Technology (NIST) traceable thermometer.

- 6.3.4. Measures to control HFSC facilities are implemented, monitored, and periodically reviewed. These measures include:
- a. controlling access to operational areas of HFSC and limiting access to authorized personnel. Non-HFSC staff are not allowed unrestricted access to operational areas of HFSC. Please see the HFSC Security Manual for additional information.
 - b. preventing contamination by maintaining clean work surfaces and examination implements.
 - c. effective separation between neighboring areas in which incompatible activities take place. Incompatible activities are separated by time or space to prevent contamination. Seized drug and toxicology analyses are performed in separate and distinct locations within HFSC and instruments are dedicated for use rather than shared between the two disciplines. Items of evidence that potentially contain trace evidence (e.g., hair, fiber) from subject and victim in the same case are analyzed at different times or in different rooms to prevent cross-contamination. Evidentiary and reference DNA samples are also handled at different times or in different locations to prevent cross-contamination.

As much as possible, HFSC is maintained in a clean and orderly condition. Each staff member is responsible for keeping his or her area clean. Janitorial staff may be used when appropriate.

6.3.4.1. Please see the HFSC Security Manual for further information regarding security procedures and facility access.

- 6.3.5. HFSC does not routinely perform laboratory activities outside its building. However, if HFSC needs to perform laboratory activities (such as obtaining reference fingerprints at the courthouse, or due to extenuating circumstances) at sites or facilities outside of its permanent control, staff will ensure that the facilities and environmental conditions are



suitable and will document in the case record the laboratory activities conducted off-site (see the Procedure for Transferring HFSC Records for Off-site Access for additional information). This does not apply to crime scene processing because those facilities and environmental conditions are beyond HFSC's control.

6.4. Equipment

- 6.4.1. HFSC is furnished with the proper equipment needed for the collection, sampling, examination, and testing activities performed by staff. This includes appropriate analytical instrumentation, measuring equipment, software, measurement standards, reference materials, reference data, reagents, consumables, and auxiliary apparatus necessary to perform these activities. Staff will not use personal equipment unless otherwise specified in sectional SOPs (e.g., Crime Scene Unit personal measuring devices that have been checked and approved by section management). If staff believe equipment is not operating properly, section management must be notified as soon as possible.
- 6.4.2. HFSC only uses equipment that is under its direct control. All equipment used for forensic services at HFSC must follow the requirements set forth in this document.

Non-HFSC personnel are prohibited from using HFSC equipment to conduct casework activities such as analyzing or processing evidence; however, they may use HFSC equipment for other HFSC approved activities, such as research and instrument maintenance.

- 6.4.3. Equipment is handled, transported, and stored according to manufacturers' recommendations to ensure proper function and to prevent contamination, damage, or deterioration. If necessary, additional instructions will be documented in sectional SOPs. If manufacturers' information is not available, section management should determine the proper procedures for handling, transport, storage, and maintenance of that equipment. When equipment that is sensitive to movement (e.g., balances) is moved, a performance check must be conducted. Equipment is operated only by authorized forensic practitioners, or, in the case of trainees or interns, under the direction of authorized forensic practitioners. Forensic practitioners are typically authorized to operate equipment through completion of section-specific training programs. Additional information regarding authorizations can be found in Section 6.2. Details may also be found in authorization memos. Equipment manuals should be stored near the equipment or in a location agreed upon by sectional staff.

General service equipment not used for measurement purposes (e.g., hot plates, stirrers, non-volumetric glassware, non-CSU cameras, and refrigerators) will be maintained through visual examination, safety checks, and cleaning as necessary. The equipment will be removed from service if these checks indicate a problem with the ongoing use of the equipment. Volumetric equipment is visually examined and cleaned as necessary. Microscopes and attachments are cleaned and serviced periodically. Fume hoods and super glue chambers that are vented to the fume hood exhaust system are checked annually by an external vendor. See applicable sectional SOPs for additional information.



Sections that re-use disposable equipment will have a procedure, validation study, carry-over study, or some similar document to ensure these items do not contribute to contamination through misuse or re-use. See applicable sectional SOPs for further information. Sections that do not re-use disposable equipment are not required to state this in their sectional SOP.

6.4.3.1. Reagents used in HFSC are of a quality that ensures the validity and reliability of the testing conclusions reported by HFSC.

Reagents prepared in-house are labeled with the identity of the reagent, concentration (if applicable), date of preparation or lot number, and, as applicable, storage requirements. Reagents received from a commercial provider without a lot number shall follow the requirements for reagents prepared in-house. Water supplied by the City of Houston and further purified by HFSC is exempt. Records are maintained identifying who made the reagent and the components used in preparation. When necessary, sectional SOPs contain further instructions related to special storage conditions, hazard warnings, and expiration dates. The Forensic Biology section follows the labeling requirements in this manual and those outlined in the FBI QAS for DNA Testing Laboratories where applicable.

If a reagent is transferred to a secondary container (e.g., a section prepares a bulk solution of a reagent then transfers it to smaller bottles for use by each analyst), the secondary container shall be labeled with the identity of the reagent and the date of preparation or lot number. This applies to commercially prepared reagents as well as those prepared in-house. This does not apply to reagents transferred to temporary containers for immediate use, such as beakers or culture tubes, nor is required if vials are too small for the required information. Small vials may be labeled with an identifying code that can be traced back to the identity and lot number of the reagent.

Sectional SOPs will specify the frequency of reliability testing for reagents. Reagents not meeting quality control criteria are removed from use and affected casework, if any, is reviewed.

6.4.3.2. Reference collections of data or items/materials encountered in casework that are maintained for identification, comparison, or interpretation purposes (e.g., mass spectral libraries, drug samples, firearms, bullets, cartridges, DNA profiles, frequency databases) are documented, uniquely identified as a reference sample, handled properly to protect the characteristics, and controlled. If the item is collected from casework, documentation of this must be included as part of the case record. See applicable sectional SOPs for additional information.

6.4.4. Each section must verify that equipment is calibrated, or performance checked to ensure specified requirements are met before being placed into service or returned to service.



6.4.5. Equipment and corresponding software and hardware used for testing, examinations, and sampling must be capable of achieving the accuracy required by SOPs and comply with specifications relevant to the testing being conducted. Equipment that significantly affects the quality of an examination requires regular quality control through performance verification, external calibration, and/or intermediate checks. Section SOPs contain additional details when applicable.

6.4.6. Measuring equipment is calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the reported results and/or
- calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7. HFSC has a calibration program. The calibration program is reviewed during internal audits and as part of the management review. Adjustments are made to the program as necessary.

Calibration records are maintained by the section and should be stored in Qualtrax.

6.4.7.1. HFSC calibration program

- a. The following is a list of equipment requiring external calibration:
 - pipettes.
 - gauge blocks.
 - digital force gauges.
 - standard reference length measuring devices.
 - standard reference weights (non-standard reference weights are not held to the same criteria as standard reference weights. Refer to sectional SOPs for more information regarding non-standard weights and how they are verified, or performance checked.)
 - balances.
 - FARO 360° laser scanners.
- b. The vendor conducting the calibration must demonstrate and provide documentation of competence, capability, and traceability. Competence is verified by selecting an ISO/IEC 17025–accredited calibration laboratory. Capability can be determined by reviewing the calibration provider’s scope of accreditation, and, in lieu of accreditation, a competent vendor may also be one that provides certificates of traceability to a national standard such as the National Institute of Standards and Technology (NIST). For devices that have little to no effect on the overall quality of testing, calibration vendors that can provide NIST traceability will be considered competent. HFSC maintains documentation of calibration activities.
- c. Calibration services are coordinated by section management and/or Logistics & Equipment. Requirements are determined by the type of



equipment and the needs of the section. The calibration service coordinator is responsible for communicating calibration requirements to the calibration provider. Equipment calibration documentation is maintained by the section. Section management or designee is responsible for reviewing the calibration certificate for accuracy. Accuracy includes but is not limited to:

- ensuring the unique identifier for the equipment is accurate.
- ensuring the 'as found' and/or 'as left' measurements are within tolerance.

The 'as found' measurements are taken before any adjustments are made. The 'as left' measurements are taken after any adjustments are made. If the 'as found' measurements are out of tolerance, the quality division shall be notified and the effect, if any, the equipment had on casework shall be determined. If the 'as left' measurements are out of tolerance and cannot be brought into tolerance by the calibration technician, the equipment must be taken out of service.

- d. When equipment requires calibration, the calibration will be performed at least annually by an external vendor unless otherwise specified in sectional SOPs. The frequency of the calibration interval depends on the function of the equipment. The interval for checking equipment calibrations will not be less stringent than manufacturers' recommendations unless there is data to support a less frequent calibration program. The new calibration interval must be approved by the Quality Division.

6.4.8. Equipment (or the container in which the equipment is stored) that requires calibration will be labeled with the last calibration date and the date the next calibration is due. Equipment with a defined period of validity (such an instrument with a required annual preventive maintenance that needs to be completed by an external provider) will be labeled with the date performed and the date the next service is due. The purpose of the listed date is to ensure that the user is aware when the equipment may require service or calibration. The external service or calibration does not have to occur by that exact due date if the equipment continues to perform within its specification and continues to be fit for purpose.

6.4.9. Equipment that does not meet quality control criteria and that is not immediately repaired must be taken out of service. The equipment is labeled or marked to indicate that it is out of service until repaired and shown by calibration or performance check to perform correctly. The instrument/equipment maintenance record is updated to show the date and reason it was removed from service. If applicable, technical sections will determine if the equipment defect had an effect on testing results. In instances when defects have a technical impact on results, they may be handled as nonconforming work (see section 7.10).



6.4.10. When intermediate checks are needed to maintain confidence in the performance of equipment, the nature and frequency of such checks are specified in applicable section SOPs. Manufacturers' recommendations or specifications will be considered when conducting these checks. Equipment that fails intermediate checks are removed from service. When appropriate, affected casework is reviewed. These intermediate checks are documented. If an intermediate check is missed, the equipment must be labeled or marked out of service until performance checked prior to use on casework.

In addition to the annual balance calibration, sectional personnel complete a balance performance check at least monthly. Performance checks are not required each month if the balance is not used monthly. If the balance has not been performance checked within the current month, a check will be performed prior to use.

Specific time frames for maintenance of equipment used in DNA testing will follow the FBI QAS for Forensic DNA Testing Laboratories guidelines whenever stricter than those stated in this manual.

6.4.11. If calibration and reference material data include correction factors that differ from those currently in use, the correction factor will be updated accordingly on section specific worksheets. As an example, if a thermometer has a correction factor of $\pm 2^{\circ}\text{C}$ after calibration, that correction factor will be incorporated and documented into subsequent temperature readings.

6.4.12. Results of quality control checks on testing equipment are reviewed to ensure that no inadvertent adjustments have been made that invalidate test results. When practical, access to equipment operational parameters may be restricted.

6.4.13. When equipment and its software are significant to the analysis or test performed, HFSC maintains the following information:

- a. the identity of equipment and any corresponding forensic software and/or hardware.
- b. the manufacturer's name, type of equipment (e.g., mass spectrometer, microscope) identification, and serial number or other unique identification. This identification may be in the form of an asset management tag.
- c. documentation that equipment has been validated, verified, or performance checked prior to use to ensure it performs as expected.
- d. the section to which the equipment is assigned.
- e. calibration records (records shall include dates of calibrations and results), operating acceptance criteria for use in casework, and the due date of the next calibration.
- f. reference material documentation, including results of testing, acceptance criteria, relevant dates, and expiration/re-testing dates.
- g. documentation of maintenance plan and maintenance activities, as appropriate.
- h. equipment records including records of malfunction, damage, modification, repair, adjustments, and repairs. Maintenance, repairs, and performance



verifications are recorded in instrument logbooks (maintained by each section) or an electronic equivalent as soon as possible after completion.

6.5. Metrological Traceability

6.5.1. Reference Standards and Materials

HFSC utilizes calibrated and traceable reference standards and certified reference materials to establish metrological traceability of measurements to ensure the validity of results.

6.5.1.1. Reference standards and certified reference materials are linked to appropriate references through a documented and unbroken chain of calibrations, each of which contributes to the uncertainty of measurement.

Certificates of analysis provided by manufacturers are maintained in a location designated by the section management. A certificate of analysis received with a drug or other standard will generally serve to establish the initial quality of that standard. Reference material should not be stored with evidence samples. Manufacturers' instructions or sectional SOPs are followed to prevent contamination, avoid deterioration, and protect the integrity of the material. When available, suppliers of reference standards and certified reference materials used to establish or maintain measurement traceability are either:

- a. a National Metrology Institute that is a signatory to the BIMP – CIMP Mutual Recognition Arrangement with the calibration to be performed listed in Appendix C of the BIPM key comparison database (KCDB); or
- b. a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be performed listed in a scope of accreditation; or
- c. an accredited reference material producer that is accredited to ISO/IEC 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in the ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material.

6.5.1.2. If there is no certified reference material supplier meeting the requirements stated above, HFSC will confirm suitability, measurement capability, and measurement traceability for the product being purchased. Documentation of confirmation will be maintained.

