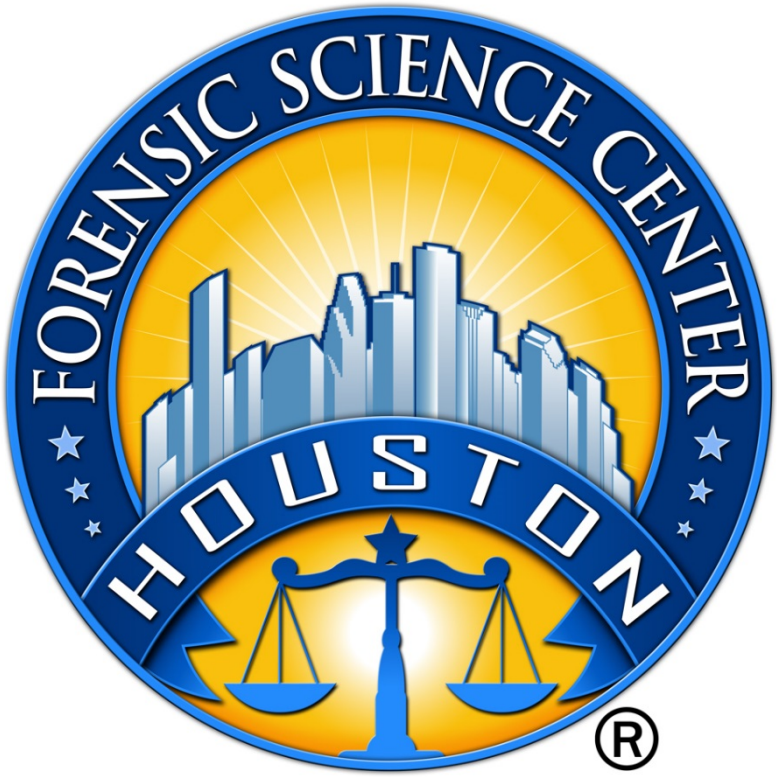

Houston Forensic Science Center

Quality Manual

Quality Division

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NOTICE TO STAKEHOLDERS

Houston Forensic Science Center's accrediting body requires that we notify stakeholders of our procedures in certain circumstances. The Houston Forensic Science Center (HFSC) can make notification on a case-by-case basis or through a general notification to all stakeholders. A stakeholder is a person or agency requesting analytical or crime scene assistance from HFSC. HFSC may also refer to its stakeholders as customers or clients. This notice serves as a general notification. Submission of evidence to the organization indicates the stakeholders' agreement with these terms:

- **Technical staff will review each request for analysis.** This review ensures that the stakeholder's needs are clear and that HFSC can meet those needs.

- **HFSC will determine the most appropriate method or methods of analysis based upon the information provided by the stakeholder.** Once HFSC accepts a request for analysis, the accepted request is considered a contract (as described by ANAB) between the requestor and HFSC.

- **HFSC will select the item or items most appropriate for analysis and may elect not to analyze all items based on the needs and circumstances of the case.** HFSC does not consider this a change to the contract and does not notify the stakeholder. For specific information regarding the HFSC Forensic Biology Case Management Policy, please refer to the HFSC website.

- **HFSC will notify the stakeholder if the proposed analysis requires the consumption or is reasonably likely to consume all the evidence.** Unless a consumption order is received, HFSC may refuse to conduct analysis if there is not sufficient evidence to complete testing AND reserve sufficient sample for additional testing or retesting. This also applies if a laboratory event limits the amount of evidence available for analysis. HFSC will issue laboratory reports indicating that analysis will not be conducted until a court-approved consumption order is received. 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. See 5.10 for further information. HFSC may proceed with analysis if permission to consume is obtained from the submitting agency when there is no suspect listed in the case or if there is no assigned district attorney. 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 and must become a part of the case record.

- **HFSC will use generally accepted and validated methods.** However, policy does allow for deviations from validated methods when necessary. Staff members are required to document deviations from validated methods in case records. They are not required to communicate these deviations to the stakeholder on a case-by-case basis.

- Upon completion of analysis, HFSC will return the evidence to the submitting entity. HFSC may keep a small portion of the evidence item, e.g. cutting from a sheet or blanket, for additional future analysis.

1. Terms and Definitions

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

administrative records	Records, such as case-related conversations, evidence receipts/chains of custody, description of evidence packaging and seals, phone logs, court orders, subpoenas, test reports, and other pertinent information, that do not constitute data or information resulting from testing.
administrative review	Review of case records for consistency with Houston Forensic Science Center policy and for editorial correctness.
acceptance criteria	The expected outcome from a reagent quality control test using known positive and negative standards and controls.
association	A relationship which is concluded to exist between individuals and/or objects based upon testing.
audit	A systematic, independent, documented process for obtaining records, statements of fact, or other relevant information and assessing it objectively to determine the extent to which specified requirements are fulfilled.
calibration	The adjustment of an instrument or piece of equipment to an indicated standard or value to ensure precision and accuracy.
can	Possibility or capability
case records	Administrative records, examination records, and any other applicable technical records, whether electronic or printed, generated or received by Houston Forensic Science Center, pertaining to a particular case.
category of testing	A specific type of analysis within an accredited discipline of forensic science. (See *Sub-discipline*.)
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 test	The evaluation of a person's knowledge, skill, and ability prior to performing independent testing (casework) or specific tasks that create items that could be used for testing.
conclusion	A statement in an examination report that summarizes the interpretations of examination results in disciplines with established identification criteria. The term

	conclusion also refers to a judgment made or decision reached based on the results of analysis/examination.
contract	An agreement between the laboratory and the stakeholder to provide testing and/or crime scene processing services. Do not confuse this contract to provide laboratory services with written contracts that must be approved by the Finance Division.
control sample	A standard of comparison for verifying or checking the finding of an experiment.
controlled document	A document that is distributed in an organized way (usually electronically) to ensure that the latest approved version is identifiable.
controls	Samples tested in parallel with experimental samples and designed to demonstrate that a procedure and laboratory supplies worked correctly.
corrective action	Action taken to correct departures from approved policies and procedures in the management system and/or technical operations.
crime scene	Scene of an incident prior to establishing whether a crime or other action requiring investigation has taken place or not. The crime scene may include both primary (where the crime occurred and/or where a body is located) and secondary scenes (the area surrounding the primary scene.
critical equipment	Tools or supplies that require calibration or a performance check prior to use and periodically thereafter. (Measuring devices used by the crime scene unit are not be considered critical. Please see the crime scene standard operating procedures for additional details.)
critical task	Any task that has a significant effect on the quality of an examination test.
discipline	A major area of testing in forensic science
document	Information in any medium, including, but not limited to, a paper copy, computer disk or tape, audio or videotape, photograph, overhead transparency, or photographic slide.
document control	The process or system for ensuring that controlled documents, including revisions, are reviewed, approved, and released by the proper issuing authority and then distributed to personnel performing the prescribed activities. It also includes subsequent document revision along with tracking and controlled release of new versions.

evidence	Item received or created by HFSC for the purpose of testing
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.
Health and Safety Coordinator	An individual (however titled) designated by top management who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the requirements of the safety system are implemented and maintained.
individual characteristic database	A computerized, searchable collection of information generated from samples of known origin from which individual characteristic information originates (i.e. reference biological specimens, known fingerprints, electronic fingerprint records, test fired ammunition).
inconsistency	A reported result that differs from the consensus result. Inconsistencies may be classified as administrative, systemic, analytical, or interpretive.
internal audit	An annual in-house audit that gauges compliance with ISO/IEC 17025, ISO/IEC 17020, and/or HFSC's own policies. Internal audits are conducted by Houston Forensic Science Center personnel.
key management	Key management includes top management, and section managers and supervisors. The CEO or COO may identify other positions for inclusion as key management.
may	Permission
method	The course of action or technique followed in conducting a specific analysis or comparison leading to analytical results.
must	A requirement
nonconformance	Nonconforming work is the result of an act, error, deviation from an approved procedure/process, or omission that has affected the accuracy, reliability, and/or integrity of HFSC's testing or reports.
non-standard method	A method (not published in international, regional, or national standards or by reputable technical organizations or scientific texts or journals) developed

	by an organization that has been validated to confirm that the method is fit for the intended use.
objective	*(1)* A measurable, definable goal that once accomplished furthers the progress of Houston Forensic Science Center. *(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 set of operations run to determine if a piece of equipment produces examination results consistent with specified parameters. Performance checks are conducted when new equipment is used with existing technical procedures, equipment is moved to another physical location, or existing equipment is modified or undergoes maintenance that could change its performance.
policy	A guiding principle, operating practice, or plan of action governing decisions made by Houston Forensic Science Center.
preventive action	An action intended to eliminate the cause of a potential nonconformance or other undesirable situation.
procedure	The manner in which an operation is performed; a set of directions for performing an examination or analysis; the actual parameters of the methods used.
proficiency test	A test to evaluate the capability and performance of analysts, technical support personnel, and other Houston Forensic Science Center personnel. In open tests, HFSC personnel are aware they are being tested; in blind tests, they are not.
quality audit	A management tool used to evaluate and confirm activities related to quality. Its primary purpose is to verify compliance with the operational requirements of the quality system.
quality control check	A procedure used to ensure the continued reliability and accuracy of reagents and equipment.
quality manual	A document stating the quality policy and describing the various elements of the quality system and quality practices of a business or organization (e.g., this Houston Forensic Science Center manual).
reagent	A substance used because of its known chemical or biological activity.
request	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 is a request. Electronic requests can be made through the LIMS.
root cause analysis	A process used to identify the root cause(s) of nonconformance.
safety manual	A document stating the safety policy and describing the various elements of the safety system of an organization or business.
sample selection	Selecting items or portions of items to test based upon analyst training, experience, and competence and without assumptions about homogeneity.
sampling	A defined procedure whereby a part of a substance, material, or product is taken as a representative sample of the whole for examination.
shall	Required
should	Recommended
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.
subcontractor	An individual or business that independently performs a service for HFSC that HFSC is accredited to provide.
sub-discipline	A specific type of analysis within an accredited discipline of forensic science. (See *category of testing.*)
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. They may include forms, contracts, work sheets, work notes, test reports, calibration certificates, and stakeholders' notes.
technical staff	Individuals who conduct and/or direct the analysis of forensic casework samples, investigate crime scenes, interpret data, and/or reach conclusions. Technical staff may also be referred to as *forensic analysts, supervisors, managers, examiners,* and *investigators.*
technical support personnel	Individuals who perform casework-related duties at the direction of an analyst but do not issue test reports related to conclusions reached.

tender	A tender is HFSC's response to the stakeholder's request. This may include an automated LIMS notification.
test record	Administrative and technical (examination) records generated during or pertaining to testing performed.
testing	Using a procedure to determine one or more characteristics of a test item.
top management	President/Chief Executive Officer (CEO), Vice President/Chief Operating Officer (COO), Treasurer/Chief Financial Officer (CFO), HFSC General Counsel, and HFSC directors are considered top management.
traceability	The property of a measurement result whereby the result can be related to a reference through a documented, unbroken chain of calibrations, each contributing to the uncertainty of measurement.
uncertainty of measurement	An estimated value, within specified confidence limits, that depicts a value of variability that can be attributed to a quantitative value.
uncontrolled document	A document that is not a part of an organization's document control system (or a copy of a controlled document provided for informational purposes only).
validation	The documented process of ensuring a test method is fit for purpose for its intended use and consistently produces reliable results.
verification	Procedure used to evaluate the validity of a test result or opinion by repeating the comparison between a known and unknown.
will	A requirement (future tense)

2. Job Posting and Job Descriptions

Descriptions of job duties are available from HFSC Human Resources Division upon request. Open positions are posted internally on the HFSC intranet and/or externally on the HFSC website. Please see HFSC Human Resources Division for further information.

Forensic Analysts, Supervisors, Managers, and Examiners may be responsible for:

- conducting analytical tests
- conducting forensic investigations
- planning tests and evaluating results
- reporting opinions and interpretations
- developing, validating, and modifying methods
- documenting, collecting, preserving, and processing evidence
- testifying in courts of law as an expert witness

Training notebooks and/or authorization memos contain further detailed information specific to the responsibilities of each technical staff member.

The term *staff member* is used throughout this manual to indicate any person employed by HFSC or is a civilian or classified assigned to HFSC. All technical staff members as well as temporary employees, interns, and volunteers functioning in a technical capacity within HFSC are expected to abide by this manual.

3. References

HFSC will follow the guidelines 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, any applicable supplemental requirements, and the current FBI *Quality Assurance Standards for Forensic DNA Testing Laboratories.*

HFSC utilizes 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.

4. Management Requirements.

4.1. Organization

4.1.1. HFSC is a publicly funded local government corporation.

4.1.2. HFSC conducts its investigation and testing activities to meet accreditation standards and to satisfy the needs of its stakeholders. This includes using standardized and validated methods and/or procedures to conduct quality forensic testing and investigations in an impartial manner. HFSC has a quality management system that provides stakeholders with confidence that its technical and investigation services are accurate and impartial. HFSC considers any recipient of its reports and/or services to be a stakeholder. This includes, but is not limited to, law enforcement agencies, prosecutors, defense attorneys, forensic laboratories, and the public.

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

4.1.3. All operations performed by HFSC, both at its permanent facilities and at sites away from its permanent facilities, will conform to the practices described within this quality manual. HFSC currently provides services in the forensic disciplines of seized drugs, toxicology, biology, firearms, latent prints, digital and multimedia, and crime scene processing. Staff members also provide courtroom testimony related to these same services.

All staff members are expected to remain objective, impartial, and independent when working a case, investigating and collecting evidence at a scene, and when testifying. Staff members should not be influenced by extraneous information, political pressure, or other outside influences. Instances of such should be reported to the staff member's manager or his/her designee, and/or division director or Quality Division. Refer to the conflict of interest and undue influence policy found at the end of this manual.

