

**Houston Forensic Science Center**  
**Quality Manual**  
Quality Division



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## NOTICE TO STAKEHOLDERS

Houston Forensic Science Center's (HFSC) accrediting body, ANAB (ANSI [American National Standards Institute] National Accreditation Board), requires that we notify stakeholders of our technical procedures in certain circumstances. 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 HFSC 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 (see section 7.1).
- **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 (see section 7.2).
- **HFSC will select the item or items most appropriate for analysis and may elect to not 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. Specific information regarding the management of Forensic Biology cases is listed on the HFSC website under DNA Case Acceptance Policy.
- **HFSC will notify the stakeholder if the proposed analysis requires the consumption of or is reasonably likely to consume all the evidence.** Unless permission is granted from the stakeholder or a consumption order is received, HFSC will not proceed with analysis (see section 7.1.4).
- **HFSC will use generally accepted and validated methods.** However, policy does allow for deviations from validated methods when necessary. Prior to deviating from validated methods, staff members are required to obtain approval from section management and to document the deviation and the approval in the case or batch record (see sections 7.2.1.7 and 8.2.2). Information regarding the deviation will be included in the report.
- **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, as part of a reference collection, e.g. botanical material for reagent quality control checks, or for training purposes.
- **All legal requests and Public Information Act requests should be forwarded to HFSC's General Counsel and Public Information Officer, respectively.** However, legal requests relating to casework should be handled in accordance with the Evidence Handbook, available on the HFSC website, and section 4.2 of this manual.



## 1. Scope

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

## 2. References

HFSC staff will follow the requirements set forth in this manual as well as those in the current version of ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories, any applicable supplemental requirements, and the current FBI *Quality Assurance Standards for Forensic DNA Testing Laboratories*. Applicable sections are accredited by and follow the requirements of the Texas Forensic Science Commission (TFSC). HFSC will also meet applicable requirements of standards on the Organization of Scientific Area Committees (OSAC) for Forensic Science Registry. Key management will determine OSAC Registry applicability on at least an annual basis. If TFSC requirements conflict with OSAC standards, HFSC will follow the TFSC requirements.

HFSC uses the JCGM 200:2012 *International vocabulary of metrology – Basic and general concepts and associated terms (VIM)* for scientific definitions associated with uncertainty of measurement. A copy of this document can be found at [www.bipm.org/en/publications/guides/vim.html](http://www.bipm.org/en/publications/guides/vim.html) and in Qualtrax.

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



### 3. Terms and Definitions

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

administrative records	Records, 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 case.
category of testing	A specific type of analysis within an accredited discipline of forensic science. (See <i>Sub-discipline</i> .)
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 <i>conclusion</i> 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.
decision rule	A rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
deviation	A planned departure from a procedure/process that is pre-approved by section management.
discipline	A major area of testing in forensic science
document	Information in any medium, including, but not limited to, a paper copy, computer disk or tape, audio or videotape, photograph, overhead transparency, or photographic slide.
document control	The process or system for ensuring that controlled documents, including revisions, are reviewed, approved, and released by the proper issuing authority and then distributed to personnel performing the prescribed activities. It also includes subsequent



	document revision along with tracking and controlled release of new versions.
evidence examination	Item received or created by HFSC for testing
examination records	A process that uses approved technical procedures to characterize, quantitate, or interpret evidence. 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.
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 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, violation of an approved procedure/process, or omission that has affected the accuracy, reliability, and/or integrity of HFSC's testing or reports. A nonconformance is not the same as a deviation (see 'deviation').
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 another undesirable situation.
procedure	The way an operation is performed; a set of directions for performing an examination or analysis; the actual parameters of the methods used.
proficiency test	A test to evaluate the capability and performance of technical staff, technical support personnel, and other Houston Forensic Science Center personnel. In open tests, HFSC personnel are aware they are being tested; in blind quality control (QC) 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.
Safety Network	Individual(s) (however titled) designated by top management who, irrespective of other responsibilities, works in conjunction with the Business Development Director to ensure that the requirements of the safety system are implemented and maintained.
sample selection	Selecting items or portions of items to test based upon 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 <i>category of testing</i> .)
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 <i>forensic analysts, forensic examiners, supervisors, managers, examiners, and investigators</i> .
technical support personnel	Individuals who perform casework-related duties at the direction of technical staff 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



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	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)



## 4. General Requirements

### 4.1. Impartiality

- 4.1.1. HFSC is a publicly funded local government corporation with its own formal budget adequate to meet the objectives of the laboratory. As an autonomous organization, all activities conducted at HFSC are undertaken in a manner that ensures impartiality of its operations.
- 4.1.2. HFSC management, beginning with the CEO, is committed to impartiality in all laboratory activities. All staff members are expected to remain objective, impartial, and independent when working a case, investigating and collecting evidence at a scene, and when testifying in court. Staff members should not be influenced by extraneous information, political pressure, or other outside influences. Instances of such should be reported to management.
- 4.1.3. 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. If a staff member feels that an entity is attempting to or has exerted influence or pressure on them, that individual must notify HFSC management immediately.

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 demonstrated competency. 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 must be reported immediately to key management.

4.1.3.1. Top management will ensure that:

- a. the HFSC Code of Ethics is integrated into the professional conduct of its personnel.



- b. all staff members (including independent contractors who perform technical work at HFSC) annually review the HFSC Code of Ethics. Additional ethics training may include the review of other related documents, such as the *Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists*, or documents approved by professional organizations such as the American Society of Crime Laboratory Directors, the American Board of Criminalistics, or the American Society for Quality. New technical staff and independent contractors who perform technical work at HFSC that begin employment after HFSC's annual ethics training must, at a minimum, complete a documented review of the HFSC Code of Ethics within the calendar year. When applicable, they should also review any additional ethics training provided by HFSC during that calendar year (e.g., watch the videotape of the training if one exists and complete any related tests in Qualtrax).
- c. appropriate actions are taken if there is a failure to review the document within the time frame allocated. This action may result in loss of computer privileges, access to the building, or further disciplinary action. Management is obligated to act if staff violate the HFSC Code of Ethics.

4.1.4. All HFSC staff are responsible for assessing any risk to impartiality their actions may have on the work they perform. HFSC management also works to minimize this risk through annual ethics training, internal audits and management reviews. HFSC takes risk to impartiality into consideration when working with external entities, including its stakeholders, subcontractors, and vendors. Risk involving external entities is minimized using established HFSC corporate policies and procedures.

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

## 4.2. Confidentiality

4.2.1. HFSC is responsible for the management of all information obtained from stakeholders and created as part of its business operations. HFSC considers such information proprietary and regards it as confidential. HFSC does not release confidential information to unauthorized personnel. Although HFSC has a public website where it posts documents including, but not limited to, policies, corrective actions and personnel records such as SOQs, it does not publicly post case-specific details such as subject names unless required to do so under the terms of the Texas Public Information Act.

All staff members have an obligation to safeguard confidential information that is obtained in an official capacity and are responsible for safeguarding confidential information from unauthorized distribution. Staff members will not access or disclose any confidential information except when legally authorized or approved by key management. Staff may not release case-related information directly to the news media, family



members, or others without the permission of key management. All public information and media requests must be directed to HFSC's Communications Director.

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

Staff members may make case records and copies of case records available to authorized entities only. Authorized entities include, but are not limited to, police officers with a legitimate need for the records, prosecuting attorneys, attorneys of record, and those with valid court orders or subpoenas. Requests for release of records should be directed to Client Services/Case Management (see Client Services & Case Management Division Standard Operating Procedures). Distribution to unauthorized entities is prohibited and inquiries from unauthorized entities should be referred to the appropriate law enforcement or criminal justice agency. All questions related to release of records should be addressed to key management. See section 7.8.1 for information regarding releasing verbal results.

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



## 5. Structural Requirements

- 5.1.** HFSC is a publicly funded local government corporation with the legal authority to provide forensic services to its stakeholders.
- 5.2.** The president/chief executive officer (CEO), the highest-ranking official at HFSC, is responsible for the overall operations at HFSC. The vice president/chief operating officer (COO) and Directors (Quality, Crime Scene/Multimedia) have authority over their respective divisions and are responsible for ensuring the division's conformance with accreditation standards. See Terms and Definitions for further information on top management.

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.

- 5.2.1.** 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.

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

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

- 5.3.** HFSC provides a range of forensic services as specified in its ISO/IEC 17025 scope of accreditation, including Seized Drugs (previously called Controlled Substances), Toxicology, Firearms, Latent Prints, Crime Scene, Multimedia and Forensic Biology. Other HFSC divisions and departments include Human Resources (HR), Quality, Information Technology (IT), Finance, Research and Development, Business Development, Communications/Public Information, Client Services/Case Management (CS/CM), Information Strategy, and Lean Six Sigma Development (LSS) Group. Only the accredited disciplines listed on HFSC's scope of accreditation will claim conformity to ISO/IEC 17025 accreditation requirements.
- 5.4.** HFSC conducts its investigation and testing activities, both at its permanent laboratory facilities and at crime scenes, in accordance with the practices described in this manual to meet accreditation standards, regulatory authorities such as the Federal Bureau of Investigations (FBI), 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.

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.

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

5.4.2. Certain HFSC disciplines are also accredited by and follow the requirements of the Texas Forensic Science Commission (TFSC).

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

HFSC maintains its policies and procedures as controlled documents to ensure consistent application of all laboratory practices and to ensure validity of its testing and processing results. Staff members will follow HFSC's quality management system 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 will follow the most stringent policy.