6.5.1.3. HFSC does not perform calibration services.

6.5.2. Measurement results obtained from reference standards are traceable to the SI units. Examples include NIST traceable weights and thermometers. The performance of



reference standards is checked before and after any adjustment. Traceability of measurement results to SI units are documented through:

- a. calibration records provided by a laboratory meeting the requirements specified in section 6.5.1.1, or
- b. certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI, or
- c. direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

6.5.3. When metrological traceability to the SI units is not technically possible, traceability to an appropriate reference is demonstrated through:

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

6.6. Externally Provided Goods and Services

6.6.1. HFSC ensures the suitability of externally provided goods and services affecting laboratory activities when they are:

- a. intended for incorporation into HFSC's activities. These goods and services include but are not limited to:
 - reagents.
 - equipment.
 - reference standards.
 - reference materials.
 - external sub-contractors hired to perform technical work on behalf of HFSC.
 - independent contractors hired by HFSC to perform technical work at HFSC.
- b. provided, in part or in full, directly to the stakeholder as received. HFSC does not provide externally sourced goods and services directly to the stakeholder.
- c. used in support of HFSC operations. These goods and services include but are not limited to:
 - calibration services.
 - proficiency test providers.
 - equipment service contractors.

6.6.2. HFSC Procurement Procedures for Goods and Services

- a. Prior to purchasing or subcontracting goods and services, requirements of the goods or services are defined, reviewed, approved, and documented by HFSC management. Procurements and procurement requests are submitted through a Qualtrax workflow that is reviewed and approved by, at a minimum, section



management and the Finance Division. Procurement procedures are approved by HFSC's Board of Directors prior to being issued in Qualtrax. HFSC also employs a general counsel who reviews legal documents related to purchasing, subcontractors and external providers. General counsel should be consulted in drafting or reviewing legal documents for externally provided goods and services.

- b. HFSC's Logistics and Equipment Division and /or section management is responsible for evaluating external providers.
- Criteria for evaluating and selecting external providers will include one or more of the following:
 - accreditation or certification if required under ISO/IEC 17025 and/or the TFSC.
 - availability of resources.
 - technically competent personnel.
 - references.
 - historical data.
 - ability to provide services in a timely manner.
 - ability to provide cost-effective services.
 - ability to provide adequate documentation to support accreditation, quality assurance, traceability, purity, or concentration.
 - ability to provide clear, accurate and concise reports documenting all technical work (e.g., calibration services).
 - ability to demonstrate use of validated methods.
 - ability to consistently supply goods and/or services that meet HFSC quality assurance standards.
 - ability to ensure that goods and/or services provided will not negatively impact the quality of forensic analyses. Whenever practical, HFSC will purchase supplies and services from businesses that are accredited.
 - The above criteria are also used to monitor and re-evaluate the performance of externally provided goods and services.
 - Additionally, HFSC verifies that purchased supplies, reagents, and consumables that affect the quality of tests meet SOP specifications or sectional requirements prior to initial use. This verification may be accomplished by determining that the item or items received are the same as what was ordered. Initials or a signature on a packing slip or purchase order signify that the supply has been inspected. The inspection may involve comparing catalog numbers, described quality, or other relevant information to verify that each item received is the same as the item ordered and (where applicable) meets the specifications listed in sectional SOPs. Please contact the Logistics and Equipment Division for more information.
 - Re-evaluation of the subcontractor is performed upon contract expiration and renewal or if a significant technical error impacting the accuracy of the results is identified.



- Documentation of procurement, performance monitoring, and re-evaluation activities is maintained by the section or Finance Division, as appropriate.
 - Certificates of analysis received with purchased chemicals or reagents should be maintained. Sectional personnel are responsible for verifying that requested supplies meet requirements specified in SOPs and for storing supplies according to each manufacturer's recommendations.
 - Reagents used for DNA analysis will be checked in accordance with the FBI QAS for DNA Testing Laboratories.
 - HFSC maintains an approved vendor list for services and supplies that affect the quality of forensic activities. To add a vendor to the approved list, a Vendor Approval Form or workflow must be approved by section management and then submitted to the Logistics and Equipment Manager. Whenever possible, approved vendors will have appropriate ISO certification. Approved vendors may also be those who supply certificates of analysis for reagents or standards, ship supplies in a timely manner, and provide the supplies at an acceptable cost. A list of approved vendors is available in Qualtrax. Once approved, the vendor may be used company wide.
 - In certain instances, providers and subcontractors require accreditation. Individual subcontractors providing forensic testing services in Seized Drugs, Toxicology, Forensic Biology and Firearms/Toolmarks in the State of Texas are required to be licensed by TFSC (see section 6.2.1). HFSC may also require individual subcontractors to have professional certifications. HFSC is responsible for verifying and documenting that these requirements are met and maintained.
- c. HFSC ensures that externally provided goods and services conform to the laboratory's established procedures through sectional quality control measures listed in technical procedural manuals. HFSC does not provide externally purchased goods and services as defined in section 6.6.1 directly to our stakeholders.
- d. If externally provided goods and services do not meet HFSC's requirements when received by the logistics specialist, the specialist will notify the provider as well as the HFSC staff member who placed the order. If an issue with externally provided goods or services is found by the section, the information will be provided to the Logistics and Equipment Division. An attempt will be made to resolve any issues with the external provider. If the issues cannot be resolved, HFSC may choose to refrain from doing business with that provider.

6.6.3. HFSC shall communicate requirements for goods and services to our external providers as described in the Finance Division's procurement procedures.

- a. Purchase orders and/or contracts will specify which goods and services are required.
- b. Contracts with personnel will specify competency requirements. Contracts for any testing or validations that HFSC intends to perform at an external provider's facility will include HFSC's requirements for the work to be



done at the provider's facility. This process extends to providers who perform services at sites other than HFSC (such as contract employees working off-site).



7. Process Requirements

7.1. Review of Requests, Tenders, and Contracts

Contracts for forensic services are reviewed and approved by the CFO. HFSC's Finance Department is responsible for contracts related to the purchasing of goods and services (see section 6.6). This section of the Quality Manual specifically addresses the review of requests from stakeholders for specific forensic services such as phone calls requesting crime scene processing, written requests, such as submission forms, or requests received through HFSC's portal for forensic testing.

7.1.1. HFSC reviews all requests for forensic services.

- a. HFSC receives most requests for forensic services via the JusticeTrax "Where's my Results" Portal or through the HFSC-HPD property room auto-request process. By accepting these requests for services into JusticeTrax LIMS, HFSC is documenting that the request for forensic services has been reviewed.

HFSC may receive requests for forensic services through other means, such as telephone calls, emails, or delivery services. These requests are considered reviewed and accepted when the request is created in LIMS by section management or designee.

HFSC will notify stakeholders if all or part of a request cannot be fulfilled, in some instances this may be after an auto-request had been accepted. HFSC may forward evidence to other laboratories or request forensic investigation services from other investigation agencies on behalf of the stakeholder.

- b. Requests for forensic services are reviewed to ensure that:
 - HFSC has the capabilities and resources to meet the stakeholder's request.
 - HFSC's testing methods and/or evidence investigation services can meet the stakeholder's requirements.
 - HFSC personnel seek clarification from the stakeholder when necessary to fulfill a request. This may include determining the probative nature and value of the evidence and/or crime scene and defining or discussing testing or investigation methods with the stakeholder before casework or the crime scene investigation begins.
- c. If subcontractors are used to fulfill any part of a request, HFSC will ensure that the subcontractors meet requirements specified in section 6.6 of this document. Reports from subcontractors regarding testing of evidence (outsourced reports) are uploaded into LIMS.
- d. Unless otherwise specified, the stakeholder agrees to allow HFSC to use the scientific knowledge and expertise of its forensic practitioners to choose and apply appropriate testing and processing methods, including sampling, to the evidence.

7.1.2. HFSC informs stakeholders when requested methods are inappropriate or out of date.



- 7.1.3. When stakeholders request a statement of conformity to be included in HFSC reports, the specification or standard and the decision rule used will be clearly defined and communicated, unless inherently defined in the standard procedures.
- 7.1.4. Differences between the request for forensic services and HFSC's contract with its stakeholder will be resolved if the differences are identified before work commences. However, discrepancies between evidence received and the request are often not identified until the evidence is inventoried or after an examination has begun. See section 7.4.1.
- HFSC may need specific information from the stakeholder to fulfill a request for analysis. In such circumstances, HFSC will contact the stakeholder to obtain the needed information. If, after a minimum of five business days, the stakeholder has not responded, HFSC can close the request. The section must notify the stakeholder that the request was closed.
- 7.1.5. HFSC informs stakeholders before deviating from an agreed-upon request for analysis or crime scene investigation. However, crime scene investigation services may be extended beyond the initial request.
- 7.1.6. Changes in requested services are communicated to affected forensic practitioners as soon as possible. Changes necessitated by HFSC are communicated to the stakeholder. If a request needs to be amended after work has begun, the review process will be repeated, and amendments will be communicated to affected staff members.

If HFSC receives a written request to terminate analysis before work is completed, the request shall be documented in the case record and stakeholders shall be notified. The following are options for notifying stakeholders:

- If work was initiated and there were no completed results, opinions, or interpretations, a notification report will be issued denoting that the request was not completed. However, this notification report does not preclude resumption of future testing if requested by the stakeholder.
- If work was initiated and partial results are available, it is up to the discretion of the section to determine if these results will be reported. Based on the work commenced, the section may determine that partial results will not be reported as they may be confusing or misleading to the stakeholder. In these instances, a comment will be included to explain this situation and that a subsequent request for analysis can be placed by the stakeholder in the future.

If neither option is appropriate, contact Legal.

- 7.1.7. HFSC strives to maintain good working relationships with its stakeholders. Maintaining these relationships may require:
- asking for clarification if the request is unclear.
 - maintaining appropriate contact with the stakeholder during lengthy examinations.
 - maintaining confidentiality.



- seeking feedback from stakeholders.
- providing explanations or interpretations of reports.

Staff members are available to assist stakeholders regarding evidence submission. If technical questions arise during the submission process, the staff member receiving the evidence will contact the appropriate forensic practitioner or manager for assistance. Under normal circumstances, individuals who are not staff members are not allowed to observe testing. This helps to ensure confidentiality of case information, limits potential for contamination, and ensures security of evidence and case records. Special arrangements may be made to comply with court-ordered observations, see HFSC's Expert Observation Policy.

Observing testing in a specific case is not synonymous with touring the laboratory. Tours, including media access, that are scheduled in advance and guided by HFSC staff, may be allowed in laboratories except for Forensic Biology. Tours through the Forensic Biology/DNA lab spaces are not allowed due to contamination concerns, unless permission is granted by HFSC's CEO and the DNA Technical Leader. If members of the media take video or still images of work being generally conducted in the laboratory, the CEO or designee shall notify section management. Section management or designee shall ensure the confidentiality of case information, limit potential for contamination and ensure security of evidence and case records.

7.1.8. All communications with stakeholders that may affect requests, analyses, results, or interpretations shall be documented in the case record. This does not extend to general communications from stakeholders, such as requests for information about the status of reports or requests for copies of reports.

7.1.9. The extent of database searches (e.g., CODIS, AFIS, NIBIN) used in forensic casework is communicated to stakeholders through reports or via the HFSC website.

7.2. Selection, Verification and Validation of Methods

7.2.1. Selection and Verification of Methods

Section 7.2.1 addresses requirements for the selection of methods and requirements to ensure methods are fit for purpose. If methods are from published sources, the process for ensuring they are fit for their intended use is referred to as method verification. A method verification typically evaluates some, but not all, performance characteristics studied in a formal method validation (see section 7.2.3).

7.2.1.1. HFSC uses appropriate methods and procedures for all laboratory activities, and, where appropriate, an estimation of uncertainty as well as statistical techniques for data analysis. Evidence examinations are conducted in a scientifically valid manner. A critical component in ensuring validity is the documentation of procedures used for examinations. Examination includes sampling, handling, transport, and preparation of tested items, and, where appropriate, an estimation



of uncertainty as well as statistical techniques for test data analysis. Procedures and methods are fit for the purposes required/requested by the stakeholder.

7.2.1.1.1. HFSC technical sections use methods and procedures appropriate for all associated data analyses and interpretations. See sectional SOPs for specific criteria.

7.2.1.1.2. Disciplines that compare data from an unknown to a known must have sectional SOPs that specify criteria to be used to first determine whether the unknown has characteristics suitable for comparison. Then the unknown can be compared to the known.

7.2.1.1.3. HFSC does not perform calibration services.

7.2.1.2. HFSC maintains documentation related to the selection and verification of methods, including relevant published standards (e.g., ASTM or OSAC standards), references for outside validation studies, verification procedures, and reference data, and ensures that these references and/or documents are available to applicable staff. Section management ensures that these references and/or documents are kept up to date and relevant. Supporting documentation including manuals, standards, and operating instructions are either maintained in Qualtrax or in the appropriate section.

7.2.1.3. Forensic practitioners are responsible for ensuring that the most recent validated methods are in use unless not appropriate or possible to do so.

When utilizing methods from an external source, section management shall supplement the method with additional instructions to ensure staff are able to consistently apply the method to casework.

7.2.1.4. In most instances, the stakeholder does not specify the method to be used. HFSC will determine the most appropriate method and inform the stakeholder of the method chosen by listing the method in the laboratory report.

7.2.1.5. Prior to implementation of a method validated elsewhere, section management or designee shall verify that the method works for its intended purpose. Sections should work with the Quality Division to determine what performance characteristics need to be verified.

7.2.1.6. When method development is required, the method shall be validated as a planned activity performed by authorized forensic practitioners. Section management is responsible for ensuring that appropriate equipment and resources are available for the project. As the validation plan proceeds, section management or designee will periodically review the progress to ensure the needs of the stakeholders continue to be met (see section 7.2.2). Modifications to the plan shall be approved and authorized by section management or designee.



