Houston Forensic Science Center
Quality Manual
Quality Division
# Table of Contents

1. Terms and Definitions ................................................................................................................. 5
2. Job Descriptions .......................................................................................................................... 10
3. References .................................................................................................................................. 11
4. Management Requirements ......................................................................................................... 12
   4.1. Organization ............................................................................................................................. 12
   4.2. Management System ............................................................................................................... 14
   4.3. Document Control .................................................................................................................... 18
   4.4. Review of Requests, Tenders, and Contracts .......................................................................... 20
   4.5. Subcontracting of Tests and Calibrations ................................................................................ 21
   4.6. Purchasing Services and Supplies ......................................................................................... 21
   4.7. Service to the Customer ......................................................................................................... 22
   4.8. Complaints ............................................................................................................................... 23
   4.9. Control of Nonconforming Testing Work ................................................................................. 23
   4.10. Improvement .......................................................................................................................... 25
   4.11. Corrective Action .................................................................................................................... 25
   4.12. Preventive Actions ................................................................................................................ 27
   4.13. Control of Records ............................................................................................................... 27
   4.15. Management Reviews .......................................................................................................... 33
5. Technical Requirements .............................................................................................................. 35
   5.1. General ..................................................................................................................................... 35
   5.2. Personnel ................................................................................................................................. 35
   5.3. Accommodation and Environmental Conditions ..................................................................... 39
   5.4. Test Methods and Method Validation .................................................................................... 42
   5.5. Equipment ............................................................................................................................... 45
   5.6. Measurement Traceability ....................................................................................................... 47
   5.7. Sampling .................................................................................................................................. 49
   5.8. Handling of Evidence .............................................................................................................. 50
   5.9. Assuring the Quality of Test Results ....................................................................................... 53
   5.10. Reporting the Results .......................................................................................................... 58
6. Communication and Correspondence Procedure .......................................................................... 62
7. Laboratory Information Management System ............................................................................. 63
8. Legal Requests, Public Information Act Requests, and Disclosures of HFSC Information .......................... 64
9. Conflict of Interest and Undue Influence ................................................................................................. 65
NOTICE TO CUSTOMERS

Houston Forensic Science Center’s accrediting body requires that customers be notified in certain circumstances. Notification can be made on a case-by-case basis or through a general notification to all customers. This notice will serve as a general notification. Submission of evidence to the organization indicates agreement with these terms:

- **HFSC personnel will review each request for analysis.** This review ensures that the customer’s needs are clear and that HFSC can meet those needs.

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

- **HFSC will select the item or items most appropriate for analysis and may elect not to analyze all items based on the needs and circumstances of the case.** HFSC does not consider this a change to the contract and does not notify the customer.

- **HFSC will notify the customer if the proposed analysis requires the consumption of all the evidence.**

- **HFSC will use generally accepted methods that have been validated.** However, policy does allow for deviations from procedure when necessary. Deviations are documented within the case record but may not be communicated on a case-by-case basis.
1. Terms and Definitions

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

- **administrative records**: Records, such as case-related conversations, evidence receipts, 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.

- **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.

- **case records**: Administrative records, examination records, and any other applicable technical records, whether electronic or printed, generated or received by Houston Forensic Science Center, pertaining to a particular case.

- **category of testing**: A specific type of analysis within an accredited discipline of forensic science. (See *Sub-discipline*.)

- **certified reference material**: Reference material, accompanied by a certificate, with a value certified by a procedure that establishes traceability to an accurate realization of the unit in which the values are expressed, and for which each certified value is accompanied by uncertainty at a stated confidence level.

- **competency**: The requisite knowledge, skills, and abilities to perform a critical task.

- **competency test**: The evaluation of knowledge and ability that a person undergoes prior to performing independent casework.

- **conclusion**: A statement in an examination report that summarizes the interpretations of examination results in disciplines with established identification criteria. The term *conclusion* is also used to refer to a judgment made or decision reached based on the results of analysis/examination.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>control sample</td>
<td>A standard of comparison for verifying or checking the finding of an experiment.</td>
</tr>
<tr>
<td>controlled document</td>
<td>A document that is distributed in an organized way (usually electronically) to ensure that the latest approved version is identifiable.</td>
</tr>
<tr>
<td>controls</td>
<td>Samples tested in parallel with experimental samples and designed to demonstrate that a procedure and laboratory supplies worked correctly.</td>
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<tr>
<td>crime scene</td>
<td>Scene of an incident prior to establishing whether a crime or other action requiring investigation has taken place or not. The crime scene is not solely restricted to the location of the incident but also includes areas where relevant acts were carried out before or after the crime.</td>
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<tr>
<td>critical equipment</td>
<td>Instruments or equipment that require calibration or a performance check prior to use and periodically thereafter. (Measuring devices used by the crime scene unit may not be considered critical equipment. Please see the crime scene standard operating procedures for additional details.)</td>
</tr>
<tr>
<td>critical measurement</td>
<td>A measurement that matters for court prosecution enhancements or other charges.</td>
</tr>
<tr>
<td>critical reagent</td>
<td>Any reagent that has a significant effect on the quality of an examination test. These require regular quality control through intermediate checks.</td>
</tr>
<tr>
<td>critical task</td>
<td>Any task that has a significant effect on the quality of an examination test.</td>
</tr>
<tr>
<td>document</td>
<td>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.</td>
</tr>
<tr>
<td>document control</td>
<td>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.</td>
</tr>
<tr>
<td>environmental conditions</td>
<td>Characteristics that could have an impact on the results of an examination (e.g., lighting, heating, air conditioning, ventilation, plumbing, wiring, adequacy of exhaust hoods/biosafety cabinets).</td>
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<tr>
<td>examination</td>
<td>A process that uses approved technical procedures to characterize, quantitate, or interpret evidence.</td>
</tr>
<tr>
<td>examination records</td>
<td>The documentation (whether electronic or hard copy).</td>
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</table>
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.

inconsistency Any 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 the normative references and is typically conducted by Houston Forensic Science Center personnel.

internal proficiency test A test prepared by, provided by, and controlled within Houston Forensic Science Center.

method The course of action or technique followed in conducting a specific analysis or comparison leading to analytical results.

nonconformance Work that does not conform to the specifications of the Quality Management System.

non-standard method A method (not published in international, regional, or national standards or by reputable technical organizations or scientific texts or journals) developed by an organization that has been validated to confirm that the method is fit for the intended use.

objective (1) A measurable, definable goal that once accomplished furthers the progress of Houston Forensic Science Center. (2) Without prejudice or not influenced by feelings or opinions.

ownership review A review conducted by HFSC of vendor laboratory–generated DNA records before HFSC enters the DNA data into the Federal Bureau of Investigation’s Combined DNA Index System (CODIS).

performance check A set of operations run to determine if a piece of equipment produces examination results consistent with specified parameters. Performance checks are conducted when new equipment is used with existing technical procedures, equipment is moved to another physical location, or existing equipment is modified or undergoes maintenance that could change its performance.

policy A guiding principle, operating practice, or plan of action governing decisions made by Houston Forensic Science Center.

preventive action An action intended to eliminate the cause of a potential nonconformance or other undesirable situation.
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>procedure</td>
<td>The manner in which an operation is performed; a set of directions for performing an examination or analysis; the actual parameters of the methods used.</td>
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<tr>
<td>proficiency test</td>
<td>A test to evaluate the capability and performance of analysts, technical support personnel, and other Houston Forensic Science Center personnel. In open tests, HFSC personnel are aware that they are being tested; in blind tests, they are not.</td>
</tr>
<tr>
<td>quality assurance</td>
<td>Those planned and systematic actions necessary to provide sufficient confidence that an organization’s product or service will satisfy given requirements for quality.</td>
</tr>
<tr>
<td>quality audit</td>
<td>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.</td>
</tr>
<tr>
<td>quality control check</td>
<td>A procedure used to ensure the continued reliability and accuracy of reagents and equipment.</td>
</tr>
<tr>
<td>quality control check</td>
<td>An individual (however titled) designated by top management who, irrespective of other responsibilities, has the defined authority and obligation to ensure that the requirements of the safety system are implemented and maintained.</td>
</tr>
<tr>
<td>safety manual</td>
<td>A document stating the safety policy and describing the various elements of the safety system of an organization or business.</td>
</tr>
<tr>
<td>root cause analysis</td>
<td>A process of fact finding used to identify the root cause of nonconformance.</td>
</tr>
<tr>
<td>technical review</td>
<td>Review of all examination and investigation records to ensure the validity of scientific results and conclusions.</td>
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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 customers’ notes.

technical personnel  Individuals who conduct and/or direct the analysis of forensic casework samples, investigate crime scenes, interpret data, and/or reach conclusions. Technical employees may also be referred to as forensic analysts, supervisors, managers, examiners, and investigators.

technical support personnel  Individuals who perform casework-related duties at the direction of an analyst but do not issue test reports related to conclusions reached.