**5.6.** HFSC division directors, in conjunction with key management, 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. All sections have individuals who are technically responsible and have appropriate training and technical experience in that discipline. The Quality Director has authority to make and enforce quality-related decisions across all divisions, including closing technical sections if quality-related issues arise. HFSC key management is responsible for:

- a. implementing, maintaining and improving the management system.

Key management will ensure that personnel have the means necessary to follow this quality manual and verify that complaints concerning their respective divisions are evaluated and documented. Key management will also ensure that technical staff members are trained and will monitor casework and other sectional activities to gauge compliance with the quality system.

- b. identifying departures from the management system or from technical procedures.
- c. initiating actions to prevent or minimize departures.
- d. providing reports to management regarding the performance of the management system and any need for improvement.
- e. ensuring the effectiveness of laboratory activities.

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





a. Communication

HFSC management is responsible for ensuring appropriate communication processes are followed within HFSC and that communication takes place regarding the effectiveness of the management system. These communications may take the form of company-wide or sectional meetings, emails, memos or other written correspondence, formal and informal training sessions, the HFSC intranet, internal and external newsletters and/or review of HFSC policies and procedures. HFSC encourages and supports a flow of communication throughout the company that allows for input from all staff members.

Clear, concise, and professional communications should be a hallmark of forensic science and HFSC has established procedures for communicating results (see section 7.8). HFSC encourages regularly scheduled management and analytical section meetings that use a documented agenda. These meetings are essential to supporting the flow of communications, information exchange, creative brainstorming, and the recognition of exceptional performance. Generally, attendance and 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 staff member in Qualtrax. Sectional meeting minutes and attendance records may also be used for documentation purposes if 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.

b. Integrity

Top management, with assistance from key management, 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.



## 6. Resource Requirements

### 6.1. General

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

### 6.2. Personnel

#### 6.2.1. General Personnel Requirements

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

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 (see section 7.10). Staff should understand the importance and relevance of testing and processing activities and review HFSC's mission statement, objectives and quality policy statement (see section 8.2.2) 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 (see Section 8.6). 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 stakeholders.

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 staff members.

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 in Qualtrax as well as the publicly accessible HFSC website.

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

#### 6.2.2. Training

HFSC Human Resources Division maintains descriptions of job duties, which include competency requirements, for all personnel who influence laboratory activities. Job



postings and descriptions are available upon request. Please see HFSC Human Resources Division for further information.

#### 6.2.2.1. Educational Requirements

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.

Technical staff who issue reports containing results, opinions or interpretations, and whose job duties include creating items of evidence in Firearms, Multimedia, 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 to satisfy certain sectional coursework requirements. These transcripts are maintained in the staff members' quality files.

#### 6.2.2.2. Training Requirements

HFSC has a documented training program that provides knowledge and skills needed to perform specific forensic techniques, including testing and processing of evidence. Newly hired technical staff members, including contract employees, will complete appropriate training and demonstrate competence before beginning casework. All HFSC training programs will include a documented reading of all relevant in-house policies and manuals (including but not limited to HFSC administrative policies and procedures, the Health and Safety Manual, the Security Manual, and the Quality Manual).

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

- a. the knowledge, skills and abilities necessary for new staff to perform their job duties.
- b. general knowledge of forensic science.
- c. ethical practices in forensic science.



- d. the application of law to forensic science, criminal law, civil law, and court room testimony.
- e. provisions for retraining.
- f. provisions for maintaining skills and expertise.
- g. criteria for acceptable performance.

Training program activities will also include, at a minimum:

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

Training is carried out under the direction of the appropriate key management or a qualified designee. 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.

The section manager and/or DNA technical leader 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. Staff must exhibit the ability to convey results and conclusions and the significance of them in an appropriate manner before being declared competent to perform casework or to create items that could be used for testing.

### 6.2.3. Competency

All technical staff members conducting casework, regardless of academic qualifications or past work experience, must satisfactorily complete a competency test prior to being authorized to perform tests, create or process items, issue reports, offer opinions or interpretations, perform technical reviews or testify in court. Satisfactorily completing the test(s) means the intended results were achieved. Competency testing is also required for technical staff who cross-train in a new discipline and for 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.

#### 6.2.3.1. Competency 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 staff member's ability to communicate technical and HFSC-specific information. There may be other means of meeting the testimony requirement, such as a courtroom testimony class that includes a mock trial. However, a class that does not include a mock trial does not meet this requirement. Consult the Quality Division in advance for approval of other methods.

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

Non-technical 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-technical staff member testifies in court for the first time.

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

HFSC may provide additional training to technical staff already authorized to perform casework. Examples include learning new analytical techniques or utilizing new technologies. Section management will ensure that staff complete a practical examination (competency test) and are issued authorization memos prior to performing casework. This type of training does not require staff to fulfill all the requirements specified in Section 6.2.

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

Competency for testimony evaluation can be demonstrated through the following:

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

#### 6.2.4. Communication

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

#### 6.2.5. HFSC has documented procedures for the following:

- a. Competency requirements for technical staff  
Sectional training programs include documented competency requirements for each discipline and/or subdiscipline within that section.
- b. Selection of personnel  
Section management works with HR to develop job descriptions for technical positions. These job descriptions shall include the educational requirements listed in clause 6.2.2.1. of this manual. HR is responsible for maintaining records related to job descriptions or postings.
- c. Staff training  
Key management formulates goals with respect to the education, training, and skills of HFSC personnel. HFSC's training goals are evaluated based on 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, written in ink (except for CSI trainees who can use pencil for scene sketches/diagrams) 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.

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

Training is documented so that it is clear what tasks were undertaken during the training program. When in training, personnel are permitted to use instruments and equipment while under the supervision of trained and authorized staff members. Trainees are not allowed to issue independent reports unless they have received authorization to do so (see sections 6.2.5.e and 6.2.6). Authorization



must be granted before trainees can issue reports during the supervised casework phase of training.

d. Staff supervision

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

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

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.

e. Staff authorization

The appropriate section manager or technical leader authorizes personnel to perform specific tasks, such as sampling, creating test items, testing, issuing reports, giving opinions, interpreting findings, conducting technical reviews, and operating specific instruments and equipment. Authorization memos are issued upon successful completion of the section-specific training manual and a competency test. New memos are issued as the technical staff member develops new competencies. Technical staff 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 the DNA technical leader before independent casework begins.

f. Monitoring competency

Competency is monitored annually through programs such as the proficiency testing and blind QC programs, continuing education, and testimony monitoring. Critical tasks that require competence include, but are not 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.

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.

HFSC maintains literature resources or provides Internet access to literature resources such as relevant books, journals, and other literature dealing with each discipline. The DNA technical leader must approve Webinars or other online training opportunities used to meet DNA continuing education requirements. Statements of qualifications (SOQ), training certificates or other records of specialized training received, are maintained in staff members' electronic quality files. SOQs are required for all technical staff members at the level of manager and below and should be updated yearly or more frequently if significant changes occur.

#### 6.2.6. Authorization

HFSC authorizes technical staff to perform laboratory activities, including but not limited to:

- a. method development, modification, verification and validation.
- b. testing, processing, sampling, creating test items, giving opinions, interpretations, statements of conformity, and operating equipment and instruments used in casework.
- c. reporting, reviewing and authorizing results.

Authorization memos are issued and signed or initialed by section management and approved by the Quality Division. Authorization is considered granted on the date a Quality Division representative signs the memo. The trainee acknowledges understanding of their competencies and authorization to perform specified duties by signing or initialing the memo. Authorization memos are maintained in Qualtrax.

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

### 6.3. Facilities and Environmental Conditions

6.3.1. 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.

6.3.2. 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 section management and should be investigated. If the environment is found to be a threat to reliable testing, conditions should be corrected in a timely fashion. Laboratory operations may be ceased in high temperature situations that could impact instruments or equipment or cause an increased risk of contamination in the Biology laboratory.





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

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

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

If the temperature of a refrigerator or freezer is out of range, adjustments should be made and the temperature rechecked and readjusted until the reading is in range. If, after adjustment the temperature remains outside the range stated above, the person who identified the problem is responsible for informing section management. Section management is responsible for arranging any necessary repairs or replacements.

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

6.3.4. Measures to control HFSC facilities are implemented, monitored and periodically reviewed. These measures include:

- a. controlling access to operational areas of HFSC and limiting the access to authorized personnel. Non-HFSC staff are not allowed unrestricted access to operational areas of HFSC. Please see the *HFSC Security Manual* for additional information.
- b. preventing contamination by maintaining clean work surfaces and examination implements.
- c. effective separation between neighboring areas in which incompatible activities take place. Incompatible activities are separated by time or space to prevent contamination. Seized drug and toxicology analyses are performed in separate and distinct locations within HFSC and instruments are dedicated for use rather than shared between the two disciplines. Items of evidence that potentially contain trace evidence (e.g., hair, fiber) from subject and victim in the same case



are analyzed at different times or in different rooms to prevent cross-contamination. Evidentiary and reference DNA samples are also handled at different times or in different locations to prevent cross-contamination.

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

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

6.3.5. HFSC does not routinely perform laboratory activities outside its building. However, if HFSC needs to perform laboratory activities (such as obtaining reference fingerprints at the courthouse) at sites or facilities outside of its permanent control, staff will ensure that the facilities and environmental conditions are suitable. This does not apply to crime scene processing because those facilities and environmental conditions are beyond HFSC's control.