7.2.1.7. Deviations from technical test methods must be documented in the case or batch record, approved by the section management prior to the deviation, and included on the report (see section 7.8.2.1 for reporting requirements). In normal situations, it is not necessary for the stakeholder to approve each deviation. However, in situations in which HFSC wishes to confirm the stakeholder's approval, the approval shall be documented in the case record.

7.2.2. Validation of Methods

7.2.2.1. HFSC management ensures that all non-standard methods are validated prior to use. This includes methods developed by HFSC and standard methods used outside their intended scope or otherwise modified. The scope of validation will encompass the scope of work for which the method is intended.

Prior to the implementation of a new method, or when there is a substantial change to a current method, the method is subjected to appropriate internal validation to assess the procedure's ability to produce high-quality, reliable results. Written documentation for each validation is maintained. Validation studies on newly validated methods include language stating that the method is fit for the intended use.

Equipment in the process of being validated must be labeled or marked to indicate it may not be used on casework until the validation is reviewed and approved by section management and the Quality Division.

7.2.2.1.1. When methods are validated by HFSC, the validation will include:

- a. a validation plan.
- b. data analysis and data interpretation.
- c. the data and acceptance criteria required to report a result, opinion, interpretation, or statement of conformity.
- d. identification of the limitations of the method.

7.2.2.2. When changes are made to a validated method, the method will be performance checked to show that the changes did not affect performance. If the changes are found to affect the original validation, a new method validation shall be performed. The new validation shall encompass, at a minimum, the specific areas affected by the changes to the method.

- The data used to determine the influence of the changes is considered part of the validation study.

7.2.2.3. The range and accuracy of the values obtainable from validated methods (e.g., uncertainty, detection limits, selectivity of the method, linearity), as assessed for the intended use, will be relevant to stakeholders' needs and consistent with specified requirements.



During validation, known samples representative of those encountered in casework are examined to determine if the procedure generates acceptable results.

Performance characteristics to be evaluated during method validation can include, but are not limited to:

- Measurement range.
- Accuracy.
- Measurement uncertainty.
- Limit of detection.
- Limit of quantitation.
- Selectivity of the method.
- Linearity.
- Repeatability or reproducibility.
- Robustness.
- Bias.

7.2.2.4. Validation studies are documented and approved by the section manager and/or the technical lead and the Quality Division. The validation documentation may be a finalized version of the validation plan if it includes the selected requirements listed in section 7.2.2.1.1 as well as requirements a – e listed below. Forensic practitioners are trained in new methods before the methods are used in casework. Additional guidelines for procedure validation may be found in section SOPs.

Validation documentation includes:

- a. the validation procedure used.
- b. specification of the requirements.
- c. determination of the method's performance characteristics.
- d. the results of the validation study.
- e. a statement of validity of the method, detailing its fitness for the intended use.

7.3. Sampling (field sampling and statistical sampling)

7.3.1. Field sampling involves the collection of evidence, typically from crime scenes for future testing.

Sections tasked with the collection of evidence from crime scenes shall utilize a sampling plan. Sampling plans may be incorporated into sectional SOPs. The sampling plan shall describe the method used for sample selection to ensure the validity of or possible impact on subsequent testing. The Crime Scene Unit is the only section at HFSC that routinely collects evidence from crime scenes. The dynamic and unpredictable nature of crime scenes, requires the Crime Scene Unit evidence collection plan to rely on the KSAs of HFSC's forensic practitioners in conjunction with information obtained at a scene from a variety of sources, including but not limited to, law enforcement and emergency service personnel (first responders).The Multimedia section assists stakeholders with the retrieval



of digital data (evidence) from off-site locations which is released to the stakeholder after retrieval.

Statistical or non-statistical sampling methods may be used to make inferences on the whole population.

7.3.2. The field sampling method shall describe:

- a. how samples or sample sites are selected and recorded.
- b. the sampling plan.
 - Confidence levels must be incorporated into statistical sampling plans if an inference is made on the whole population.
- c. how the sample is prepared from the received evidence to produce the item used for subsequent testing.

7.3.3. HFSC records relevant data related to sample selection. The documentation includes, where relevant:

- a. a reference to the sampling method used.
- b. the date and time of sampling.
- c. data to identify and describe the sample (e.g., number, amount, name).
- d. the identification of staff performing sampling.
- e. the identification of equipment used.
- f. environmental or transport conditions.
- g. diagrams or other equivalent means to identify the sampling location, when appropriate.
- h. deviations, additions to or exclusions from the sampling method and sampling plan.

See applicable sectional policies for further details.

7.4. Handling of Evidence

7.4.1. While in the care, collection, custody, and control of HFSC, all evidence items are handled in a way that protects the integrity of the evidence and prevents loss, contamination, or deleterious change.

Upon submission of evidence to HFSC, evidence packaging is inspected to ensure that it is appropriate for the type of evidence it contains. If necessary, evidence items will be repackaged to ensure evidence integrity. For example:

- dried biological stains should be in packaging that prevents mold or bacterial growth.
- sharp items should be packaged in a way that protects staff members from accidental sticks or cuts.

When possible, stakeholders should be encouraged to initial evidence seals. See section 7.4.1.1 for requirements regarding evidence handling, including sealing, by HFSC staff.



HFSC staff shall inspect evidence taken into their custody to ensure it is sealed, when applicable. Evidence seals are inspected to ensure they protect evidence from loss, cross-transfer, contamination, or deleterious change. Refer to HFSC's Evidence Handbook for guidelines regarding appropriate evidence packaging submissions for stakeholders.

The requirement for evidence to be sealed does not apply to evidence submitted for immediate analysis (e.g., test firing an officer's weapon), or when sealing evidence is not practical (such as large items, including long guns), or when it is not safe to do so (loaded firearms). Consult section management for advice on handling these items. Additional exceptions may be found in sectional SOPs.

Evidence Accepted in an Unsealed or Damaged Condition by HFSC

Before evidence is accepted by the Client Services/Case Management (CS/CM) Division, the outer container must be inspected for a seal. If the outer container is not sealed in a way that protects evidence from loss, contamination or deleterious change, CS/CM may place a corrective seal on the outer container. This correction will be documented in the case record (e.g., a comment in the chain of custody, in the case notes, photographs, etc.) for that specific item. If evidence is rejected by CS/CM due to a missing seal or packaging, CS/CM will photograph the condition of the evidence. CS/CM will give electronic notification to the stakeholder that the evidence was not sealed/packaged and therefore not accepted by HFSC.

If a section receives/accepts evidence that is not sealed/packaged properly (to the extent that evidence may have been lost, damaged, or contaminated), when the expectation is that it should have been sealed, the section will document the condition of the evidence in the case record prior to processing the item. The condition of the evidence must also be documented in the report. The person responsible for the evidence shall ensure it is properly sealed unless it is worked the same day.

Under normal circumstances original packaging is preserved. However, if evidence containing biological samples is received damaged or is damaged while in the custody of HFSC and the packaging becomes contaminated with biological material, the packaging will be photographed, then the contaminated packaging may be properly discarded in a designated biohazard disposal container. The disposal of the packaging will be documented in the case record. If the evidence is compromised by a biological contamination, evidence may have to be discarded as a biological hazard.

Rejected or Returned (Un-tested) Evidence

Evidence is inspected by HFSC staff prior to receipt and again during the inventory process. Evidence may be rejected prior to acceptance or returned to the stakeholder after being accepted but prior to testing based on condition. If the evidence is rejected or returned based on condition it will be documented in the case record and photographed when applicable. If evidence is returned un-tested a report will be issued to the stakeholder explaining why the evidence was returned. Examples of situations where evidence may be rejected or returned to the stakeholder include but are not limited to:

- the evidence is not sealed or packaged.



- the outer packaging is damaged.
- there is evidence of tampering.
- the identifying information on the packaging is missing, inconsistent, or illegible.
- the contents appear compromised.
- the contents of the package do not match the package description or case information.
- the requested testing is fundamentally inappropriate for the evidence submitted.

Note: Inappropriately autogenerated NIBIN Only requests on items that are not NIBIN eligible are returned to the stakeholder. In these instances, HFSC notifies the stakeholder but does not issue a report.

Transportation of Evidence

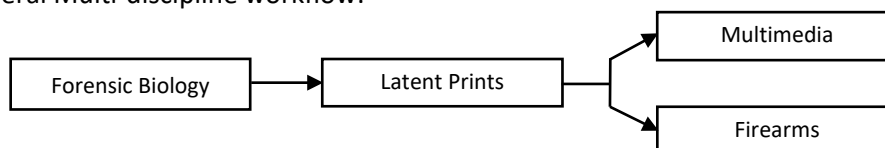
While transporting evidence to and from HFSC, all traffic laws should be followed. All doors should be locked unless someone is entering or exiting the vehicle. Evidence should be placed in a safe place, such as the trunk of a car or the cargo area of a truck or van. Evidence may be left unattended in a locked vehicle for short periods of time if the evidence is not readily visible from the outside (e.g., vehicle's windows are tinted, or the evidence is stored inside of a container). Evidence is typically transported by staff operating HFSC owned vehicles (see HFSC's Vehicle Use Policy). These requirements apply to all HFSC staff while driving an HFSC vehicle and while driving a personal vehicle for business use.

Evidence shipped off-site (e.g., out-sourcing evidence), will be properly sealed prior to transport and shipped via a commercial carrier.

Multi-Discipline Evidence Workflow

Stakeholders may request that an item of evidence be analyzed by multiple disciplines. When this happens, the usual multi-discipline workflow is Forensic Biology followed by Latent Prints then either Firearms or Multimedia (depending on the type of evidence). However, this flow may vary based on the type of evidence and the circumstances of the investigation. Requests for analysis of seized drug evidence that also includes requests for other disciplines (such as latent prints) are handled on a case-by-case basis by section management. All forensic practitioners, as well as those involved in case assignment activities, are responsible for reviewing requests to ensure that multi-discipline requests are processed in the correct order.

General Multi-discipline workflow:



Off-Site Evidence Collection

When evidence is collected off-site by HFSC forensic practitioners, the evidence is packaged in separate containers to prevent loss, cross-transfer, contamination, and/or deleterious change, whether sealed or unsealed, during transport to HFSC or an evidence



storage facility. When appropriate, further processing to preserve, evaluate, document, or render evidence safe is accomplished prior to final packaging. Requirements for off-site evidence collection are specified in sectional SOPs.

7.4.1.1. The following are requirements for all items of evidence received by HFSC.

- a. All items received are considered evidence and treated accordingly.

Evidence is stored, handled, and prepared in a manner that prevents loss, contamination, degradation, and damage. Generally, this means forensic practitioners will open and examine only one evidence item at a time. However, the nature of some analyses (such as firearms, latent prints, and multimedia) requires the comparison of multiple items at one time. Whether one or multiple items is opened at a given time, evidence will be protected as stated above.

In some disciplines, evidentiary and reference samples must be handled at different times or in different locations to prevent cross-contamination. Refer to sectional SOPs for more information.

All evidence at HFSC will be handled and stored in a safe and secure manner, and packaged evidence will generally be sealed, unless exempted under section 7.4.1. A seal is essential to controlling the integrity of the evidence. Lack of a seal could result in the integrity and quality of the evidence being questioned. An evidence container is sealed if the contents cannot readily escape and if entering the container results in obvious damage or alteration to the container or its seal. When evidence is sealed by HFSC staff, the seal shall be dated and initialed (or signed). If the evidence is taped closed, the date and initials shall cross the tape/evidence barrier; if the evidence is heat-sealed, the date and initials shall cross the seal. The seals shall be applied in a manner that is readily apparent when tampering has occurred.

Evidence must be received by HFSC in a condition that ensures evidence is protected from loss, cross-contamination, and/or deleterious change. If this requirement is not met, the evidence may be rejected by HFSC (see section 7.4.1 for additional information).

After evidence has been examined, analyzed, or otherwise tested or processed at HFSC, it will be re-sealed as soon as practicable to protect the integrity of all items. Evidence being transferred between technical sections should be sealed. Exceptions include large items (such as mattresses or bicycles) and long guns (such as rifles and shotguns).

- b. All evidence not in the process of examination is maintained in a secured, limited access area under seal, unless exempted in section 7.4.1. Proper security may be achieved by storing evidence in refrigerators or freezers,



vaults, secured areas, or locked cabinets. Please see the HFSC Security Manual for information regarding access to HFSC facilities.

For situations in which there is an expectation of frequent or multiple analyses of an item or during the process of examination of the item, the evidence item may be stored unsealed in a secure, limited access area, if the integrity of the item is maintained. During the process of examination, if a forensic practitioner needs to leave for a short time, such as for a break, the evidence may be left unattended in an area with limited access.

- c. A chain of custody is maintained for evidence submitted to HFSC, including evidence submitted for entry into individual characteristic databases. These chains are records of the submission of evidence to HFSC as well as all internal transfers. The chains of custody for items of evidence will include the dates of receipt, transfer, the storage location or name of individual assuming custody, a description or unique identifier of the evidence, and the final disposition of the evidence. The chain of custody shall be maintained in chronological order. Staff members are responsible for ensuring evidence items have appropriate item descriptions recorded in LIMS.

When evidence is sub-itemized, sub-items are tracked through the chain of custody to the same extent that original evidence items are tracked. In some instances, sub-items are packaged in a container with the original "parent" item. These items may be described as "packaged with parent" in Porter Lee LIMS. A chain of custody for the parent item will also apply to the sub-itemized "child" item packaged with the parent.