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).
2. Job Descriptions

Job postings may be obtained from HFSC Human Resources Division upon request. Staff member job descriptions and/or job postings may be found on HFSC or City of Houston websites. City of Houston job descriptions may refer to positions by titles other than those used by HFSC. For example, the City of Houston job title of Criminalist is equivalent to HFSC title Forensic Analyst, and Criminalist Specialist is equivalent to Supervisor and Senior Examiner. Please see HFSC Human Resources Division for further information.

Forensic Analysts, Supervisors, Managers, and Examiners may be responsible for:
- conducting analytical tests
- conducting forensic investigations
- planning tests and evaluating results
- reporting opinions and interpretations
- developing, validating, and modifying methods
- documenting, collecting, preserving, and processing evidence
- testifying in courts of law as an expert witness

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

The term staff member is used throughout this manual and means any person under the management responsibility of HFSC, regardless of classification as civilian, classified, employee, temporary employee, intern, or volunteer.
3. References

HFSC will follow the guidelines set forth in this manual as well as those in the current version of ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories, ISO 17020 Requirements for the Operation of Various Types of Bodies Performing Inspection, any applicable supplemental requirements, and the current FBI Quality Assurance Standards for Forensic DNA Testing Laboratories.
4. Management Requirements

4.1. Organization

4.1.1. HFSC is a publicly funded local government corporation.

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

4.1.3. All operations performed by HFSC, both at its permanent facilities and at sites away from its permanent facilities, will conform to the practices described within this quality manual. HFSC currently provides services in the forensic disciplines of drug chemistry, toxicology, biology, firearms, latent prints, audio/video, digital forensics, and crime scene processing. Staff members also provide courtroom testimony related to these same services. This manual may also be applied to other disciplines within the Houston Forensic Science Center including, but not limited to, trace evidence and questioned document analysis. All staff members are expected to remain objective, impartial, and independent when working a case, investigating and collecting evidence at a scene, and when testifying. Staff members should not be influenced by extraneous information, political pressure, or other outside influences. Instances of such should be reported to the staff member’s manager or his/her designee, and/or division director or quality director. Refer to the conflict of interest and undue influence policy found at the end of this manual.

4.1.4. HFSC includes two technical divisions: the Forensic Analysis Division and the Evidence Collection Division. Other divisions and departments include: Quality, Information Technology (IT), Training, Finance, Methods Development and Validation, and Human Resources. The division directors, in conjunction with key management personnel, have the authority and resources to carry out their duties, including improvements to the quality system, and are responsible for ensuring that daily technical and/or investigation operations follow accepted policies and procedures within their division. The division directors 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 of time. The acting division director assumes those responsibilities given to the division director until such time as the director returns to duty. The directors have authority over their respective divisions and are responsible for ensuring the division’s conformance with accreditation standards. The HFSC president/chief executive officer (CEO) has Center-wide authority. The CEO, vice president/chief operating officer (COO), and the directors are considered top management.
4.1.4.1. Regardless of job title, one staff member will function in the capacity of director for each division and will be referred to throughout this manual as the division director. In conjunction with the CEO and COO, the division directors coordinate all administrative, technical, and investigation activities of their respective divisions.

4.1.4.2. The directors have sufficient authority to make and enforce decisions within their respective divisions, including closing technical sections if concerns of a technical or quality nature arise. The quality director has authority to make and enforce quality-related decisions across all divisions, including closing technical sections if quality-related issues arise.

4.1.5. Key management includes top management, sectional managers, and supervisors. Other individuals may be identified as key management by the CEO, COO, or division directors. When appropriate, key management personnel will appoint one or more individuals who may act on their behalf. In the case of an unplanned absence, the manager may appoint a designee responsible for critical duties of the section until the manager returns to duty. Manager responsibilities include, but are not limited to:

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

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

The technical staff of HFSC has the responsibility of ensuring that all requirements of the quality system are met and failures to conform to quality standards are minimized, prevented, or eliminated. Staff should understand the importance and relevance of testing and investigation activities and review the quality goals and objectives of HFSC at least yearly. All personnel have the responsibility and authority to identify opportunities for improvement and to take appropriate measures to implement them. Technical employees will ensure that reports and case documentation are complete and will advise key management of technical problems or questionable results.

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

Staff members will follow all applicable governing procedures, such as City of Houston Administrative Procedures, Houston Police Department (HPD) General Orders (classified personnel), and HFSC administrative policies in the daily operations of HFSC. If conflicts arise
between the contents of this manual and the governing procedures, then staff members will follow the most stringent policy.

The confidentiality of customer case-related information is protected whether the information is in paper or electronic format, and the information is subject to the Texas Open Records Act. Violation of customer privacy may subject staff members to disciplinary action. See 4.13.1.3 for additional information.

Technical employees will use validated methods while examining and/or investigating forensic evidence and in meeting the needs of its customers.

All HFSC staff members are subject to random drug testing. HFSC employees are tested in accordance with HFSC policy. Classified and civilian employees of the City of Houston are tested in accordance with City of Houston policy. Staff member performance evaluations will be administered according to the policies and procedures of HFSC.

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

4.1.5.2. Each section manager is technically responsible for his/her assigned discipline(s), and has appropriate training and technical experience in that discipline. If not, he or she will coordinate with individuals familiar with the methods being used. HFSC has a quality director who is responsible for ensuring that the quality management system is followed. See 4.2.6 and HFSC organizational chart for additional information.

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

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

4.2. Management System

4.2.1. Management is committed to the ongoing development of a quality system that meets or exceeds customers’ needs and regulatory and statutory requirements. This manual is intended to aid in maintaining an environment of continual improvement in the management system and in services provided by HFSC. This manual is complemented by sectional standard operating procedures (SOPs) and training manuals. Each document is intended to work in concert with the others, but, should a conflict arise, the standards set forth in this manual will supersede those of the individual sections. In general, nontechnical policies or procedures of HFSC’s governing body will supersede the standards in this manual.
Management system documents include internal policies and procedures, controlled forms, externally prepared documents, and standards that are referenced or used in HFSC. All approved and internally generated management documents are in an electronic format and available for review by staff members. Approval may be acknowledged by digital or handwritten signature. Hard copies are considered uncontrolled documents.

Staff members may make copies, but individuals using these copies should recognize they are uncontrolled. Users are responsible for verifying that the uncontrolled copy on which they are relying is the current version of the document. Any uncontrolled document that is not current should be shredded or clearly marked to indicate that it is no longer in use.

Affected staff members are notified when controlled documents are issued, revised, or rescinded. These notifications may be made by email from the appropriate top or key management personnel or during section, division, or Center-wide meetings.

New technical employees review the quality manual, safety manual, and other section-specific documents during the training program. All technical employees are required to review the quality manual annually, and the review is documented. The quality manual, safety manual, and section-specific policy manuals are stored on secure electronic sites and are accessible from networked computers.

4.2.2. The quality system is a mechanism to ensure that HFSC’s investigation activities, examinations, documentation, and testimony remain accurate, impartial, and ethical. To this end, all staff members are responsible for following the guidelines contained in this manual. If it becomes necessary to deviate from approved procedures, then the deviation will be conducted in accordance with good laboratory practices and with the approval of the section manager, quality director, and/or division director.

Additionally, the quality system ensures that the services provided by HFSC meet or exceed the guidelines and standards set forth in ISO/IEC 17025 and ISO/IEC 17020. In achieving accreditation, HFSC will adhere to Texas House Bill 2703 from the 78th Texas Legislature, which convened in 2003.

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.

Quality assurance is a dynamic process requiring maintenance and oversight of all systems. All employees will abide by the quality system policies and procedures, such as those detailed in this manual, applicable to their job function. Technical policies and procedures are defined in sectional procedure manuals.

Top management and the quality director verify that an annual audit and management review are conducted to gauge HFSC’s continued compliance with the requirements of the quality system. The internal audit will address all elements of ISO/IEC 17025, ISO/IEC 17020, and applicable supplemental requirements for accreditation. The management review will address continuing enhancements of forensic services.

**4.2.2.1.** Top management will ensure that documented ethics training is provided to employees on a yearly basis.

Technical employees 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 personnel will conduct only those examinations and investigations for which they are qualified by education, training, and/or demonstrated proficiency. They will accurately represent their qualifications to others.

- **Professionalism**—Staff members will uphold the law as well as HFSC policies and procedures to the best of their ability. Staff members will report to key management any conflicts between their ethical responsibility and these laws and policies. Any unethical or illegal conduct by staff should be reported immediately to key management.

**4.2.2.2.** Yearly ethics training may include a review of the Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists or a review of codes of conduct adopted by professional organizations such as the American Society of Crime Laboratory Directors, the American Board of Criminalistics, or the American Society for Quality. At the discretion of top management, a documented review of the applicable organizational code of conduct may take the place of yearly training for staff members who are members of those organizations. All staff members will follow the HFSC Code of Ethics.
4.2.3. Top management, with the assistance of key management personnel and/or designees, will review the development, implementation, improvement, and continued effectiveness of the quality system. These reviews may include a review of the internal audit, communications from customers, proficiency testing results, and testimony monitoring.