4.1.4. HFSC includes the following technical disciplines: Seized Drugs (previously called Controlled Substances), Toxicology, Firearms, Latent Prints, Crime Scene, Digital and Multimedia Evidence and Forensic Biology. See the HFSC Human Resources Division for additional details concerning the organizational chart. Other divisions and departments include Information Strategy, Quality, Information Technology (IT), Finance, Research and Development, Business Development, Communications/Public Information, Client Services/Case Management, and Human Resources. The division directors, in conjunction with key management personnel, have the authority and resources to carry out their duties, including improvements to the quality system, and are responsible for ensuring that daily technical and/or investigation operations follow accepted policies and procedures.

Members of top management are usually available 24/7 to handle their respective division's affairs. If necessary, they will appoint 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. The directors have authority over their respective divisions and are responsible for ensuring the division's conformance with accreditation standards. The HFSC president/chief executive officer (CEO) and vice president/chief operating officer (COO) have authority over all functions of HFSC. See Terms and Definitions for further information on top management.

4.1.4.1. Regardless of job title, each division is headed by a staff member with authority to make decisions and coordinate administrative, technical and/or investigation activities within the division. These individuals may be the CEO, COO or directors. Please see the HFSC organizational chart for more information.

4.1.4.2. The individuals referenced in 4.1.4.1 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 if quality-related issues arise.

4.1.5. When appropriate, key management personnel will appoint one or more individuals who may act on their behalf. In the case of an unplanned absence, the manager may appoint a designee responsible for critical duties of the section until the manager returns to duty. Manager responsibilities include, but are not limited to:

- complying daily with the quality system of their respective sections
- assisting with management reviews
- reviewing and approving technical procedures within their assigned discipline
- participating in audits when requested

HFSC uses a comprehensive training program, a performance appraisal system, casework review, proficiency testing, method validation, reagent validation, and testimony monitoring to ensure the quality of work produced by their assigned staff members. Supervising techniques should ensure the quality of the work product meets applicable accreditation standards, stimulate productivity, recognize exemplary performance, and encourage a free exchange of information within HFSC.

The technical staff of HFSC has the responsibility of ensuring that all requirements of the quality system are met and failures to conform to quality standards are minimized, prevented, or eliminated. If staff becomes aware of nonconforming work, they must notify key and/or top management as soon as possible. Staff should understand the importance and relevance of testing and investigation activities and review the quality goals and objectives of HFSC at least yearly. All personnel must follow this Quality Manual and all applicable sectional procedures. All personnel also have the responsibility and authority to identify opportunities for improvement and to take appropriate measures to implement them. Technical staff will ensure that reports and case documentation are complete and will advise key management of technical problems or questionable results. Staff will also use validated methods while examining and/or investigating forensic evidence and in meeting

the needs of our stakeholders.

Personnel are protected from influences that could adversely affect the quality of work performed. Further information can be found in HFSC's policy on conflict of interest and undue influence found at the end of this manual.

Staff members will follow all applicable governing procedures, such as City of Houston Administrative Procedures, Houston Police Department (HPD) General Orders (classified personnel), and HFSC administrative policies in the daily operations of HFSC. If conflicts arise between the contents of this manual and the governing procedures, then staff members will follow the most stringent policy. Stakeholder case-related information is protected unless otherwise directed by a legal request or a request made under the Texas Public Information Act. Violation of stakeholder privacy may subject staff members to disciplinary action. See 4.13.1.3 for additional information.

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

4.1.5.2. All sections have individuals who are technically responsible and have appropriate training and technical experience in that discipline. HFSC has a Quality Division responsible for ensuring the quality management system is followed. See 4.2.6 and HFSC organizational chart for additional information.

4.1.6. Management ensures that appropriate communication processes are established, and that communication takes place regarding the effectiveness of the management system. These communications may take the form of Center-wide or sectional meetings, emails, memos or other written correspondence, formal and informal training sessions, the HFSC intranet, and/or review of HFSC policies and procedures.

4.1.7. HFSC has an individual designated to oversee its health and safety program. This individual may be assisted by a safety committee. Refer to the *HFSC Health and Safety Manual* for detailed information.

4.2. Management System

4.2.1. Management is committed to the ongoing development of our 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. This manual is complemented by sectional standard operating procedures (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 information in this manual.

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.

New technical staff members review HFSC corporate policies, the quality manual, safety manual, section-specific documents, and other policies and documents listed on the On-Boarding Checklist for New Employees during their training program. The manuals and policies are stored on secure electronic sites as well as the publicly accessible HFSC website.

4.2.2. The quality system is a mechanism to ensure that HFSC's investigation activities, examinations, documentation, and testimony remain accurate, impartial, and ethical. To this end, all staff members are responsible for following the guidelines contained in this manual. If it becomes necessary to deviate from approved procedures, then the deviation is conducted in accordance with good laboratory practices and with the documented approval of section management and the section technical leader (if the section manager is not the technical leader). Approval must be obtained prior to the deviation with the exception of the Crime Scene Unit as stated below.

4.2.2.1. Exigent circumstances may require CSIs to deviate from the CSU SOP. An exigent circumstance is one that requires an immediate action. Examples include, but are not limited to, inclement weather that may compromise evidence and situations where there is a threat to the CSIs' personal safety. CSIs should notify management prior to deviating from the sectional SOP or the Quality Manual whenever possible. If it is not possible to notify management in advance, the CSI must notify them as soon as practical. The exigent circumstance, along with management's acknowledgement, shall be documented in the case record.

Additionally, the quality system ensures that the services provided by HFSC meet or exceed the guidelines and standards set forth in ISO/IEC 17025 and accrediting body supplemental requirements. HFSC will also adhere to accreditation requirements set forth by the Texas Forensic Science Commission (TFSC).

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.

All staff members will abide by the quality system policies and procedures detailed in this manual that are applicable to their job function. Technical policies and procedures are defined in section-specific procedure manuals.

Top management and the Quality Division verify that an annual audit and management review are conducted to gauge HFSC's continued compliance with the requirements of the quality system. The internal audit will address all elements of ISO/IEC 17025 and applicable supplemental requirements for accreditation. The management review will address continuing enhancements of forensic services. Other audits may be conducted for specific purposes or to gauge compliance with specific elements of the quality management system. These audits may be done in addition to but not in lieu of a discipline specific annual internal audit.

4.2.2.2. Top management will ensure that all staff members annually review the *Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* or equivalent document. Equivalent documents may be published or approved by professional organizations such as the American Society of Crime Laboratory Directors, the American Board of Criminalistics, or the American Society for Quality. In addition to the review of these documents, HFSC may provide additional ethics training to all staff members. All staff members will follow the HFSC Code of Ethics.
Staff members are expected to adhere to ethical standards including, but not limited to, the following:

- *Objectivity*—Examinations, investigations, reports, testimony, and other communications will be objective, impartial, based on the evidence, and within the staff member's knowledge and area of expertise. Full, clear, and accurate records of examinations and crime scene investigations will be generated and maintained.
- *Competency and Proficiency*—Technical staff will conduct only those examinations and investigations for which they are qualified by education, training, and/or demonstrated proficiency. They will accurately represent their qualifications to others.
- *Professionalism*—Staff members will uphold the law as well as HFSC policies and procedures to the best of their ability. Staff members will report to key management any conflicts between their ethical responsibility and these laws and policies. Any unethical or illegal conduct by staff should be reported immediately to key management.

4.2.3. Top management, with the assistance of key management personnel and/or designees, review the development, implementation, improvement, and continued effectiveness of the quality system. These reviews may include a review of the internal audit(s), communications

from stakeholders, proficiency testing results, corrective actions, preventive actions, incident reports, and testimony monitoring.

4.2.4. HFSC's mission statement, objectives, and quality policy statement are reviewed annually and revised if necessary. At the direction of top management, the importance of meeting stakeholders' needs and any applicable statutory requirements will be communicated to staff members.

4.2.5. Quality policies that affect the technical divisions are included in this quality manual. Each forensic discipline will have its own technical procedures. Discipline-specific manuals will not be less stringent than this quality manual.

4.2.6. Key management will ensure that personnel have the means necessary to follow this quality manual. They will also verify that complaints concerning their respective divisions are evaluated and documented.

Key management personnel will ensure that technical staff members are trained and will monitor casework and other sectional activities to gauge compliance with the quality system.

Technical staff will perform their duties as outlined in the quality system.

Administrative personnel will apply applicable quality system components to clerical, administrative, or other duties performed.

Any staff member may make recommendations for improving the quality system. Recommendations may be made through the staff member's chain of command, Quality Division, or directly to the COO, CEO, or their designees.

The Quality Division will ensure that HFSC is following the guidelines set forth in this manual by:

- updating the quality manual and proposing corrections and improvements to the system
- developing quality system policies and procedures in coordination with technical staff
- addressing quality concerns or complaints
- monitoring and reviewing forensic practices that affect the quality of examination and/or investigation results, including instrument calibration and maintenance, use of reagents and standards, performing case reviews, taking corrective/preventive actions, and providing technical training as necessary
- scheduling, monitoring, and/or conducting division audits to verify compliance with policies and procedures, proficiency testing, and testimony monitoring
- maintaining quality system records and archives

To investigate and/or address a quality issue arising in any of the forensic disciplines, the quality director has the authority to order a discipline to cease casework. The CEO, COO, and/or appropriate division director will be consulted. The DNA technical leader or designee

and the Combined DNA Index System (CODIS) administrator have authority to cease DNA casework. Further information may be found in sectional procedures.

4.2.7. Top management, with assistance from key management personnel, will ensure that the integrity of the management system is maintained when changes to the system are implemented. See HFSC's Quality Policy Statement within this manual. Changes that may affect HFSC's accreditation will be approved by the Quality Division prior to implementation. Management system changes will be communicated to appropriate staff.

4.3. Document Control

4.3.1. General

HFSC controls all documents that form its management system. The term *document* may mean a paper or electronic file that includes regulations, standards, other normative documents, test methods, drawings, software, specifications, instructions, and manuals. Controlled documents that form the management system are included on the Master Document list.

This *Quality Manual* is approved by top management and reviewed by key management prior to being issued by the quality director.

Technical sectional procedures and training manuals are approved prior to issue by the section manager and the Quality Division. For sections that have a manager and a technical leader or designee, both will approve controlled documents. Other section-specific documents such as worksheets require approval by section management and the Quality Division. Worksheets may be in paper or electronic format. Paper worksheets may have electronic equivalents. Electronic worksheets may not look exactly like their paper equivalents but will be approved for use by the same authority that approved the paper version. Electronic worksheets must be included on the master document list. Worksheets that are completed through the Produce Attachment function in LIMS are approved through quality management software and are then made available for use in LIMS by the LIMS Administrator. Section managers are responsible for working with the LIMS Administrator to make sure that cases are worked using the appropriate worksheet version.

The Health and Safety Coordinator, or his/her immediate supervisor, Quality Director, and the CEO or COO approve the *Health and Safety Manual* prior to issue. The Health and Safety Coordinator and the specialist's immediate supervisor approve corporate safety forms and worksheets prior to issue.

All staff members review revisions to the *Quality Manual,* the *Health and Safety Manual,* and the *HFSC Security Manual*. Technical sectional procedure manuals are reviewed by those individuals assigned to technical positions within that section. Staff members holding nontechnical positions (e.g., CS/CM Specialists) assigned to analytical sections are required to read all general procedures that affect their position. These reviews are documented.

Controlled documents are reviewed 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.

Although administrative procedures are not covered by this Quality Manual, they are reviewed, revised, and controlled by quality management software. Administrative procedures are approved by the corresponding division director (e.g. Human Resources, Finance).

4.3.2. Document Approval and Issue

When staff members discover the need for policy and/or procedure revisions, the area of concern should be brought to the attention of the appropriate individuals.

4.3.2.1. All technical staff utilize approved documents and follow applicable section-specific documents. Those documents that are approved for use are posted in an electronic format and are available through password-protected computers.

4.3.2.2. The official versions of controlled documents are published in an electronic format and can be viewed from any networked computer and/or applicable software (*e.g.* LIMS and Mideo). 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. These notifications may be made by email from the appropriate top or key management personnel, from quality management software, or during section, division, or Center-wide meetings.

All printed copies of controlled documents are considered uncontrolled versions. The user is responsible for verifying that he/she is using the current version. Any uncontrolled document that is not current shall be shredded or clearly marked to indicate that it is no longer in use. Portions (e.g., dilution charts) 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, such as complete SOPs, are marked to ensure that they are not confused with current versions.

4.3.2.3. Technical 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 particular task. Procedures are posted in an electronic format and are the controlling documents followed by staff members.

4.3.3. Document Changes

4.3.3.1. Document changes and/or revisions will be approved using the same policy as stated above.

4.3.3.2. When revisions are made to existing documents and result in the issuance of a new manual, the altered or new text is clearly marked. One way to accomplish this is to have the new or altered text in red font. This requirement does not extend to worksheets.

4.3.3.3. Updates to controlled documents will be incorporated into new versions**.** HFSC does not allow documents to be amended by hand. However, correspondence that is intended only to clarify policies and/or procedures is allowed.

4.3.3.4. Controlled documents are stored in the quality management software. Only staff members who are members of key management or their designees can make changes and/or release new versions.

4.4. Review of Requests, Tenders, and Contracts

Unless otherwise specified, the stakeholder agrees to allow HFSC to use the scientific knowledge and expertise of its staff members to choose and apply appropriate testing and investigative methods, including sampling, to the evidence.

If a request is received that cannot be fulfilled by HFSC, then the stakeholder is notified. HFSC may forward evidence to other laboratories or request forensic investigation services from other investigation agencies on behalf of the stakeholder.

4.4.1. Requests for analysis and for evidence investigations 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

Requests are reviewed by technical staff to ensure that accurate submission information is included and that evidence is appropriately sealed. Requests for evidence investigation services are reviewed to ensure the safety of the crime scene investigator and the ability of the Crime Scene Unit to complete the requested services.
Technical aspects of the review, such as the methods to be used, are completed by technical staff in the appropriate section. When necessary, personnel will clarify the needs of the stakeholder, determine the probative nature and value of the evidence and/or crime scene, and define or discuss testing or investigation methods with the stakeholder before casework or the crime scene investigation begins.
Differences between the request or tender and the contract will be resolved before work commences. Each contract will be acceptable to HFSC and the stakeholder.