#### 6.4. Equipment

6.4.1. HFSC is furnished with the proper equipment needed for the collection, sampling, examination, and testing activities performed by staff. This includes appropriate analytical instrumentation, measuring equipment, software, measurement standards, reference materials, reference data, reagents, consumables, and auxiliary apparatus necessary to perform these activities. Therefore, staff will not use their own equipment unless otherwise specified in sectional SOPs (i.e. CSU personal measuring devices that have been checked by and approved by section management). If staff believes equipment is not operating properly, they must notify section management as soon as possible.

HFSC instruments and equipment will be used for testing purposes only by HFSC staff. Non-HFSC personnel are not allowed to use HFSC instruments or equipment.

6.4.2. Equipment used by HFSC staff for testing is normally owned by HFSC. If it is necessary to use equipment for testing that is not owned by HFSC, approval must first be obtained from section management. All equipment used for testing at HFSC must follow the requirements set forth in this document.

6.4.3. Equipment is handled, transported, and stored according to manufacturers' recommendations to ensure proper function and to prevent contamination, damage or deterioration. If additional instructions are necessary, they will be documented in sectional SOPs. If manufacturers' information is not available, section management should determine the proper procedures for handling, transport, storage, and maintenance of that equipment. When equipment that is sensitive to movement (e.g. balances) and is used to make critical measurements is moved, a performance check must be conducted. 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. Additional information regarding authorizations can be found in Section 6.2. Details may also be found in authorization memos. Equipment manuals and SOPs should be stored near the equipment or in a location agreed upon by sectional staff.

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

Reagents prepared in-house are labeled with the identity of the reagent, concentration (if applicable), date of preparation or lot number, and, as applicable, storage requirements. 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 the FBI Quality Assurance Standards (QAS) for DNA Testing Laboratories.

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.

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

6.4.4. Each section must verify that equipment is calibrated or otherwise checked to ensure it meets specified requirements before being placed into service or returned to service. This includes equipment used for collection and sampling purposes.

6.4.5. Equipment and corresponding software and hardware used for testing, examinations, and sampling must be capable of achieving the accuracy required by SOPs and must 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.

General service equipment not used for measurement purposes (i.e., hot plates, stirrers, non-volumetric glassware, non-CSU cameras, and refrigerators) will be maintained through visual examination, safety checks, and cleaning as necessary. The equipment will be removed from service if these checks indicate a problem with the ongoing use of the equipment. Volumetric equipment is visually examined and cleaned as necessary.



Microscopes and attachments are cleaned and serviced periodically. Fume hoods and super glue chambers that are vented to the fume hood exhaust system are checked annually by an external vendor. See applicable sectional SOPs for additional information. CSU cameras will be handled and maintained in accordance with CSU SOP.

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

6.4.6. 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. All critical weight, critical volume, and critical length measurement devices are certified to NIST standards.

6.4.7. 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, or in Qualtrax. These records must include the date the check was performed and the identity of the person who conducted the performance check. 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 additional information.

#### 6.4.7.1. HFSC calibration program

- a. The following is a list of critical equipment requiring external calibration:
  - pipettes
  - gauge blocks
  - trigger pull gauges
  - steel rules (steel rulers)
  - standard reference weights (non-standard reference weights are not held to the same criteria as standard reference weights. Refer to sectional SOPs for more information regarding non-standard weights and how they are verified, or performance checked.)
  - balances
- b. The vendor conducting the calibration must demonstrate and provide documentation of competence, capability, and traceability. Competence is verified by selecting an ISO/IEC 17025–accredited calibration laboratory.



Capability can be determined by reviewing the calibration provider's scope of accreditation, and, in lieu of accreditation, a competent vendor may also be one that provides certificates of traceability to a national standard such as the National Institute of Standards and Technology (NIST). For devices that have little to no effect on the overall quality of testing, calibration vendors that can provide NIST traceability will be considered competent. HFSC maintains documentation of calibration activities.

- c. Equipment calibration procedures are established according to the specific requirements of the test being conducted. Specified requirements for calibrations are listed in sectional SOPs. The interval for checking equipment calibrations will not be less stringent than manufacturers' recommendations. It will be necessary to performance check equipment after any shutdown, repair and following service or other substantial maintenance. If equipment is calibrated off-site, it will be performance checked prior to use at HFSC; refer to sectional SOPs for exceptions. It is not necessary to check equipment after calibrations are performed on site. Equipment check documentation is maintained in section logbooks.
- d. When critical equipment requires calibration, the calibration will be performed at least annually by an external vendor unless otherwise specified in sectional SOPs. The frequency of the calibration interval depends on the function of the equipment. Sectional SOPs may include further details regarding specifications and maintenance schedules for non-critical and critical equipment.

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

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 stated in this manual.

6.4.8. When practical, equipment that requires calibration will be labeled with the last calibration date and the date the next calibration is due.

6.4.9. Equipment that does not meet quality control criteria and that is not immediately repaired must be taken out of service. The equipment is labeled or marked to indicate that it is out of service until 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 (see section 7.10).



- 6.4.10. 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.
- 6.4.11. If calibration and reference material data include correction factors that differ from those currently in use, the correction factor will be updated accordingly on section specific worksheets. As an example, if a thermometer has a correction factor of  $\pm 2^{\circ}\text{C}$  after calibration, that correction factor will be incorporated and documented into subsequent temperature readings.
- 6.4.12. Results of quality control checks on testing equipment are reviewed to ensure that no inadvertent adjustments have been made that invalidate test results. When practical, access to equipment operational parameters may be restricted.
- 6.4.13. When equipment and its software is significant to the analysis or test performed, HFSC maintains the following information:
- the identity of equipment and any corresponding forensic software and/or hardware (Multimedia only).
  - the manufacturer's name, type of instrument or equipment (e.g. mass spectrometer, microscope) identification, and serial number or other unique identification. This identification may be in the form of an asset management tag.
  - documentation that equipment has been validated or performance checked prior to use.
  - the section where equipment is assigned.
  - calibration records (records shall include dates of calibrations and results), operating acceptance criteria for use in case work, and the due date of the next calibration.
  - reference material documentation, including results of testing, acceptance criteria, relevant dates, and expiration/re-testing dates.
  - documentation of maintenance plan and maintenance activities, as appropriate.
  - equipment records including records of malfunction, damage, modification, repair, adjustments and repairs. Maintenance, repairs, and performance verifications are recorded in instrument logbooks (maintained by each section) or an electronic equivalent as soon as possible after completion.

## 6.5. Metrological Traceability

### 6.5.1. Reference Standards and Materials



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

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

*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 their performance as a reference will not be invalidated. Reference standard performance is checked before and after any adjustment.

*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 reference standard and certified reference materials used to establish or maintain measurement traceability are either:

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



6.5.1.2. If there is no certified reference material (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.

6.5.1.3. HFSC does not perform calibration services.

6.5.1.4. Only calibrated and traceable critical equipment will be used when altering the traceability measurement value of a certified reference material. For example, if a certified drug standard of a specific concentration is used for quantitative measurements and requires dilution, only a calibrated and traceable pipette will be used.

6.5.2. Measurement results obtained from reference standards are traceable to the International System of Units (SI). 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.

Traceability of measurement results to SI units are documented through:

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

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

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

### **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 policies 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.

## **6.6. Externally Provided Goods and Services**

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





- a. intended for incorporation into HFSC's activities.
- b. provided, in part or in full, directly to the stakeholder as received.
- c. used in support of HFSC operations.

#### 6.6.2. HFSC Procurement Procedures for Goods and Services

- a. Prior to purchasing or subcontracting goods and services, requirements of the goods or services are defined, reviewed, approved and documented by HFSC management. HFSC also employs a general counsel who reviews legal documents related to purchasing, subcontractors and external providers. General counsel should be consulted in drafting or reviewing legal documents for externally provided goods and services.
- b. Criteria for evaluating, selecting, performance monitoring and re-evaluating subcontractors includes:
  - accreditation under ISO/IEC 17025 in performing HFSC's work and/or are accredited by the Texas Forensic Science Commission.
  - possessing the necessary resources to carry out the services being subcontracted.
  - technical competence in the area being subcontracted.
  - evaluation of sellers of critical consumables, supplies, and services (hereafter referred to as "critical supplies") to ensure that their products 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.
  - maintaining 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. The approved vendor list is maintained in Qualtrax.

In certain instances, providers and subcontractors require accreditation. Individual subcontractors providing forensic testing services in Seized Drugs, Toxicology, Forensic Biology and Firearms/Toolmarks in the State of Texas are required to be licensed by TFSC (see section 6.2.1). HFSC may also require individual subcontractors to have professional certifications. HFSC is responsible for verifying and documenting that these requirements are met and maintained.

Re-evaluation of the subcontractor is performed upon contract expiration and renewal or if a significant technical error impacting the accuracy of the results is identified.



Documentation of subcontracting tests and calibration activities is maintained by the section or Finance Division, as appropriate.

c. Purchasing Goods and Services

- HFSC purchase requests are reviewed and approved by management in accordance with directives from the Finance Division. By requesting services and supplies, management is confirming the requests meet applicable and specified sectional requirements.
- 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 (QAS) for DNA Testing Laboratories.

- d. 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.

6.6.3. When orders for externally provided goods or services are placed, HFSC follows the Finance Division's procurement procedures. The requirements for the order, any pertinent acceptance criteria, and competency requirements for personnel are communicated to the supplier through the procurement process. This process extends to providers who perform services at sites other than HFSC (such as contract employees working off-site).



