# BFS Quality Manual

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## 1 Introduction

### Mission statement

The California Department of Justice Bureau of Forensic Services (BFS) provides high quality, impartial forensic service in the interest of public safety and justice.

### Vision statement

BFS seeks to be a center of excellence in forensic science services by:

- Implementing efficient, effective, and high quality forensic techniques.
- Meeting or exceeding the highest forensic professional standards.
- Delivering to employees the highest level of training.
- Providing state-of-the-art facilities and equipment.

### Values

To achieve this vision, BFS commits to these values:

- Ensuring examinations are performed with uncompromising scientific independence and objectivity.
- Providing meaningful results in a timely manner.
- Applying quality in all efforts.
- Recognizing the worth of each employee.
- Sharing expertise and resources bureau wide.
- Ensuring the confidentiality of all records.

### Principles

BFS is committed to principles of service consistent with its values and mission, including:

- Providing a work product that is accurate, unbiased, and scientifically objective.
- Communicating openly with clients to ensure mutual understanding of anticipated services.
- Continually improving the quality and quantity of laboratory services.
- Developing knowledge, skills, and abilities of laboratory personnel.
- Motivating staff to enthusiastically implement the Quality Management System.
- Protecting the confidentiality of victim and suspect information as well as specific analytical results.

### Goals and objectives

In pursuit of its vision and in accordance with its values and principles, BFS has developed business and strategic plans. These plans outline BFS goals and define the measurable objectives required to attain them.
The Quality Management System is defined in the following documents:
- Quality Manual
- Discipline manuals, containing:
  - Technical procedures, which include quality control procedures
  - Training curricula
  - Quality assurance procedures
- Worksheets
- Templates, such as the Internal Audit Report, etc.
- Software and Databases
- Lab Policies
- Critical Action Bureau Policies
- JusticeTrax Manual (Laboratory Information Management System)
- Safety Manual
- Laboratory operations manuals, containing site-specific information
- BFS business and strategic plans

The Quality Management System applies to all units that perform and support forensic examinations that are within the BFS scope of accreditation by ASCLD/LAB-International.

**BFS adheres to a Quality Management System that follows the standards of the normative references.**

To conform to these standards, management and staff are committed to:
- Delivering quality services to client agencies using best professional practices.
- Providing a standard of service that meets or exceeds ISO/IEC 17025 and ASCLD/LAB-International requirements.
- Adhering to the Quality Management System for the purpose of ensuring the quality of client-provided services.
- Ensuring that all laboratory personnel are familiar with the Quality Management System documentation.
- Implementing the policies and procedures of the Quality Management System.
- Continually improving the effectiveness of the Quality Management System through the active participation of BFS staff.

BFS affirms its commitment to the Quality Management System and to this quality policy statement issued under the authority of the Bureau Chief.
2 Normative References

This quality manual addresses the requirements of the following normative references:


- U.S. Department of Justice (DOJ), Federal Bureau of Investigation (FBI), The FBI Quality Assurance Standards Audit for Forensic DNA Testing Laboratories, 2011.


- U.S. Department of Justice (DOJ), Federal Bureau of Investigation (FBI), The FBI Quality Assurance Standards Audit for DNA Databasing Laboratories, 2011.


## 3 Definitions

### Acceptance criteria
Specified indicators or measures employed in assessing the ability of a procedure to perform its intended purpose.

### Administrative records
Administrative records are case-specific documentation other than technical records: Examples include:
- Chain-of-custody.
- Client investigation reports.
- Service requests and records of all client communications.
- Technical and administrative reviews.

### Administrative review (AR)
A procedure used to check administrative and technical records for consistency with laboratory policy and editorial correctness.

### Alcohol
A forensic discipline that determines the level of ethyl alcohol in forensic samples.

### Analyst
An individual who conducts and/or directs the analysis of forensic casework samples, interprets data, and reaches conclusions. Used synonymously with “examiner.”

### Assistant Bureau Chief (ABC)
The Assistant Bureau Chief, under the direction of the BFS Chief, helps formulate and implement policy and procedures essential to BFS’s mission. Along with laboratory management, the Assistant Bureau Chief is responsible for the delivery of day-to-day services to the criminal justice system.

### Assistant Laboratory Director (ALD)
Under the direction of the Laboratory Director, the Assistant Laboratory Director fulfills BFS’s goals and objectives and directs the day-to-day operations of the laboratory.

### Biology
A forensic discipline concerned with the identification of biological materials.

### Bureau Chief (BC)
The Bureau Chief provides leadership consistent with the mission statement by achieving measurable objectives and also coordinates activities of the entire bureau.