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

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

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

Key management personnel will ensure that technical employees are trained and will monitor casework and other sectional activities to gauge compliance with the quality system. Technical personnel will perform their duties as outlined in the quality system. Administrative personnel will apply applicable quality system components to clerical, administrative, or other duties performed.

Any staff member may make recommendations for improving the quality system. Recommendations may be made through the staff member’s divisional chain of command or directly to the quality director, COO, CEO, or their designees. The quality director 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 personnel
- addressing quality concerns or complaints
- monitoring and reviewing forensic practices that affect the quality of examination and/or investigation results, including instrument calibration and maintenance, use of reagents and standards, performing case reviews, taking corrective/preventive actions, and providing technical training as necessary
- scheduling, monitoring, and/or conducting division audits to verify compliance with policies and procedures, proficiency testing, and testimony monitoring
- maintaining quality system records and archives

To investigate and/or address a quality issue arising in any of the forensic disciplines, the quality director has the authority to order a discipline to cease casework. The CEO, COO, and/or appropriate division director will be consulted. The DNA technical leader and the
Combined DNA Index System (CODIS) administrator have authority to cease DNA casework. Further information may be found in sectional procedures.

4.2.7. Top management, with assistance from key management personnel, will ensure that the integrity of the management system is maintained when changes to the system are implemented. Changes that affect accreditation will be approved by the applicable division director prior to implementation. Management system changes will be communicated to appropriate staff.

4.3. Document Control

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

This Quality Manual is approved by top management and reviewed by key management prior to being issued by the quality director or his/her designee.

Technical sectional procedures and training manuals are approved prior to issue by the section manager or his/her designee and the quality director or his/her designee. Other section-specific documents, such as worksheets that are required to be used, must be approved prior to issue by the section manager or his/her designee. 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.

The Health and Safety Manual is approved prior to issue by the safety coordinator, CEO or his/her designee, quality director, and the division directors.

Finance, Human Resources, Training, and IT policies and procedures must be approved prior to issue by the chief financial officer or appropriate director and the HFSC CEO or COO. Approvals and reviews are documented.

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

Controlled documents are reviewed at least once each calendar year by appropriate management personnel. Even if no revision is made as a result of the review, documentation will show that an annual review was completed.
4.3.2. Document Approval and Issue

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

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

4.3.2.2. The official versions of controlled documents are published in an electronic format and can be viewed from any networked computer. Controlled documents will not be used on casework until approved by the appropriate parties. Staff members are notified when new items are posted in the Laboratory Information Management System (LIMS) Quality Management System (QMS). All printed copies of controlled documents are considered uncontrolled versions and the user is responsible for verifying that he/she is using the current version. Portions (e.g., dilution charts) of SOPs printed for reference purposes and used in the laboratory must include the version number. These bench sheets are removed from the laboratory when they become obsolete. Obsolete documents, such as complete SOPs, are marked to ensure that they are not confused with current versions.

4.3.2.3. Technical management system documents created internally are identified by:
- title
- issue date
- page number
- total number of pages or a mark to signify the end of the document
- issuing authority

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

4.3.3. Document Changes

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

4.3.3.2. When revisions are made to existing documents and result in the issuance of a new manual, the altered or new text is clearly marked. One way to accomplish this is to have the new or altered text in red font. This requirement does not extend to worksheets. An overview of deleted information may be listed in the comments section of the QMS under document properties or included as an attachment to the revised document.
4.3.3.3. Updates to controlled documents will be incorporated into new versions. HFSC does not allow documents to be amended by hand. However, correspondence that is intended only to clarify policies and/or procedures is allowed.

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

4.4. Review of Requests, Tenders, and Contracts

The following definitions apply to requests, tenders, and contracts:

- **Request**—A request is the process utilized by a customer when seeking analysis by HFSC. For example, a submission form or letter accompanying submitted evidence that lists examinations sought by the customer is a request. Requests may also be made through the pre-log function in LIMS.

- **Tender**—A tender is HFSC’s response to the customer’s request. This may include an automated LIMS notification.

- **Contract**—A contract is a written or oral agreement to provide a customer with testing and/or crime scene processing services.

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

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

4.4.1. Requests for analysis and for evidence investigations are reviewed to ensure that:

- HFSC has the capabilities and resources to meet the customer’s request
- HFSC’s testing methods and/or evidence investigation services are capable of meeting the customer’s requirements

Requests are reviewed by technical employees to ensure that accurate submission information is included and that evidence is appropriately sealed. Requests for evidence investigation services are reviewed to ensure the safety of the crime scene investigator and the ability of the crime scene unit to complete the requested services.

Technical aspects of the review, such as the methods to be used, are completed by technical personnel in the appropriate section. When necessary, personnel will clarify the needs of the customer, determine the probative nature and value of the evidence and/or crime scene, and define or discuss testing or investigation methods with the customer before casework or the crime scene investigation begins.
Differences between the request or tender and the contract will be resolved before work commences. Each contract will be acceptable to HFSC and the customer.

4.4.2. Records of pertinent discussions with a customer about the customer’s requirements or the results of the work are maintained in a communication log, email, or equivalent record.

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

4.4.4. HFSC informs its customers before deviating from an agreed-upon analysis or crime scene investigation. Personnel in the Digital Forensic and Audio/Video units should contact the customer in advance if the requested analysis could realistically result in destruction of the evidence (e.g., cell phones).

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

4.5. Subcontracting of Tests and Calibrations

4.5.1. Subcontractor refers to an individual or entity that is not part of HFSC but performs services that are covered under HFSC’s scope of accreditation. HFSC places work only with subcontractors who comply with ISO/IEC 17025 and/or ISO/IEC 17020 in performing HFSC’s work and/or are accredited by the Texas Forensic Science Commission.

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

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

4.5.4. HFSC maintains a registry of subcontractors deemed competent to perform analysis on its behalf.

4.6. Purchasing Services and Supplies

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

4.6.2. HFSC verifies that purchased supplies, reagents, and consumables that affect the quality of tests meet SOP specifications or sectional requirements prior to initial use. This verification may be accomplished by determining that the item or items received are the
same as what was ordered. Initials or a signature on a packing slip or purchase order signify that the supply has been inspected. The inspection may involve comparing catalog numbers, described quality, or other relevant information to verify that each item received is the same as the item ordered and (where applicable) meets the specifications listed in sectional SOPs. 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.

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. Refer to section 5.1.3 for further information about critical reagents.

Reagents used for DNA analysis will be checked in accordance with the Federal Bureau of Investigation’s *Quality Assurance Standards for DNA Testing Laboratories*.

**4.6.3.** Section managers, supervisors, or their designees review and approve purchase requests before the requests are sent to HFSC’s purchasing unit. In approving these requests, the manager, supervisor, or designee is confirming the requested services or supplies meet applicable and specified requirements stated in sectional SOPs.

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

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

**4.7. Service to the Customer**

**4.7.1.** HFSC strives to maintain good working relationships with its customers. Maintaining these relationships may require:

- asking for clarification if the request is unclear
- maintaining appropriate contact with the customer during lengthy examinations
- maintaining confidentiality
- seeking feedback from customers
- providing explanations or interpretations of reports
Staff members are available to assist customers regarding evidence submission. If technical questions arise during the submission process, the staff member receiving the evidence will contact the appropriate analyst or manager for assistance.

Under normal circumstances, individuals who are not staff members are not allowed to observe testing. This policy helps to ensure confidentiality of case information, limits potential for contamination, and ensures security of evidence and case records. Special arrangements (e.g., outside normal working hours) may be made in order to comply with court-ordered observations. Consult the section manager and/or the division director for further instructions. Additional detailed information may be found in sectional policy manuals.

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

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

4.8. Complaints

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

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

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

4.9. Control of Nonconforming Testing Work

4.9.1. Issues regarding the quality of technical services provided by HFSC are brought to the attention of the appropriate section manager and the quality director, or their designees. The division directors, quality director, sectional manager, DNA technical leader, 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.
*Class I* errors are those that have an immediate impact on the quality of HFSC’s work product. Class I nonconformances include false identifications and false-positive results.

*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.

*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.

The quality director will ensure that Class I and Class II issues are brought to the attention of the appropriate division director and manager. Class I and Class II errors will be fully documented and reported using a Corrective Action Form. (See 4.11.) The manager or technical leader is responsible for investigating and reporting the occurrence to the quality division in a timely fashion. The investigation includes a review of any affected casework, root cause analysis, and corrective actions taken to prevent a recurrence. The nature of the nonconformity dictates whether immediate action is necessary. Common sense must be employed when determining what constitutes nonconformity. Minor departures from accepted policy will normally require only a correction. The issuance of an amended report will serve as customer notification.

Class III errors are corrected and documented. If the same error occurs routinely for the same staff member or under the same circumstances, then the error may be elevated in class.