Dates and times of evidence transfers shall not be changed in or deleted from the electronic chain of custody in JusticeTrax or Porter Lee. Instead, a comment must be added to the corresponding transfers to document when the physical transfers occurred. The following chain of custody issues require Qualtrax workflows (JusticeTrax or Porter Lee):

- A transfer was missed or erroneously recorded, no comment was added, and there were subsequent transfers.
- An existing comment needs to be edited, added or deleted.

If an electronic evidence transfer cannot be captured at the time of physical transfer because of network issues and/or maintenance issues, the transfer will be documented as soon as practicable with the comment "Item # was physically transferred to "NAME OF LOCATION" on DATE at TIME (AM/PM). The electronic transfer was not captured due to network issues". A LIMS Request Form workflow is not required because the inability to electronically capture the transfer was outside of the staff member's control.

Chain of custody procedures apply to blind quality control samples once they are submitted to HFSC as evidence until the case is completed. The



chains of custody may be ended by the Quality Division upon completion of the case. Samples may be disposed of or reused for other cases. Applicable sections of HFSC will have a procedure for the operation of individual characteristic databases (CODIS, AFIS, and NIBIN). See Forensic Biology, Latent Prints, and Firearms sectional SOPs for further information.

Individual characteristic database samples treated as evidence will meet the chain of custody, evidence sealing and protection, evidence storage, and evidence marking requirements of HFSC. These samples include test fired ammunition produced in the laboratory, known blood or standard biological samples, and record print cards (or their electronic image equivalents which are commonly referred to as records) of known individuals.

When evidence is submitted for entry into characteristic databases, the chain of custody will be tracked to the same extent as evidence submitted for analysis.

- d. Each person acknowledges by signature, initials, or secure electronic equivalent, at the time of submission or transfer, when evidence is transferred from person to person or to a storage location.

The chains of custody shall include the date of receipt or transfer, a description of the evidence or a unique identifier, and the name of the person(s) transferring the evidence. When applicable, the location to or from which the evidence is being transferred will also be documented. Transfers must either be from a person to a location, a location to a person, or from one person to another person. For paper COCs, all entries denoting a location must be preceded by or followed by the identity of the person placing or removing the item from that location.

When evidence is transferred using LIMS, staff should run a custody inquiry to ensure the intended transfer was captured in LIMS and the evidence was transferred to the correct person or location.

- e. Generally, evidence is returned to the stakeholder after completion of analysis. Laboratory reports include a statement regarding the disposition of evidence. Evidence that is not in the care, custody, or control of HFSC will not be retrieved by HFSC for the sole purpose of transporting that evidence to court. The requestor must obtain that evidence from the investigative/requesting agency to whom the evidence was returned.

Sections may choose to keep small portions of evidence items for future analysis, additions to reference collections, use as reagent quality control checks, or for training/research purposes. No chain of custody is required unless the intent is to perform future testing. Examples include small



- cuttings from sheets or blankets, test fires, or botanical material. Reports will notify stakeholders when a portion of evidence is retained at the lab.
- f. HFSC notifies its stakeholders when items of evidence are collected or created. If these items are retained by HFSC for future testing, they will be preserved in an appropriate manner conducive to future testing.

If HFSC receives evidence in an insufficient quantity to complete testing AND reserve sufficient sample for additional testing, or the evidence will be destroyed through testing, the laboratory will only proceed with the analysis if one of the following occurs:

- a court order is received for testing related to pending criminal charges that have been filed by the prosecutor's office or written consent of both the assigned prosecutor and the defense attorney of record. Exceptions to this requirement must be approved by HFSC's legal counsel.
- written consent of both the assigned prosecutor and the defense attorney of record is received for a case that has been disposed, but the parties are seeking post-conviction relief.
- permission is obtained from the submitting agency in cases where there is no suspect listed in the case record. The submitting agency must confirm that criminal charges have not been filed by the prosecutor's office (typically the District Attorney's Office).

All communications regarding permission to consume evidence shall be documented in the case record.

If a laboratory accident (e.g., dropped evidence, broken blood tube) or other circumstance arises that compromises the original evidence and requires consumption of the evidence or use of a reserved portion (e.g., last blood tube in blood alcohol analysis), the laboratory will stop the analysis. In both instances, a request to consume will be communicated to the submitting agency either by email or in a report. The communication will include the reason why the analysis was not completed or conducted. Testing will not resume until permission is obtained from the submitting agency, or both the assigned prosecutor and defense attorney of record. When a consumption order is required (see sectional SOPs for details) the text of the order (or a certificate of service signed by the prosecutor of record) must make clear that the defendant or his or her legal counsel had a timely opportunity to object to entry of the order before moving forward with analysis. If HFSC is aware of a defense attorney of record, then the same principle will apply (evidence will not be consumed without defense attorney permission). The permission to consume must be documented in the case record.



- 7.4.2. Evidence received for examination is labeled with a unique identifier. This unique identification is retained throughout the life of the evidence item while at HFSC and is used during evidence transfers to, within, and from HFSC.

All evidence items received (this includes items received but not tested) are identified and tracked using the LIMS. This system allows for subdividing groups of evidence, transfer of evidence within HFSC, and receipt and return of evidence.

- 7.4.2.1. Individual evidence items or containers must be marked with a unique identifier. An item designator will be used with the unique case number to distinguish items within a case. If marking the evidence is not possible or could affect the integrity of the item, then the proximal container will be labeled.

- 7.4.3. If, at the time of inventory, the condition of the evidence is not as expected or specified by the stakeholder, refer to sections 7.1.4, 7.4.1, and 7.8.1 for instructions to document and address the discrepancies.

If clarification regarding the condition of the evidence is needed, or when additional information is needed, the stakeholder will be consulted. This communication is documented within the case record. In some instances, the stakeholder may require evidence to be tested even though specified conditions were not met. In these situations, HFSC will include a disclaimer in the report that clearly indicates which results are affected.

- 7.4.4. If evidence must be stored under specified environmental conditions, those conditions will be maintained, monitored, and recorded. See section 6.3.3 for information on temperature monitoring.

7.5. Technical Records

- 7.5.1. HFSC retains records of original observations derived from analyses, processing, and reviews (administrative and technical), records of derived data, and sufficient information to establish an audit trail. **Original observations shall not be destroyed (thrown away, shredded, torn-up, etc.). Examples of original observation include but are not limited to worksheets, case notes (or any hand-written case related information), and training records.** Case records contain sufficient information to facilitate, if possible, the identification of the factors affecting uncertainty and to enable any test to be repeated under conditions as close as possible to those of the original.

Observations, data, calculations, and other examination documentation are recorded at the time they are collected or made and are uniquely identified (forensic case number, agency case number). Who performed all stages of laboratory activities and the date each stage was performed shall be documented in the case record. If examination records or original observations are made on nontraditional media (i.e., sticky notes, paper towels, gloves), then the original medium is retained in the case record. If the original medium is retained, it must be affixed in the case record in a manner that prevents it from becoming



lost, damaged, or destroyed. The original medium, or the page to which it is affixed, must be properly identified with the unique identifier, date, and name/initials of the analyst. An electronic equivalent may be created and retained in the case record if the original nontraditional media poses a safety risk (such as biohazard/chemical contaminations). Once an electronic equivalent (e.g., scan, photograph) is created, then the original hard copy may be destroyed (e.g., for safety risks) after the scan or other electronic image is found to be legible and accurate.

Equipment, instrumentation, or forensic software used during analysis that has a significant influence on the results of the test/examination shall be recorded in the case record. Instrument operating parameters are recorded in the case record or in a retrievable form that is available for review.

When data and/or results are checked by a second individual this check will be documented in the case record to indicate data/results were checked, by whom, and when.

7.5.1.1. All administrative and examination documents are retained. Case record documentation includes but is not limited to:

Administrative documentation

- submission forms/requests for analysis.
- evidence inventory and description.
- chains of custody.
- communication records (e.g., emails, phone calls).
- report(s) of analysis.
- documentation of technical and administrative review.
- subpoenas.
- discovery requests.
- quality incident/corrective action reports.
- administrative documents, such as search warrants and vehicle examination forms, supplied by the stakeholder.

Examination documentation

- raw data.
- photographs – see below.
- worksheets.
- case associated notes.
- notes regarding analysis.
- graphs and chromatograms.
- standards and controls.
- other documents produced and used to reach a conclusion.

Examination quality photographs and photographs taken to document the condition of evidence shall be retained in LIMS, the case folder, or other HFSC



approved repositories such as Caseworks (also referred to as Mideo), Dataworks, section designated server/hard drive(s), or sections specific storage locations in SharePoint. Staff member computer hard drives and OneDrives are not approved repositories. Images must be associated to the FCN or ACN, or to a batch file. HFSC does not require the retention of duplicate and/or poor-quality photographs. The case number need not be present if photographs are taken for training purposes.

If printed copies of electronic examination records, including photographs, do not include the unique identifier, date, and identification of the person who performed the activity, the missing information shall be added to the copy.

Pages of internally generated examination or investigation records are numbered using a system that indicates the total number of pages. This applies to hardcopy records, including those that are scanned into an electronic record keeping system. Records created in an electronic system and maintained only in an electronic system are not subject to this requirement. When examination records are recorded on both sides of a page, each side is treated (identified and initialed) as a separate page. HFSC permits but does not encourage the use of both sides of a page.

Supporting documentation such as quality control results, standards used, calibrators, and positive/negative controls, may be stored in the case file or in designated locations within each section. Alternatively, these items may be scanned into the associated electronic records in LIMS.

- 7.5.1.2. Abbreviations, acronyms, and symbols are acceptable in examination records if the meanings are readily comprehensible to a reviewer and the meaning of the abbreviation or symbol is documented in the sectional SOP or worksheets. Abbreviations that are in common use do not have to be listed in a table of abbreviations, such as chemical element symbols and standard units of measure.
- 7.5.1.3. Technical records (administrative and examination documentation) are of sufficient detail to support the conclusions. Documentation is such that in the absence of the forensic practitioner or report, another competent forensic practitioner could evaluate what was done and interpret the data. This includes the identity of equipment/instruments used to support conclusions and the forensic practitioner conducting the analysis.
- 7.5.1.4. Case records on paper must be legible and recorded using ink. This requirement does not apply to administrative documents submitted by the stakeholder. Exceptions may be made if environmental conditions prevent the use of ink. Pencil may be used if appropriate for making diagrams or tracings. While original notes may be recopied, all original notes must be maintained as a permanent component of the case record.



7.5.1.5. When a test result or observation is rejected, the reason for the rejection, the identity of the individual(s) rejecting the result or observation, and the date shall be recorded.

7.5.1.6. HFSC does not perform calibration services.

7.5.2. Modifications to the case record made prior to technical/administrative review will be documented by the person making the change.

When making corrections to paper documents, a single line is drawn through the error and the error is initialed. Mistakes are not erased, made illegible, or deleted. Erasures on crime scene sketches are not considered mistakes and are not subject to these requirements. These requirements also do not apply to changes and alterations made on administrative documents provided to HFSC by the stakeholder.

When making corrections to electronic records, equivalent measures are taken to preserve original data. Any changes made to completed examination records generated and/or maintained in an electronic form are tracked, which means sufficient information is provided to determine what was changed and who made the change. Computer software programs with audit log functionality may be used for this purpose.

Modifications made to the case record after the technical/administrative review process has started must indicate who made the correction and the date the correction was made. Dates may be documented in the review checklist, case record, review DUI, or electronic equivalent.

HFSC does not consider reports to be examination documentation. Therefore, draft reports do not have to be maintained.

No staff member will make a notation on an HFSC record, whether the record is on paper or in an electronic format, which could reasonably be construed as having been made by a person other than the one making the notation.

7.6. Evaluation of Measurement Uncertainty

7.6.1. Documentation of laboratory methods includes an estimation of the uncertainty of measurement (UM) when appropriate. The purpose of calculating the UM is to ensure that quantitative results provided to stakeholders can be understood within the context of accuracy and precision of the methods used. An estimation of uncertainty is determined for quantitative measurements when these numerical values are listed on the report and there is a reasonable expectation that a stakeholder will use these results to determine, prosecute, or defend the type or level of criminal charge. Estimation of UM is not required for qualitative tests. Examples of measurements that require an estimation of uncertainty include the barrel length of a long gun, overall length of a long gun, controlled substance weights, and blood alcohol values. Uncertainty is reported using the same units as the measurement it supports. Refer to sectional SOPs for further details on reporting guidelines.



- 7.6.1.1. Affected sections of HFSC will have and apply procedures for estimating UM. The procedure for estimation of measurement uncertainty includes:
- the specific measuring device or instrument used for a reported test result to be included in or evaluated against the estimation of measurement uncertainty for that test method.
 - the process of rounding the expanded uncertainty.
 - the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%).
 - the schedule to review and/or recalculate the measurement uncertainty.

7.6.2. HFSC does not perform calibration services.

7.6.3. When estimating uncertainty, all uncertainty components important to the given situation (those that could contribute more than 10% to total UM) will be considered.

If the nature of the test precludes rigorous, metrological, and statistically valid calculation of uncertainty, then HFSC will at least attempt to identify the components of uncertainty and make a reasonable estimation. Reasonable estimates will be based upon knowledge of the performance of the method and on the measurement scope and will make use of any previous experience and validation data.