## 7. Process Requirements

### 7.1. Review of Requests, Tenders, and Contracts

#### 7.1.1. HFSC reviews all requests, tenders, and contracts.

- a. HFSC stakeholders may submit requests for testing to HFSC. Prior to testing, HFSC reviews all requests. 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 processing 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.

- b. 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 evidence is appropriately sealed. Requests for crime scene processing services are reviewed to ensure the safety of the crime scene investigators 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.

- c. If subcontractors are used to fulfill any part of a request, tender or contract, HFSC will ensure that the subcontractors meet requirements specified in section 6.6 of this document. Reports from subcontractors regarding testing of evidence (outsourced reports) are uploaded into LIMS.
- d. HFSC also reviews requests for services that will be handled by its subcontractors.

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



7.1.3. When stakeholders request a statement of conformity to be included in HFSC reports, the specification or standard and the decision rule used will be clearly defined and communicated, unless inherently defined in the standard procedures.

7.1.4. Differences between the request or tender and the contract will be resolved before work commences. Each contract will be acceptable to HFSC and the stakeholder. This also applies to stakeholder requests for crime scene processing. CSIs are expected to apply their training and experience to process and investigate each scene as thoroughly as possible while following the CSU SOP. This may include doing more at scenes than the stakeholder originally requested. However, CSIs will do only those tasks for which they have been authorized (see section 6.2 of this manual). If the CSI and lead investigator (however named) cannot come to a consensus on scene processing, the CSI should contact CSU management before proceeding. This communication with management must be documented in the case record.

Discrepancies in case-related information may result in HFSC's refusal to accept or analyze the evidence in question. If a minor discrepancy between the submission information and the evidence received is discovered during the review of a request, it will be noted in the case record and may also be included in reports issued by HFSC. If significant discrepancies are noted HFSC will provide 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 without obtaining permission from the submitting agency or a consumption order. Permission from the submitting agency can be obtained if there is no suspect listed in the case record or when there is no assigned district attorney. Otherwise a consumption order is required. 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, a request to consume will be communicated to the submitting agency either by email or in a report. The communication will include the reason why analysis was not completed or conducted. Testing will not resume until permission is obtained. When a consumption order is required (see sectional SOPs for details) the text of the order (or a certificate of service signed by the prosecutor of record) must make clear that the defendant or his or her legal counsel had a timely opportunity to object to entry of the order before moving forward with analysis. If HFSC is aware of a defense attorney of record, then the same principle will apply (evidence will not be consumed without defense attorney permission). The permission to consume must be documented in the case record.

HFSC may need specific information from the stakeholder to fulfill a request for analysis. In such circumstances, HFSC will contact the stakeholder to obtain the needed information. If, after five business days, the stakeholder has not responded, HFSC can close the request. The section must notify the stakeholder that the request was closed then 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.

7.1.5. HFSC informs stakeholders before deviating from an agreed-upon request for analysis or crime scene investigation. However, Crime Scene Investigation services may be extended beyond the initial request. Personnel in sections (such as Multimedia or Firearms) should contact the stakeholder in advance if the requested analysis could realistically result in destruction of the evidence (e.g., cell phones or firearms).

7.1.6. 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.

7.1.7. HFSC strives to maintain good working relationships with its stakeholders. Maintaining these relationships may require:

- asking for clarification if the request is unclear.
- maintaining appropriate contact with the stakeholder during lengthy examinations.
- maintaining confidentiality.
- seeking feedback from stakeholders.
- providing explanations or interpretations of reports.

Staff members are available to assist stakeholders regarding evidence submission. If technical questions arise during the submission process, the staff member receiving the evidence will contact the appropriate technical staff member 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 the laboratory. Tours that are scheduled in advance, guided by HFSC staff and brief in nature may be allowed in laboratories except for 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 to comply with court-ordered observations. Other special arrangement may be approved by HFSC general counsel. Consult the section manager and/or the division director for further instructions. Additional detailed information may be found in sectional policy manuals.

7.1.8. 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.

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

## **7.2. Selection, Verification and Validation of Methods**

### **7.2.1. Selection and Verification of Methods**

7.2.1.1. Evidence examinations are conducted in a scientifically valid manner. A critical component in ensuring validity is the documentation of procedures used for examinations. Examination includes sampling, handling, transport, and preparation of tested items, and, where appropriate, an estimation of uncertainty as well as statistical techniques for test data analysis. Procedures and methods are fit for the purposes required/requested by the stakeholder.

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

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

7.2.1.1.3. HFSC does not perform calibration services.

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



manuals, standards, and operating instructions, are either maintained in Qualtrax or in the appropriate section.

- 7.2.1.3. Methods selected for use from external sources (such as a manufacturer's validated method, ASTM or OSAC standards, or methods published in peer reviewed journals) must be approved for use by section management. Selected methods incorporated into SOPs are approved by section management and reviewed by section staff. If HFSC uses methods from external sources, section management will include a review of the external method during SOP revisions to ensure the section is in compliance with the most current version.
- 7.2.1.4. In most instances, the stakeholder does not specify the method to be used. As stated in the *Notice to Stakeholders* at the start of this document, HFSC will determine the most appropriate method or methods of analysis based on the information provided by the stakeholder. 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, and include wherever applicable, the adoption of OSAC Registry standards. When necessary, the method will be supplemented with additional details to ensure consistent application. 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 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.

- 7.2.1.5. Prior to implementation of a method validated elsewhere, HFSC performs in-house testing to demonstrate the method works and expected results are obtained. This verification is documented and is approved by section management and the Quality Division before it is approved for use on casework. If the issuing body revises the method, then HFSC will repeat the performance check to ensure the revised method works in-house.
- 7.2.1.6. HFSC develops methods as a planned project approved by section management and implemented by authorized personnel. Section management is responsible for ensuring that appropriate equipment and resources are available for the project. As validation studies proceed, section management will periodically review the progress to ensure it continues to meet the needs of the stakeholders (see section 7.2.2).
- 7.2.1.7. Deviations from standard test methods must be documented in the case or batch record and report and approved by the section manager and/or 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.

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 section 7.2.2). Please refer to the Multimedia sectional SOPs for exceptions to this validation requirement.

### 7.2.2. Validation of Methods

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

Prior to the implementation of a new method, or when there is a substantial change to a current method, the method is subjected to appropriate internal validation to assess the procedure's ability to produce high-quality, reliable results. All validations are completed by authorized 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.

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

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

- a. data interpretation.
- b. data required to report test results, opinions, or interpretations.
- c. identification of the limitations of the test method, reported test results, opinions and interpretations.

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.





The Multimedia section 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 Multimedia, 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 (for Multimedia evidence refer to the Multimedia Exigency/Non-Validated Procedures Exception SOP). 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.

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

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

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

7.2.2.4. Validation studies are documented and approved by the section manager and/or the DNA technical lead 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.

Validation documentation includes:

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

### 7.3. Sampling

7.3.1. Sections using a sampling plan to address stakeholder requests shall meet the requirements outlined in clauses 7.3.2. and 7.3.3. HFSC technical sections commonly



select samples based on the nature of the request and the probative value of the evidence.

7.3.2. When a sampling method is utilized, the procedure(s) must include:

- a. the selection of samples or sites.
  - b. the sampling plans.
  - c. how the sample is prepared from the received evidence to produce the item used for subsequent testing.
- The sampling method will also:
    - 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.

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

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

See applicable sectional policies for further details.

## 7.4. Handling of Evidence

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



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

- dried biological stains should be in packaging that prevents mold or bacterial growth.
- sharp items should be packaged in a way that protects staff members from accidental sticks or cuts.
- 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 guidelines regarding appropriate evidence packaging submissions for stakeholders.

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

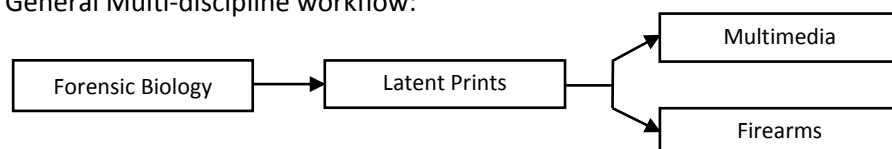
Exceptions may be made for large or bulky items that do not easily lend themselves to sealing. Consult key management for advice on handling these items.

HFSC's corporate Vehicle Use Policy provides 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.

### Multi-Discipline Evidence Workflow

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

General Multi-discipline workflow:





### **Stakeholder Evidence in an Unsealed or Damaged Condition**

Before evidence is accepted by Client Services/Case Management (CS/CM) Division, the outer container must be inspected for a proper seal. If evidence is not properly sealed upon acceptance, CS/CM 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 or evidence notes for that specific item. If evidence is rejected by CS/CM 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.

### **Evidence Accepted in an Unsealed or Damaged Condition by CS/CM**

If evidence is not sealed and/or not packaged and was inadvertently accepted by CS/CM from the stakeholder for distribution to HFSC technical sections, 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.

### **Evidence Received in an Unsealed or Damaged Condition by the Section**

If a section receives evidence from CS/CM that is not sealed/packaged properly, the section will document the condition of the evidence in their case record prior to processing the item. If the package appears damaged, the damaged area will be photographed. The condition of the evidence upon receipt and any steps taken to remediate the seal or packaging will be communicated to the stakeholder in the test report (this does not apply to the Toxicology Section as their evidence is accessioned by CS/CM). If a package appears to be in good condition and closed in a manner that prevents access (e.g., the package is closed with evidence tape, but the tape is not initialed), staff do not need to remediate the seal if they have received the evidence for processing.