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

4.4.3. Records of pertinent discussions with a stakeholder about the stakeholder's requirements or the results of the work are maintained in a communication log, email, or equivalent record.

4.4.4. HFSC also reviews requests for services that will be handled by its subcontractors.

4.4.5. HFSC informs its 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. Personnel in the Digital and Multimedia Evidence section should contact the stakeholder in advance if the requested analysis could realistically result in destruction of the evidence (e.g., cell phones).

4.4.6. Changes in requested services are communicated to affected staff members as soon as possible. Changes necessitated by HFSC are communicated to the stakeholder. If a contract needs to be amended after work has begun, the review process will be repeated and amendments will be communicated to affected staff members.

4.5. Subcontracting of Tests and Calibrations

4.5.1. HFSC places work only with subcontractors who comply with ISO/IEC 17025 and/or ISO/IEC 17020 in performing HFSC's work and/or are accredited by the Texas Forensic Science Commission.

4.5.2. The stakeholder is notified of subcontracting arrangements. When appropriate, HFSC will gain the stakeholder's approval, preferably in writing, prior to beginning casework or crime scene processing.

4.5.3. HFSC accepts responsibility for the work of the subcontractor except in those cases in which the stakeholder or regulatory authority specifies which subcontractor is to be used. If the subcontractor is specified, then this requirement does not apply.

4.5.4. If services are subcontracted, section management must maintain a list of approved subcontractors deemed competent to perform analysis on its behalf and provide this list to the Quality Division. Approved subcontractors will be added to the approved subcontractor list.

4.6. Purchasing Services and Supplies

4.6.1. HFSC purchases reagents and materials that are of the appropriate quality for use. If the requested item is not available, the appropriate section manager or his/her designee should be consulted to determine if a substitution is acceptable.

4.6.2. 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 see the Client Services & Case Management Supply Storeroom Logistics Specialist for further details.

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 Federal Bureau of Investigation's *Quality Assurance Standards for DNA Testing Laboratories*.

4.6.3. Purchase requests are reviewed and approved in accordance with directives from the Finance Division. By requesting services and supplies, key management is confirming the requests meet applicable and specified requirements stated in sectional SOPs.

4.6.4. Sellers of critical consumables, supplies, and services (hereafter referred to as "critical supplies") are evaluated to ensure that their product will not negatively impact the quality of forensic analyses. Sectional SOPs identify the characteristics of a reagent or critical supply (e.g., 95% ethanol) if the characteristic is relevant and critical to accurate testing procedure. Whenever practical, HFSC will buy critical supplies and services from businesses that are accredited.

The Quality Division maintains an approved vendor list for critical services and supplies that affect the quality of testing. To add a vendor to the approved list, a vendor evaluation form must be approved by the division director and then submitted to the Quality Division. Whenever possible, approved vendors will have appropriate ISO certification. Approved vendors may also be those who supply certificates of analysis for reagents or standards, ship supplies in a timely manner, and provide the supplies at an acceptable cost.

Historical data may be used to confirm the reliability of a supplier's products or services. An approved supplier may be removed from a list of approved suppliers if quality concerns are identified with products or services provided. Any such action will be communicated to the appropriate staff members.

4.7. Service to the Stakeholders

4.7.1. 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 analyst or manager for assistance.

Under normal circumstances, individuals who are not staff members are not allowed to observe testing. This policy helps to ensure confidentiality of case information, limits potential for contamination, and ensures security of evidence and case records. Observing testing is not synonymous with touring a laboratory. Tours that are scheduled in advance, guided by HFSC staff and brief in nature may be allowed in laboratories with the exception Biology. Tours through the Biology/DNA lab spaces are not allowed due to contamination concerns. Special arrangements (e.g., outside normal working hours) may be made in order to comply with court-ordered observations. Consult the section manager and/or the division director for further instructions. Additional detailed information may be found in sectional policy manuals.

Pertinent communications with stakeholders relating to evidence submission or analysis are documented and maintained as part of the case record.

4.7.2. HFSC seeks feedback (positive or negative) from its stakeholders. Stakeholder feedback may be sought through personal communication, testimony review, attendance at meetings, and/or through periodic surveys. The responses are maintained and feedback is reviewed by top and/or key management as appropriate in order to improve HFSC's management system, testing activities, and stakeholder services.

4.8. Complaints

4.8.1. Complaints received from clients are recorded using a Complaint Form. Staff members receiving a complaint will resolve the complaint if within their authority and will contact the appropriate key management personnel as soon as practical.

Complaints related to the quality system will be directed to the Quality Division. If deemed credible, they will be forwarded to the appropriate individual for initiation of action and documentation. Formal corrective action will be initiated if warranted. See 4.11 for more information. Section-specific complaints will be forwarded to the appropriate person in key management. That individual will determine the validity of the complaint and, if warranted, take appropriate action. If a complaint is determined to be invalid, documentation will be kept to support that determination.

Information concerning the complaint should be communicated to the complainant throughout this process. Upon completion of actions taken, the complainant will be notified that the complaint has been closed.

4.9. Continuous Quality Improvement

4.9.1. HFSC continually improves the effectiveness of its management system through quality policies, objectives, audit reports, data analysis, nonconformances, corrective and preventive actions, management reviews, Center meetings, proficiency testing, blind proficiency testing, staff member performance evaluations, testimony monitoring, and/or feedback.

4.10. Nonconformances

4.10.1. Nonconforming work is an act, error, deviation from an approved procedure/process, or omission that has affected the accuracy, reliability, and/or integrity of HFSC's testing or reports.

Management system and technical nonconformances may be identified through internal audits, assessments, management reviews, or stakeholder or staff feedback.

4.10.2. Reporting of Nonconformances

Individuals involved in or aware of nonconforming issues regarding the quality of technical services provided by HFSC must report the nonconformance to the appropriate section manager and the Quality Division, as soon as possible after discovery. The division directors, quality director, sectional manager, DNA technical leader or designee, and (in some instances) the CODIS administrator have the authority to halt (or resume) work in HFSC and implement other necessary short-term responses to nonconformities.

The manager, technical leader or designee is responsible for ensuring the occurrence is reported to the Quality Division in a timely fashion.

Nonconformances may be reported to the Quality Division in a number of ways including, but not limited to:

- Email
- Meeting request
- Phone conversation
- In person
- Quality management software
- Incident Form or Corrective Action Report

Once nonconformance(s) are reported to the Quality Division, the Quality Division will make the initial determination if the nonconformance will be tracked as a quality incident or if it requires corrective action. The Quality Division depends on section management to provide insight into technical issues arising in the disciplines. Management and the Quality Division are expected to collaborate on the categorization of the nonconformance, determining how to address the nonconformance, and root cause analysis. If the Quality Division and section

management disagree on how to handle a nonconformance/potential nonconformance, the CEO and/or COO may be consulted.

Unless a single occurrence significantly impacts the quality of our work, it will be handled as an incident. Systemic issues and issues affecting the quality of our service or work product are handled as corrective actions. Staff members may reference quality flowcharts posted in work areas for an overview of this process.

4.10.3. Quality Incidents

Quality Incidents are nonconformances that have limited or no impact on the quality of our work product but still need to be documented. Incidents are monitored by the Quality Division to track reoccurrences at the section level and lab wide. Continued reoccurrences may be elevated to a corrective action. These types of events will be documented using the Incident Form or quality management software.

4.11. Corrective Action

Nonconformances that have a significant impact on the quality of work product are documented using a corrective action form or through quality management software. Deadlines for completion of corrective actions and incidents are built into the management software. Turnaround times for corrective actions and incidents documented using a form rather than the software workflows will be communicated to the involved parties. The target timeframe for completion is 30 working days. The Quality Division acknowledges there may be instances where this timeframe is not reasonable.

Corrective actions are taken when necessary to eliminate the root cause of the nonconformance and to prevent its reoccurrence. Corrective action may also be taken to address management system concerns. The nature of the nonconformity dictates whether immediate action is necessary.

The purpose of this policy is to maintain and improve the quality of work performed by HFSC. While it is not the purpose or intent of this policy to single out an individual or section, singling out an individual may occur as a byproduct of the process. Efforts are made to maintain the confidentiality of the parties involved. Non-conformances noted during an audit can be reported using a corrective action form.

HFSC's corrective action procedure includes:

- identifying the person responsible for carrying out the corrective action
- identifying the cause of the problem through root cause analysis
- classifying the class level of the corrective action
- stakeholder notification
- implementing an action plan
- closing corrective actions
- monitoring the effectiveness of the corrective actions taken

These nonconformances will be fully documented and reported in clear, active language whenever possible. The Quality Division is responsible for maintaining these records.

The following instances always require corrective action:

- intentional wrongdoing involving work product, crime scene examination, analysis or reporting
- error(s) that impact the accuracy of reported results
- willful failure to follow approved procedures that could affect reported results
- testimony in which a staff member intentionally misrepresents his/her education, training, or experience

4.11.1. Responsibility for Corrective Action investigations

The Quality Division, with input from the section managers and/or supervisors, the DNA technical leader or designee, and (in some instances) the CODIS administrator, will delegate or initiate an investigation into nonconforming issues and identify the person responsible for carrying out the corrective action. Other individuals may be used as resources based on their background, position in the forensic community, or skill set, either inside or outside HFSC.

4.11.2. Root Cause Analysis

The first step in the corrective action investigation is an effort to determine the root cause of the apparent nonconformance. This process is conducted by the Quality Division at the direction of the Quality Director. If the cause is not obvious, an analysis of potential causes will be conducted. The investigation may include a review of casework to determine if the occurrence is systemic. Causes may be related to, but are not limited to, requirements, evidence, procedures, personnel training, consumables, or equipment and its calibration.

If the root cause is determined to be personnel related, the nonconformance is addressed through the HFSC Progressive Corrective Action Policy.

Examples Of Corrective Actions After Root Cause Analysis

Depending upon the nature of the problem or error, appropriate corrective actions may include the following:

- If the error is determined to be in the method, the method may be removed from use on casework, modified, or moderated by additional controls as necessary. Other cases in which the same method was used may be reviewed.
- If the error is determined to be caused by an instrument or other equipment used in the test, the error will be corrected and documented. Other cases in which the same instrument or equipment was used may be reevaluated and appropriate action taken.
- If the error rests with a staff member, it will be determined if the error was the result of inadequate or inappropriate training or is an isolated incident and not likely to recur. If the original training is found to be faulty, appropriate additional training or evaluation will be completed. If the original training is determined to be adequate, the review will attempt to identify the specific cause of the problem or error. See Human Resources Progressive Corrective Action Policy.

- If the error is determined to be administrative or clerical in nature, the documentation and review process will be studied and revised, if appropriate, to minimize the reoccurrence of this error.

Corrective actions will be of the appropriate degree and magnitude to correct the problem, reduce the risk and create a long-term resolution to prevent recurrence.

4.11.3. Selection and implementation of corrective actions

4.11.3.1. Corrective actions are classified by the following class levels:

Class I errors are those that have an immediate impact on the quality of HFSC's work product. Class I nonconformances include those instances where the reliability of the tests performed, or the report is questionable. Examples include, but are not limited to, false identifications, false-positive results, contamination that results in the entire evidence sample being compromised and chain of custody errors that are systemic.

Class II errors may affect the quality of the work but are not serious enough to cause immediate concern for the overall quality of HFSC's work product. Class II nonconformances include missed identifications and false-negative results. This class includes errors that are likely to continue unless appropriate corrective action is taken. Even though corrective action is necessary, the reliability of results is not in question.

Class III errors are inconsistencies having minimal effect or significance on quality, are unlikely to recur, are not systemic, and do not affect the fundamental reliability of HFSC's work product. Class III nonconformances include administrative or transcription errors. If the same error occurs routinely for the same staff member or under the same circumstances, then the error may be elevated in class.

4.11.4. Closing Corrective Actions

4.11.4.1. The Quality Division will ensure that corrective actions are brought to the attention of the appropriate key management personnel. The Quality Division is responsible for following up and closing out the corrective action process. Closing a corrective action means that no additional action, except for monitoring the effectiveness of the corrective action, is planned. The Quality Division may reopen a corrective action if the nonconformance recurs or if it is later determined that further action is needed.

4.11.4.2. Stakeholder Notification Of Corrective Action

- Copies of closed Incident and Corrective Action Reports are added as reports in LIMS and posted on HFSC's eDiscovery site. HFSC will notify the Texas Forensic Science Commission when top management deems it appropriate.
- Laboratory reports must clearly indicate when Corrective Action and/or Incident Reports are associated with a case. This applies only to the discipline and requests

involved in the quality action, not to all reports associated with the case. However, this does not require the amendment of a report that has already been issued for the sole purpose of mentioning the quality action.

- If a Corrective Action or Incident results in an amended report being issued, the amended report will clearly indicate that there is an associated quality action and will serve as stakeholder notification.
- The posting of incidents and corrective actions to the eDiscovery site does not replace the required disclosure or notification stated below.

In accordance with Texas law, HFSC management or general counsel will notify the Texas Forensic Science Commission of instances of professional negligence or misconduct. Notification will also be made to the HFSC board of directors and HFSC 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:

- intentional misconduct by a technical staff member
- 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 its test reports
- a significant event or nonconformity related to an accreditation standard for which there is a reasonable expectation that knowledge of the event by parties external to HFSC would call into question the quality of our work or integrity of our staff members

4.11.5. Monitoring Corrective Actions

The Quality Division will monitor the nonconformance to determine if the corrective action was effective. Additional actions will be taken as necessary to prevent a reoccurrence. The corrective action process is reviewed during the annual management review.

Key management has the authority to request and/or conduct a special audit if the corrective action casts doubt on HFSC's compliance with its own policies, procedures, or with accreditation standards. Additional audits will be conducted as necessary.

4.12. Preventive Actions

4.12.1. All staff members are encouraged to monitor work flow, technical procedures, and management system practices for potential improvements or sources of nonconformance.

4.12.2. These opportunities for improvement, also called Preventive Actions, will be directed to appropriate key management for evaluation. Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to identified problems or complaints.