Nontechnical issues may be addressed through the appropriate key or top management personnel. If necessary, the division director, manager, quality director, and/or human resources director will work together to address this type of issue. (See 4.7 and 4.8.) Refer to the HFSC “Progressive Corrective Action Policy” for additional information.

Customers will be notified if their casework is recalled.

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
4.10. Improvement

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

4.11. Corrective Action

4.11.1. General
HFSC may have to correct existing technical procedures when nonconforming work or departures from management system policies/procedures or technical operations are identified. Corrective action may also be taken to address management system concerns. Management system and technical concerns may be identified through such activities as internal audits, assessments, management reviews, or customer or staff feedback. The quality director, with input from division directors, sectional managers/supervisors, the DNA technical leader, and (in some instances) the CODIS administrator will delegate or initiate an investigation into nonconforming issues. Other individuals may be used as resources based on their background, position in the forensic community, or skill set, either inside or outside HFSC. Nonconforming work is defined as an act, error, or omission that has affected the accuracy, reliability, and/or integrity of HFSC’s testing or evidence examination reports. Nonconforming work must be reported to the appropriate division director and quality director as soon as possible after detection. The quality director will determine if the nonconformance requires corrective action. Corrective action is required in the following instances:

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

An Incident Form is used in the initial stages of reporting the nonconformance to the quality division. If corrective action is required, then the HFSC Corrective Action Reporting Form (CAR) will be completed.

HFSC’s corrective action policy includes:
- identifying the person responsible for carrying out the corrective action
- establishing the scope of measures taken
- notifying customers when reports are amended
- identifying the root cause of the problem
- implementing a long-term solution to prevent a recurrence
- monitoring the effectiveness of the corrective actions taken

The purpose of this policy is to maintain and improve the quality of work performed by HFSC. While it is not the purpose or intent of this policy to single out an individual or section, singling
out an individual may occur as a byproduct of the process. Efforts are made to maintain confidentiality of the parties involved.

4.11.2. Root Cause Analysis

The first step in the corrective action investigation is an effort to determine the root cause of the apparent nonconformance. This process is conducted at the direction of the quality director. If the cause is not obvious, an analysis of potential causes will be conducted using a common sense approach. Causes may be related to, but are not limited to, customer requirements, evidence, procedures, personnel training, consumables, or equipment and its calibration.

4.11.3. Selection and Implementation of Corrective Actions

Corrective actions will be taken, when needed, to eliminate the root cause of the nonconformance and to prevent a recurrence. These actions will be documented using the CAR form. The quality division maintains signed copies of these records. Depending upon the nature of the problem or error, appropriate corrective actions may include the following:

- If the error is determined to be in the method, the method may be removed from use on casework, modified, or moderated by additional controls as necessary. Other cases in which the same method was used may be reviewed.
- If the error is determined to be caused by an instrument or other equipment used in the test, the error will be corrected and documented. Other cases in which the same instrument or equipment was used may be reevaluated and appropriate action taken.
- If the error rests with a staff member, it will be determined if the error was the result of inadequate or inappropriate training or is an isolated incident and not likely to recur. If the original training is found to be faulty, appropriate additional training or evaluation will be completed. If the original training is determined to be adequate, the review will attempt to identify the specific cause of the problem or error. Actions taken to address personnel issues may be confidential and may be handled by HFSC Human Resources in accordance with HFSC’s “Progressive Corrective Action Policy.”
- If the error is determined to be administrative or clerical in nature, the documentation and review process will be studied and revised, if appropriate, to minimize the recurrence of this error.

Corrective actions will be of the appropriate degree and magnitude to correct the problem and reduce the risk of recurrence.

The quality director is responsible for following up and closing out the corrective action process.

4.11.4. Monitoring Corrective Actions

The quality division will monitor the occurrence to determine if the corrective action was effective. Additional actions will be taken as necessary to prevent a recurrence. The corrective action process will be reviewed during the annual management review.
4.11.5. Additional Audits

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

4.12. Preventive Actions

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

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

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

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

4.13. Control of Records

4.13.1. General

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

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

- the test report(s)
- reference to the technical procedures used during analysis and any deviation
- identifiers and descriptions of the items analyzed
- identity of the technical employee(s) performing the examination(s)
- identity of the technical and administrative reviewers

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

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

Access to case records stored in an electronic format associated with LIMS, Foray or MIDEO Systems Caseworks software is granted through the authority of the applicable Division Director or his/her designee. 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 division.

4.13.1.2. Records are legible, in a readily retrievable format, and are stored in secure locations. They may be maintained in hard copy or electronic format. Paper files and microfiche are stored in limited-access areas, whether in HFSC offices or in secure, off-site facilities. Paper-based case files may also be stored in the custody of an HFSC staff member.

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

Quality, administrative, and technical records will be kept for at least five years or one full accreditation cycle, whichever is longer. If pertaining to DNA, those same records are kept for at least 10 years. Records are typically scanned into a secure, backed-up electronic system. The electronic versions of these records are maintained indefinitely, unless HFSC is otherwise ordered by the customer or by legal requirements (expunction). The paper copies of these scanned records may be stored or shredded. Top management may authorize the disposal of quality and/or technical records in accordance with HFSC records retention policy. Documents and records will be shredded or otherwise disposed of in a manner that ensures the confidentiality of the information.

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

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

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

4.13.2. Technical Records

4.13.2.1. HFSC retains records of original observations, records of derived data, and sufficient information to establish an audit trail. Case records contain sufficient information to facilitate, if possible, the identification of the factors affecting uncertainty and to enable any test to be repeated under conditions as close as possible to those of the original. These records include, when applicable, the identities of those playing significant roles (the technical employee, reviewers, and the person responsible for sampling), information about the performance of each test, and the review of results. Equipment or instrumentation used during analysis that has a significant influence on the results of the test/examination shall be recorded in the case record. 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.

Instrument operating parameters are recorded in the case record or in a retrievable form that is available for review.

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

4.13.2.3. Changes and alterations will be initialed by the person making the change. When striking out information in a case record, a single line is drawn through the error and initialed. Mistakes are not erased, made illegible, or deleted. Erasures on crime scene sketches are not considered mistakes and are not subject to these requirements. In the
case of electronic records, equivalent measures are taken to preserve original data. If an error is found in a report after it is reviewed and approved, an amended report will be issued. The amended report will document the corrections or changes made to the previous report.

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 that could reasonably be construed as having been made by a person other than the one making the notation.

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

**Administrative documentation**
- submission forms/request for analysis
- evidence inventory and description
- chain of custody
- communication logs
- report(s) of analysis
- documentation of technical and administrative review
- subpoenas
- discovery requests

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

Administrative documentation must contain the assigned forensic case number. Examination documentation must contain the forensic case number and the initials or identity of the examiner. Evidence Collection Division’s administrative and examination documentation are considered uniquely identified when either the forensic case number or the requesting agency identifier is used. 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.

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

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

4.13.2.6. The unique case identifier and the staff member’s handwritten initials or secure electronic equivalent are on each page of examination documentation. Examination records that bear the unique identifier and initials on an original record may be copied for filing in multiple places without the necessity of placing original identifiers on each copy. If electronic records are printed, the unique identifier will be on each page of the printed documentation. When electronic records are viewed on a computer, the unique identifier will be visible on the screen. If the staff member’s initials are visible in a photograph, then it is not necessary to add handwritten initials.

4.13.2.7. If allowed by law, a qualified staff member may review, interpret, report, or testify regarding the examinations, investigation notes, or critical findings of another HFSC staff member. When examination records are prepared by individuals other than the one who interprets the findings, prepares the report, and/or testifies concerning the records, the individuals who prepare the records will initial their work product and the person preparing the report will initial each page of associated examination records. Someone who testifies to the work of another examiner should document a review of applicable case records prior to testimony. 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.

4.13.2.8. All administrative records received or generated by the Center for a specific case must include the unique case identifier and the identity of the individual adding the information to the case record.

4.13.2.9. When multiple cases are analyzed simultaneously, the unique identifier of each case is recorded on the printout if a single printout is used. The printout may be kept in a single file and referenced in all the other case files for which data is included.
4.13.2.10. 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.

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

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

4.13.2.13. Abbreviations, acronyms, and symbols are acceptable in examination records if the meanings are readily comprehensible to a reviewer and the meaning of the abbreviation or symbol is documented in the sectional SOP. Abbreviations that are common in a discipline and understood by anyone in that discipline do not have to be listed in a table of abbreviations. Examples include, but are not limited to, chemical element symbols and standard units of measure.


4.14.1. HFSC conducts an annual audit, using its current policies and procedures, accreditation standards, supplemental requirements, and the FBI Quality Assurance Standards for DNA Testing Laboratories as guidelines. This internal audit is planned and organized by the quality director or designee and is completed by trained and qualified staff that are, if possible, independent of the section being audited. The audit includes direct observation of examinations and interviews with staff members.