### **Rejected or Returned (Un-tested) Evidence**

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

- the evidence is not properly sealed or packaged.
- the outer packaging is damaged.
- there is evidence of tampering.
- the identifying information on the packaging is missing or illegible.
- the contents appear compromised.



- the contents of the package do not match the package description or case information.
- the requested testing is fundamentally inappropriate for the evidence submitted.

#### **Off-Site Evidence Collection**

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 an 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.

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

- a. All items received are considered evidence and treated accordingly.
- b. 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, Multimedia) 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.

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

All evidence 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.

After evidence has been examined, analyzed, or otherwise tested or processed at HFSC, it will be re-sealed as soon as practicable.

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. Please see the *HFSC Security Manual* for further information on facility requirements.

- c. For situations in which there is an expectation of frequent or multiple analyses of an item or during the process of examination of the item, the evidence item may be stored unsealed in a secure, limited-access area, if the integrity of the item is maintained. During the process of examination, if a 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.

- d. 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.

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.

If there are issues with chains of custody in LIMS, a JusticeTrax or Porter Lee LIMS Request Form workflow shall be initiated in Qualtrax. Dates and times of transfers shall not be changed in the electronic chain of custody. Instead, a comment must be added to the corresponding transfers to document when the physical transfers occurred. Any comments made in the chains of custody transfers explaining the issue must be included in the workflow for approval. After the workflow has been approved by the Quality Division, the LIMS administrator is responsible for making any changes or additions to the comment in the LIMS chain of custody.

If changes or additions to the comments are needed for a Porter Lee LIMS workflow, an IT ticket must be completed by the person who initiated the workflow.

If a JusticeTrax workflow is approved with the original comments, no further action is required by the person who initiated the workflow. However, if a



comment is changed or added during the workflow approval process, the person who initiated the workflow is responsible for uploading the workflow to the case record in LIMS once the workflow has closed.

If a Porter Lee workflow is approved with the original comments, no further action is required by the person who initiated the workflow. However, if a comment is changed or added during the workflow approval process, an IT ticket is required. A Porter Lee LIMS Administrator will upload documentation of the change or addition to the case record.

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

- e. 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.

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

- f. 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 protected from loss, cross-transfer, contamination, and deleterious change through application of these evidence-handling procedures. The 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.



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.

- g. Generally, evidence is returned to the stakeholder after completion of analysis. Exceptions are specified in sectional SOPs. HFSC reports include a statement regarding the disposition of evidence. Evidence that is not in the care, custody or control of HFSC will not be retrieved by HFSC for the sole purpose of transporting that evidence to court. The requestor must obtain that evidence from the investigative/requesting agency to whom the evidence was returned.
- h. HFSC notifies its stakeholders when items of evidence are collected or created. If these items are retained by HFSC, they will be preserved in a manner conducive to future testing.

7.4.2. 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.

7.4.2.1. Individual evidence items or containers must be marked with a unique identifier. An item designator will be used with the unique case number to distinguish items within a case. If 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.

7.4.3. If, at the time of inventory, the condition of the evidence is not as expected or specified by the stakeholder refer to section 7.1 for instructions to document the discrepancies. If clarification regarding the condition of the evidence is needed, or when additional information is needed, the stakeholder will be consulted. This communication is documented within the case record. In some instances, the stakeholder may require evidence to be tested even though specified conditions were not met. In these situations, HFSC will include a disclaimer in the laboratory report that clearly indicates which results are affected.

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

## 7.5. Technical Records





7.5.1. 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.

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. This check will be documented in the case record 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.

7.5.1.1. 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
- 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 and examination documents must be uniquely identified by either the assigned forensic case number or the requesting agency identifier (agency case number). Examination documentation must also have the initials or name of the examiner, or secure electronic equivalent, on each page.

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 the staff member's initials are visible in a photograph, then it is not necessary to add handwritten initials. 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.

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 records in LIMS.

- 7.5.1.2. Abbreviations, acronyms, and symbols are acceptable in examination records if the meanings are readily comprehensible to a reviewer and the meaning of the abbreviation or symbol is documented in the sectional SOP. 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.
- 7.5.1.3. 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.
- 7.5.1.4. Case records on paper must be legible and recorded using ink. This requirement does not apply to administrative documents submitted by the stakeholder.



Exceptions may be made if environmental conditions prevent the use of ink. Pencil may be used if appropriate for making diagrams or tracings. While original notes may be recopied, all original notes must be maintained as a permanent component of the case record unless captured electronically and the electronic copy has been found to be legible and accurate.

- 7.5.1.5. 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, 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, Caseworks (also called Mideo) or Dataworks. Computer hard drives and individual OneDrives are not approved repositories.

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 staff member has verified the image uploaded to the repository 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.

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.

If a situation arises in which evidence can be recorded or collected only by photography, then the photograph is treated as evidence. These photographs will be tracked with a chain of custody.

7.5.1.6. HFSC does not perform calibration services. Data related to repairs, preventive maintenance and external calibrations of testing equipment is maintained as described in section SOPs.

7.5.2. Modifications to the case record made prior to technical/administrative review will be documented by the person making the change. When striking out information on paper documents, a single line is drawn through the error and the error is initialed. Mistakes are not erased, made illegible, or deleted. Erasures on crime scene sketches are not considered mistakes and are not subject to these requirements. These requirements also do not apply to changes and alterations made on administrative documents provided to HFSC by the stakeholder. Modifications made to the case record after the technical/administrative review process has started must be dated and initialed.

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.

HFSC does not consider test reports to be examination documentation. Therefore, drafts of test reports do not have to be maintained.

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

## 7.6. Evaluation of Measurement Uncertainty

7.6.1. Documentation of laboratory methods includes an estimation of the uncertainty of measurement (UM) when appropriate. The purpose of calculating the UM is to ensure that quantitative results provided to stakeholders can be understood within the context of accuracy and precision of the methods used. An estimation of uncertainty is determined for quantitative measurements when these numerical values are listed on the 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. Examples of measurements that require an estimation of uncertainty include the barrel length of a long gun, overall length of a long gun, controlled substance weights, and blood alcohol values. Uncertainty is reported using the same units as the measurement it supports. Refer to sectional SOPs for further details on reporting guidelines.



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

7.6.2. HFSC does not perform calibration services.

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

If the nature of the test precludes rigorous, metrological, and statistically valid calculation of uncertainty, then HFSC will at least attempt to identify the components of uncertainty and make a reasonable estimation. Reasonable estimates will be based upon knowledge of the performance of the method and on the measurement scope and will make use of any previous experience and validation data. The form of reporting of the result will not give a wrong impression of the uncertainty.

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

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

## 7.7. Ensuring the Validity of Results

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

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



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

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

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

- the verification is performed by an individual currently authorized to perform the testing.
  - the verification is documented in the case record, including who performed the verification, when it was performed, and the results of the verification.
  - the case record includes documentation of situations where the verification does not agree with the original test results. If an agreement cannot be reached between the verifier and the 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.
- h. correlation of results for different characteristics of an item.
  - i. review of reported results.

The following are requirements for the technical, administrative and testimony review processes.

Chains of custody must be reviewed 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. Technical staff 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.

Personnel who interpret, report, or testify regarding the examinations, investigation notes, or critical findings of another HFSC staff member will complete a documented review of all relevant pages of the examination record. 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 and/or the DNA technical leader. Initialing applicable pages of the record may serve as documentation of this review. This does not apply if the staff member is presenting business records only.

#### Technical Reviews

- 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.
- 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.
- 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.
- 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.
- All changes made to administrative and technical records because of verification, technical review or administrative review must be tracked in the case and/or the batch record. Section management will determine what tracking method is used. 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.
- The technical review includes a review of all examination records and the test report to ensure:
  - the report is accurate, and the data supports the results and/or conclusions in it.
  - associations are properly qualified, if applicable.



- the report contains all the required information.
- The technical review ensures that the case records and the report conform with proper technical sectional procedures and quality policies.
- 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.
- To ensure the quality of forensic results, HFSC may subject completed casework to secondary review.

#### Administrative Reviews

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 performed on 100% of completed casework.

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 7.8.2 and 7.8.3) is included.

#### Testimony Reviews

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. When a staff member testifies, they must complete a Qualtrax Testimony Tracking and Monitoring Notification workflow, whether the testimony was monitored or not. If their testimony was monitored, a copy of the completed evaluation form must be uploaded to the workflow and added to their Qualtrax Quality File.

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

- Testimony may be monitored through direct observation (preferably by a section manager or supervisor or his/her designee), a review of court transcripts, 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, the reviewer and the witness's supervisor or manager. 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 act to remediate the problem. Recommendations for remediation may include, but are not limited to, communications training, remedial technical training, additional mock court training, or a review of technical procedures or methods. 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.

In addition to monitoring testimony by direct observation, HFSC conducts reviews of testimony transcripts. Typically, one transcript per staff member will be reviewed annually, if available. The transcript review will be blind, meaning the staff member will not know when testifying whether that transcript will be selected for review. The transcript review will be conducted by a committee. The committee will typically include one individual technically competent in the scientific discipline of the witness, one member of the Quality Division, and one lay person who may be a non-technical HFSC staff member or an individual not employed by or assigned to HFSC. The results of the committee's review will be shared with the staff member by an individual deemed technically competent in the task covered by the testimony.