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

- 7.6.4. Sections must maintain records of their UM estimations. These records will include:
- a statement defining the measurement.
 - a statement of how traceability is established for the measurement.
 - the equipment (e.g., measuring device(s) or instrument(s)) used.
 - all uncertainty components considered.
 - all uncertainty components of significance, including those that arise from sampling, and how they were evaluated.
 - data used to estimate repeatability, intermediate precision, and/or reproducibility.
 - all calculations performed.
 - the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.

7.7. Ensuring the Validity of Results

7.7.1. Sectional SOPs will define applicable quality control procedures for monitoring the validity of tests undertaken. These metrics are recorded so that trends are detectable and so that, when practical, statistical techniques can be applied to the review of these results. This monitoring will be planned and reviewed and may include the following:

- use of certified reference material and/or internal quality control using secondary reference material. When applicable, appropriate controls and standards are



specified in sectional SOPs and the data is retained in the case record or associated quality control documents.

- b. use of alternative instrumentation that has been calibrated to provide traceable results.
- c. functional check(s) of measuring and testing equipment.
- d. use of check or working standards with control charts, where applicable.
- e. intermediate checks on measuring equipment.
- f. replicate tests using the same or different methods.
- g. retesting of items.

Regardless of whether retesting is required, when a comparative verification is performed on evidence items, it includes the following:

- the verification is performed by an individual currently authorized to perform the testing.
- the verification is documented in the case record, including who performed the verification, when it was performed, and the results of the verification.
- the case record includes documentation of situations where the verification does not agree with the original test results. If an agreement cannot be reached between the verifier and the forensic practitioner, the disagreement will be brought to section management for resolution.
- the resolution of any discrepancy shall be documented in the case record.

Comparative disciplines may also participate in blind verifications as part of the blind QC program. For disciplines in which an independent second analysis or verification of data is required, case information and conclusions made by the first forensic practitioner may be temporarily masked from the second forensic practitioner. The second forensic practitioner then performs an independent examination of the evidence. After the second forensic practitioner records their conclusions, the conclusions from both forensic practitioners are evaluated for consistency. If the conclusions are not consistent with one another, the forensic practitioners must follow section policies regarding consultation and/or conflict resolution.

- h. correlation of results for different characteristics of an item.
- i. review of reported results.

HFSC requires the technical review of reported results, see section 7.7.1.l. Sectional SOPs may contain additional review requirements.

Administrative Reviews

An administrative review of the case record is conducted prior to the release of the laboratory report. The review is documented in LIMS and/or in the case record and is conducted by someone other than the author of the report. Administrative reviews are performed on 100% of completed casework.

The administrative review includes:



- review of the report for spelling and grammatical accuracy.
 - review of all administrative records to ensure that the assigned case number is on each page.
 - review of all examination records to ensure that the inclusion of the unique identifier, date, and identity of the person who performed each stage of analysis.
 - review of the report to ensure that all key information (see sections 7.8.2 and 7.8.3) is included.
- j. an intralaboratory comparison program to monitor and ensure the validity of results.
- k. blind QC testing. HFSC's Blind QC program is not an ISO 17043 accredited proficiency test program. The program is not intended to replace or meet the performance monitoring requirements of the accrediting body. Sections may choose to use certain blind QC tests as a monitoring activity to be referred to as an internal proficiency test. In these instances, the test will be documented as such, and acceptance criteria will be pre-established, and section 7.7.5.f will apply. The blind QC program consists of the testing or examination of samples that are blind to the personnel involved in the process. This type of testing evaluates the entire quality system and monitors laboratory performance from evidence submission to the final report. HFSC creates and designs these tests to mimic real casework. The Quality Division administers and introduces these tests into the workflows of forensic practitioners in the same manner as all other evidence and casework.
- l. Review of technical records, reports, and testimony
1. Technical reviews are performed by forensic practitioners who are authorized to perform the work they are reviewing.
 - Reviews are conducted by individuals who have been competency tested and authorized in that category of testing. The Quality Division strongly encourages sectional SOPs to incorporate technical review training into their training programs. Inexperienced forensic practitioners newly authorized to perform independent casework are strongly encouraged to gain expertise through experience in that category of testing at HFSC prior to being authorized to perform technical reviews.
 - Section management has the discretion to determine the number of practice reviews completed before the individual is deemed competent. However, the Quality Division has the authority to request additional practice reviews before approving the review authorization, to help ensure that each authorized forensic practitioner can perform an effective technical review.
 2. Forensic practitioners may not conduct a technical review on their own work product. Technical reviews are not conducted by the author of the examination records or test report under review. Unless otherwise noted in sectional procedures, the primary forensic practitioner is considered the author of the report.



Technical and administrative reviews may be conducted by the same person.

3. The Crime Scene Unit will perform a technical review on at least 75% of each investigator's casework. These reviews should be spread out to cover processing completed throughout the year. All other disciplines are required to complete a technical review on all completed casework.
4. Testimony Reviews

HFSC forensic practitioners who testify regarding work performed at HFSC will have their testimony monitored at least once each calendar year. Testimony may be monitored through direct observation (preferably by a section manager or supervisor or designee), a review of court transcripts, videotaped testimony, or by other means. HFSC recognizes that transcripts may not be available from the courts within the calendar year; therefore, the Quality Division may accept transcript reviews that occur after the end of the calendar year if there is documentation that the transcript was requested prior to the end of the year. When a staff member testifies, they must complete a Qualtrax Testimony Tracking and Monitoring Notification workflow (testimony workflow) as soon as practicable, whether the testimony was monitored or not, and whether the testimony was for HFSC or for another agency. **When a staff member's** testimony is monitored, a copy of the completed evaluation form must be uploaded to their Qualtrax Quality File.

Testimony evaluations are conducted by individuals deemed technically competent in that area of expertise based on training, experience, and competency (see section 6.2.3.2).

- Testimony evaluation will be based on the following as applicable:
 - appearance and poise.
 - clarity of communication.
 - identification of evidence.
 - ability to present scientific information in an easily understood manner.
 - consistency of testimony with case documentation.
 - performance under cross-examination.

The person who monitored the testimony is responsible for documenting their observations on a Testimony Evaluation Form as soon as practicable. The completed evaluation form must be reviewed with and signed by the witness, the monitor, and **section management**. The witness should be given appropriate feedback, positive and negative, noting any area needing improvement. The witness is then responsible for uploading the completed evaluation form to their testimony workflow and uploading a copy to their Qualtrax quality folder.

If the evaluation indicates the possibility of a serious problem (either with the witness or with a procedure) or the overall presentation is



unacceptable, then management will act to remediate the problem. Recommendations for remediation may include, but are not limited to, communications training, remedial technical training, additional mock court training, or a review of technical procedures or methods. Actions taken are documented through the Quality Division.

Documentation, typically in the form of a memo, will be maintained for each forensic practitioner who does not give testimony during a calendar year. This documentation will be added to staff members' quality files.

- Testimony monitoring records must be maintained per HFSC's Records Retention Policy.

In addition to monitoring testimony by direct observation, HFSC conducts reviews of testimony transcripts. Typically, one transcript per forensic practitioner will be reviewed annually, if available. The transcript review will be conducted by a committee. The committee will typically include one individual technically competent in the scientific discipline of the witness, one member of the Quality Division, and one lay person who is not a member of the section being reviewed. The lay person may be an individual not employed by HFSC. The results of the committee's review will be shared with the forensic practitioner by an individual deemed technically competent in the task covered by the testimony.

5. Forensic practitioners who interpret, report, or testify regarding the examinations, investigation notes, or findings of another HFSC forensic practitioner will complete a documented review of all relevant pages of the examination record. Someone who testifies to the work of another forensic practitioner who did not conduct the original review, shall review applicable case records prior to testimony and document their review in the case record.

Technical sections are responsible for establishing technical review criteria.

Chains of custody must be reviewed during the technical or the administrative review to ensure all transfers were captured and are accurate.

Evidence submitted to HFSC for analysis should not be returned to the stakeholder until after the technical and administrative reviews are completed. This ensures the evidence is readily available if questions arise during the review process.

Technical reviews, administrative reviews, and batch reviews should be documented and tracked in review DUIs in JusticeTrax LIMS. Sections may choose to use additional methods of documenting their review process.



Testimony reviews are documented on a Testimony Review Form and are retained in Qualtrax.

6. Technical Reviews

- HFSC conducts a technical review of examination records and laboratory reports to ensure that conclusions of forensic practitioners are reasonable, within the constraints of validated scientific knowledge, and supported by examination records, notes, and/or diagrams. Technical or ownership reviews are conducted on all reports or records that contain analytical results, conclusions, or associations. See DNA General SOP for further information on ownership review.
- All reports undergo a technical review prior to being released, except for Crime Scene. Reports are reviewed to ensure that results, opinions, and interpretations are accurate. A record of the review is made to indicate that the conclusion has been checked and agreed to, by whom, and when.
- Review documentation is an original observation and shall be retained as part of the technical record. See section 7.5.1 for details.

7. The technical review ensures that the case records and the report conform with proper technical sectional procedures and quality policies.

8. All changes made to administrative and technical records because of verification, technical review or administrative review must be tracked in the case and/or the batch record. Section management will determine what tracking method is used. If non-electronic forms such as worksheets or checklists are used, they must be added to the case and/or the batch record.

When an area of concern is identified that cannot be resolved between the forensic practitioner and the reviewer, the section's technical management will be referred to for resolution. Even when resolved, sectional management should be notified if technical issues arise.

- To ensure the quality of forensic results, HFSC may subject completed casework to secondary review, commonly referred to as a post-mortem review.

7.7.2. HFSC monitors performance by participating in external proficiency testing when available. The purpose of proficiency tests is to demonstrate the ongoing competence of HFSC and/or that of its forensic practitioners by comparison with results of other laboratories. Forensic practitioners should participate in the portions of a proficiency test that are most closely reflective of their current casework responsibilities. Participation beyond that of current casework responsibilities should be avoided.

Proficiency tests are purchased from external test providers.



7.7.2.1. HFSC's proficiency testing program meets at least the minimum requirements set by its accrediting body. CS/CM staff are not subject to proficiency test requirements.

Forensic practitioners performing DNA analysis will comply with the proficiency requirements of the FBI QAS for Forensic DNA Testing Laboratories. The date the test is due in-house will be used for calculating the time between DNA proficiency tests.

Each technical discipline will successfully complete at least one external proficiency test per calendar year, if one is available, for each discipline listed on HFSC's scope of accreditation in which HFSC provides services.

7.7.3. Quality control data is analyzed, used to control and, if applicable, improve HFSC activities. If the results of data analysis are outside predefined criteria, action is taken to correct the problem and to prevent incorrect results from being reported. Examination results will not be released if quality control data are outside of defined criteria. Further detailed information can be found in applicable sectional SOPs.

7.7.4. Monitoring Performance of Personnel

HFSC monitors the performance of personnel who perform laboratory activities and evidence handling tasks. Monitoring of laboratory activities is described below; monitoring of evidence handling tasks is described in the CS/CM SOP.

HFSC monitors laboratory activities through the successful completion of proficiency tests (internal or external). Each forensic practitioner must complete one proficiency test per year in the forensic disciplines in which he/she has been authorized. DNA forensic practitioners and technicians will complete two tests per year. This test may be internal or external. A competency test may take the place of a proficiency test during the first calendar year that a forensic practitioner is authorized to conduct casework. However, DNA forensic practitioners and technicians will enter the proficiency-testing program within eight months of competency.

7.7.5. HFSC's process for monitoring the performance of the laboratory and personnel shall:

- a. ensure that results are not known or readily available to the participant.
- b. ensure that approved methods are followed as closely as possible. In addition, forensic practitioners must also follow the provider's instructions for external proficiency tests. Some exceptions may apply. For example, evidence descriptions and itemizations in LIMS may differ from those in routine casework. An external provider's data sheets will be completed in addition to any required report. Results recorded on the data sheet shall mirror that on the report and vice versa. In addition, proficiency test reports shall mimic the reporting format and language of normal casework as closely as practicable.



Technical review, verification, and administrative review policies will be followed as they are in casework. Testing participants may not discuss the results of the test with another test taker prior to the final due date. Should consultation be required, the individuals with whom the proficiency test is discussed may not perform a technical or administrative review of the test. Consultation may not be with individuals who have knowledge regarding the test beyond the information that is available from the individual performing the test in question. If the individual consulted is aware of results or observations made by another forensic practitioner, that information may not be used to aid the test taker. This does not preclude one individual from reviewing multiple tests or from acting as a second reader on multiple tests.

- c. establish criteria for successful performance prior to the monitoring activity being conducted.

Proficiency tests are evaluated for conformance to the expected results. If the expected results are not obtained, section management and the Quality Division will investigate. The results of the investigation will determine how unexpected results are documented, and if a Nonconformance workflow needs to be initiated.

Section managers are informed of the results of all applicable participants. The **section management** and the DNA Technical Leader and CODIS administrator (if applicable), are required to sign the proficiency test results forms. These signatures serve as documentation of their acknowledgment of any discrepancies in the proficiency test results.

- d. The Quality Division shall work with section management to ensure the quality of monitoring activities prior to the performance being monitored. For external proficiency tests, see section 7.7.7.a.

If direct observations are used as a monitoring activity, section management shall ensure appropriate forensic examinations are chosen. The observation shall be performed by someone authorized in that activity and able to observe without interfering.

- e. HFSC does not perform calibration services.
- f. notify ANAB within 30 days when expected results are not obtained during performance monitoring.