The quality director, in conjunction with managers and section supervisors, will select an audit team. This team will include a lead auditor (typically the quality director or his/her designee) and team members who will be assigned a specific discipline to audit. Each of these team members will have audit training prior to conducting the audit. This documented training may be provided by external sources or conducted in-house. Whenever possible, teams will include at least one formally trained auditor. Audit documents, including criteria to be assessed, will be provided to the auditors. Upon completion, each auditor will provide to the lead auditor objective evidence observed for any finding or nonconformance. This information will be shared with the appropriate managers and division directors.
The quality director is responsible for providing an audit report to the division directors. Any necessary corrective action will be taken in a timely and appropriate manner.

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

4.14.1.1. The audit is conducted annually, typically covering the 12-month period prior to HFSC’s accreditation anniversary date. The quality division will meet with top management to determine a specific time frame, typically a one-month window, in which the audit will be conducted. This time frame may be adjusted to accommodate the schedules of the audit team. Changes to the agreed-upon time frame will be communicated to top management.

4.14.1.2. Records of the annual audit are retained through at least one accreditation cycle or five years, whichever is longer. DNA records are maintained for at least 10 years. Records may be scanned for long-term storage or sent to off-site storage according to city and/or HFSC regulations.

4.14.2. HFSC takes corrective action and notifies affected customers in writing if the audit results cast doubt on the effectiveness of HFSC’s forensic operations or the validity of testing and/or investigating results.

4.14.3. The areas of activity audited, the audit findings and corrective actions that arise from them are documented.

4.14.4. Follow-up audits will be conducted, if necessary, to verify the implementation and effectiveness of corrective actions taken as a result of the audit.

4.15. Management Reviews

4.15.1. A documented review is conducted by top management officers and/or their designees to determine the suitability and effectiveness of management activities. This management review includes, but may not be limited to, the following:
- the suitability of policies and procedures
- reports from managers and supervisory personnel
- the outcome of recent internal audits
• corrective and preventive actions
• assessments by external bodies
• results of interlaboratory comparisons or proficiency tests
• changes in the volume and type of work
• customer feedback
• complaints
• the fulfillment of quality and sectional objectives
• recommendations for improvement
• documentation of any latent print conflict resolutions
• other relevant factors, such as quality control activities, resources, and staff training

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

A management review is conducted at least once each calendar year. The quality division will meet with top management to determine a specific time frame, typically a one-month window, in which the review will be conducted. Changes to the mutually agreeable time frame will be communicated to affected parties.

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

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

5.1. General

5.1.1. HFSC takes into account critical factors that affect the reliability of its test and investigation results. These factors include (numbers refer to sections below):
- personnel (5.2)
- accommodation (facilities) and environmental conditions (5.3)
- test methods and validation (5.4)
- equipment (5.5)
- measurement traceability (5.6)
- sampling (5.7)
- evidence handling (5.8)

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

5.1.3. Reagents used in HFSC are of a quality that ensures the validity and reliability of the testing conclusions reported by HFSC. The quality of reagents is verified before use and periodically thereafter to ensure their reliability as defined in sectional procedures. Reagents not meeting quality control criteria are removed from use and affected casework, if any, is reviewed.

5.1.3.1. Reagents prepared in HFSC are labeled with the identity of the reagent, concentration (if applicable), and date of preparation or lot number. If safety labeling is required, that labeling will follow the requirements of the Health and Safety Manual. Records are maintained identifying who made the reagent and verifying that it worked as expected when tested. This reliability testing occurs before use or, if appropriate, concurrent with the test. When necessary, sectional SOPs contain further instructions related to special storage conditions and hazard warnings.

5.2. Personnel

5.2.1. HFSC has a documented training program that provides knowledge and skills needed to perform specific tests. Key management ensures the competence of all who operate equipment, perform tests, evaluate results, and sign test reports by reviewing the staff member’s training binder prior to independent casework. At the discretion of the manager, an individual or individuals are assigned to oversee the training of new employees. This trainer or his/her designee is responsible for supervising the staff member throughout the training process.


5.2.1.1. Each technical discipline within HFSC has a training program. Newly hired technical staff members, including contract employees, will complete appropriate training and demonstrate competence before beginning casework. Sectional training manuals also include information related to retraining and maintenance of skills.

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

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

Training may be modified for staff members with previous training and/or experience at another laboratory. However, all staff members, whether previously trained or not, will undergo competency testing before beginning casework.

Technical competency can be achieved and recognized through the following:

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

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

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

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

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

Documentation of training is maintained. Documentation will include statement of qualifications (SOQ), résumés or curriculum vitae, and records of specialized training received. Transcripts will be maintained for those staff members in positions that require a college education. These requirements apply to all technical staff members at the level of manager and below.

5.2.1.2. If applicable, technical employees will undergo training in the presentation of evidence in court. This will include mock courtroom testimony. Non-analytical staff members and those who do not analyze evidence associated with active cases are not required to undergo mock trial training. The mock trial does not have to be conducted before the technical employee begins casework. However, whenever possible, the mock trial will be conducted before the technical employee testifies in court for the first time.

5.2.2. Key management formulates goals with respect to the education, training, and skills of HFSC personnel. HFSC’s training goals are evaluated in light of present and perceived workload demands during annual management review to align competencies with customers’ 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 supervisor. Effectiveness may be evaluated by how well content meets stated goals or objectives and by the performance of trainees on quizzes, competency tests, oral examinations, and/or proficiency testing.

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

Staff members are encouraged to join professional organizations. They may attend conferences and seminars if funding is available. Staff members may be allowed to attend training while on duty.
5.2.3. HFSC staff members will be employed by or contracted to the laboratory. If contracted employees or additional technical or key support personnel are used, HFSC will ensure that these individuals are supervised, competent, and adherent to HFSC management system rules during on-the-job hours.

5.2.4. HFSC utilizes City of Houston and/or HFSC job descriptions or postings. See HFSC Human Resources personnel for additional information.

5.2.5. Training is documented so that it is clear what tasks were undertaken during the training program. The appropriate section manager authorizes specific personnel to perform particular types of sampling, perform testing, issue reports, give opinions, interpret findings, and operate specific instruments and equipment. When in training, personnel are authorized to use instruments and equipment while under the supervision of trained and authorized staff members.

5.2.6. Technical Personnel Qualifications

5.2.6.1. Education
Analysts working in the Drug Chemistry discipline must have a baccalaureate or advanced degree in a natural science or closely related field. This education includes the successful completion of at least 30 hours of chemistry.

Analysts working in the Toxicology discipline must possess a baccalaureate or advanced degree in toxicology, a natural science, or a closely related field. This education includes the successful completion of at least 30 hours of chemistry.

Analysts working in the Biology discipline must possess a baccalaureate or advanced degree in a natural science or closely related field and, where applicable, meet the educational requirements of the FBI’s Quality Assurance Standards for Forensic DNA Testing Laboratories.

Analysts working in the Firearms discipline must meet the educational requirements specified in the job description or posting for their job. This includes possessing a baccalaureate or advanced degree in physical science or a closely related field.

Examiners and/or investigators assigned to the Latent Prints, Digital, Audio/Video, or Crime Scene disciplines will meet the educational and/or training requirements specified in the appropriate job description or posting for their job and in sectional SOPs.

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

5.2.6.2. Competency Testing
All technical staff members conducting casework, regardless of academic qualifications or past work experience, must satisfactorily complete a competency test in each category of
testing prior to assuming casework responsibility in that category. Performance is considered satisfactory if the intended results are achieved. Letters of authorization are issued after satisfactory completion of the competency test(s).

Technical support personnel are those individuals who perform casework-related duties within HFSC at the direction of a technical employee but do not issue reports related to conclusions reached. Regardless of academic qualifications or past work experience, they must satisfactorily complete a competency test prior to assuming responsibility for tasks that could reasonably be expected to affect the outcome of testing performed by HFSC.

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

5.2.6.2.1. Competency memos and supporting documentation are reviewed and approved by the quality director or his/her designee and the section manager before independent casework begins.

5.2.6.2.2. For staff members whose job responsibilities include conducting casework and/or writing test or investigation reports, an initial competency test will include:

- an examination of sufficient unknown samples to cover the anticipated spectrum of assigned duties and evaluation of the individual’s ability to perform proper testing methods
- a written or oral examination to assess the individual’s knowledge of the discipline, category of testing, or task being performed
- 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)

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. Exceptions to the above requirements may be granted upon written approval of the section manager and the quality division.

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

5.3. Accommodation and Environmental Conditions

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

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

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

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

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

Temperatures should be monitored and recorded. This may be done in a variety of ways. One way to monitor temperatures is to record temperatures in a log that includes the date, temperature, and the recorder’s name or initials. Manual recordings should be done at least once each week. Another way to monitor and record temperature is by using the Temperature @lert (TempAlert) monitoring system. The TempAlert system transmits temperature readings wirelessly to a secure website, which is monitored and controlled by designated personnel. When the TempAlert system is used, it is not necessary for personnel to record temperature readings manually. All temperature logs and/or temperature reports are kept for at least five years or one full accreditation cycle, whichever is longer.