Suggestions received from stakeholders should also be forwarded to appropriate key management.

Preventive actions will be formulated, reviewed and, if approved by the appropriate key management, documented using a Preventive Action Report (PAR) form or quality management software. Completed reports are forwarded to the Quality Division. The Quality Division will monitor the effectiveness of the preventive action. The implementation of a preventive action plan should be communicated to affected staff members in a timely fashion. Preventive actions will be evaluated during the yearly management review.

4.13. Control of Records

4.13.1. General

4.13.1.1. A case record is maintained for each request for analysis and crime scene investigation accepted by HFSC. Effective February 1, 2014, case records were identified by an assigned forensic case number. Prior to this date, records may have been identified by the forensic case number, agency case number, laboratory number, or other unique identifier.

Case records are collections of technical and case-specific administrative records and may include:

- the test report(s)
- reference to the technical procedures used during analysis and any deviation
- identifiers and descriptions of the items analyzed
- identity of the technical staff performing the examination(s)
- identity of the technical and administrative reviewers
- Quality Incident and/or Corrective Action Reports
- LIMS change request forms and/or workflow reports

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

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

Access to case records stored in an electronic format associated with LIMS, Foray or MIDEO Systems Caseworks software is granted through the authority of the applicable section manager or technical leader. If access is granted to an approved software vendor, that access will be granted for a single session via an email request to or from a designated staff member for a specified purpose. This access to the system is fulfilled through the HFSC IT Department.

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

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

Quality, administrative, and technical records will be kept for at least five years or one full accreditation cycle, whichever is longer. If pertaining to DNA, those same records are kept for at least 10 years. Records are typically scanned into a secure, backed-up electronic system. The electronic versions of these records are maintained indefinitely, unless HFSC is otherwise ordered by the stakeholder or by legal requirements (expunction). The paper copies of these scanned records may be stored or shredded. Records will not be shredded before the scanned version has been compared to the original to ensure all pages were scanned and are legible. When scanned documents are part of a case record, verification includes ensuring the scanned version is added to the correct case record. It is the responsibility of the individual shredding the documents to ensure 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. Top management may authorize the disposal of quality and/or technical records in accordance with HFSC records retention policy. 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 the record or copies of the record upon request from its stakeholders.

4.13.1.3. All records are held secure and in confidence. Staff members have the responsibility to safeguard all confidential information obtained in their official capacity from unauthorized distribution. Staff members will not access or disclose any confidential information except when disclosure is legally authorized or approved by key management. Staff members are not authorized to disclose any portion of a case record to an unauthorized third party, and they should consult key management for assistance if necessary. See HFSC's policy on disclosure of information and court orders for further information.

4.13.1.4. Electronic records are stored using LIMS, MIDEO, quality management software, 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 backup tapes are stored in a secure manner. Access to electronic records is limited to those having user names and passwords issued at the direction of top or key management.

4.13.2. Technical Records

4.13.2.1. HFSC retains records of original observations, records of derived data, and sufficient information to establish an audit trail. 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. If an examination record or original observations are made on nontraditional media (i.e., sticky notes, paper towels, gloves), then either the original media or an electronic equivalent is retained in the case record. Once an electronic equivalent (i.e., scan, photograph) is created, then the original hard copy may be destroyed 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.

4.13.2.2. Observations, data, calculations, and other examination documentation are recorded at the time they are collected or made and are uniquely identified (forensic case number, agency case number/laboratory number). It should be clear from the case record who performed all stages of analysis/examination and the date each stage was performed. Records should show the date images such as chromatograms and photographs were collected. When a test result or observation is rejected, the reason for the rejection, the identity of the individual(s) rejecting the result or observation, and the date shall be recorded.

The Crime Scene Unit, Digital/Multimedia, Firearms and Latent Print laboratories must keep all photographic images, regardless of photographic quality, taken during the examination process. These images are considered examination documentation that could be used in lieu of the evidence. The images must be included in the case record and stored in an approved HFSC repository such as LIMS, Mideo or Dataworks.

The Biology, Seized Drugs and Toxicology laboratories (and CS/CM when documenting packaging) do not typically use photographs in lieu of the actual evidence items. Therefore, when a photograph is taken that is of poor photographic quality (e.g. blurry, the entire item was not captured in the image frame), it will not be considered part of the case record. However, the blurry or otherwise unusable photograph must be preserved in an approved HFSC repository (such as LIMS, Mideo or Dataworks) or a section-maintained Sharepoint repository. Therefore, no photograph, regardless of photographic quality, may be deleted unless that photograph has been added to an approved repository and the analyst has verified that the image uploaded correctly. The

images in this repository must have, at a minimum, the forensic or agency case number that the photograph is associated with. In instances where this information cannot be ascertained, the photographs must then be saved according to batch record information.

If duplicate photographs (e.g. multiple good quality photographs of the same item) are captured, it is only necessary to upload one of the photographs to the case record. The additional duplicate photographs shall be retained in the same manner as mentioned above.

Computer hard drives and individual OneDrives are not approved repositories.

When the Crime Scene Unit processes non-HPD scenes, any collected evidence and all media onto which scene photographs have been captured must be returned to the agency and a CD/DVD copy of the photographs must be kept in the case folder/record. The return of the media must be documented on the chain of custody.

See 5.8.4.4 for additional information. If a situation arises that causes the information above to conflict with 5.8.4.4, clause 5.8.4.4 will prevail for all disciplines.

4.13.2.3. Changes and alterations will be initialed by the person making the change. When striking out information in a case record, a single line is drawn through the error and initialed. Mistakes are not erased, made illegible, or deleted. Erasures on crime scene sketches are not considered mistakes and are not subject to these requirements. These requirements do not apply to changes and alterations made on administrative documents provided to HFSC by the stakeholder.

In the case of electronic records, equivalent measures are taken to preserve original data. Any changes made to completed examination records generated and/or maintained in an electronic form are tracked, which means sufficient information is provided to determine what was changed and who made the change. The audit log function in LIMS may be used for this purpose.

If an error is found in a report after it is reviewed and approved, an amended report will be issued. The amended report will document the corrections or changes made to the previous report. HFSC does not consider test reports to be examination documentation. Therefore, drafts of test reports do not have to be maintained.

If an amended report will change the technical findings or correct a false identification, Quality shall be notified via one of the methods listed in 4.10.2. Examples include but are not limited to:

- A seized drug report where the incorrect drug or weight was listed
- A report where a false positive or false negative was listed
- A toxicology report where the incorrect drug or alcohol concentration was listed
- A DNA report where incorrect statistics were listed

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.

4.13.2.4. Technical records are of sufficient detail to reproduce or allow the review of examination or investigation results. The following constitutes a technical record of analysis performed and, when applicable, will be maintained in the case record:

Administrative documentation

- submission forms/requests for analysis
- evidence inventory and description
- chains of custody
- communication logs
- report(s) of analysis
- documentation of technical and administrative review
- subpoenas
- discovery requests
- Quality Incident/Corrective Action Reports
- LIMS change request forms and/or workflow reports
- administrative documents, such as search warrants and vehicle examination forms, supplied by the stakeholder

Examination documentation

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

Administrative documentation must be identified by the assigned forensic case number. Examination documentation must have the forensic case number and the initials or name of the examiner on each page, or secure electronic equivalent. Crime Scene Unit administrative and examination documentation are considered uniquely identified when either the forensic case number or the requesting agency identifier is used. Examination records that bear the unique identifier and initials on an original record may be copied for filing in multiple places without the necessity of placing original identifiers on each copy. If electronic records are printed, the unique identifier will be on each page of the printed documentation. When electronic records are viewed on a computer, the unique identifier will be visible on the screen. If the staff member's initials are visible in a photograph, then it is not necessary to add handwritten initials.

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 of HFSC. Alternatively, these items may be scanned into the associated electronic record in LIMS.

4.13.2.5. Examination documentation is of sufficient detail to support the conclusions. Documentation is such that in the absence of the examiner or test report, another competent examiner could evaluate what was done and interpret the data. This includes the identity of instruments used and the personnel conducting the analysis.

4.13.2.6. If allowed by law, a qualified staff member may review, interpret, report, or testify regarding the examinations, investigation notes, or critical findings of another HFSC staff member. Someone who testifies to the work of another examiner shall document a review of applicable case records prior to testimony. Documentation of the review may be accomplished by initialing the appropriate pages in the examination record, by using a review checklist, or by specifying the pages or dates of analysis that were reviewed and relied upon. Other methods may be used and are subject to the approval of the section manager. This does not apply if the staff member is presenting business records only.

Case records on paper must be legible and recorded using ink. Exceptions may be made if environmental conditions prevent the use of ink. Pencil may be used if appropriate for making diagrams or tracings. While original notes may be recopied, all original notes must be maintained as a permanent component of the case record unless captured electronically and the electronic copy has been found to be legible and accurate. These requirements do not apply to administrative documents submitted by the stakeholder.

When a critical finding is independently checked by a second individual, it will be conducted by someone authorized to perform independent checks in that category of testing. A record is made to indicate that the finding was checked, agreed to, by whom, and when. This independent check should not be confused with a technical review. Further information related to independent checks may be found in applicable sectional SOPs.

Abbreviations, acronyms, and symbols are acceptable in examination records if the meanings are readily comprehensible to a reviewer and the meaning of the abbreviation or symbol is documented in the sectional SOP. Abbreviations that are common in a

discipline and understood by anyone in that discipline do not have to be listed in a table of abbreviations. Examples include, but are not limited to, chemical element symbols and standard units of measure.

4.14. Internal Audits

4.14.1. HFSC conducts an annual audit, using its current policies and procedures, accreditation standards, supplemental requirements, and the FBI Quality Assurance Standards (QAS) for DNA Testing Laboratories as guidelines. 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. The audit includes direct observation of examinations and interviews with staff members.

The Quality Division, in conjunction with managers and section supervisors, 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 or will have had audit training. 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 the key management personnel.

The Quality Division is responsible for providing an audit report to top management. Any necessary corrective action will be implemented in a timely and appropriate manner.

Required DNA audits (may be 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 analyst in the specific DNA technology being performed and at least one qualified auditor are a part of the DNA audit team. The qualified analyst and the qualified auditor may be the same person. A qualified auditor is a current or previously qualified DNA analyst 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.

4.14.1.1. The audit is conducted annually, typically covering the 12-month period prior to HFSC's accreditation anniversary date. The Quality Division will communicate with top management regarding the time frame in which the audit will be conducted. This time frame may be adjusted to accommodate the schedules of the audit team. Changes to the agreed-upon time frame will be communicated to top management.

4.14.1.2. Records of the annual audit are retained through at least one accreditation cycle or five years, whichever is longer. DNA records are maintained for at least 10 years.

Records may be scanned for long-term storage or sent to off-site storage according to city and/or HFSC regulations.

4.14.2. 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 investigating results.

4.14.3. The areas of activity audited, the audit findings and corrective actions that arise from them are documented. Internal audit teams must directly observe tests being conducted within each discipline.

4.14.4. 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.

4.15. Management Reviews

4.15.1. A documented review is conducted by top management officers and/or their designees to determine the suitability and effectiveness of management activities. This management review includes, but may not be limited to, the following:

- the suitability of policies and procedures
- reports from managers and supervisory personnel
- the outcome of recent internal audits
- corrective and preventive actions
- assessments by external bodies
- results of interlaboratory comparisons or proficiency tests
- changes in the volume and type of work
- stakeholder feedback
- complaints
- the fulfillment of quality and sectional objectives
- recommendations for improvement
- documentation of any latent print conflict resolutions
- other relevant factors, such as quality control activities, resources, and staff training

Top management will verify that concerns raised during the management review are properly addressed.

A management review is conducted at least once each calendar year. The Quality Division will communicate with top management regarding the time frame in which the review will be conducted. Changes to the mutually agreeable time frame will be communicated to affected parties.

Records of these reviews are maintained for at least one accreditation cycle or five years, whichever is longer.

Findings from management reviews and the actions that arise from them are documented. Top management ensures that actions taken to address nonconformances are carried out within an appropriate and mutually agreeable time frame.

5. Technical Requirements

5.1. General

5.1.1. HFSC takes into account critical factors that affect the reliability of its test and investigation results. These factors include (numbers refer to sections below):

- personnel (5.2)
- accommodation (facilities) and environmental conditions (5.3)
- test methods and validation (5.4)
- equipment (5.5)
- measurement traceability (5.6)
- sampling (5.7)
- evidence handling (5.8)

5.1.2. The extent to which the factors listed in 5.1.1 contribute to the total uncertainty in measurements differs between types of tests conducted. HFSC takes these factors into account when developing test methods and procedures, in the training and qualification of technical staff members, and in the selection and calibration of its equipment and instruments.

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

Reagents prepared in HFSC are labeled with the identity of the reagent, concentration (if applicable), date of preparation or lot number, and, as applicable, storage requirements. 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 and hazard warnings. The Biology Section follows the labeling requirements in this manual and those outlined in QAS.

5.1.4. Sectional SOPs will specify the frequency of reliability testing for reagents. Reagents will be tested before use or, if appropriate, concurrent with the test. Reagents not meeting quality control criteria are removed from use and affected casework, if any, is reviewed.

5.2. Personnel

5.2.1. HFSC has a documented training program that provides knowledge and skills needed to perform specific tests. Key management ensures the competence of all who operate equipment, perform tests, evaluate results, and sign test reports by reviewing the staff member's training binder prior to independent casework. Section management appoints an individual or individuals to oversee the training of new staff members. This trainer is responsible for supervising the staff member throughout the training process.

5.2.1.1. Each technical discipline within HFSC has a training program. Newly hired technical staff members, including contract employees, will complete appropriate training and

demonstrate competence before beginning casework. Sectional training manuals also include information related to retraining and maintenance of skills.