7.7.6. HFSC has a proficiency plan that:

- a. conforms to the requirements set forth in this manual and to the applicable requirements in ANAB's Forensic Science Testing and Calibration Laboratories Accreditation Requirements.
- b. ensures inclusion of a portion of the components/parameters and equipment/technologies within each discipline listed in HFSC's scope of accreditation.



If proficiency tests (internal or external) are not feasible, HFSC may choose to perform observation-based monitoring of applicable casework as delineated in the monitoring plan.

- 7.7.7. HFSC uses approved proficiency test providers when available and ensures that:
- a. approved providers are appropriate for the type of testing and operate in accordance with the ISO/IEC 17043 standard, or,
 - b. if there are no commercial accredited proficiency tests available for a discipline, an alternate proficiency test plan will be created and approved by ANAB.
 - c. proficiency results are submitted to the external provider on or before the provider's due date. Any exceptions will be documented.
- 7.7.8. The Quality Division maintains records of HFSC's monitoring program. The records include:
- a. participating sections.
 - b. design and review of the test-cycle program.
 - c. expected results.
 - d. location of testing.
 - e. records submitted to the test provider, if applicable.
 - f. evaluation of results and actions taken for unexpected results.
 - g. feedback on individual performance provided to the participants.

Proficiency test records will be retained per HFSC's Records Retention Policy.

7.8. Reporting of Results

7.8.1. General

Reports are maintained in LIMS and are titled "Laboratory Report" followed by report number. Historical reports may be stored electronically, in paper case records, or on microfilm. HFSC reports are issued once technical and administrative review milestones are met.

Technical results can be verbally released or discussed with appropriate parties prior to issuing a report when a documented verification or review of a technical nature has been performed on the information being released. The release of information must also have documented approval from section management in the case record prior to its release. The release of technical information prior to issuing a report should be limited to extraordinary circumstances in which a serious incident is being actively investigated and the results may offer key leads. Additional extraordinary circumstances may include release of results to comply with applicable laws, court rulings and orders, or similar legal requirements (such as providing results to assist prosecutors and defense attorneys meet and confer about biological evidence testing in death penalty cases). Please consult HFSC Legal Counsel and the Quality Division for more information on how to handle these types of situations.

CSU and Multimedia are exempt from this requirement only when they are at a scene because of the collaborative nature of their job functions.



7.8.1.1. Laboratory reports are signed by the forensic practitioner who reviewed the results and authorized their release.

The assigned forensic practitioner is responsible for the accuracy and completeness of the report. These reports contain conclusions and opinions that address the purpose for which work is undertaken and should be formatted to minimize the possibility of misunderstanding or misuse. Supporting information that is not included in the report is readily available in the case record.

If a report needs to be issued and the assigned forensic practitioner is on leave or has departed HFSC, section management or designee shall sign the report on behalf of the forensic practitioner. The report shall reference that the forensic services were performed by another forensic practitioner, list the forensic practitioner's name, and state that the report was signed on behalf of the forensic practitioner.

7.8.1.1.1. The authorizer of the results shall also review the technical record. By signing the report, the authorizer is acknowledging that he/she has reviewed the technical record.

7.8.1.2. Results of forensic testing shall be provided to the stakeholder in the form of a report. Results are communicated accurately, clearly, unambiguously, and objectively.

7.8.1.2.1. Written reports are provided to stakeholders, usually in an electronic format generated from LIMS.

7.8.1.2.2. The following supporting information, where applicable, will be included in reports:

- a. items of evidence (evidence collected by or created by forensic practitioners, evidence received from stakeholders), including items not tested. Additional information may be found in sectional SOPs.
 - If partial work is performed on an item of evidence, the work completed will be reported unless prohibited for legal reasons. See section 7.1.6 for additional information.
- b. significance of associations whether by a statistical or qualitative statement.
- c. clearly communicated reasons when the reported results indicate that no definitive conclusion can be reached.
- d. initial database entries.

7.8.1.2.3. HFSC does not perform calibration services.

7.8.1.3. HFSC has a simplified laboratory report agreement with its stakeholders. The agreement specifies that sections 7.8.2.1.h and 7.8.2.1.i are available in the case record but are not included on reports.



7.8.2. Common Requirements for Laboratory Reports

7.8.2.1. The following must be included on reports unless an exception is documented by an acknowledged simplified report agreement (see section 7.8.1.3):

- a. title.
- b. name and address of the laboratory.
- c. location where the activities were performed, if different from above. If a laboratory activity is performed remotely documentation will be made in the case record to indicate which activities were completed off-site.
- d. unique identifier shall be present on each page and each page shall be recognized as part of the report; a clear identification of the end of the report (e.g., page X of Y).
- e. name and contact information of the stakeholder.
- f. identification of the method used. Reported results obtained using unvalidated methods will not contain an accreditation statement or accreditation body logo.
- g. description, identification, and when necessary, the condition of the items.
- h. date of receipt of evidence and the date of sampling, where sampling is critical to the validity and application of the results (see section 7.8.1.3).
- i. date the testing was performed (see section 7.8.1.3).
- j. date the report was issued.
- k. sampling plan, if relevant to the validity of the results.
- l. statement that the results relate only to the items tested.
- m. where appropriate, units of measurements.
- n. deviations from the technical test method will be documented in the report.
- o. identification of the person authorizing the report.
- p. clear identification when tests are performed by subcontractors. If the results of the subcontracted tests are included on a report that refers to accreditation, approval shall be obtained from the subcontractor to include excerpts from the subcontractor's report or certificate.

Note: Reports (may be referred to as notifications) that do not contain test results, opinions, or interpretations are not subject to the above requirements.

7.8.2.2. HFSC is responsible for all reported information, except when the information is provided by the stakeholder. If included in reports, information provided by the stakeholder, including data, shall be identified. HFSC reports include a disclaimer stating that it is not responsible for information provided by the stakeholder since this information could affect the validity of results. Unless otherwise noted, reports will reflect the results of evidence as received from the stakeholder.

7.8.3. Specific Requirements for Laboratory Reports



- 7.8.3.1. In addition to the information listed in section 7.8.2, laboratory reports shall, where necessary for the interpretation of results, include the following:
- a. information on the specific test conditions, such as environmental conditions.
 - b. statement of compliance/noncompliance with requirements and/or specifications.
 - c. information on uncertainty when it is relevant to the validity or application of the test results, when a stakeholder requests the information, or when the uncertainty affects compliance to a specification limit.
 - The measurement of uncertainty shall:
 - be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by the regulatory body, a statute, case law, or other legal requirement.
 - include the measured quantity value, y , along with the associated expanded uncertainty, U , and the coverage probability.
 - be in the form of $y \pm U$.
 - be limited to at most two significant digits unless there is documented rationale for reporting additional significant digits.
 - be reported to the same level of significance as the measurement itself.
 - d. opinions and interpretation, if appropriate.
 - e. additional information that may be required by specific methods or stakeholders.

7.8.3.1.1. The State of Texas does not prohibit reporting measurement uncertainty. HFSC will follow statute requirements for reporting when applicable (e.g., reporting cocaine hydrochloride vs cocaine base for federal cases).

- 7.8.3.2. When HFSC is responsible for the sampling, laboratory reports shall meet the requirements listed in section 7.8.5 where necessary for the interpretation of test results.

7.8.4. HFSC does not perform calibration services.

7.8.5. Reporting Sampling – Specific Requirements

In addition to the requirements listed above, laboratory reports containing results of sampling shall include the following when necessary for the interpretation of the results:

- a. date of sampling.
- b. unambiguous identification of the substance sampled.
- c. the location of sampling, including any diagrams, sketches, or photographs.
- d. reference to the sampling plan and procedures used.



- The report shall include confidence levels and corresponding inferences regarding the population.
- e. details of any environmental conditions during sampling that might affect the interpretation of the test results.
- f. information required to evaluate measurement uncertainty for subsequent testing.

7.8.6. Reporting Statements of Conformity

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

7.8.6.2. Reported statements of conformity shall include:

- a. results to which the statements of conformity apply.
- b. which specifications, standards or parts thereof are met or not met.
- c. the decision rule applied (unless it is inherent in the requested specification or standard).

7.8.7. Reporting Opinions and Interpretations

7.8.7.1. When opinions or interpretations are included in laboratory reports, they will be provided by forensic practitioners who have completed appropriate training and are authorized to express opinions and interpretations.

7.8.7.2. Opinions and interpretations shall be based on examination results and are clearly marked as such when included in the laboratory report.

7.8.7.3. Opinions and interpretations not detailed in a report may be verbally communicated with the stakeholder only by technically authorized staff members. A record of the opinion or interpretation must be documented in the case record.

7.8.8. Amendments to Laboratory Reports

7.8.8.1. If technical errors or omissions, or other quality-related concerns, are noted on reports after they have been issued, an amended report is required. Amended reports shall include a statement that clearly identifies what report is being amended, and the reason for the amendment.

If a report requires amending, Quality shall be notified through the Qualtrax Nonconformance workflow, and the workflow should include the intended report comment. Once Quality has reviewed and approved the comment, the report can be amended. If an amended report is part of an incident or corrective action, the report statement shall reference the quality tracking number (see section 7.10).



- 7.8.8.2. If a report requires amending, HFSC will issue a new report. The new report will be uniquely identified by an amended report statement in the header of the report, the issue date, and the unique identifier. The amended report header statement will reference the original report, which may be identified by the original issue date.
- 7.8.8.3. If re-analyzing evidence is necessary (for example, if the original examiner has retired or new technology is available), a new request may be generated, and a new report will be issued. The new report will reference the original report or previous analysis. If a quality tracking number has been assigned to nonconforming work related to the re-analysis, the new report will reference the number.

7.9. Complaints Related to Technical Procedures and the Quality System

- 7.9.1. HFSC has a documented procedure for receiving, evaluating, and resolving complaints. Complaints can be submitted to HFSC through the Complaints & Issues link on the HFSC website (<http://www.hfsctx.gov>) or initiated by staff using the Complaint Form located in Qualtrax in the Quality > Forms folder. HFSC also provides a link on emails that can be used by recipients to provide feedback. If HFSC receives negative feedback from a survey response, the Quality Division will investigate and determine if the feedback should be tracked as a complaint.
- 7.9.2. Staff members receiving a complaint will resolve the complaint if within their authority to do so (e.g., if a stakeholder needs clarification or additional information regarding technical results). If the complaint is related to a specific case, the complaint and its resolution will be documented in the case record. If a complaint cannot be readily resolved, or if the complainant requests an investigation into their complaint, the person who receives the complaint must forward the complaint to the Quality Division. If Quality receives a section-specific complaint, they will notify and work with section management to resolve the complaint. Personnel-related complaints should be directed to and processed by section management and HR.
- 7.9.3. Processing complaints related to quality.
- Upon receipt, unresolved complaints are submitted to the Quality Division for review to determine whether the complaint is valid. If a Complaints & Issues survey is determined to be invalid, documentation will be kept supporting that determination. When necessary, complaints are investigated to determine the appropriate decisions and actions needed for resolution. The investigation will be handled through the Quality Division and section management.
 - Complaints and their resolutions are tracked through the Quality Division. Formal corrective action will be initiated if warranted (see section 8.7).
 - Actions taken to address complaints are approved by the Quality Division to ensure they are appropriate for resolving the concern.



- 7.9.4. Complaints & Issues surveys will be reviewed and evaluated by the Quality Division upon receipt. The evaluation includes gathering the relevant information necessary to validate the credibility of the complaint. Quality will review the complaint to ensure all relevant information is documented.
- 7.9.5. Whenever possible, the complainant is notified when HFSC receives the complaint and may be updated with relevant progress reports.
- 7.9.6. The final resolution of the complaint will be made by, or reviewed and approved by, an individual not involved in the HFSC activities in question.
- 7.9.7. If the complainant has provided HFSC with contact information, HFSC will notify the complainant with a formal notice when the complaint is resolved.

7.10. Nonconforming Work

- 7.10.1. HFSC has a procedure to address any laboratory activities that do not conform to its own procedures or the agreed requirements of its stakeholders. Nonconforming work includes but is not limited to the unapproved deviation from a policy, procedure, process, or other quality management document (e.g., quality, safety, or security manuals), equipment malfunctions, mishandling of evidence, inaccurate testimony, inaccurate analysis, and/or reporting of results that may affect the accuracy, reliability, and/or integrity of HFSC's testing or laboratory reports. Nonconformances, whether involving the management system or technical work, may be identified through internal audits, assessments, management reviews, stakeholders, or staff.

There may be situations or errors that affect reported results or impact the technical work that is outside of the control of HFSC. For example, system issues in the CODIS or AFIS systems identified by the proprietor. Depending on the impact on case(s), HFSC may choose to address the issue as nonconforming work to document what occurred and the actions taken to address the issue. Such situations may result in root causes and/or corrective actions that HFSC cannot address.

For the purposes of AR 3181 compliance, nonconforming work procedures will be initiated when CS/CM conducts an incorrect evidence transfer or evidence is discovered to be misplaced in storage locations that prevent CS/CM from conducting evidence tasks, including evidence audits.

The following procedures are employed when nonconforming work is identified:

- a. the Quality Division, under the direction of the Quality Director, has responsibility and authority to manage nonconforming work. The Quality Division works with HFSC management and appropriate forensic practitioners to ensure that nonconforming work is reported and resolved appropriately.

Section management is responsible for notifying Quality of nonconforming work as soon as practicable. The division directors, Quality Director, section managers and, in some instances, the DNA technical leader and/or CODIS administrator (or



their designees) have the authority to halt work at HFSC and implement other necessary short-term responses to nonconformities. Nonconforming work, and any work stoppages, shall be reported to the Quality Division as soon as practicable by email, phone, Teams, Qualtrax, in-person, or other similar means.