5.3.3. HFSC provides effective separation between neighboring areas in which incompatible activities take place. Incompatible activities are separated by time or space to prevent contamination. Work surfaces and examination implements are cleaned. Controlled substance and toxicology analyses are performed in separate and distinct locations within HFSC, and instruments are dedicated for use rather than shared between the two disciplines. Items of evidence that potentially contain trace evidence (e.g., hair, fiber) from opposing sides in the same case are analyzed at different times or in different rooms to prevent cross-contamination. Additionally, evidentiary and reference DNA samples are handled at different times or in different locations to prevent cross-contamination.
5.3.4. Access to operational areas of HFSC is controlled, and access is granted by top management.

5.3.4.1. Security at HFSC facilities includes a combination of armed officers, overall building security, and area-specific alarm systems, including motion detectors. The primary methods of securing HFSC are the use of badge readers and the alarm system. The electronic badge security system is independent, autonomous, and separate from Houston Police Department security systems. The HFSC security system allows HFSC to track who enters its controlled-access areas. An electronic alarm system monitored by the City of Houston secures HFSC’s evidence storage and analytical areas. These security measures are supplemented by keys to restrict access only to those authorized to enter specific areas. Top management has granted access if an individual has electronic badge and/or key access to the area in question. Houston Police Department employees not managed by HFSC do not have unescorted access to HFSC facilities. The Houston Police Department accesses HFSC’s computer system only as needed to submit evidence and request analysis (through LIMS). Top management or a designee maintains keys, alarm codes, and associated records. Keys should be engraved or stamped with a unique identifier prior to issue. Excess keys that aren’t issued do not have to be engraved or stamped prior to issue but are maintained in a secure location and labeled in a manner to identify to which lock they belong. Doors that open into HFSC-controlled space and do not also require an identification badge to open are controlled through critical keys. Records showing the total number and assignment of critical keys are maintained and are required to be audited annually.

HFSC staff members display their identification badge while on duty and in accordance with applicable parent agency or building security policies. Temporary visitor name tags are issued by HFSC and/or building security. Staff members do not loan or give their assigned keys, identification badge, passwords, or alarm codes to any other person. Visitors are escorted while within limited-access areas of HFSC. City employees, including housekeeping staff, are allowed unescorted access to administrative areas of HFSC. Administrative areas are defined as those spaces within HFSC dedicated to clerical and/or administrative functions. At no time will any individual not employed by or supervised by HFSC be allowed unescorted access to areas where evidence is or is expected to be located.

The loss or compromise of any key, badge, password, or alarm code is promptly reported to top management or their designees. If necessary, actions are taken to prohibit access using the compromised medium. Resignation or termination of a staff member requires the immediate return of all access media. Locks, combinations, and/or codes will be changed as necessary.

Evidence storage areas are secured to prevent theft, and access is limited and controlled. Evidence storage conditions are designed to prevent loss, deterioration, and contamination and to maintain the integrity and identity of evidence, both before and after analysis. While not in the process of examination, evidence is stored in such
designated areas as vaults and personal storage lockers. Evidence is not stored in administrative areas.

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

5.3.6. HFSC has a health and safety program led by a representative group of HFSC staff members. One of these staff members acts as the health and safety officer, or safety specialist. Additional details are found in the Health and Safety Manual.

5.4. Test Methods and Method Validation

5.4.1. General

Evidence examinations are conducted in a scientifically valid manner. A critical component in ensuring validity is the documentation of procedures used for examinations. Examination includes sampling, handling, transport, and preparation of tested items, and, where appropriate, an estimation of uncertainty as well as statistical techniques for test data analysis. Equipment and instrument manuals should be available for reference purposes. Deviations from standard test methods are documented in the case record and are approved by the section manager or his/her designee. Unless otherwise instructed by the customer, HFSC chooses the best method for conducting analyses. In normal situations then, it is not necessary for the customer to approve each deviation; however, in situations in which HFSC wishes to confirm the customer’s approval, the section manager or his/her designee should contact the customer before deviating from a standard method. Procedures and methods are fit for the purposes required/requested by the customer.

5.4.2. Selection of Methods

HFSC uses methods that meet customers’ needs. The methods used may be published in international, national, or regional standards by reputable technical organizations in relevant scientific publications or may be specified by the equipment manufacturer. Published protocols undergo a performance check to show that intended results can be obtained internally before being used in casework. Control samples or replicate testing will be used with infrequently performed tests to show that these tests are giving appropriate results. Sectional SOPs will identify infrequently performed tests or analyses, if any.

5.4.3. Laboratory-Developed Methods

Prior to a substantial change to or the implementation of a new method/procedure, the method is subjected to appropriate internal validation (see 5.4.5.1 for definition) to assess the procedure’s ability to produce high-quality, reliable results. All validations are completed by qualified personnel. Written documentation for each validation is maintained. Reports on newly validated methods include language stating that the method is fit for the intended use.
5.4.4. Non-standard Methods

If it is necessary to employ non-standard methods, approval will be obtained from the section manager and the customer prior to use. The non-standard method will be validated prior to use on evidence items. See the Digital Forensic and Audio/Video sectional SOPs for exceptions to this validation requirement.

5.4.5. Method Validation

5.4.5.1. *Validation* is the confirmation by examination and objective evidence that the particular requirements for a specific use are fulfilled.

5.4.5.2. New technical procedures used by HFSC are validated before being used in casework. HFSC validates nonstandard methods, laboratory-developed methods, standard methods used outside their intended scope, and modifications and amplifications of standard methods to confirm that these methods are fit for their intended use. 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. HFSC records the validation results, the procedure used for the validation, and a statement about the method’s suitability for the intended use. Validation studies are documented and approved by the section manager 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.

There may be time-sensitive instances in which technical sections, such as the Digital Forensic and Audio/Video laboratories, 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 performance verification if the examiner uses due caution to maintain the integrity of the evidence. Supervisory approval is required in these situations, and the circumstances of the case and the analytical processes employed must be fully documented in the case record. These reports will not contain an accreditation statement or the logo of an accrediting body.

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

5.4.6. Estimation of Uncertainty of Measurement

Documentation of laboratory methods includes an estimation of the uncertainty of measurement (UM) when appropriate. The purpose of calculating the UM is to ensure that quantitative results provided to customers 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 customer will use these results to determine, prosecute, or defend the type or level of criminal charge. Estimation of UM is not required for qualitative tests that do not result in numerical values or for quantitative tests in which the numerical value obtained is not reported. Examples of measurements that require an estimation of uncertainty include the barrel length of a long gun, overall length of a long gun, controlled substance weights, and blood alcohol values. Uncertainty is reported using the same units as the measurement it supports. Refer to sectional SOPs for further details on reporting guidelines.

5.4.6.1. HFSC does not perform calibrations.

5.4.6.2. Affected sections of HFSC will have and apply procedures for estimating UM. This estimation complies with applicable UM policies adopted by HFSC’s accrediting body.

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

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

5.4.7. Control of Data

5.4.7.1. Manual calculations and data transfers are checked during any technical review. Detailed information may be found within sectional SOPs.

5.4.7.2. When a computer or automated equipment is used for the acquisition, processing, recording, reporting, storage, or retrieval of test data, HFSC will ensure the following:
- Computer software developed by HFSC is adequately validated and its performance verified as fit for use. Commercial off-the-shelf software in general
use within its designed application range will be considered sufficiently validated. This includes word processing, database, or instrument-associated software.

- Data generated electronically is protected by limiting access to the equipment and by allowing only authorized individuals to use the equipment. See section 4.13.
- Computers and automated equipment will be operated in compliance with the manufacturer’s recommendations or guidelines specified in sectional SOPs.

5.5. Equipment

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

5.5.2. Equipment and corresponding software used for testing and sampling must be capable of achieving the accuracy required by SOPs and comply with specifications relevant to the testing being conducted. Equipment that significantly affects the quality of an examination requires regular quality control through internal validation, performance verification, external calibration, and/or intermediate checks. Section SOPs contain additional details when applicable. Before being placed into service, equipment, including that used for sampling, is calibrated or checked to establish that it meets sectional specifications.

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

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

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

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

5.5.5. HFSC maintains the following equipment information when it is available:
- identity of equipment and any corresponding software
- manufacturer’s instructions
- status records (dates, results, and copies of reports; certificates or records of calibrations, adjustments, and acceptance criteria; and the due date of the next calibration)
- documentation of maintenance and maintenance plan when appropriate
- records of equipment and instrument malfunction, damage, modification, and repair
- section where equipment is located

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

5.5.6. Measuring equipment is handled, transported, and stored according to manufacturers’ recommendations in order to prevent contamination or deterioration. If additional instructions are necessary, they will be documented in sectional SOPs. If manufacturers’ information is not available, the section manager should determine the proper procedures for handling, transport, storage, and maintenance of that equipment. If appropriate, equipment used to make critical measurements undergoes a performance check before use if it has been moved since last use.