Training is carried out under the direction of the appropriate key management personnel or a qualified designee. Training may include, but is not limited to:

- review of written materials, such as journal articles, books, and in-house procedure manuals
- laboratory exercises that demonstrate practical skills
- discipline-specific written and/or oral examinations that demonstrate understanding of the scientific subject matter and the laboratory activities associated with it
- on-the-job training, such as observing an experienced crime scene investigator as he/she processes a scene
- successful completion of a competency test that demonstrates the staff member's ability to properly convey results and conclusions and the significance of those results and conclusions

Training may be modified for staff members with previous training and/or experience at another laboratory. However, all staff members, whether previously trained or not, must successfully complete competency testing before beginning casework or creating items that could be used for testing.

Technical competency can be maintained through the following:

- demonstrated competency
- training
- experience
- casework supervision
- continuing education through professional development
- proficiency testing
- compliance with established scientific protocols and proper professional ethics

The section manager and/or DNA technical leader or designee will evaluate the new staff member's credentials and modify the training program if applicable. Previous training records summarizing court qualifications, courses taken, and other supporting documentation will be obtained when practical.

To maintain competency, skills, and expertise, technical staff members are encouraged to participate in continuing education. Section-specific continuing education requirements, such as those for DNA analysts and CODIS administrators, must be met. Skills and expertise can be maintained by:

- attendance at meetings, seminars, and conferences
- participation in scientific working groups
- review of current and applicable literature
- presentation and submittal of content for publication in professional journals

- presentations at technical meetings
- participation in college-level and other specialized courses
- completion of webinars or other online training opportunities

Webinars or other online training opportunities used to meet DNA continuing education purposes must be approved by the technical leader or designee.

The statements of qualifications (SOQ) and training certificates or other records of specialized training received are maintained in staff members' electronic quality files. SOQs are required for all technical staff members at the level of manager and below.

5.2.2. Key management formulates goals with respect to the education, training, and skills of HFSC personnel. HFSC's training goals are evaluated in light of present and perceived workload demands during annual management review to align competencies with stakeholders' needs, to promote professional development, and to ensure that mandated training is provided. These goals are outlined in each discipline's training manual. The effectiveness of in-house training is evaluated by the trainer and/or section management. Effectiveness may be evaluated by how well content meets stated goals or objectives and by the performance of trainees on quizzes, competency tests, oral examinations, and/or proficiency testing.

Technical trainees are responsible for maintaining a training notebook or equivalent record-keeping system that includes documentation of goals and objectives, exercises, exams, and other documentation supporting their training activities. Further details may be found in sectional training manuals. Letters of authorization are issued upon successful completion of the section-specific training manual and a competency test. New letters are issued as the technical staff member develops new competencies. Competency is evaluated annually through the proficiency-testing program. Critical tasks that require competence include, but may not be limited to, collecting evidence samples, performing visual and chemical examinations, operating equipment and instruments, interpreting results, writing reports, testifying in court, and performing technical reviews.

Staff members are encouraged to join professional organizations. They may attend conferences and seminars if funding is available. Staff members may be allowed to attend training while on duty.

5.2.3. HFSC staff members will be employed by or under contract to the laboratory. If contracted employees or additional technical or key support personnel are used, HFSC will ensure that these individuals are supervised, competent, and adherent to HFSC management system rules during on-the-job hours.

5.2.4. See HFSC Human Resources personnel for information related to job descriptions or postings.

5.2.5. Training is documented so that it is clear what tasks were undertaken during the training program. The appropriate section manager or DNA Technical Leader authorizes specific personnel to perform particular tasks, such as of sampling, testing, issuing reports, giving opinions, interpreting findings, conducting technical reviews, and operating specific instruments and equipment. When in training, personnel are authorized to use instruments and equipment while under the supervision of trained and authorized staff members.

5.2.6. Technical Staff Qualifications

5.2.6.1. Education

Analysts in the Biology, Seized Drugs, or Toxicology disciplines who issue reports that include results of testing, an opinion, or an interpretation and whose job duties include creating items of evidence, must have a baccalaureate or advanced degree in a chemical, physical or biological science or forensic science. In addition, Seized Drugs and Toxicology analysts must have successfully completed at least 30 semester hours of chemistry. DNA analysts must also meet the educational requirements of the FBI's Quality Assurance Standards for Forensic DNA Testing Laboratories.

The Chief Executive Officer, Chief Operations Officer and technical management positions must meet the minimum educational requirements stated in the job posting or job description.

Analysts who issue reports containing results, opinions, or interpretations, and whose job duties include creating items of evidence, in Firearms, Digital and Multimedia Evidence, Latent Prints, and Crime Scene disciplines must meet the minimum educational requirements stated in the job posting or job description.

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

Transcripts are required to verify completion of coursework and degree(s) to satisfy certain sectional coursework requirements. These transcripts are maintained in the staff members' quality files.

5.2.6.2. Competency Testing

All technical staff members conducting casework, regardless of academic qualifications or past work experience, must satisfactorily complete a competency test prior to performing any tests or creating items that could be used for testing. This also includes technical staff cross training in a new discipline and technical support personnel. Technical support personnel are those individuals who perform casework-related duties within HFSC at the direction of a technical staff member but do not issue reports related to conclusions reached.

This competency test will include:

- a practical examination that covers the spectrum of anticipated work to be performed.
- 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.
- writing a test report to demonstrate the individual's ability to properly convey results and/or conclusions and the significance of the results and/or conclusions (if applicable).
- courtroom testimony training- the testimony requirement can be met through a mock trial or oral examination that gauges the analyst's ability to communicate technical and HFSC-specific information. There may be other means of meeting the testimony requirement. However, a testimony class that does not include a mock trial does not meet this requirement. Consult the Quality Division in advance for approval of other methods.

Exceptions to the above requirements may be granted upon written approval of the Quality Division.

Authorization memos are issued after the intended results of the competency test(s) are satisfactorily achieved. Analysts 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). Authorization memos and supporting documentation are reviewed and approved by the Quality Division and the section manager and/or technical leader or designee before independent casework begins.

In the event that a technical staff member neither performs casework nor completes a proficiency test in a discipline for a period of 12 months or longer, (the period of time may be less than 12 months based upon the discretion of the section manager and/or top management) he or she must successfully complete a competency test prior to resuming casework in that discipline.

Non-analytical staff members and those who do not analyze evidence or create items that could be used for testing associated with active cases are not required to undergo mock trial training. However, whenever possible, a mock trial will be conducted before the non-analytical staff member testifies in court for the first time.

5.2.7. HFSC maintains literature resources or provides Internet access to literature resources such as relevant books, journals, and other literature dealing with each discipline.

5.3. Accommodation and Environmental Conditions

5.3.1. HFSC facilities are equipped with utilities and environmental conditions to ensure a comfortable work environment. HFSC ensures that neither testing nor test results are at risk of invalidation or diminished quality because of environmental conditions. Technical requirements for accommodation and environmental conditions are noted in sectional SOPs. Concerns related to environmental conditions that could affect casework should be brought to the attention of the section manager and should be investigated. If the environment is found to be a threat to reliable testing, conditions should be corrected in a timely fashion.

5.3.2. HFSC monitors and records environmental conditions when required by relevant specifications, methods, and procedures or when they 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 the temperatures are monitored. Testing is stopped if environmental conditions jeopardize testing results.

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

- refrigerators: >0°C to 10°C (>32°F to 50°F)
- freezers: ≤0°C (≤32°F)

If the temperature of a refrigerator or freezer is out of range, adjustments should be made and the temperature rechecked and readjusted until the reading is in range. If after making adjustments the temperature remains outside the range stated above, contact the section manager or supervisor for assistance with possible repairs.

Temperatures should be monitored and recorded. This may be done in a variety of ways. 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 the Temperature @lert (TempAlert) monitoring system. The TempAlert system transmits temperature readings wirelessly to a secure website, which is monitored and controlled by designated personnel. When the TempAlert system is used, it is not necessary for personnel to record temperature readings manually. All temperature logs and/or temperature reports are kept for at least five years or one full accreditation cycle, whichever is longer.

Thermometers and temperature probes used to measure critical temperatures are verified at least annually against a NIST traceable thermometer.

5.3.3. HFSC provides effective separation between neighboring areas in which incompatible activities take place. Incompatible activities are separated by time or space to prevent contamination. Work surfaces and examination implements are cleaned. Controlled substance 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 opposing sides in the same case are analyzed at different times or in different rooms to prevent cross-contamination. Additionally, evidentiary and reference DNA samples are handled at different times or in different locations to prevent cross-contamination.

5.3.4. Access to operational areas of HFSC is controlled and limited to those needing access. Non-HFSC staff members are not allowed unrestricted access to operational areas of HFSC. Please see the *HFSC Security Manual* for further information.

5.3.5. 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.

5.3.6. HFSC has a health and safety program led by a Health and Safety Coordinator and a group of HFSC staff members. Additional details are found in the *Health and Safety Manual*.

5.4. Test Methods and Method Validation

5.4.1. General

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.

Deviations from standard test methods must be documented in the case record and approved by the section manager and technical lead (the section manager may also be the technical lead) prior to the deviation. Unless otherwise instructed by the stakeholder, HFSC chooses the best method for conducting analyses. 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 section manager or his/her designee should contact the stakeholder before deviating from a standard method.

5.4.1.1. Sectional SOPs will specify appropriate procedures used to interpret test data.

5.4.1.2. Disciplines that compare data from an unknown to a known must have sectional SOPs that specify criteria to be used to determine whether the unknown has suitable characteristics for comparison to one or more known item(s).

5.4.2. Selection of Methods

HFSC uses methods that meet stakeholders' needs. The methods used may be published in international, national, or regional standards by reputable technical organizations in relevant scientific publications or may be specified by the equipment manufacturer. Validations conducted by the scientific community (as in standard or published methods) are considered validated but will be verified as working in-house before use on casework. HFSC validates nonstandard methods, laboratory-developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that these methods are fit for their intended use.

Control samples or replicate testing will be used with infrequently performed test methods to show the tests are giving appropriate results. Sectional SOPs will identify infrequently performed tests or analyses, if any.

5.4.3. Laboratory-Developed Methods

Prior to a substantial change to or the implementation of a new method/procedure, the method is subjected to appropriate internal validation (see 5.4.5.1 for definition) to assess the procedure's ability to produce high-quality, reliable results. All validations are completed by qualified personnel. 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.

5.4.4. Non-standard Methods

If it is necessary to employ non-standard methods, approval will be obtained from the section manager (or technical lead) and the stakeholder prior to use. The non-standard method will be validated prior to use on evidence items. See the Digital and Multimedia Evidence sectional SOPs for exceptions to this validation requirement.

5.4.5. Method Validation

5.4.5.1. New test methods used by HFSC are validated before being used in casework and shall include:

- data interpretation
- data required to report a test result, opinion, or interpretation
- the identity of limitations of the test method, reported test results, opinions and interpretations
- when a currently validated method, including associated data interpretations, needs additional validation
- a validation plan that provides direction for parameter evaluation and parameter acceptance criteria to determine if the method is fit-for-purpose prior to starting a method validation

During validation, known samples representative of those encountered in casework are examined to determine if the procedure generates acceptable results. Validation of quantitative analyses includes a determination of the procedure's accuracy and precision over the range of concentrations expected in casework and establishes analytical limits, such as quantitation, limit of detection, or reporting cut-off (if appropriate). The validations are as extensive as necessary to meet the needs of the given application.

Validation studies are documented and approved by the section manager or designee and Quality Director or one or more of their designees. Affected staff members are trained in new techniques before the techniques are used in casework. Additional guidelines for procedure validation may be found in section SOPs.

Digital and Multimedia Evidence sections can use published validation studies from reputable scientific, law enforcement, or educational organizations in lieu of an internal validation. In these circumstances, these forensic tools are performance verified prior to use in casework. There may be time-sensitive instances in which technical sections, such as Digital and Multimedia Evidence, may need to deviate from validated procedures. In extraordinary cases in which evidence might be compromised if analysis is not attempted in a timely fashion, methods may be employed without prior validation or performance verification if the examiner uses due caution to maintain the integrity of the evidence. Supervisory approval is required in these situations, and the circumstances of the case and the analytical processes employed must be fully documented in the case record. These reports will not contain an accreditation statement or the logo of an accrediting body.

5.4.5.2. 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.

5.4.5.3. Prior to implementation of a validated method new to HFSC, in-house tests must demonstrate that the reliability and performance characteristics of the method conform to those of that method documented elsewhere. Records of the performance verification are maintained.

5.4.6. Estimation of Uncertainty of Measurement

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 test 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 that do not result in numerical values or for quantitative

tests in which the numerical value obtained is not reported. 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.

5.4.6.1. HFSC does not perform calibrations.

5.4.6.2. Affected sections of HFSC will have and apply procedures for estimating UM. The procedure for estimation of measurement uncertainty shall:

- require 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
- include the process of rounding the expanded uncertainty
- require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%)
- specify the schedule to review and/or recalculate the measurement uncertainty

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. The form of reporting of the result will not give a wrong impression of the uncertainty.

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

5.4.6.4. Sections must maintain records of their UM estimations. These records will include:

- statement defining the measurement
- 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 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

5.4.7. Control of Data

5.4.7.1. Manual calculations and data transfers are checked during technical review and are not conducted by the person who performed the calculation(s) or the data transfers. Detailed information may be found within sectional SOPs.

5.4.7.2. When a computer or automated equipment is used for the acquisition, processing, recording, reporting, storage, or retrieval of test data, HFSC will ensure the following:

- computer software developed by HFSC is adequately validated and its performance verified as fit for use. Commercial off-the-shelf software in general use within its designed application range will be considered sufficiently validated. This includes word processing, database, or instrument-associated software.
- data generated electronically is protected by limiting access to the equipment and by allowing only authorized individuals to use the equipment. See section 4.13.1.1.
- computers and automated equipment will be operated in compliance with the manufacturer's recommendations or guidelines specified in sectional SOPs.

5.5. Equipment

5.5.1. HFSC is furnished with the proper analytical equipment needed for the examinations performed by its staff members. In cases in which HFSC needs to use equipment outside its permanent control, HFSC will ensure that applicable accreditation requirements (such as those in ISO/IEC 17025) are met.

5.5.2. 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 internal validation, performance verification, external calibration, and/or intermediate checks. Section SOPs contain additional details when applicable. Before being placed into service, equipment, including that used for sampling, is calibrated or checked to establish that it meets sectional specifications. Equipment and instrument manuals should be available for reference purposes.