- 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.
- j. an intralaboratory comparison program to monitor and ensure the validity of results.
- k. a blind QC program as part of the intralaboratory comparison program. The blind QC program consists of the testing or examination of samples that are blind to the personnel involved in the process. This type of testing evaluates the entire quality system as it monitors laboratory performance from evidence submission to the final report. HFSC creates these tests and designs them to mimic real casework. The Quality Division administers and introduces these tests into the workflows of



technical staff in the same manner as all other evidence and casework. However, staff do not know whether they are analyzing a real case or participating in a blind QC test.

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

Corrective action procedures are applied to nonconforming work related to the blind QC program.

- 7.7.2. HFSC maintains a documented proficiency testing program. The proficiency of all technical staff is tested to the extent of their casework authorizations. The 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 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 staff are aware they are participating in a proficiency test. **Section management and staff should use good time management to distribute, complete the test, and submit the results to the vendor on or before the due date.**

- 7.7.2.1. 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.

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 between DNA proficiency tests, the date the test is due in-house will be used.

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 discipline 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 no commercial proficiency test provider can fulfill all a section's proficiency test needs, such as crime scene investigation, additional internal proficiency tests may be created and administered.**

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

#### 7.7.4. Monitoring Performance of Personnel

HFSC monitors personnel who influence results of testing activities through the successful completion of blind QC cases and proficiency tests. Each technical staff member and technical support person engaged in non-DNA testing activities in the forensic disciplines in which he/she has been qualified must complete one proficiency test per year. 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.

7.7.5. HFSC monitors the performance of blind QC cases, proficiency tests or observation-based testing by:

- a. ensuring that results are not known or readily available to the participant.
- b. following approved methods as closely as possible when completing proficiency tests. In addition, technical staff 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. **Results recorded in the data sheet shall mirror that in the test report and vice versa. In addition, proficiency test reports shall mimic the reporting format and language of normal casework as closely as practicable.**

Technical review, verification, and administrative review policies will be followed as they are in casework. **Testing participants may not discuss the results of the**



test with another test taker prior to the final due date. Should consultation be required, the 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 QC test and participants are not aware they are being tested. The section management 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.

- c. evaluating 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 Multimedia section, may not mimic routine casework. For instance, Multimedia 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 staff member 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 staff member’s abilities to answer these investigative questions.

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



- d. ensuring the quality of proficiency tests by using approved providers (see 7.7.7) and blind QC tests by preparing tests at HFSC in collaboration with section management.
- e. HFSC does not perform calibration services.

7.7.6. HFSC has scheduled proficiency testing programs that:

- a. conform to the requirements set forth in this manual and to the applicable requirements in ANAB's Forensic Science Testing and Calibration Laboratories Accreditation Requirements.
- b. ensure testing is representative of the types of samples, the methods used, and the types of equipment used in case work. This will also reflect the disciplines listed in HFSC's scope of accreditation.

7.7.7. HFSC uses approved proficiency test providers when available and ensures that:

- a. approved providers are appropriate for the type of testing and operate in accordance with the ISO/IEC 17043 standard, or,
- b. if there are no commercially available proficiency tests available for disciplines such as crime scene investigation, an internal proficiency test will be created and administered only after the internal testing scheme is approved by ANAB. Other alternate means of meeting proficiency testing requirements must be approved by ANAB.
- c. proficiency results are submitted to the external provider on or before the provider's due date. Any exceptions will be documented.

7.7.8. The Quality Division maintains records of the Blind QC and proficiency testing programs.

The records include:

- a. participating sections.
- b. design and review of the test-cycle program.
- c. expected results.
- d. location of testing.
- e. records submitted to the test provider, if applicable.
- f. evaluation of results and actions taken for unexpected results.
- g. feedback on individual performance provided to the participant.

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.

## 7.8. Reporting of Results

### 7.8.1. General

HFSC testing results and discrepancies (e.g. broken blood tubes, mishandling of evidence) that arise during analysis are reported accurately, clearly, unambiguously, objectively, and in active voice. For information related to the reporting of discrepancies see section 7.1.4.



Testing 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.

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 provided to the stakeholder once technical and administrative review milestones are met.

If HFSC receives a written request to terminate analysis before the work is completed, a report will be issued indicating this. The written request, which may be submitted by email, will become part of the case record. Results of work that has been completed must be included in the report, but no additional analysis will be done. If all analytical work is completed before the request is received, a full test report will be written and issued to the stakeholder.

Technical results can be released prior to issuing a report when a documented technical review has been performed on the information being released. The release of information must also have documented approval from section management in the case record. The release of technical information prior to issuing a report should be limited to extraordinary circumstances in which a serious incident is being actively investigated and the results may offer key leads. For the Multimedia section, written approval is not required.

7.8.1.1. Written reports are signed by the authorizer of the results. By signing the report, the authorizer is documenting that they have reviewed the report.

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

7.8.1.2. Results are communicated accurately, clearly, unambiguously and objectively to stakeholders in the form of a report.



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

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

- a. items of evidence, including items not tested, as per sectional SOPs.
- b. significance of associations whether by a statistical or qualitative statement.
- c. clearly communicate reasons when the reported results indicate that no definitive conclusion can be reached.
- d. initial database entries.

7.8.1.2.3. HFSC does not perform calibration services.

7.8.1.3. Any information listed in clauses 7.8.2 to 7.8.7 not included in the report will be included in the case record.

## 7.8.2. Common Requirements for Reports

7.8.2.1. The following must either be included on reports (those followed by “required on report”) or included in the case record if they are not part of the report:

- a. title (required on report).
- b. name and address of the laboratory (required on report).
- c. location where the activities were performed, if different from above (required on report).
- d. unique identifier shall be present on each page and each page shall be recognized as part of the test report, a clear identification of the end of the report (e.g. page X of Y) (required on report).
- e. name and contact information of the stakeholder.
- f. identification of the method used (required on report).
- g. description, identification, and when necessary, the condition of the items (required on report).
- h. date of receipt of evidence and the date of sampling, where sampling is critical to the validity and application of the results.
- i. date the testing was performed.
- j. date the report was issued (required on report).
- k. sampling plan, if relevant to the validity of the results (required on report).
- l. statement that the results relate only to the items tested.
- m. where appropriate, units of measurements (required on report).
- n. deviations from the test method (required on report).
- o. identification of the person authorizing the report (required on report).
- p. clear identification when tests are performed by subcontractors (required on report). 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.



7.8.2.2. HFSC is responsible for all information provided in its reports, except for information provided by the stakeholder (such as names, agency case numbers, etc.). Data regarding evidence items (such as weights or volumes) provided by the stakeholder must be clearly identified. Information provided by the stakeholder that can affect the validity of the results shall be clearly marked. HFSC is usually responsible for sampling the evidence but, in cases in which it is not responsible, the report will state the results apply to the sample as it was received.

### 7.8.3. Specific Requirements for Test Reports

7.8.3.1. In addition to the information listed in 7.8.2, reports shall, where necessary for the interpretation of results, include the following:

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

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

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

7.8.4. HFSC does not perform calibration services.

### 7.8.5. Reporting Sampling – Specific Requirements





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

- a. date of sampling.
- b. unambiguous identification of the substance sampled location of sampling, including photographs, if applicable.
- c. the location of sampling, including any diagrams, sketches, or photographs.
- d. reference to the sampling plan and procedures used.
  - the report shall include confidence levels and corresponding inferences regarding the population
- e. details of any environmental conditions during sampling that might affect the interpretation of the test results.
- f. information required to evaluate measurement uncertainty for subsequent testing.

#### 7.8.6. Reporting Statements of Conformity

7.8.6.1. Requirements for including statements of conformity to a specification or standard, such as measurement uncertainty, on reports are specified in sectional SOPs. These requirements may not be identified as 'statements of conformity' but rather address the specific requirement, such as 'estimation of the uncertainty of measurement'. Sectional SOPs specify when uncertainty of measurement will be included on reports.

7.8.6.2. Reported statements of conformity shall include:

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

#### 7.8.7. Reporting Opinions and Interpretations

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

7.8.7.2. Opinions and interpretations are clearly marked as such when included in the test report.

7.8.7.3. Verbal results may be released after the report is issued. However, verbal results may only be released by the report writer or section management. This verbal release of information must be documented in the case record.

#### 7.8.8. Amendments to Reports



7.8.8.1. 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.

If a report requires amending, Quality shall be notified through the Qualtrax IR/CAR Reporting workflow. Amended reports require a comment that identifies what changes were made. For administrative changes, the Qualtrax workflow should include the intended comment as well as an uploaded copy of the original report. Once Quality has reviewed and approved the comment, the report can be amended. The amended report should be uploaded to the workflow once it is released. Workflows that describe administrative errors may be closed by Quality as “no action needed” if there is no risk associated with the change. Amendments that change the technical findings will be tracked as incidents or corrective actions, depending on the risk associated with the technical change (see section 7.10). Examples of technical findings include but are not limited to:

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

7.8.8.2. Amended reports will be clearly identified and will contain a reference to the original report that it is replacing. Amending reports may require the assistance of an HFSC LIMS administrator.

7.8.8.3. If it is necessary to issue a new report, such as re-analyzing evidence, the new report will be uniquely identified and reference the original report.

## 7.9. Complaints Related to Technical Procedures and the Quality System

7.9.1. HFSC has a documented procedure for receiving, evaluating and resolving complaints. Complaints can be submitted to HFSC using the complaint form or online survey. Both can be accessed through the Contact Us link on the HFSC website (<http://www.houstonforensicscience.org/contact-us.php>) and can be submitted by stakeholders, staff, or the public.