5.5.7. Equipment that does not meet quality control criteria and that is not immediately repaired is taken out of service. The equipment is labeled or marked as 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.

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

5.5.9. When equipment goes outside the direct control of HFSC and is used for testing and/or investigation outside HFSC, then staff members verify that the function and calibration status are satisfactory before the equipment is returned to in-house service. Records of such checks are maintained.
5.5.10. When intermediate checks are needed to maintain confidence in the calibration of instruments or equipment, the nature and frequency of such checks are specified in applicable section SOPs. Manufacturers’ recommendations or specifications will be considered when conducting these checks. Equipment or instruments that fail intermediate checks are removed from service. When appropriate, affected casework is reviewed. These intermediate checks are documented.

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

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

5.6. Measurement Traceability

5.6.1. General

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. A measurement that matters is one that is used, or may reasonably be expected to be used, by a laboratory customer to determine, prosecute, or defend the type or level of criminal charges. 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. Critical equipment is defined as tools or supplies that require calibration or a performance check prior to use and periodically thereafter. Measuring devices used by the Crime Scene unit may be checked before being placed into service but are typically not considered critical. Please see the Crime Scene unit SOP for further information.

Instruments used for critical measurements are calibrated by external calibration laboratories that will demonstrate traceability to the International System of Units (SI) when possible. The vendor conducting the calibration must demonstrate and provide documentation of competence, capability, and traceability. Competence is verified by selecting an ISO/IEC 17025–accredited calibration laboratory. Capability can be determined by reviewing the calibration provider’s scope of accreditation, and, in lieu of accreditation, a competent vendor may also be one that provides certificates of traceability to a national standard, such as that of the National Institute of Standards and Technology (NIST). For devices that have little to no effect on the overall quality of testing, calibration vendors that can provide NIST traceability will be considered competent.
All critical weight, critical volume, and critical length measurement devices are certified to NIST standards. The frequency of the calibration interval depends on the function of the measurement device.

Balances undergo annual calibration by an external vendor. Documentation of calibration is kept by HFSC. In addition to the annual calibration, sectional personnel complete a calibration/performance check at least monthly. When the use of a balance is infrequent, performance checks are not required each month; however, a check will be performed prior to use. Weights are verified on an externally calibrated balance at least once each calendar year. Once this verification is complete, the verified weights can then be used to conduct the required calibration checks performed monthly or prior to use. Pipettes and fume hoods also undergo annual calibration by an external vendor.

Equipment (including thermometers and TempAlert probes) used to record critical temperatures will be verified at least once every two years. Standard reference weights will be externally certified in accordance with the corresponding calibration certificates or at least once every three years. Specific time frames for maintenance of equipment and/or instruments used in DNA testing will follow Quality Assurance Standards for Forensic DNA Testing Laboratories guidelines whenever stricter than those recommended in this manual.

Equipment calibration procedures are established according to the specific requirements of the test being conducted. It will normally be necessary to check equipment calibration after any shutdown and following service or other substantial maintenance. The interval for checking equipment calibrations will not be less stringent than manufacturers’ recommendations.

5.6.2. Specific Requirements

5.6.2.1. Calibration
HFSC does not perform calibrations under its accreditation certificate.

5.6.2.2. Testing

5.6.2.2.1. Laboratory equipment is operated to ensure that measurements that matter are traceable to the SI whenever possible. This does not apply if the contribution of the calibration to the total uncertainty is negligible. (See 5.6.1.)

5.6.2.2.2. If traceability to SI units is not possible or relevant, then HFSC may provide confidence in measurements by establishing traceability to such standards as certified reference materials, specified methods, or consensus standards.

5.6.3. Reference Standards and Reference Material

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

5.6.3.2. Reference Materials

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

5.6.3.2.1. Reference collections of data or items/materials encountered in casework that are maintained for identification, comparison, or interpretation purposes (for example, mass spectral libraries, drug samples, bullets, cartridges, DNA profiles, frequency databases) are fully documented, uniquely identified, and properly controlled. Additional information appears in applicable sectional SOPs.

5.6.3.3. Intermediate Checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer, or working standards and reference material are carried out according to defined sectional procedures and schedules.

5.6.3.4. Transport and Storage

Reference materials are handled, transported, stored, and used according to manufacturers’ instructions or approved section-specific policy manuals.

5.7. Sampling

5.7.1. HFSC will have a sampling plan and procedures for sampling when it carries out sampling of substances, materials, or products for testing purposes. See applicable sectional policies for further details.
5.7.2. Customer-requested deviations from sampling procedures will be documented. See applicable sectional policies for detailed information.

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

5.8. Handling of Evidence

5.8.1. Evidence is handled while in the care, collection, custody, and control of HFSC in a way that protects the integrity of the evidence and prevents loss, contamination, or deleterious change.

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

- dried biological stains should be in packaging that prevents mold or bacterial growth
- sharp items should be packaged in a way that protects staff members from accidental sticks or cuts
- firearms are rendered safe by qualified personnel

In general, the staff member receiving the submitted evidence will ensure that the item is appropriately sealed. Sectional SOP’s may provide more information regarding evidence that may be accepted in an unsealed condition. Evidence seals are inspected to ensure they protect evidence from loss, cross-transfer, contamination, or deleterious change. Refer to HFSC’s Evidence Handbook for additional information regarding appropriate evidence packaging.

5.8.1.1. A chain of custody is maintained for evidence submitted to HFSC and will be completed or updated appropriately. The chain of custody is a record of the submission of evidence to HFSC as well as all internal transfers. The chain of custody includes the date of receipt or transfer and a description or unique identifier of the evidence. Evidence submission and transfers, including those to or from persons or locations, are documented by signature, initials, or secure electronic equivalent, at the time of submission or transfer.

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

5.8.1.2. Evidence must be received by HFSC in a condition that ensures that it is protected from loss, cross contamination or deleterious change. A proper seal is
essential to controlling the integrity of the evidence. 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. Lack of a proper seal could result in the integrity or quality of the evidence being questioned. All evidence received by HFSC will be properly sealed and will also be labeled with the initials or signature of the individual placing the seal.

If evidence is submitted to HFSC and does not contain a proper seal, meaning that the integrity or quality of the evidence is in question, the evidence may be rejected for submission and this action will be documented on a report to the customer. Alternatively, the seal may be corrected by the submitter or an HFSC staff member and the correction as well as the condition of the evidence upon receipt will be documented on the report.

If evidence is submitted without the seal being labeled with initials or signature, the evidence may be rejected for submission and this action will be documented on a report to the customer. Alternatively, the seal may be labeled by the submitter or an HFSC staff member and the action will be documented on the report.

If evidence is submitted to HFSC and its identity is compromised or if the requested testing is fundamentally inappropriate for the evidence submitted, then the evidence will be rejected for analysis.

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

5.8.2. Evidence received for analysis 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.

5.8.3. LIMS is used to identify and track evidence. This system allows for subdividing groups of evidence, transfer of evidence within HFSC, and receipt and return of evidence. If, at the time of analysis, there are inconsistencies in the identification of the evidence to a case or to an individual that make definitive identification of the evidence questionable, then the inconsistencies will be documented on the report. Alternatively, HFSC may return the evidence to the submitting agency and issue a report stating the evidence was rejected for analysis and the reason(s) for the rejection.
5.8.4. Departures from normal or specified conditions described in test methods will be documented within the case record. When further clarification is needed (e.g., when doubt exists about the suitability of an item for testing, the analysis needed is not specified in sufficient detail), the customer is contacted. This communication is documented within the case record.

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

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

5.8.5.1. All evidence not in the process of examination is maintained in a secured, limited-access area under proper seal. Proper security may be achieved by storing evidence in locked cabinets, refrigerators or freezers, vaults, or rooms. Limited access is access limited to personnel authorized by the appropriate division director. Access has been granted by the division director if the staff member has a key, alarm code, or badge that allows access to a given area of HFSC. Individuals who have not been granted access to certain areas of HFSC may enter those areas if they are escorted by a staff member who has been granted access.

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

5.8.5.2.1. Without a justifiable expectation of frequent analyses or examination, then evidence is maintained in a secured limited-access area under proper seal.

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

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

5.8.5.5. When evidence is collected off-site by HFSC staff members, the evidence is packaged in separate containers to prevent loss, cross-transfer, contamination, and/or deleterious change, whether sealed or unsealed, during transport to HFSC or evidence storage facility. When appropriate, further processing to preserve, evaluate, document, or render evidence safe is accomplished prior to final packaging. Evidence collected from an off-site location by HFSC staff members is identified, packaged, and entered into the evidence management system, RMS, or LIMS as soon as practical.

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

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

Samples not created by HFSC but handled temporarily for database entry purposes may not be treated as evidence but will be handled in a way that protects the integrity of the samples and their usefulness for comparative purposes.