General service equipment not used for measurement purposes (i.e., hot plates, stirrers, non-volumetric glassware, cameras, and refrigerators) will be maintained through visual examination, safety checks, and cleaning as necessary. 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 vented to the fume hood exhaust system are checked annually by an external vendor. See applicable sectional SOPs for further information.

Sections that re-use disposable equipment will have a procedure, validation study, carry-over study, or some similar document to ensure and show that 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.

5.5.3. Equipment and instruments are operated only by authorized personnel or, in the case of trainees or interns, under the direction of authorized personnel. Personnel are typically authorized to operate equipment and instruments through completion of section-specific training programs. Further details may be found in authorization memos. Equipment manuals and SOPs are readily available. Equipment manuals should be stored near the equipment or in a location agreed upon by sectional staff. SOPs are accessible by approved staff from networked computers.

5.5.4. Sectional personnel utilize equipment and instruments that are adequate for the specific tasks and that are in proper working order.

Each instrument or piece of equipment and its software or hardware used for testing and significant to the result shall, when practical, be uniquely identified. This identification may take the form of an asset management tag.

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

- identity of equipment and any corresponding software
- forensic software and/or hardware (Digital and Multimedia Evidence only)
- manufacturer's name, type of instrument or equipment (e.g. mass spectrometer, comparison microscope) identification, and serial number or other unique identification
- manufacturer's instructions
- status records (dates, results, and copies of reports; certificates or records of calibrations, adjustments, and acceptance criteria; and the due date of the next calibration)
- documentation of maintenance and maintenance plan when appropriate
- records of equipment and instrument malfunction, damage, modification, and repair
- section where equipment is located

Maintenance, repairs, and performance verifications are recorded in instrument logbooks or an electronic equivalent as soon as possible after completion.

5.5.6. Measuring equipment is handled, transported, and stored according to manufacturers' recommendations in order to prevent contamination or deterioration. If additional instructions are necessary, they will be documented in sectional SOPs. If manufacturers' information is not available, the section manager should determine the proper procedures for handling, transport, storage, and maintenance of that equipment. If equipment that is sensitive to movement (e.g. balance) and is used to make critical measurements is moved, a performance check must be conducted.

5.5.7. Equipment that does not meet quality control criteria and that is not immediately repaired must be taken out of service. The equipment is labeled or marked to indicate that it is out of service until it has been repaired and shown by calibration or performance check to perform correctly. The instrument/equipment maintenance record is updated to show the

date and reason it was removed from service. If appropriate, HFSC will examine the effect of the defect on previously conducted tests and will institute any necessary corrective action. 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.

5.5.8. Whenever practical, equipment that requires calibration is labeled with the last calibration date and the date the next calibration is due.

5.5.9. When equipment goes outside the direct control of HFSC and is used for testing and/or investigation by non-HFSC personnel, then staff members verify that the function and calibration status are satisfactory before the equipment is returned to in-house service. Records of such checks are maintained.

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

5.5.10.1. Once established, any extension of the interval of intermediate checks shall be based on empirical data and an evaluation of risk.

5.5.11. HFSC does not perform its own calibrations. Procedures describing correction factors used during performance verifications will be defined in sectional SOPs, if applicable.

5.5.12. Testing equipment, including hardware and software, is safeguarded from adjustments that would invalidate test results. All equipment used for examinations is operated only by qualified personnel. Additional information may be found in applicable sectional SOPs.

5.6. Measurement Traceability

5.6.1. General

5.6.1.1. All equipment used for testing, including equipment for subsidiary measurements, that has a significant effect on the accuracy or validity of the test result, is calibrated before being put into service. For measuring devices that have a significant effect on the accuracy or validity of the reported result and the result is a measurement that matters, the calibration is performed by an ISO/IEC 17025 accredited calibration laboratory that can demonstrate traceability to the International System of Units (SI) when possible. A *measurement that matters* is one that is used, or may reasonably be expected to be

used, by a laboratory stakeholder to determine, prosecute, or defend the type or level of criminal charges.

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 that of 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.

Sectional SOPs contain details for ensuring the calibration of critical equipment. Calibration/performance check records are maintained, preferably in a location near the instrument or equipment. Measuring devices used by the Crime Scene Unit may be checked before being placed into service but are typically not considered critical. Please see the Crime Scene Unit SOP for further information.

All critical weight, critical volume, and critical length measurement devices are certified to NIST standards. The frequency of the calibration interval depends on the function of the measurement device. Sectional SOPs may include further details regarding specifications and maintenance schedules for non-critical and critical equipment.

The following is a list of critical equipment calibrated at least annually by an external vendor unless otherwise specified in sectional SOPs:

- pipettes
- gauge blocks
- trigger pull gauges
- steel rules (steel rulers)
- standard reference weights
- balances

In addition to the annual balance calibration, sectional personnel complete a performance check at least monthly. When the use of a balance is infrequent, performance checks are not required each month; however, a check will be performed prior to use.

Documentation of calibrations is kept by HFSC.

Specific time frames for maintenance of equipment and/or instruments used in DNA testing will follow Quality Assurance Standards for Forensic DNA Testing Laboratories guidelines whenever stricter than those recommended in this manual.

Equipment calibration procedures are established according to the specific requirements of the test being conducted. The interval for checking equipment calibrations will not be less stringent than manufacturers' recommendations. It will

normally be necessary to check equipment calibration after any shutdown, repair and following service or other substantial maintenance. It is not necessary to check equipment after calibrations are performed on site.

5.6.1.2. Calibration intervals will not be extended unless approved in advance by the Quality Division. Approval will not be given until after the Quality Divison reviews a study completed by the section that includes empirical data and an evaluation of risks involved in extending the time period.

5.6.1.3. Sections seeking to remove equipment or instruments from a calibration schedule must submit a study to the Quality Division that demonstrates the item does not have a significant effect on sampling, the test result, or the total uncertainty of the test result. The study must include objective evidence to demonstrate this insignificant contribution. The Quality Division will notify section management of the approval or denial of the request.

5.6.1.4. Vendors who calibrate reference standards and vendors who calibrate equipment that have a significant effect on the accuracy of test results, sampling and total uncertainty must be, if available, either:

- 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)
- 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 to be performed listed in a scope of accreditation

5.6.1.5. If an external calibration supplier is not available that meets the requirements specified in 5.6.1.4, HFSC will confirm competency, measurement capability, and measurement traceability for the supplier and the service being purchased and will maintain documentation of the vendor's competency.

5.6.1.6. HFSC does not perform calibrations.

5.6.2. Specific Requirements

5.6.2.1. Calibration

HFSC does not perform calibrations under its accreditation certificate.

5.6.2.2. Testing

- Laboratory equipment is operated to ensure that measurements that matter are traceable to the SI whenever possible. This does not apply if the contribution of the calibration to the total uncertainty is negligible. (See 5.6.1.)
- If traceability to SI units is not possible or relevant, then HFSC may provide confidence in measurements by establishing traceability to such standards as certified reference materials, specified methods, or consensus standards.

5.6.3. Reference Standards and Reference Material

Reference standards, reference materials, and calibrations of equipment/reference standards used to establish and/or maintain measurement traceability are considered critical by HFSC.

5.6.3.1. Reference Standards

Reference standard refers to a traceable benchmark or level of quality that is used to calibrate equipment measuring values reported in SI units. Examples include NIST-traceable weights and thermometers. Reference standards are not to be used as both calibrators and controls unless it is shown that their performance as a reference will not be invalidated. The performance of reference standards is checked before and after any adjustment.

5.6.3.2. Reference Materials

Reference material is certified by a technically valid procedure and typically accompanied by a traceability certificate issued by a certifying body. Reference materials are traceable to SI units of measurement or to certified reference materials, when applicable. Internal reference materials are checked as far as is technically and economically practical. If it is not possible or appropriate to trace reported results to SI units, HFSC will ensure the reliability of reported results, when practical, using certified reference materials.

Certificates of analysis provided by manufacturers are maintained in a location designated by the section manager. 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 certified reference materials used to establish or maintain measurement traceability shall be either:
    - 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)
    - 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

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

- If a CRM is changed in a way that alters the traceable measurement value, then the equipment used to alter the CRM must be evaluated for applicability of measurement traceability accreditation requirements.

- For sections seeking an extension in the interval of performance checks, they must submit a study that includes empirical data and an evaluation of risk for approval by the Quality Division. See 5.6.1.2 and 5.6.1.3.

- Reference collections of data or items/materials encountered in casework that are maintained for identification, comparison, or interpretation purposes (for example, mass spectral libraries, drug samples, firearms, bullets, cartridges, DNA profiles, frequency databases) are documented, uniquely identified as a reference sample, 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.

5.6.3.3. Intermediate Checks

Performance checks (or performance verifications) needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards and reference material are carried out per defined sectional procedures and schedules. An increase in the timeframe between performance check intervals shall be based on empirical data and an evaluation of risk.

5.6.3.4. Handling, Transporting and Storing Reference Standards and Reference Materials

Reference standards and reference materials must be handled, transported, stored, and used according to manufacturers' instructions or approved section-specific policy manuals to protect the integrity of the materials and to address any unique safety concerns for staff members handling the items. Reference standards and reference materials are handled, transported, and stored in a manner that prevents loss, damage, contamination, or deterioration.

5.7. Sampling

5.7.1. For the Seized Drug section, which may require the use of a sampling plan in testing, the plan and procedure(s) must:

- include an evaluation of the selected population for homogeneity
- ensure the population has a reasonable expectation of homogeneity before using the sampling plan
- make use of probability and provide an opinion or interpretation with a minimum confidence level of 95.45% (often referred to as approximately 95%)
- ensure each item selected meets the sampling plan level of confidence to be tested completely

- provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity

See applicable sectional policies for further details.

5.7.2. Stakeholder-requested deviations from sampling procedures will be documented. See applicable sectional policies for detailed information.

5.7.3. HFSC records relevant data related to sample selection. See applicable sectional policies for detailed information.

5.8. Handling of Evidence

5.8.1. All evidence items are handled while in the care, collection, custody, and control of HFSC 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
- firearms are rendered safe by qualified personnel

In general, the staff member receiving the submitted evidence will ensure that the item is properly sealed. Evidence seals are inspected to ensure they protect evidence from loss, cross-transfer, contamination, or deleterious change. Refer to HFSC's Evidence Handbook for additional information regarding appropriate evidence packaging.

Chain of custody procedures apply to blind quality control (BQC) samples once they are submitted to HFSC as evidence.

Read HFSC's corporate Vehicle Use Policy for information related to transportation of test items/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 must never be left in a visible area, such as the front or back seats, of an unattended vehicle. These requirements apply to all HFSC staff while driving an HFSC vehicle and while driving a personal vehicle for business use.

5.8.1.1. A chain of custody is maintained for evidence submitted to HFSC, including evidence submitted for entry into characteristic databases. These chains are records of the submission of evidence to HFSC as well as all internal transfers. The chains of custody include the date of receipt or transfer and a description or unique identifier of the

evidence. Staff members are responsible for ensuring evidence items have appropriate item descriptions recorded in LIMS.

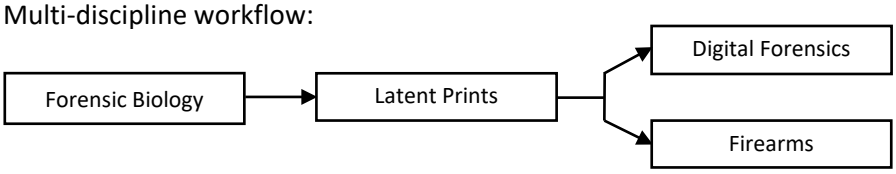
Each person acknowledges by signature, initials, or secure electronic equivalent, at the time of submission or transfer, when evidence transfers from person to person or to a storage location.

If an electronic transfer is not captured in LIMS, it shall be added immediately upon discovery. The date and time of the transfer will reflect the date and time of discovery and a comment will be added to explain what the actual transfer date and time were. Similarly, if the chronological order of the physical transfer was not initially captured, a comment shall be added to explain the correct order of events. For both situations, a LIMS change request shall be initiated. JusticeTrax change requests are initiated through a workflow in Qualtrax and Porter Lee change requests are initiated either through the current LIMS Request Form or, once published, a workflow in Qualtrax. Any comments made in the chains of custody must be included in the workflow for approval. After the change request form and/or workflow have been approved by the Quality Division, the LIMS administrator is responsible for making any changes to the comment to the LIMS chain of custody.

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

5.8.1.1.2. 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 Digital Forensics (depending on the type of evidence). However, this flow may vary based on the type of evidence and the circumstances of the investigation. Requests for analysis of seized drug evidence that also includes requests for other disciplines (such as latent prints) are handled on a case by case basis by section management. All analysts, 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. The case record must clearly indicate those situations where section management was consulted for guidance on the flow of analysis.

Multi-discipline workflow:



5.8.1.1.3. 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.

5.8.1.1.4. All evidence stored by HFSC will be properly sealed. A proper seal is essential to controlling the integrity of the evidence. Lack of a proper seal could result in the integrity and quality of the evidence being questioned. An evidence container is properly sealed if the contents cannot readily escape and if entering the container results in obvious damage or alteration to the container or its seal. All seals placed on evidence by HFSC staff must include the initials or signature of the individual placing the seal on the item.

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. Before evidence is accepted, the outer container must be inspected for a proper seal. If evidence is not properly sealed upon acceptance, the Client Services and Case Management (CS/CM) Division may place a corrected seal over the original seal to ensure it meets HFSC's expectations before it is delivered to the section and/or stored by HFSC. A corrected seal is a proper seal placed on the evidence by a CS/CM staff member when the evidence is observed to have a seal but does not meet the description of a proper seal set forth in this manual. This correction will be documented in the chain of custody comments for that specific item.

The requirement for evidence to be sealed does do not apply to evidence submitted for immediate analysis (e.g. test firing an officer's weapon) or to evidence such as long guns submitted for NIBIN entry only. Additional exceptions may be found in sectional SOPs.