7.9.2. Staff members receiving a complaint will resolve the complaint if within their authority to do so, *e.g.* if a stakeholder needs clarification or additional information regarding technical results. If the complaint is related to a specific case, the complaint and its resolution will be documented in the case record. If a complaint cannot be readily resolved, or if the complainant requests an investigation into their complaint, the person who receives the complaint must document it on an HFSC complaint form and forward the complaint to the Quality Division. If Quality receives a section-specific complaint, they will notify and work with section management to resolve the complaint. Complaints concerning employees should be directed to and processed by section management and HR.



#### 7.9.3. Processing complaints related to quality

- a. Upon receipt, unresolved complaints are submitted to the Quality Division for review to determine whether the complaint is valid. If a complaint is determined to be invalid, documentation will be kept supporting that determination. When necessary, complaints are investigated to determine the appropriate decisions and actions needed for resolution. The investigation will be handled through the Quality Division and section management.
- b. Complaints and their resolutions are tracked through the Quality Division. Formal corrective action will be initiated if warranted (see section 8.7).
- c. Actions taken to address complaints are reviewed by the Quality Division to ensure they are appropriate for resolving the initial concern.

7.9.4. Complaints will be reviewed and evaluated by the Quality Division upon receipt. The evaluation includes gathering the relevant information necessary to validate the credibility of the complaint. Quality will review the complaint to ensure all relevant information is documented.

7.9.5. Whenever possible, the complainant is notified when HFSC receives the complaint and is updated with relevant progress reports.

7.9.6. The final resolution of the complaint will be made by, or reviewed and approved by, an individual not involved in the HFSC activities in question.

7.9.7. If the complainant has provided HFSC with contact information, HFSC will notify the complainant with a formal notice when the complaint is resolved.

### 7.10. Nonconforming Work

7.10.1. HFSC has a procedure to address any laboratory activities that do not conform to its own procedures or the agreed requirements of its stakeholders. Nonconforming work is the result of an act, error, violation of an approved procedure/process, or omission that has affected the accuracy, reliability, and/or integrity of HFSC's testing or reports. Nonconforming work includes mistakes as well as unapproved departures from approved procedures. Nonconformances, whether involving the management system or technical work, may be identified through internal audits, assessments, management reviews, stakeholders or staff.

The Quality Division must be notified of nonconforming issues regarding the quality of technical services provided by HFSC 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 several ways including, but not limited to:

- email
- meeting request
- phone conversation
- in person
- Qualtrax

Once nonconformance(s) are reported to the Quality Division, the Quality Division will determine if the nonconformance will be tracked as no action needed, a quality incident or if it requires corrective action (see section 8.7). A meeting may be needed to determine this. Unless a single occurrence significantly impacts the quality of the work, it will be handled as an incident. Systemic issues, issues affecting quality or issues posing a risk to services or work products are handled as corrective actions.

The following procedures are employed with nonconforming work:

- a. the Quality Division, under the direction of the Quality Director, has responsibility and authority to manage nonconforming work. Nonconforming work is tracked through IR/CAR Reporting workflow in Qualtrax. The Quality Division works with HFSC management and appropriate technical staff to ensure that nonconforming work is reported and resolved appropriately.
- b. the actions taken to address nonconforming work are based upon the risk levels established by HFSC.
- c. nonconforming work is evaluated by the Quality Division, in conjunction with management if applicable, to determine the significance and whether it has an impact on the analysis of reported results. If the evaluation process determines there is a potential problem in relation to the validity of results, the nonconformance will proceed through the corrective action process. The evaluation may determine the nonconformance is a one-time occurrence that does not have a significant impact on the validity of results.
- d. based on the evaluation of the nonconformance, a decision will be made regarding the acceptability of the work. If a correction is needed, it will be made following approved procedures and approved by section management, and, if needed, by the Quality Division and key management.
- e. if nonconforming work affects reported results and when evidence needs to be recalled for additional testing because of nonconforming work, HFSC will notify its stakeholders.
  - If evidence is recalled, the stakeholder will be notified either in writing or verbally. Documentation of the notification will be included in the case record.
  - 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 (see section 7.8.8.1).
  - 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.
- f. if the decision was made to halt work based on the significance of the nonconformance, the Quality Director is responsible for authorizing the resumption of work.

7.10.2. HFSC maintains documentation of nonconforming work in Qualtrax.

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

## 7.11. Control of Data and Information Management

7.11.1. HFSC maintains and manages case related information using a laboratory information management system (LIMS). Through LIMS, staff have access to the data and information needed to perform laboratory activities, including issuing reports. Additionally, staff have access to data storage software applications required to perform their duties, including data generated by scientific equipment or stored in imaging software platforms such as Caseworks (also called Mideo) and Dataworks.



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.

7.11.2. HFSC uses commercially available off-the-shelf LIMS software designed for forensic applications for collecting, processing, recording, reporting, reviewing, storage or retrieval of data. The administrator will ensure the proper functioning of interfaces within LIMS by the laboratory.

7.11.2.1. When computer software is developed by HFSC, it 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.

7.11.3. HFSC ensures that LIMS:

- a. is accessed only by authorized personnel.
- b. is safeguarded against tampering and loss.
- c. is operated in an environment that complies with the provider's or laboratory's specifications or, in the case of non-computerized systems, proves conditions that safeguard the accuracy of manual recording and transcription.
- d. is maintained in a manner that ensures the integrity of the data and information.
- e. system failures that prohibit or limit staff ability to access and work in LIMS and actions taken to address such failures are recorded.

7.11.4. HFSC LIMS are housed off-site in the government cloud (secure remote servers accessed via the internet) through the Microsoft Azure platform. This platform is CJIS compliant and complies with the requirements of this document.

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

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



## 8. Management System Requirements

### 8.1. General

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

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

### 8.2. Management System Documentation

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

8.2.1.1. The ISO/IEC 17025 standard requires HFSC to address the following words in writing: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, and specify.

8.2.2. 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 except for the Crime Scene Unit as stated below.

- Exigent circumstances may require CSIs to depart 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 exigent circumstances make it impractical to notify management in advance, the CSI must notify them as soon as possible. The exigent circumstance, along with management's acknowledgement, shall be documented in the case record.



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.

**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.

8.2.3. Top management, with the assistance of key management, 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.

8.2.4. All HFSC documents and processes related to the fulfillment of ISO/IEC 17025 requirements, all additional accreditation requirements specified by ANAB and TFSC, and all regulatory requirements are included in the management system documentation. Such documents include, but are not limited to, this Quality Manual, Safety Manual, the Security Manual, administrative policies, and section specific operating procedures and training manuals. Quality policies that affect the technical divisions are included in this quality manual and be expanded in sectional SOPs. 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 nontechnical information that is included in this manual. Discipline-specific manuals will not be less stringent than this quality manual. OSAC Registry includes standards applicable to individual forensic science disciplines as well as cross-disciplinary use. Discipline-specific manuals will be updated with applicable OSAC Registry standards on at least an annual basis.





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

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, providing technical training as necessary, and adherence to OSAC Registry standards wherever applicable
- 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

### 8.3. Control of Management System Documents

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

All staff members (including independent contractors who perform technical work at HFSC) 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.

#### 8.3.2. Document Approval, Issue, and Review

- a. 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, 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 Qualtrax 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.

**When new or revised standard operating procedures or training manuals are approved and issued in Qualtrax, section management will ensure that the most current versions are made available in eDiscovery.**

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, from Qualtrax, or during section, division, or Center-wide meetings.

The **Business Development Director**, Quality Director, CEO, and COO approve the *Health and Safety Manual* prior to issue. **At a minimum, the Business Development Director will** approve corporate safety forms and worksheets prior to issue.

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

- b. Controlled documents are reviewed and updated as needed at least once each calendar year by appropriate management personnel. Even if no revision is made after the review, documentation will show that an annual review was completed.
- c. Document version histories, issue dates, and review and approval histories are maintained in Qualtrax for controlled documents.  
Changes to controlled documents are made through the following process:
  - document changes and/or revisions are approved using the approval policy stated above.
  - when revisions are made to existing documents and result in the issuance of a new manual, the altered or new text is clearly marked. One way to accomplish this is to have the new or altered text in red font. This requirement does not extend to worksheets.



- 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, not change policies/procedures, is allowed.
  - controlled documents are stored in Qualtrax. Only staff members who are members of key management or their designees can make changes and/or release new versions.
- d. 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).
- e. Management system documents created internally are identified by:
- title
  - issue date
  - page number
  - total number of pages or a mark to signify the end of the document
  - issuing authority.
- Technical procedure manuals are formatted with headers and/or footers that contain required information. Forms are formatted in a way that is practical and applicable to that task. Procedures are posted in an electronic format and are the controlling documents followed by staff members.
- f. Controlled documents are uncontrolled when printed. Staff members are responsible for ensuring they are utilizing the most current version when using a printed document. Any uncontrolled document that is not current shall be shredded or clearly marked to indicate that it is no longer in use. Portions (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.

#### 8.4. Control of Records

- 8.4.1. 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.
- 8.4.2. Records shall be stored in an environment designed to prevent damage, deterioration, and loss. Case files stored on-site are grouped by section and 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 section management.

Quality, administrative, personnel (including training) and technical records will be



stored or shredded in accordance with the HFSC Record Retention Policy and Record Retention Schedule. HFSC's policy meets or exceeds the record retention requirements of its accrediting body and the FBI.