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

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

5.9. Assuring the Quality of Test Results

5.9.1. Sectional SOPs will define applicable quality control procedures for monitoring the validity of tests undertaken. These data are recorded so that trends are detectable and so that, when practical, statistical techniques can be applied to the review of these results. To ensure the quality of forensic results, HFSC may subject completed casework to retesting and case records to secondary review. This monitoring will be planned and reviewed and may include the following:

- use of certified reference material and/or internal quality control using secondary
reference material
- participation in a proficiency-testing program
- replicate testing
- retesting of items
- correlation of results for different characteristics of an item

When applicable, appropriate controls and standards will be specified in sectional SOPs, and their use will be recorded in the case record.

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

5.9.3. HFSC maintains a documented proficiency-testing program. The proficiency of all technical personnel is tested to the extent of their casework authorizations. This proficiency program is a reliable means of verifying that HFSC’s technical procedures are valid and that the quality of each technical employee’s work is maintained. The purpose of proficiency tests is to demonstrate the ongoing competence of HFSC and/or that of its technical employees and to identify content areas or skill sets for which additional training or more stringent quality control may be necessary.

Proficiency samples may be either internal or external. Internal tests are developed by HFSC and may involve the reanalysis of previously tested samples or, in the case of crime scene processing, an observatory evaluation. External tests are examinations prepared by, provided by, and reported to sources outside HFSC.

Technical review, verification, and administrative review policies will be followed as they are in casework. Should consultation be required, the one or more individuals with whom the proficiency is discussed may not perform a technical or administrative review of the test. Consultation may not be with individuals who have knowledge regarding the test beyond the information that is available from the individual performing the test in question. If the individual consulted is aware of results or observations made by another staff member, that information may not be used to aid the test taker. This does not preclude one individual from reviewing multiple tests or from acting as a second reader on multiple tests. These statements do not apply if the proficiency evaluation is a blind test and participants are not aware they are being tested. The section manager or quality director 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 provider, then that test is deemed “unsuccessful” and corrective action is initiated.

5.9.3.1. When completing proficiency tests, those tested will follow HFSC’s own approved methods as closely as possible. 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.

5.9.3.2. HFSC’s proficiency program will comply with the requirements of its accrediting body.

5.9.3.3. Each technical staff member and technical support person engaged in non-DNA testing activities will successfully complete at least one proficiency test per calendar year in forensic disciplines in which he/she has been qualified. DNA analysts and technicians will complete two tests per year. Successfully completing a proficiency test means either obtaining the expected results or completing appropriate corrective actions. This test may be internal or external. A competency test may take the place of a proficiency test during the first calendar year that an analyst is authorized to conduct casework. However, DNA analysts and technicians will enter the proficiency-testing program within six months of competency.

Proficiency tests are evaluated both in terms of conformance to the expected results and the quality of supporting documentation. Significant discrepancies between the reported results and the expected results will be handled according to HFSC’s corrective action policy. 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.

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

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

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

5.9.3.5. Records of proficiency testing may include:

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

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

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

5.9.4. HFSC conducts a technical review of examination records and test reports to ensure that conclusions of technical employees 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. Reviews are conducted by individuals having expertise gained through training and experience in that category of testing, and a record of the review is made to indicate that the conclusion has been checked and agreed to, by whom, and when.

The Evidence Collection Division will perform a technical review on at least 25% of each investigator’s casework. These reviews should be spread out to cover processing completed throughout the year. A technical review will be conducted on at least 25% of the audio/video casework completed each month. This review must cover a sampling of each examiner’s work. Other HFSC disciplines are required to complete a technical review on 100% of completed casework.

When an area of concern is identified that cannot be resolved between the technical employee 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.

5.9.4.1. The technical review includes a review of all examination records and the test report to ensure:
• records and the report conform with proper technical sectional procedures and quality policies
• the report is accurate and the data support the results and/or conclusions in it
• associations are properly qualified, if applicable
• the report contains all the required information

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

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

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

5.9.5.1. The administrative review includes:
• review of the test report for spelling and grammatical accuracy
• review of all administrative records to ensure that the assigned unique case identifier is on each page
• review of all examination records to ensure that the unique case identifier and technical employee initials or signature are on each page
• review of the report to ensure that all key information (see 5.10.2 and 5.10.3) is included

Unless approved in advance by the appropriate division director or his/her designee, the technical review and administrative review will not be conducted by the same individual.

5.9.6. The testimony of HFSC technical staff members is monitored at least once each calendar year. More frequent monitoring may be appropriate for inexperienced personnel. A copy of the completed evaluation form is stored in a retrievable format. Testimony may be monitored through direct observation (preferably by the section supervisor or his/her designee), a review of court transcripts, through solicitation of court officials, videotaped testimony, or other means whereby the following can be evaluated:
• appearance and poise
• clarity of communication
• identification of evidence
• ability to present scientific information in an easily understood manner
- consistency of testimony with case documentation
- performance under cross-examination

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

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

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

5.10. Reporting the Results

5.10.1. General

HFSC testing results are reported accurately, clearly, unambiguously, and objectively. These results are reported in LIMS and include information requested by the customer, information necessary for the interpretation of the results, and all information required by the method used. An accrediting body’s symbol may be 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 prior to coding into LIMS.

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

Discrepancies in case-related information may result in HFSC’s refusal to accept or analyze the evidence in question. In those cases, HFSC nonetheless provides a report. Examples of discrepancies that may result in a report to the customer 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 customer case identifier) on evidence labels
• improper seals on outermost evidence container
• 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

Additional information may be found in sectional SOPs. Minor discrepancies will be noted in the case record and may also be included in reports issued by HFSC

5.10.1.1. It is not necessary to issue a test report if HFSC receives a written request to terminate analysis before the work is completed. This written request, which may be submitted by email, will become a part of the case record. If all analytical work is completed before the request is received, a report will be written. Analytical work related to training and validation studies do not require a report. Non-analytical work also does not require a written report. Only infrequently and only when approved in writing by a supervisor, manager, or a designee may technical results be released to a customer before the report is issued. The reasons for issuing results without a report must be compelling and extraordinary (e.g., where a serious incident is being actively investigated and the technical results may offer key leads to successful and rapid resolution of the incident). When technical results are released prior to issuing a report, this fact should be documented in the case record, which should include a description of the results released.

5.10.2. Test Reports
The following supporting information, if applicable, is available in the case record and may be included in the test report:
• identification of methods used
• description and identification of items tested
• date the testing was performed
• sampling plan, if relevant to the validity of the results
• statement that the results relate only to the items tested
• changes to the test method
• estimated UM

5.10.3. Additions to Test Reports
5.10.3.1. In addition to the information listed in 5.10.2, test reports will, where necessary for the interpretation of the results, include the following:
• deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions
• statement of compliance/noncompliance with requirements and/or specifications
• information on uncertainty when it is relevant to the validity or application of the
test results, when a customer requests the information, or when the uncertainty affects compliance to a specification limit
- opinions and interpretations
- additional information that may be required by specific methods or customers

5.10.3.2. In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following when necessary for the interpretation of test results:
- date(s) of sampling
- unambiguous identification of the substance sampled
- location of sampling, including photographs, if applicable
- reference to the sampling plan and procedures used
- details of any environmental conditions during sampling that might affect the interpretation of the test results
- deviations from the established sampling plan

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

Verbal results may be released only by the assigned technical employee, the section’s technical management, or a qualified technical employee. This verbal release of information should be documented within the case record. See 5.10.1.1 for further information.

5.10.3.3. Outsourced reports will be scanned into LIMS.

Case-related information will not be released directly to the news media, family members, or others without permission of top management but will be released as directed by court order.

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

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

5.10.4. Calibration Certificates

HFSC does not issue calibration certificates.
5.10.5. Opinions and Interpretations

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

5.10.6. Testing Results Obtained from Subcontractors

Results of tests performed by subcontractors are clearly identified as such.

5.10.7. Electronic Transmission of Results

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

5.10.8. Format of Reports

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

5.10.9. Amendments to Test Reports

An amended report will be issued when necessary and will clearly communicate the reason for the amendment. The new report will be clearly identified and will contain a reference to the original report that it is replacing. Amending reports may require the assistance of HFSC’s LIMS administrator.
6. Communication and Correspondence Procedure

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

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

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

Refer to the HFSC confidentiality policy for further information.
7. Laboratory Information Management System

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

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

Information contained in LIMS is incorporated into monthly reports and yearly management reviews. Additional reports can be written to address individual or sectional needs.
8. Legal Requests, Public Information Act Requests, and Disclosures of HFSC Information

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

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

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

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

For situations not listed above, the appropriate key management personnel should be contacted for assistance.
9. Conflict of Interest and Undue Influence

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

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

All staff members have the obligation to safeguard confidential information obtained in an official capacity. Staff members are prohibited from accessing or disclosing any confidential information except when legally authorized and are responsible for safeguarding it from unauthorized distribution.

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