Exceptions may be made for large or bulky items that do not easily lend themselves to sealing. Consult key management personnel for advice on handling these items.

Evidence will be rejected if its identity is compromised or if the requested testing is fundamentally inappropriate for the evidence submitted. If evidence is rejected due to a missing seal or is not packaged, CS/CM will photograph the condition of the evidence. The evidence will remain in the custody of the stakeholder until it is properly sealed/packaged. CS/CM will give electronic notification to the stakeholder that the evidence was not properly sealed/packaged and therefore not accepted by HFSC.

If evidence is not sealed and/or not packaged and was inadvertently accepted from the stakeholder, CS/CM will photograph the condition of the evidence, remediate the seal, and upload the photographic documentation into the LIMS

case record. The evidence will be assigned to the appropriate section and will proceed with analysis.

If a section receives evidence from CS/CM that is not sealed/packaged properly, the section will photograph the condition of the evidence prior to processing the item. The condition of the evidence upon receipt and the steps taken to remediate the seal or packaging will be communicated to the stakeholder in the test report. This does not apply to toxicology as their evidence is accessioned by CS/SM.

5.8.2. Evidence received for examination is uniquely identified. This unique identification is retained throughout the life of the evidence item in HFSC and is used during evidence transfers to, within, and from HFSC. See sectional SOPs for specific details on identifying evidence.

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. If, at the time of inventory, there are inconsistencies in the identification of the evidence to a case or to an individual that make definitive identification of the evidence questionable, HFSC will return the evidence to the submitting agency and issue a report stating the evidence was rejected for analysis and the reason(s) for the rejection.

5.8.3. If, upon receipt, the condition of the evidence is not as expected or specified by the stakeholder, the condition will be documented in the case record. 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. See section 5.10.1. for criteria regarding rejection of test items.

5.8.4. Evidence is stored, handled, and prepared in a manner that prevents loss, contamination, degradation, and damage. Generally, this means examiners will open and examine only one evidence item at a time. However, the nature of some analyses (such as Firearms, Latent Prints, Digital and Multimedia Evidence) requires the comparison of multiple items at one time. Whether one or multiple items are opened at a given time, evidence will be protected as stated above. If evidence must be stored under specified environmental conditions, those conditions will be maintained, monitored, and recorded. (See 5.3.2 for information on temperature monitoring.)

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.

5.8.4.1. All evidence not in the process of examination is maintained in a secured, limited-access area under proper seal. Proper security may be achieved by storing evidence in refrigerators or freezers, vaults, rooms, or locked cabinets. Limited access is access

limited to personnel authorized by the appropriate division director. Access has been granted by the division director if the staff member has a key, alarm code, or badge that allows access to a given area of HFSC. Individuals who have not been granted access to certain areas of HFSC may enter those areas if they are escorted by a staff member who has been granted access.

5.8.4.2. 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, as long as the integrity of the item is maintained. During the process of examination, if a technical staff member needs to leave for a short time, such as for a break, the evidence may be left unattended in an area with limited access.

- Unless there is a justifiable expectation of frequent analyses or examinations, evidence is maintained in a secured limited-access area under proper seal.

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

5.8.4.4. If a situation arises in which evidence can be recorded or collected only by photography, then the photograph is treated as evidence. Printed photographs will be tracked with a chain of custody. Electronic photographs will be stored in a secure limited access database.

5.8.4.5. When evidence is collected off-site by HFSC staff members, 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 evidence storage facility. When appropriate, further processing to preserve, evaluate, document, or render evidence safe is accomplished prior to final packaging. Evidence collected from an off-site location by HFSC staff members is identified, packaged, and entered into the evidence management system, RMS, or LIMS as soon as practical.

Applicable sections of HFSC will have a procedure for the operation of individual characteristic databases. See DNA, Latent Prints, and Firearms sectional SOPs for further information.

Individual characteristic database (CODIS, AFIS, and NIBIN) 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.

Individual characteristic database samples under the control of HFSC are uniquely identified and are protected from loss, cross-transfer, contamination, and deleterious change by evidence-handling procedures. These samples are treated in a manner that reasonably ensures their utility as comparison materials.

Access to individual characteristic database samples under the control of HFSC is restricted to those persons authorized by the appropriate division director to have access. These persons may include, but are not limited to, individuals responsible for database maintenance, administration, and equipment repair.

5.9. Assuring the Quality of Test Results

Sectional SOPs will define applicable quality control procedures for monitoring the validity of tests undertaken. These data are recorded so that trends are detectable and so that, when practical, statistical techniques can be applied to the review of these results. To ensure the quality of forensic results, HFSC may subject completed casework to retesting and case records to secondary review. 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
- participation in a proficiency-testing program
- replicate testing
- retesting of items
- correlation of results for different characteristics of an item

When applicable, appropriate controls and standards will be specified in sectional SOPs, and the data will be retained in the case record or associated quality control documents.

5.9.1. When a comparative verification is performed on evidence items:

- the verification will be done by an individual currently authorized to perform the testing.
- the verification will be documented in the case record including who performed the verification, when it was performed, and the results of the verification.
- the case record will include 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 analyst or examiner, the disagreement will be brought to section management for resolution.
- the resolution of any discrepancy shall be documented in the case record.

5.9.2. Quality control data is analyzed and, if found to be 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.

5.9.3. HFSC maintains a documented proficiency-testing program. The proficiency of all technical staff is tested to the extent of their casework authorizations. This proficiency program is a reliable means of verifying that HFSC's technical procedures are valid and that the quality of

each technical staff member's work is maintained. The purpose of proficiency tests is to demonstrate the ongoing competence of HFSC and/or that of its technical staff and to identify content areas or skill sets for which additional training or more stringent quality control may be necessary.

Proficiency samples may be either internal or external. *External tests* are examinations prepared by, provided by, and reported to sources outside HFSC. *Internal tests* are developed by HFSC and may involve the reanalysis of previously tested samples, external proficiency tests not reported to sources outside HFSC or, in the case of crime scene processing, an observatory evaluation. These two types of proficiency tests are open in nature, meaning the analysts are aware they are participating in a proficiency exam.

5.9.3.1. Analysts will follow HFSC's own approved methods as closely as possible when completing proficiency tests. In addition, analysts must also follow the provider's instructions for external proficiencies. 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 test report.

Technical review, verification, and administrative review policies will be followed as they are in casework. Should consultation be required, the one or more individuals with whom the proficiency is discussed may not perform a technical or administrative review of the test. Consultation may not be with individuals who have knowledge regarding the test beyond the information that is available from the individual performing the test in question. If the individual consulted is aware of results or observations made by another staff member, 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. These statements do not apply if the proficiency evaluation is a blind test and participants are not aware they are being tested. The section manager or Quality Division should be consulted for further assistance.

If work performed on a proficiency test causes sufficient concern during the review process to warrant withholding the results from the external or internal provider, then that test is deemed "unsatisfactory" and corrective action is initiated.

5.9.3.2. HFSC's proficiency program meets at least the minimum requirements set by its accrediting body. CS/CM staff members who accession Toxicology evidence are not subject to the proficiency testing program because the accessioning process involves preparation of samples for analysis but does not include creating items for analysis nor does it include actions that impact results of analysis. HFSC does not consider CS/CM's creation of electronic child evidence items in LIMS to be synonymous to creating an item for analysis. See the CS/CM SOP for a definition and description of the accessioning process.

5.9.3.3. Each technical staff member and technical support person engaged in non-DNA testing activities will successfully complete at least one proficiency test per calendar year in forensic disciplines in which he/she has been qualified. DNA analysts 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 an analyst is authorized to conduct casework. However, DNA analysts and technicians will enter the proficiency-testing program within six months of competency.

Proficiency tests are evaluated both in terms of conformance to the expected results and the quality of supporting documentation. Successfully completing a proficiency test means either obtaining the expected results or completing appropriate corrective actions. Discrepancies between the reported results and the expected results will be evaluated by section management or a technically competent staff member to determine if the results are consistent with HFSC's policies and procedures. If the results are not consistent and these discrepancies are significant, the test is deemed "unsatisfactory" and corrective action is initiated. Significant discrepancies are those that raise an immediate concern regarding the quality of HFSC's work product. Examples include erroneous identifications or false-positive findings. Key management has the authority to implement corrective action policies for less significant occurrences, such as missed identifications or false-negative results.

Some external proficiency tests, such as those in the Digital/Multimedia Evidence (DME) section, may not mimic routine casework. For instance, DME staff are routinely asked to image/extract derivative data but do not routinely interpret the extracted information. Current proficiency tests provide the extracted derivative data and test the analyst on interpretation of the data. HFSC considers interpretation of the derivative data to be investigative in nature, not forensic. The success of the test will not depend solely upon the analysts' abilities to answer these investigative questions.

Section managers are informed of the results of all applicable participants. In addition, the DNA technical leader or his/her designee will inform the CODIS administrator of all applicable non-administrative discrepancies that affect results or conclusions.

- DNA analysts and technical support personnel performing DNA analysis will comply with the proficiency requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories. For calculating the time period between DNA proficiency tests, the date the test is due in-house will be used.

5.9.3.4. HFSC will successfully complete at least one external proficiency test, if one is available, for each discipline in which HFSC provides services. Within a four-year period, HFSC will complete at least one proficiency test in each major sub-category listed on its scope of accreditation. Approved providers will be used when available. Approved providers are those that operate in accordance with the ISO/IEC 17043 standard. If an approved provider is not available, HFSC will locate other sources for external tests. If there is no provider of commercially available proficiency tests for such disciplines as crime scene investigation, an internal proficiency test will be created and administered.

- External proficiency results used to satisfy 5.9.3.4. will be submitted to the external provider on or before the provider's due date. Any exceptions will be documented.

5.9.3.5. Records of proficiency testing may include:

- test set identifier
- how samples were obtained or created
- identity of the staff members completing the test
- test results
- discrepancies noted, if applicable
- an indication that the test has been reviewed and feedback provided to the participants
- details of corrective actions taken, if applicable
- examination documents to support any conclusions drawn from the results

Tests of proficiency may include observation of performance, which may be administered to crime scene personnel. All the above information may not be reported in such instances. See the Crime Scene SOPs for further details.

5.9.3.6. Proficiency test records will be retained for at least one full accreditation cycle or five years, whichever is longer. DNA records will be kept for at least ten years.

5.9.3.7. In addition to open proficiency testing, HFSC also participates in blind proficiency testing. HFSC creates these tests and designs them to mimic real casework. The Quality Division administers and introduces these tests into the analyst's workflow in the same manner as all other evidence and casework. However, analysts do not know whether they are analyzing a real case or participating in a blind test. This type of testing evaluates the entire quality system as it monitors laboratory performance from evidence submission to the final report.

Comparative disciplines may also participate in blind verifications as part of the blind proficiency test program. In processes in which an independent second analysis or verification of data is required, case information and conclusions made by the first analyst are temporarily masked from the second analyst. The second analyst then performs an independent examination of the evidence. After the second analyst records their conclusions, the conclusions from both examinations are evaluated for consistency. In the event that the conclusions are not consistent with one another, the analysts follow section policies regarding conflict resolution.

Corrective action procedures are applied to nonconforming work related to blind proficiency tests and blind verifications.

Regardless of the type of proficiency test, analysts are required to complete the test using approved methods and procedures and in the timeframe set by the Quality Division.

5.9.4. HFSC conducts a technical review of examination records and test reports to ensure that conclusions of technical staff 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 SOPs for further information on ownership review.

In most instances, the technical review is completed before the test report is released. A record of the review is made to indicate that the conclusion has been checked and agreed to, by whom, and when.

Reviews are conducted by individuals having expertise gained through training and experience in that category of testing. The technical review competency test must 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)
- mock technical reviews of real case record(s) that are then technically reviewed by an already authorized individual.

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.

The Crime Scene Unit will perform a technical review on at least 50% 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.

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

All changes made to administrative and technical records as a result of verification, technical review or administrative review must be tracked in the case and/or the batch record. Section management will determine what tracking method is used. When non-electronic forms such as worksheets or checklists are used, these must be added to the case and/or the batch record. Electronic tracking is acceptable if a report can be run on the information.

5.9.4.1. The technical review includes a review of all examination records and the test report to ensure:

- records and the report conform with proper technical sectional procedures and quality policies
- the report is accurate and the data support the results and/or conclusions in it
- associations are properly qualified, if applicable
- the report contains all the required information

5.9.4.2. Technical reviews are conducted by individuals authorized by the section's management in the category of testing being reviewed. The reviewer must also have knowledge of HFSC's quality procedures. In most instances, it is not necessary for the technical reviewer to be an HFSC staff member or an active analyst, examiner, and/or investigator who has up-to-date passing scores on proficiency tests in the discipline being reviewed. Refer to applicable sectional SOPs (e.g., Forensic Biology DNA-related SOPs) for further information. The technical review will be documented in LIMS and/or the paper case record.

5.9.4.3. Technical reviews are not conducted by the author or coauthors of the examination records or test report under review. Unless otherwise noted in sectional procedures, the primary technical staff member is considered the author of the report.

5.9.5. An administrative review of the case record is conducted prior to the release of the test 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 completed on 100% of completed casework.

5.9.5.1. The administrative review includes:

- review of the test 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 unique case identifier and technical staff member initials or signature are on each page
- review of the report to ensure that all key information (see 5.10.2 and 5.10.3) is included

Chains of custody must be reviewed either during the technical or the administrative review to ensure all transfers were captured and are accurate. Technical and administrative reviews may be conducted by the same person. Analysts may not conduct a technical or administrative review on their own work product.

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.

5.9.6. The testimony of HFSC technical staff members is monitored/evaluated at least once each calendar year. More frequent monitoring may be appropriate for inexperienced personnel. A copy of the completed evaluation form is stored in a retrievable format. Testimony may be monitored through direct observation (preferably by a section manager or supervisor or his/her designee), a review of court transcripts, through solicitation of court officials, videotaped testimony, or other means whereby the following can be evaluated:

- 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 completed evaluation form must be reviewed with and signed by the witness and reviewer. The witness should be given appropriate feedback, positive and negative, noting any area needing improvement.