The Quality Division, with input from section management, will delegate or initiate an investigation into nonconforming work and identify individuals responsible for collaborating with the Quality Division.

- b. appropriate actions are taken to address nonconforming work based on the level of risk to the technical record or to the stakeholder's investigation. Risks are assessed for each nonconformance as part of the quality investigation.
- c. the Quality Division works with section management to evaluate the significance of the nonconformance and to determine the level of risk to the technical work or the quality management system, and the impact on any previously reported results.

HFSC uses a qualitative approach to establish risk levels associated with nonconforming work. Several factors are considered when determining the risk level, including the impact to HFSC's management system or work product, the likelihood of a recurrence, and whether the nonconformance was systemic or a one-time occurrence.

HFSC evaluates nonconforming work and assigns categories based on the following risk levels:

Risk Level: minimal to none (no action needed)

Investigation into nonconforming work that determines there was little to no impact on the management system or technical work will not require a root cause analysis or corrective action plan. Documentation in the case record is required. Continued recurrences may be elevated to a quality incident or corrective action.

Risk Level: Low (Incident)

Nonconforming work with a low impact on the management system or any technical work, including reported results, are documented as incidents and assigned a quality tracking number. Incidents do not require a root cause analysis nor a formal corrective action plan, although corrective actions may be required to remediate the nonconformance. Continued recurrences may be elevated to a corrective action.

Risk Level: Moderate to High (corrective action)

Nonconforming work that affects the quality of work and may be serious enough to cause immediate concern for the overall quality of HFSC's work product. Moderate to high risk nonconformances are tracked as corrective actions and



assigned a quality tracking number. A root cause analysis is required, as well as actions taken to mitigate the nonconformance. Moderate to high nonconforming work may require disclosure to HFSC's accrediting bodies.

- d. based on the evaluation of the nonconformance, a decision will be made regarding the acceptability of the work. If a forensic examination is deemed unacceptable, it will be re-worked when possible. Evidence will be recalled if necessary.

Nonconforming work identified through the blind QC program will be reviewed by the Quality Division and section management to determine whether there is a risk to case work or an opportunity for improvement and documented as appropriate.

- e. HFSC notifies stakeholders of nonconforming work that affects reported results and when evidence needs to be recalled for additional testing by uploading closed corrective actions and incident reports (quality reports) to LIMS. Quality reports are also uploaded to HFSC's external public facing site. There may be instances where the stakeholder is notified prior to the release of the quality report. Such notification shall be documented in the case record.
 - If a corrective action/incident involves casework and a laboratory report has not yet been issued, the report shall reference the quality tracking number. This applies only to the discipline and requests involved in the quality action, not to all reports associated with the case. In instances when the report has been issued before the nonconformance was discovered, if is not necessary to amend the report for the sole purpose of mentioning the quality report.
 - If a corrective action or incident results in an amended report, the amended report will reference the quality tracking number and will serve as stakeholder notification (see section 7.8.8.1).
 - In accordance with Texas law, HFSC management or general counsel will notify the TFSC of instances of professional negligence or misconduct. Notification will also be made to the HFSC Board of Directors and HFSC's accrediting body. Legal entities will be notified in accordance with Texas Code of Criminal Procedure 39.14 (commonly referred to as the Michael Morton Act). Occurrences that require notification include, but are not limited to:
 - professional negligence or misconduct by a forensic practitioner.
 - misrepresentation of education, training, or experience.
 - other situations or conditions that raise immediate and/or significant concerns affecting the quality of HFSC's work or the reliability of reported results.
- f. if work was halted, the resumption of work shall be a cooperative decision between the Quality Director and section management. The DNA technical lead shall be involved in the decision to resume work for Forensic Biology.

7.10.2. The Qualtrax Nonconformance workflow is used to document nonconforming work when there is a moderate to high risk to the management system or to technical work.



Nonconforming work with a minimal to low risk may be documented as a Nonconformance workflow, a memo, or in the case record.

The Quality Division will work with section management to determine the appropriate method for documenting minimal to low-risk nonconforming work, with the ultimate decision and documentation approval resting with the Quality Division.

- 7.10.3. Corrective actions are implemented when the evaluation of nonconforming work identifies a risk of recurrence or when there is doubt regarding conformity of HFSC's operations with its own management system (see section 8.7).

7.11. Control of Data and Information Management

7.11.1. HFSC staff members have access to the data and information necessary to conduct requested forensic services. Case-related information shall be maintained in paper case records or electronically. Software programs utilized by HFSC for forensic services and data storage include but are not limited to: JusticeTrax, Porter Lee, Mideo, Qualtrax, and SharePoint.

7.11.2. HFSC uses commercially available off-the-shelf LIMS software designed for forensic applications for collecting, processing, recording, reporting, reviewing, storage, or retrieval of data. The LIMS administrators validate software to ensure the proper functioning of interfaces within LIMS prior to introduction. Changes, including laboratory software configurations or modifications to commercial off-the-shelf software, shall be authorized, documented, and validated prior to implementation.

7.11.2.1. Software developed by HFSC shall have a validation plan. The section responsible for developing the software shall maintain the validation documentation.

7.11.3. HFSC ensures that LIMS:

- a. is accessed only by approved personnel. If an external individual (e.g., vendor or contractor) needs access to an HFSC network, an HFSC employee will grant them access as appropriate.
- b. is safeguarded against tampering and loss.
- c. is operated in an environment that complies with the provider's or laboratory's specifications or, in the case of non-computerized systems, proves conditions that safeguard the accuracy of manual recording and transcription.
- d. is maintained in a manner that ensures the integrity of the data and information.
- e. system failures that prohibit or limit staff ability to access and work in LIMS and actions taken to address such failures are recorded.

7.11.4. HFSC LIMS are housed off-site in the government cloud through the Microsoft Azure platform. This platform is Criminal Justice Information Services (CJIS) compliant and complies with the requirements of this document.



7.11.5. The HFSC LIMS administrators maintain relevant instruction materials, manuals, and reference data regarding LIMS. This information is available to all HFSC staff utilizing LIMS.

7.11.6. Manual calculations and data transfers are checked prior to or during technical and/or administrative review and the review is conducted by a person other than the person who performed the calculation(s) or the data transfers. Detailed information may be found within sectional SOPs.

When worksheets (e.g., Excel spreadsheets) are used in casework to process data or perform calculations based on data they shall be determined to be fit for purpose, provide consistent and reliable results, and shall be controlled. Modifications to these worksheets shall be checked to verify that any changes made did not adversely affect the functionality of the worksheet prior to use.



8. Management System Requirements

8.1. General

8.1.1. HFSC has a management system that is established, documented, implemented, and maintained in a manner that supports and demonstrates compliance to the standards set forth in ISO/IEC 17025, the ANAB Forensic Science Testing and Calibration Laboratories Accreditation Requirements, the TFSC, OSAC Registry standards, where applicable, its own policies and procedures. HFSC operates its management system in accordance with Option A (clause 8.1.2) of ISO/IEC 17025 clause 8.1.

8.1.2. The following sections describe HFSC's management system documentation (8.2), control of documents (8.3), control of records (8.4), actions to address risk and opportunities (8.5), improvements (8.6), quality incidents and corrective actions (8.7), internal audits (8.8), and management reviews (8.9).

8.2. Management System Documentation

8.2.1. HFSC manages and maintains policies and procedures appropriate to the range of its activities for the fulfilment of accreditation standards. HFSC ensures that its policies and procedures are available to all staff and are implemented at all levels of HFSC operations. Acknowledgement of the review of HFSC policies and procedures by staff is maintained in Qualtrax.

8.2.1.1. The following words are required to be addressed in writing when used in the Quality Manual: agreed, authorize, define, instructions, method, plan (noun only), procedure, program, record, schedule, and specify.

8.2.2. The quality system is a mechanism to ensure that HFSC provides competent, impartial, and consistent forensic services. To this end, all staff members are responsible for following the requirements contained in this manual.

Deviations that affect entire sections (or division, or the entire company) shall be utilized sparingly. These changes shall be documented in a memo signed by management and the Quality Division and shall reference the clause and issue date/version number of the document. The memo shall be shared with all affected staff and shall document critical information, such as when the deviation goes into effect, any unique circumstances that it addresses, or if it is only applicable for a given period. If the deviation leads to a permanent change, it shall be incorporated into the next SOP revision.

One-time deviations where revising a controlled document is not necessary nor affects the entire section shall be documented and approved by section management. When the deviation is casework related, case records shall contain documentation of the deviation and section management approval.



An exception for the timing of approval will be made for the Crime Scene Unit when there are exigent circumstances. Please see the Crime Scene Unit SOP for additional information.

Clarification for the interpretation of sectional SOPs may be documented in the form of a memo, signed by the section manager and Quality Division. The memo shall be provided to all applicable staff. Clarification memos regarding the Quality Manual will be signed by the Quality Director and provided to all staff.

8.2.3. HFSC management reviews the development, implementation, improvement, and continued effectiveness of the quality system. These reviews may include internal audit(s) reports, external assessment reports, annual management review reports, blind quality control reports, complaints, communications from stakeholders, proficiency testing results, quality reports, preventive action reports, and testimony evaluations.

8.2.4. All HFSC management system documents related to the fulfillment of accreditation requirements are available in Qualtrax. Such documents include, but are not limited to, this Quality Manual, the Safety Manual, the Security Manual, administrative policies, and section SOPs and training manuals. Quality policies that affect the technical divisions are included in this Quality Manual and may be expanded in sectional SOPs. This manual is complemented by sectional SOPs and training manuals. Each document is intended to work in concert with the others, but should a conflict arise, the standards set forth in this manual will supersede those of the individual sections unless sectional requirements are more restrictive than those in this manual. In general, nontechnical corporate policies and procedures will supersede corresponding nontechnical information that is included in this manual. Discipline-specific manuals will not be less stringent than this Quality Manual.

Quality Records

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

- internal audit reports.
- management reviews.
- corrective and preventive actions.
- proficiency tests.
- testimony monitoring.
- training records.

HFSC adopts OSAC Registry standards applicable to individual forensic science disciplines and inter-disciplinary standards. When applicable standards are published on the OSAC Registry a representative(s) from the Quality Division and a representative(s) from the technical section will review the standard and develop a plan that establishes an appropriate timeline for the completion of a gap analysis. While the target timeline for completion of a gap analysis is 7 months from the date of publication, specific deadlines will be determined by considering several factors (e.g., the number of standards published within the same timeframe, the number of standards published within the same



discipline, the complexity of the standard). Upon completion of the gap analysis, the section will commit to an action plan timeline for compliance to the standard.

8.2.5. All HFSC personnel have access to the parts of the management system documentation applicable to their duties and responsibilities. This access is provided through Qualtrax. All staff are assigned a Qualtrax system user identification and password and are expected to use Qualtrax to access all management system documentation applicable to their job functions. Management system documents include internal policies and procedures, controlled forms, externally prepared documents, and standards that are referenced or used in HFSC. All internally generated management documents that are approved for use are in an electronic format and available for review by staff members. Approval may be denoted by digital or handwritten signature.

8.3. Control of Management System Documents

8.3.1. HFSC controls all documents that form its management system. The term *document* may mean a paper or electronic file that includes regulations, standards, test methods, drawings, software, specifications, instructions, and manuals. Controlled documents that form the management system are maintained in Qualtrax. Service contracts are uploaded to Qualtrax under the purview of the Finance Division rather than the quality system.

All staff members (including independent contractors who perform technical work at HFSC) review revisions to the Quality Manual, the Safety Manual, and the Security Manual. Sectional SOPs are reviewed by those individuals assigned to technical positions within that section. Staff members holding nontechnical positions assigned to analytical sections are required to read all general procedures that affect their position. These reviews are documented.

8.3.2. Document Approval, Issue, and Review

- a. This Quality Manual is approved by executive management and reviewed by section management prior to being issued by the Quality Director.

Technical sections and CS/CM procedures, training manuals and worksheets are approved by the section manager or designee, and the Quality Division prior to issue. These documents are controlled and maintained in Qualtrax. The DNA Technical Leader must also approve all controlled documents issued within the Forensic Biology Section.

When new or revised SOPs or training manuals are approved and issued in Qualtrax, section management will ensure that the most current versions are posted on HFSC's external facing site.

Controlled documents will not be used on casework until approved by the appropriate parties. Staff members are notified when controlled documents are issued, revised, or rescinded.



Although administrative procedures are not covered by this Quality Manual, they are reviewed, revised, and controlled in Qualtrax. Administrative procedures are approved by the corresponding division director or designee (e.g., HR, Finance).

- b. Controlled documents are reviewed and updated as needed at least once each calendar year by appropriate management personnel. Even if no revision is made after the review, documentation will show that an annual review was completed.
- c. Document version histories, issue dates, and review and approval histories are maintained in Qualtrax for controlled documents. Changes to controlled documents are made through the following process:
 - document changes and/or revisions are approved using the approval policy stated above.
 - when revisions are made to existing documents and result in the issuance of a new manual, the altered or new text is clearly marked in red font. Other means of delineating changes to new revisions must be approved by the Quality Director prior to use. These requirements do not extend to worksheets.
 - controlled documents are stored in Qualtrax. Document reviews, revisions, and edits are made by management or their designee.
- d. The official versions of controlled documents are published in an electronic format and can be viewed from any networked computer.
- e. Management system documents created internally are identified by:
 - title.
 - issue date.
 - page number.
 - total number of pages or a mark to signify the end of the document.
 - issuing authority.