When making electronic versions of records, the original documents will not be shredded prior to the time frames listed in the Record Retention Schedule. Documented verification that the scanned documents were compared to the originals to ensure all pages were scanned and are legible must also be completed prior to shredding the originals. When scanned documents are part of a case record, verification includes ensuring the scanned version is added to the correct case record. 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. Documents and records will be shredded or otherwise disposed of in a manner that ensures the confidentiality of the information.

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

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

### Case Records

A case record is maintained for each request for analysis and crime scene investigation accepted by HFSC. Case records are identified by an assigned forensic case number or the requesting agency identifier (agency case number). Prior to February 1, 2014, 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 deviations
- 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

Access to case records stored in an electronic format associated with LIMS, Mideo or Dataworks 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 and/or the HFSC LIMS administrators.

### Quality Records

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

## 8.5. Actions Taken to Address Risks and Opportunities

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

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

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

8.5.1.1. Risks and opportunities related to health and safety are addressed by the **Business Development Director and the Safety Network**.

8.5.2. HFSC takes actions to address risks and opportunities through:

- a. the preventive action process or Lean Six Sigma (LSS) projects when risks are identified that may have a negative impact on HFSC activities or when opportunities are identified that will result in improvements. These actions may include risk assessments of technical processes.
- b. the integration of action plans into HFSC's management system and evaluating their effectiveness. When risks are associated with nonconforming work, the plan will include actions taken to reduce the likelihood of recurrence and the evaluation of the effectiveness of those actions.



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

## 8.6. Improvements

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

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.

Preventive actions will be formulated, reviewed and, if approved by the appropriate key management, documented using a Preventive Action Report (PAR) form or Qualtrax. 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.

HFSC has a dedicated LSS group tasked with soliciting suggestions for improvement opportunities by HFSC staff. These opportunities are evaluated to determine if their implementation will improve HFSC efficiency and effectiveness. Once an LSS project is selected, risks and opportunities are incorporated and assessed throughout the project.

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

## 8.7. Corrective Actions and Quality Incidents

The purpose of HFSC's quality corrective action and quality incident procedure is to maintain and improve the quality of work performed by HFSC. While not the purpose or intent, singling out an individual may occur as a byproduct of the process. Efforts are made to maintain the confidentiality of the parties involved.



Corrective actions and quality incidents are categorized based on the nature of the nonconforming work (see section 7.10) and the risk they pose to the work product. Nonconformances may be identified through several means including self-reporting, case record reviews, internal audits, assessments, management reviews, or stakeholder or staff feedback and are initiated through the IR/CAR Reporting workflow in Qualtrax. A quality tracking number is assigned to all IR/CAR workflows that are categorized as quality incidents or corrective actions. After the workflows are finalized, Qualtrax generates an incident/corrective action report.

Quality incidents are used to address nonconformances that have limited or no impact on the quality of our work product but still need to be documented. Root cause analysis is not required. Continued reoccurrences may be elevated to a corrective action. Once the Qualtrax incident report is finalized, it will be uploaded by the Quality Division to eDiscovery and to all involved case or batch records.

Corrective actions are used to address nonconformances that have a significant impact on the quality of our work product and require root cause analysis to determine the actions needed to prevent recurrence. Once the Qualtrax corrective action report is finalized, it will be uploaded by the Quality Division to eDiscovery and to all involved case or batch records.

If a workflow is submitted but the nonconforming work is determined to have no impact on the quality of or presents no risk to the work product, it will be closed as 'no action needed' and no quality tracking number will be assigned to the notification. When a workflow is closed as 'no action needed', the case record does not require documentation of the workflow and no report will be generated through Qualtrax. Continued reoccurrences may be elevated to a quality incident or corrective action.

HFSC's corrective action procedure includes:

- determining the risk associated with the nonconformance
- stakeholder notification
- implementing an action plan
- closing corrective actions
- monitoring the effectiveness of the corrective actions taken.

Corrective actions and quality incidents will be fully documented and reported in clear, active language whenever possible. The Quality Division is responsible for maintaining these records.

The Quality Division, with input from section management, the DNA technical leader, and (in some instances) the CODIS administrator, will delegate or initiate an investigation into nonconforming issues and identify individuals responsible for collaborating with the Quality Division to document, review, and approve corrective action and quality incident reports. Other individuals may be used as resources based on their background, position in the forensic community, or skill set, either inside or outside HFSC. If the involved staff member(s) believes the nonconformance was inappropriately categorized, this concern should be communicated to the Quality Division and section management. The Quality Division and/or key management will ultimately decide on the appropriate category.



8.7.1. When nonconforming work has a significant impact on the quality of work product, management shall:

- a. document the nonconforming work using the Qualtrax IR/CAR Reporting workflow. The risk the nonconforming work poses to the validity of laboratory activities will be evaluated. When risks are determined to have an impact on testing or reports, actions will be taken to control and correct the work.
- b. evaluate the need for action to address the cause of the nonconformance and take actions to prevent or reduce recurrence by reviewing and analyzing the nonconformity and determining if other instances of similar nonconforming work exist.

Root cause analysis 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 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.

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.

#### **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 inadequate, 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 the HFSC 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 recurrence 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.

- c. implement any actions needed to ensure that the issue is resolved, and the chance of recurrence is eliminated or reduced. Actions will also be taken to address the consequence of the nonconforming work, including issuing amended reports and notifying stakeholders, the TFSC, and ANAB if appropriate. Examples of such actions include, but are not limited to, revising SOPs or retraining personnel.
- d. monitor nonconformances to determine if the corrective action was effective. Additional actions will be taken as necessary to prevent recurrence. The evaluation of the effectiveness of corrective actions may be documented through the CAR/IR Follow-Up Report workflow in Qualtrax or reviewed during the annual management review.

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

- e. take appropriate action to address any risks or opportunities identified during an investigation of nonconforming work.
- f. take appropriate actions to address deficiencies in the management system, if necessary.
- g. address nonconforming work in a timely manner. Deadlines for completion of corrective actions and quality incidents are built into Qualtrax. The target timeframe for completion is **30 working days for incidents and 50 working days for corrective actions**. The Quality Division acknowledges there may be instances where this timeframe is not reasonable.

#### 8.7.2. 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.

- 8.7.3. HFSC retains documents related to nonconforming work through the IR/CAR Reporting workflow in Qualtrax.
- a. The workflow tracks the description of the nonconformance, actions taken, and root causes. Nonconformances will be fully documented and reported in clear, active language whenever possible. The Quality Division is responsible for maintaining these records.
  - b. Actions taken to address nonconformances are documented in the workflow under "actions taken", and the effectiveness of those actions may be evaluated through the CAR/IR Follow-up Report workflow, and when necessary, through follow-up audit reports.

### **Closing Corrective Actions**

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.

## **8.8. Internal Audits**

- 8.8.1. HFSC conducts an annual audit to ensure the management system:
- a. conforms to all appropriate requirements such as current policies and procedures, accreditation standards, supplemental requirements, the FBI Quality Assurance Standards (QAS) for DNA Testing Laboratories, and OSAC Registry standards. The internal audit is planned and organized by the Quality Division and is completed by trained and qualified staff that are, if possible, independent of the section being audited.
  - b. is effectively implemented and maintained.
- 8.8.1.1. The audit is conducted annually, typically covering the 12-month period 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.

### **8.8.2. HFSC Internal Audit Program**



- a. The Quality Division, in conjunction with managers and section supervisors, will plan, establish, implement and maintain an audit program. Internal audit plans take into consideration changes that have been implemented that affect laboratory processes and results from previous audits. Internal audits are conducted annually. Prior to each audit, the Quality Division will select an audit team. This team will include a lead auditor (typically a member of the Quality Division) and team members who will be assigned a specific discipline to audit. Each of these team members will have 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 key management.
- b. The Quality Division will establish the scope and criteria for each laboratory section prior to each section's internal audit. The audit includes direct observation of processes and interviews with staff members.
- c. Audit teams communicate with section management through opening and closing meetings and daily briefings. The audit team publishes the final audit results in the form of a report that is provided to relevant key management.
- d. Any necessary corrective action will be implemented in a timely and appropriate manner. HFSC takes corrective action and notifies affected stakeholders in writing if the audit results cast doubt on the effectiveness of HFSC's forensic operations or the validity of testing and/or investigation results.

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

- e. The areas of activity audited, the audit findings and corrective actions that arise from them are documented and the records are retained. 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 ten years. Records may be scanned for long-term storage or sent to off-site storage according to HFSC policy.

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 is 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.

## 8.9. Management Reviews

8.9.1. The Quality Division, in conjunction with top management, ensures that a documented review of the management system is performed to determine the suitability, adequacy and effectiveness of the management system. This review includes a review of policies and objectives related to the fulfillment of accreditation standards and supplemental requirements. 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.

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

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

- a. internal and external changes relevant to HFSC activities.
- b. fulfillment of management and sectional objectives.
- c. the suitability of policies and procedures.
- d. the status of actions from previous management reviews.
- e. the outcome of recent internal audits.
- f. corrective and preventive actions.
- g. assessments by external bodies.
- h. changes in the volume and type of work or in the range of laboratory activities.
- i. stakeholder feedback.
- j. Complaints.
- k. the effectiveness of any implemented improvements.
- l. adequacy of resources.
- m. results of risk identification.
- n. results of interlaboratory comparisons or proficiency tests.
- o. other relevant factors, such as quality control activities, resources, and staff training.
- p. recommendations for improvement.

8.9.3. The Quality Division issues a management review report that includes:

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