If the evaluation indicates the possibility of a serious problem (either with the witness or with a procedure) or the overall presentation is unacceptable, then key management (for example, the section manager, quality director, or division director) will take action to remediate the problem. Recommendations for remediation may include, but are not limited to, communications training, remedial technical training, additional mock court training, or a review of technical procedures or methods. The actions taken must be documented through the Quality Division.

Documentation, typically in the form of a memo, will be maintained for each technical staff member who does not give testimony during a calendar year. This documentation will be added to staff member quality files. Staff must complete a Qualtrax Testimony Workflow after they testify, whether the testimony was monitored or not.

It is HFSC's goal to monitor each analyst both in person and via transcript review annually. The transcript review will be blind, meaning the analyst will not know when testifying whether or not that particular transcript will be selected for review. This allows HFSC to compare testimony given when analysts are aware they are being monitored to testimony given when they are unaware. The transcript review group 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 may be a non-technical HFSC staff member or an individual not employed by or assigned to HFSC. Testimony evaluations are conducted by individuals deemed technically competent based on expertise gained through training and experience in that category of testing. If monitored by a team, at least one team member must be technically competent in that category of testing. The competency requirement does not apply to blind transcript reviews unless those reviews are used to meet the yearly testimony evaluation requirement. The following are examples of how competency can be demonstrated:

- authorized to perform casework in the task covered by the testimony
- authorized to technically review tasks covered by the testimony
- A testimony evaluation competency test may 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.

5.9.7. Testimony monitoring records must be kept for at least one accreditation cycle or five years, whichever is longer. DNA records must be kept for at least ten years.

5.10. Reporting the Results

5.10.1. General

HFSC testing results and anomalies (e.g. broken blood tubes, mishandling of evidence) that arise during analysis are reported accurately, clearly, unambiguously, objectively, and in active voice. These results are reported in LIMS and include information requested by the stakeholder, information necessary for the interpretation of the results, and all information required by the method used. An accrediting body's symbol is used on laboratory reports issued by accredited disciplines of HFSC. Accredited disciplines may also include an accreditation statement on their reports. The symbol and/or statement will be approved by the Quality Division before being added to LIMS report templates.

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

Discrepancies in case-related information may result in HFSC's refusal to accept or analyze the evidence in question. In those cases, HFSC nonetheless provides a report. Examples of discrepancies that may result in a report to the stakeholder indicating the evidence has been rejected for analysis include:

- inconsistent subject name (including when the name is not exactly the same on all documentation or evidence items and when the evidence and submission information do not match) when the evidence is associated with a particular individual (such as in biology or toxicology)
- conflicts between dates of birth on the evidence item and the submission form, or LIMS equivalent, when the evidence is associated with a particular individual
- inconsistent case identifiers on evidence and submission form or LIMS equivalent
- absence of pertinent information (subject name and stakeholder case identifier) on evidence labels
- compromised evidence (e.g., a leaking or cracked container or one with indication of tampering)
- inconsistent descriptions on evidence received, including those on a submission form, or LIMS equivalent, and in evidence documentation

When evidence is rejected for analysis, the reason for the refusal will be photographed whenever applicable (e.g. discrepancies between documentation and evidence items, improper seals, compromised evidence) or documented in writing.

If HFSC receives evidence in an insufficient quantity to complete testing AND reserve sufficient sample for additional testing, the laboratory will not proceed with analysis. 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. second blood tube in alcohol analysis), the laboratory will stop the analysis. In both instances, reports will be issued (written in clear active voice, when possible) stating the reason why analysis was not completed or conducted. The laboratory requires a written court order and an indication that defense counsel was given an opportunity to object to the ordered consumption of evidence before proceeding with testing.

Sectional SOPs may contain additional information. Minor discrepancies will be noted in the case record and may also be included in reports issued by HFSC.

5.10.1.1. If HFSC receives a written request to terminate analysis before the work is completed, a report will be issued indicating this request. The written request, which may be submitted by email, will become a part of the case record. Results of work that has been completed must be included in the report but no additional analysis will be done. If all analytical work is completed before the request is received, a test report will be written. Analytical work related to training and validation studies do not require a report. Non-analytical work also does not require a written report.

HFSC may need specific information from the stakeholder in order to fulfill a request for analysis. In such circumstances, HFSC will contact the stakeholder in an attempt to obtain the needed information. If after five business days the stakeholder has not responded, HFSC will close the request. After a section has notified the stakeholder that the request has been closed, that section must also notify other HFSC disciplines who have open requests on the same evidence. All requests where work has not yet started will be administratively closed until further information is received from the stakeholder.

Technical results, with written approval by a supervisor or manager, may be released to a stakeholder prior to issuing a report in extraordinary circumstances in which a serious incident is being actively investigated and the technical results may offer key leads. See sectional SOPs for approved exceptions to this requirement. For the Digital and Multimedia Evidence section, written approval by a supervisor or manager is not required. When technical results are released prior to issuing a report, this fact will be documented in the test report with a description of what was released.

Verbal results may be released after the report has been issued by the report writer, sectional technical management, or a qualified technical member. This verbal release of information must be documented within the case record.

5.10.2. Test Reports

The following supporting information, if applicable, is available in the case record and may be included in the test report:

- items of evidence, including items not tested, are included in reports as per sectional SOPs
- results of all testing performed (partial and complete)
- the report author's documented review of the test record if the author is not the person that performed the work
- significance of associations whether by a statistical or qualitative statement
- clearly communicate the reasons when the reported results indicate that no definitive conclusion can be reached
- initial database entries
- associations resulting from a database search
- identification of methods used
- description and identification of items tested
- date the testing was performed
- sampling plan, if relevant to the validity of the results
- statement that the results relate only to the items tested
- changes to the test method
- estimated UM reported in the format of y (measured quantity value) ± U (expanded uncertainty) and the units of y and U are consistent
- include the coverage probability
- the rounded expanded uncertainty is reported limited to two significant digits
- the rounded expanded uncertainty is reported to the same level of significance as the measurement result

5.10.3. Additions to Test Reports

5.10.3.1. In addition to the information listed in 5.10.2, test reports will, where necessary for the interpretation of the results, include the following:

- deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
- statement of compliance/noncompliance with requirements and/or specifications
- 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
- opinions and interpretations
- additional information that may be required by specific methods or stakeholders

5.10.3.2. In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following when necessary for the interpretation of test results:

- date(s) of sampling
- unambiguous identification of the substance sampled
- location of sampling, including photographs, if applicable

- reference to the sampling plan and procedures used
- details of any environmental conditions during sampling that might affect the interpretation of the test results
- deviations from the established sampling plan

Newly written test reports are maintained by LIMS. Historical reports may be stored electronically, in paper case records, or on microfilm. Once permission to access LIMS web pre-log (the stakeholder/customer portal) is granted by HFSC, stakeholders will have a valid log-in user ID and password that are to be used to access test reports. Reports will be available for download by the stakeholder once technical and administrative review milestones are met.

5.10.3.3. Outsourced reports will be scanned into LIMS.

5.10.3.4. HFSC personnel who issue findings, including writing test reports and providing testimony based on the examination records generated by another person, will complete a documented review of all relevant pages of examination records in the case record.

Documentation of the review may be accomplished by initialing the appropriate pages in the examination record, by using a review checklist, or by specifying the pages or dates of analysis that were reviewed and relied upon. Other methods may be used and are subject to the approval of the section manager.

5.10.4. Calibration Certificates

HFSC does not issue calibration certificates.

5.10.5. Opinions and Interpretations

When opinions or interpretations are included in test reports, they will be provided by technical staff who have completed appropriate training. Opinions and interpretations are clearly marked as such when included in the test report.

5.10.6. Testing Results Obtained from Subcontractors

Results of tests performed by subcontractors are clearly identified as such. If the results of the subcontracted tests are included in a test report that refers to accreditation:

- approval shall be obtained from the subcontractor to include excerpts from the subcontractor's report or certificate.
- the accreditation symbol of the subcontractor shall not be used on the report if the subcontractor is not accredited by ANAB.

5.10.7. Electronic Transmission of Results

The transmission of test results by telephone, fax, email, or other electronic means is subject to the Control of Data section of this manual (5.4.7).

5.10.8. Format of Reports

Test reports are formatted to minimize the possibility of misunderstanding or misuse.

5.10.9. Amendments to Test Reports

If errors or omissions are noted on test reports after they have been issued, then an amended report is required. An amended report will clearly communicate the reason for the amendment. The new report will be clearly identified and will contain a reference to the original report that it is replacing. Amending reports may require the assistance of HFSC's LIMS administrator or IT Division.

5.10.10. Use of the ANAB or ASCLD/LAB Accreditation Symbol or Business Names

5.10.10.1. HFSC uses only an approved ANAB logo and the logo is used only on reports issued by forensic disciplines that have been accredited by ANAB. Additionally, HFSC will ensure that:

- we use the ANAB logo, business name, or business acronym only as it appears on the certificate of accreditation
- we use the ANAB logo and accreditation statement only in reference to the ANAB Forensic Testing accreditation program
- we do not claim accreditation status if a test method is used that was not approved by ANAB
- we claim accreditation status only for accredited disciplines
- we do not imply that ANAB accepts responsibility for our results
- we do not imply that its products, processes, systems or staff are approved by ANAB

5.10.10.2. In addition to the requirements above, when used on reports, HFSC will ensure that:

- reports for unaccredited sections do not use the accreditation symbol or otherwise imply the sections are accredited
- in reports that refer to accreditation:
  - opinions or interpretations are based on test results for which accreditation is held
  - opinions or interpretations outside the scope of accreditation but based on those test results for which accreditation is held, are clearly identified as such by a disclaimer

5.10.10.3. HFSC does not use the ILAC mark.

6. Communication and Correspondence Procedure

Clear, concise, and professional communications should be a hallmark of forensic science, and HFSC has established procedures for technical communication and official correspondence written by HFSC staff members. HFSC management assumes responsibility for ensuring that appropriate communication processes are followed within HFSC and that communication takes place regarding the effectiveness of the management system. Management encourages regular staff meetings that use a documented agenda. These meetings are one mechanism for the exchange of information. Also important is having a proper flow of communication throughout HFSC that allows for input from all staff members.

Tact, diplomacy, and professionalism are required in all communications. Direct communication is encouraged within HFSC, within analytical units, and between technical staff members regarding technical matters. Administrative matters should be communicated utilizing the established chain-of-command system of supervisory notification and endorsement.

HFSC also encourages regularly scheduled management and analytical section meetings. These meetings are essential to supporting the flow of communications, information exchange, creative brainstorming, and the recognition of exceptional performance. Generally, minutes of meetings should be documented and made available for review.

Section managers/supervisors are responsible for communicating to staff when sectional documents, including but not limited to SOPs, worksheets, and checklists, are revised and when new validations are approved for use on casework. These communications must be documented. One way to document this is through a test assigned to each analyst in Qualtrax. Sectional meeting minutes may also be used for documentation purposes as long as the meeting minutes clearly show what was discussed and include names of all parties present during the discussion. If meeting minutes are used, managers/supervisors are also responsible for disseminating the information to staff who were not present at the meeting. This also applies if meetings are used for training and educational purposes. All training materials presented in a section meeting, however named, must also be presented to all staff not present during the meeting. The documentation requirement applies in all these situations.

7. Laboratory Information Management System

HFSC maintains and manages information using a laboratory information management system (LIMS).

LIMS assists management in tracking and determining the efficiency and effectiveness of HFSC's operations by providing personnel with statistical data helpful in budgetary planning, resource allocation, and other planning initiatives.

Information contained in LIMS is incorporated into monthly reports and yearly management reviews. Additional reports can be written to address individual or sectional needs.

8. Legal Requests, Public Information Act Requests, and Disclosures of HFSC Information

Laboratory management is responsible for the protection of HFSC's facilities and facility contents. Part of this responsibility is to ensure that only those individuals who have proper authorization are provided access to HFSC's secure areas and confidential records.

Specific instructions for release of evidence may be found in sectional procedure manuals. Transfers of evidence directly to or from HFSC will be documented.

HFSC instruments and equipment will not be used for analytical purposes by any personnel not affiliated with HFSC.

In the normal course of business, HFSC staff members may supply information to attorneys and stakeholders who are associated with a case. Evidence record affidavits will be completed when requested. The evidence affidavit is a legal document that records the evidence items being stored by HFSC at the time of the affidavit request. These requests are typically made by the District Attorney's Office. On receipt of such a request, HFSC will complete a thorough review of hardcopy and electronic records and evidence storage locations. These reviews may include applicable microfilm records, paper records, and electronic records maintained in LIMS. After these reviews are complete, an affidavit will be prepared. All affidavits will be notarized and a copy made prior to release to the requesting agency. The copy, along with any other documentation generated during the review, will become a part of the case record.

For situations not listed above, the appropriate key management personnel should be contacted for assistance.

9. Conflict of Interest and Undue Influence

HFSC management strives to ensure that inappropriate influence on the professional judgment of staff members is absent, including any undue internal or external commercial, financial, political, or other pressures and influences that might adversely affect the quality of HFSC's forensic services. To this end, personnel will not engage in activities that may diminish confidence in HFSC's competence, impartiality, judgment, or operational integrity.

All conflict of interest concerns and situations that could cause undue pressure or adversely affect the quality of work will be brought to the attention of management as soon as possible. HFSC's management has the responsibility and authority to receive such reports and take action on staff member concerns within each section. Serious instances of undue influence on analytical findings or forensic investigations will be reported to top management.

All staff members have the obligation to safeguard confidential information obtained in an official capacity. Staff members are prohibited from accessing or disclosing any confidential information except when legally authorized and are responsible for safeguarding it from unauthorized distribution. Staff members may not release case-related information directly to the news media, family members, or others without permission of top management. All media requests for information must be directed to HFSC's Communications Director.

Staff members may make case records and copies of case records available to authorized entities only. Authorized entities include, but are not limited to, police officers with a legitimate need for the records, internal affairs personnel, prosecuting attorneys, and those with valid court orders or subpoenas. Distribution to unauthorized entities is prohibited. All questions related to release of records should be addressed to key management.