Technical procedure manuals are formatted with headers and/or footers that contain required information. Forms are formatted in a way that is practical and applicable to that task. Procedures are posted in an electronic format and are the controlling documents followed by staff members.

- f. Controlled documents are uncontrolled when printed. Staff members are responsible for ensuring they are utilizing the most current version when using a printed document. Any uncontrolled document that is not current shall be shredded or clearly marked to indicate that it is no longer in use. Portions of SOPs printed for reference purposes and used in the laboratory must include the issue date. These bench sheets are removed from the laboratory when they become obsolete. Obsolete documents are marked to ensure that they are not confused with current versions.

8.4. Control of Records

- 8.4.1. Records are legible, in a readily retrievable format, and stored in secure locations. They may be maintained in hard copy or electronic format. Paper files and microfilm are stored



in limited-access areas, whether in HFSC offices or in secure, off-site facilities. Paper-based case files may also be stored in the custody of an HFSC staff member.

- 8.4.2. Records shall be stored in an environment designed to prevent damage, deterioration, and loss. Case files stored on-site are grouped by section and should be filed numerically by unique case identifier. Technical records, such as reagent logs, maintenance or calibration logs, and temperature logs, are stored in an orderly fashion in locations designated by the section management.

Quality, administrative, personnel (including training) and technical records will be stored or shredded in accordance with the HFSC Record Retention Policy and Record Retention Schedule. HFSC's policy meets or exceeds the record retention requirements of its accrediting body and the FBI.

When making electronic versions of records, the original documents will not be shredded prior to the time frames listed in the Record Retention Schedule. Documented verification that the scanned documents were compared to the originals to ensure all pages were scanned and are legible must also be completed prior to shredding the originals. When scanned documents are part of a case record, verification includes ensuring the scanned version is added to the correct case record. The individual shredding the documents is responsible for ensuring a true and correct electronic copy has been made. Section management has the authority to determine how this verification process is documented. One acceptable method is to include a comment in the LIMS case record. Documents and records will be shredded or otherwise disposed of in a manner that ensures the confidentiality of the information.

Regardless of the format of the record (electronic, paper, microfilm), HFSC will provide copies of the record upon request from its stakeholders.

- Electronic records are stored using LIMS, Mideo, Qualtrax, or on a network server. Electronic storage systems are backed up and secured to protect the records and to prevent unauthorized access or amendment of the records. Changes to records stored in LIMS are tracked through the system's audit log function. The LIMS database is password protected and backed-up to a secure location. Access to electronic records is limited to those having usernames and passwords issued at the direction of management.

Case Records

A case record is maintained for each request for forensic services and is identified by an FCN or ACN. Prior to February 1, 2014, records may have been identified by the FCN, ACN, laboratory number (sometimes referred to as the L number), or another unique identifier.

8.5. Actions Taken to Address Risks and Opportunities

- 8.5.1. HFSC evaluates risks and opportunities associated with its laboratory activities through the following:



- a. evaluating the management system to ensure that it achieves its intended results (see section 8.9).
- b. enhancing opportunities to achieve HFSC objectives and fulfill its purpose (see section 8.2).
- c. preventing or reducing potential failures so that HFSC can continue providing quality work to stakeholders (see section 8.7).
- d. achieving improvements (see section 8.6).

Risks and opportunities are identified through management system activities which may include, but are not limited to, risk assessments of technical section processes, recommendations raised during internal audits and external assessments, preventive actions, personnel training programs, case record and testimony reviews, proficiency testing, HFSC's blind QC program, corrective actions, and external complaints.

8.5.1.1. HFSC Executive Management Team shall designate individuals responsible for assessing risks and opportunities related to HFSC's safety program.

8.5.2. HFSC documents actions taken to address risks and opportunities through:

- a. preventive actions and risks assessments.
- b. the integration of action plans into HFSC's management system and evaluation of their effectiveness. When risks are associated with nonconforming work, the action plan will include actions taken to reduce the likelihood of recurrence and the evaluation of the effectiveness of those actions.

8.5.3. Actions taken by HFSC management to address risks and opportunities are appropriate for the potential impact the risks and opportunities have on the validity of testing or processing activities.

8.6. Improvements

8.6.1. Management is committed to the ongoing development of HFSC's quality system with the goal of meeting or exceeding stakeholders' needs and regulatory and statutory requirements. This manual is intended to aid in maintaining an environment of continuous improvement in the management system and in services provided by HFSC. HFSC continually identifies and selects opportunities to improve the effectiveness of its management system through a variety of activities including, but not limited to, management reviews, corrective and preventive actions, evaluating risks and opportunities, internal audits, external assessments, reviewing technical procedures, proficiency tests, the blind QC testing program, and suggestions from personnel.

HFSC utilizes several avenues to evaluate and report opportunities for improvements, including through the Quality Division's preventive action process. Proposed preventive actions are evaluated by the Quality Division in conjunction with section management to determine if they will ultimately benefit HFSC. Preventive actions can include but are not limited to the creation of a new process, increasing the efficiency of an existing process, or



making a positive change to an existing process with the goal of minimizing error or increasing transparency and/or consistency.

HFSC has a dedicated LSS group tasked with soliciting HFSC staff suggestions for improvement opportunities. These opportunities are evaluated to determine if their implementation will improve HFSC efficiency and effectiveness.

8.6.2. HFSC seeks feedback (positive or negative) from its stakeholders. Stakeholder feedback may be sought through personal communication, attendance at meetings, and/or through periodic surveys. In addition, a feedback survey link has been added to HFSC emails and the same feedback survey can be found in the "Contact Us" section of the HFSC website. The responses are maintained and provided to appropriate section management. This feedback can be used to improve HFSC's management system, testing activities, and stakeholder services. HFSC will document a response to any negative feedback received and take action to resolve concerns as applicable.

8.7. Corrective Actions

The purpose of HFSC's corrective action and quality incident procedure is to maintain and improve the quality of work performed by HFSC. Nonconforming work is evaluated to determine the appropriate risk level (see section 7.10).

HFSC shall notify its accrediting bodies of nonconforming work that affects the integrity of laboratory activities and is related to an accreditation requirement within 30 days of occurrence. If the nonconformance is identified after 30 days, it shall be disclosed immediately.

8.7.1. When nonconforming work has a significant technical impact the Quality Division shall consult with appropriate management to:

- a. take any immediate actions needed to control and correct the nonconforming work. The Quality Division will work with management to assess the consequences of nonconforming work and take appropriate corrective actions.
- b. evaluate the need for action to address the cause of the nonconformance and develop corrective actions to prevent or reduce recurrence. The evaluation will include reviewing and analyzing the nonconformity, determining the root cause only for moderate to high-risk nonconformities ("corrective actions"), and determining if other instances of similar nonconforming work have occurred or could occur.

Personnel related nonconformances may be addressed through HR's Progressive Corrective Action Policy.

- c. implement actions that resolve the issue and prevent or reduce recurrence. Actions will also be taken to address the consequence of the nonconforming work, including issuing amended laboratory reports if necessary (see section 7.10.1).
- d. monitor actions taken to determine effectiveness. Additional follow-up actions will be taken if the initial actions did not prevent recurrence or if further



improvements are necessary. The effectiveness of corrective actions may be documented through the Nonconformance Follow-Up Report workflow in Qualtrax, during internal audits reviews, or during the annual management review.

- e. Update risks and opportunities identified during the investigation into the action taken if necessary.
- f. take appropriate actions to address deficiencies in the management system, if necessary.
- g. address nonconforming work in a timely manner. Deadlines for completion of corrective actions are built into Qualtrax. The target timeframe for completion is 50 working days for corrective actions. The Quality Division acknowledges there may be instances where this timeframe is not reasonable. The turnaround time for corrective actions will be evaluated during the annual management review.

8.7.2. Corrective actions are developed and implemented to appropriately address the effects of the nonconformance.

8.7.3. HFSC retains records of:

- a. a description of the nonconformance, actions taken, and root causes.
- b. the results of any corrective actions.

8.8. Internal Audits

8.8.1. HFSC conducts an internal audit to ensure the management system:

- a. conforms to all appropriate requirements such as current policies and procedures, accreditation standards, supplemental requirements, the FBI QAS for DNA Testing Laboratories, and OSAC Registry standards if applicable. The internal audit is planned and organized by the Quality Division and is completed by trained and qualified staff that are, if possible, independent of the section being audited.
- b. is effectively implemented and maintained.

8.8.1.1. The audit is conducted annually, typically covering the 12-month period since the previous internal audit or the period since the previous full external assessment.

8.8.2. HFSC Internal Audit Program

- a. The Quality Division, in conjunction with section management, will plan, establish, implement, and maintain an audit program. Internal audit plans take into consideration changes that have been implemented that affect laboratory processes and results from previous audits. Prior to each audit, the Quality Division will select an audit team. This team will include a lead auditor (typically a member of the Quality Division) and team members who will be assigned a specific discipline to audit. Each of these team members will have received audit training prior to the start of the audit. This documented training may be provided by external sources or conducted in-house. Whenever possible, teams will include at least one formally trained auditor. Audit documents, including criteria to be assessed, will be provided to the auditors. Upon completion, objective evidence



observed for any finding or nonconformance will be provided to the lead auditor. This information will be shared with section management.

- b. The Quality Division will establish the scope and criteria for each laboratory section prior to each section's internal audit. Technical section audits include direct observations of a sample of accredited services within each discipline.
- c. Audit teams communicate with section management through opening and closing meetings and periodic briefings. The audit team publishes the final audit results in the form of a report that is provided to management and posted to HFSC's external facing site.
- d. Any necessary corrective action will be implemented in a timely and appropriate manner. HFSC takes corrective action and notifies affected stakeholders in writing if the audit results cast doubt on the effectiveness of HFSC's forensic operations or the validity of testing and/or investigation results.

Follow-up audits will be conducted, if necessary, to verify the implementation and effectiveness of corrective actions taken because of the audit. The audit team is not required to give advanced notice of the follow-up audit to section management or staff.

- e. The areas of activity audited, the audit findings, and corrective actions that arise are documented and the records are retained. Records of the internal audit are retained per HFSC's records retention policy.

Required DNA audits (maybe internal or external) occur at least once each calendar year and are at least six months apart but no more than eighteen months apart. Audits completed outside this time frame do not satisfy this annual audit requirement. At least one person who is, or has been, a qualified forensic practitioner in the specific DNA technology being performed and at least one qualified auditor are a part of the DNA audit team. The qualified forensic practitioner and the qualified auditor may be the same person. A qualified auditor is a current or previously qualified DNA forensic practitioner who has successfully completed the FBI's DNA auditor training course. An external DNA audit will be conducted every two years in accordance with FBI quality assurance standard requirements. The external audits will be planned by the HFSC Quality Division.

8.9. Management Reviews

- 8.9.1. The Quality Division, in conjunction with executive management, ensures that a documented review of the management system is performed to determine the suitability, adequacy and effectiveness of the management system. Policies and objectives related to the fulfillment of HFSC's accreditation requirements, QAS requirements, and OSAC standards shall be included in the management review.

As part of the management review, the DNA Technical Leader will review and address the overall effectiveness of the Forensic Biology section. The DNA Technical Leader will also make recommendations for improvements to the Forensic Biology section and the DNA quality system as it applies to the section.



8.9.1.1. The management review is conducted at least once each calendar year.

8.9.2. The management review includes, but is not limited to:

- a. internal and external changes relevant to HFSC activities.
- b. fulfillment of management and sectional objectives.
- c. the suitability of policies and procedures.
- d. the status of actions from previous management reviews.
- e. the outcome of recent internal audits.
- f. corrective and preventive actions.
- g. assessments by external bodies.
- h. changes in the volume and type of work or in the range of laboratory activities.
- i. stakeholder and personnel feedback.
- j. complaints.
- k. the effectiveness of any implemented improvements.
- l. adequacy of resources.
- m. results of risk identification.
- n. outcome of the assurance of the validity of results.
- o. other relevant factors, such as results of performance monitoring, outcome of inventory verifications (CS/CM only), staff training, and recommendations for improvement.

8.9.3. The Quality Division issues a management review report summarizing the findings outlined in section 8.9.2. The report is reviewed by management and shared with staff.

The management review includes:

- a. the effectiveness of the management system and its processes.
- b. improvements to HFSC activities related to the fulfillment of its current policies and procedures, accreditation standards, and supplemental requirements.
- c. provision of additional resources required by HFSC to fulfill its obligation to the stakeholders.
- d. any need for change.



9. Wording Removed from Previous Version

Clause Number	Page	Wording removed
3	10	Item(s) placed in a storage location with an incorrect environmental condition.
6.4.1	29	HFSC equipment will only be used for forensic casework and/or training by HFSC staff. If training is provided by contractors, the contractors may use HFSC equipment for training purposes. Non-HFSC personnel are not allowed to use HFSC equipment.
7.1.6	40	...a report will be issued indicating this. The written request, which may be submitted by email, will become part of the case record. Results of work that has been completed must be included in the report, unless there are legal reasons, such as a court order or warrant issues, that prohibit the reporting of results. HFSC's legal counsel should be consulted in these situations. No additional analysis will be performed. If all analytical work is completed before the request is received, a full report will be written and issued to the stakeholder
7.7.1.1.4	59	If their...the workflow and added to...
7.10.1.c	71	...not...