### Bureau of Forensic Services (BFS)
A bureau within the California Department of Justice with the mandate to provide forensic services to law enforcement agencies within the State of California. The Bureau of Forensic
| **Bureau Quality Assurance Manager (BQAM)** | The Bureau Quality Assurance Manager, under the direction of the Bureau Chief, is responsible for monitoring compliance with the BFS Quality Management System and implementing corrective actions as needed. |
| **Calibration** | A measurement or a series of measurements made by an outside vendor that establishes a relationship between known measurement reference standards and a laboratory’s measurement equipment. When used to establish measurement traceability, the calibration also demonstrates a connection to the international system of units and has a related uncertainty associated with the calibration. A calibration should not be confused with an adjustment of measurement equipment (self-or auto-calibration) or with a verification of calibration (Intermediate Check). |
| **Case file** | The hard-copy portion of the case record. |
| **Case record** | Documentation that includes administrative, quality, and technical records, either in hardcopy or electronic form, pertaining to a particular case. |
| **Category of testing** | A specific type of analysis within an accredited discipline of forensic science. |
| **Certificate to Perform Casework or Data Bank Work** | A form used to document the authorization by laboratory management for an analyst to perform casework or data bank work as described on the form. This documentation is commonly referred to as “authorization” to perform casework or data bank work. |
| **Certified reference material (CRM)** | A specific type of reference material that is purchased with certification documenting that the material meets specific property values (e.g. concentration or purity) and includes information on the associated traceability and uncertainty. |
| **Chain of custody** | Procedures to maintain and document the chronological history and account for the integrity of each item of evidence by tracking its handling and storage while the evidence is under BFS control. |
Client agency

An authorized government agency that submits evidence or samples to BFS for scientific examinations. Client agencies expect BFS to deliver independent and unbiased forensic services conforming to its Quality Management System. BFS retains the final authority to make decisions with respect to the scope of services to be provided, the examinations to be performed and the reports generated.

For the purpose of this manual the terms customer, client and client agency are synonymous.

Competency

The requisite knowledge, skills and abilities to perform a critical task.

Competency test

The final examination provided to a trainee after completion of a training curriculum is successfully completed. It evaluates an examiners ability to work in any discipline prior to commencement of independent casework.

Computer systems

A complete, working computer to include any software and peripheral devices.

Conclusion

A statement in an examination report which summarizes the interpretations of examination results. The criteria for interpretations are specified in the discipline manuals.

Continuing education

The process of maintaining knowledge in a discipline.

Control

An examination performed in parallel with experimental samples and designed to demonstrate that a procedure worked correctly.

Controlled document

A document that is distributed in such a way as to ensure that the recipients only have access to the latest approved revisions. Examples of controlled documents include: Quality Manual, Discipline Manuals and forms.

Controlled Substances

A forensic discipline that identifies legislatively controlled drug substances and related materials.

Corrective action

The process used to correct a level I or level II nonconformance.
<table>
<thead>
<tr>
<th><strong>Criminal Justice System</strong></th>
<th>The system which promulgates the judicial process in California. The system is primarily comprised of judges, district attorneys, and law enforcement agencies.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical Action Bureau policies and procedures</strong></td>
<td>Critical Action Bureau policies and procedures are generated by the Bureau Chief, or designee, in response to a quality-related situation that requires immediate action, and may circumvent the usual improvement process (QM 4.10). Such policies and procedures may be revised, rescinded, or incorporated into existing Quality Management System documents as needed.</td>
</tr>
<tr>
<td><strong>Critical measurement</strong></td>
<td>A measurement that may have a judicial or regulatory significance such as, references to measurement values in the California Code of Regulations that have an effect on prosecution. For example, weight enhancements for controlled substances cases and blood alcohol concentrations for driving under the influence cases. These measurements typically require traceability and an estimation of uncertainty.</td>
</tr>
<tr>
<td><strong>Critical supply and service</strong></td>
<td>A supply or service which must meet one or more essential specifications to ensure the quality of a test result.</td>
</tr>
<tr>
<td><strong>Critical tasks</strong></td>
<td>Critical tasks are those skills or duties related to the collection and examination of samples, including conducting visual and chemical examinations, operating equipment, interpreting results, providing opinions, and generating reports.</td>
</tr>
<tr>
<td><strong>Developmental validation</strong></td>
<td>The initial scientific research, formulation, and validation of a novel technical procedure.</td>
</tr>
<tr>
<td><strong>Digital evidence</strong></td>
<td>Information of probative value that is stored or transmitted in binary form.</td>
</tr>
</tbody>
</table>
| **Discipline manual** | A manual produced by subject matter experts, usually Technical Advisory Groups which details:  
  • The approved technical procedures for use in examinations of a discipline.  
  • The training curricula used to train analysts to perform in independent casework in a discipline. |
<p>| <strong>DNA</strong> | The identification and comparison of genetic markers from biological material. |</p>
<table>
<thead>
<tr>
<th>Document</th>
<th>Information in any medium including, but not limited to, paper copy, computer disk or tape, audio or videotape, photograph, overhead or photographic slide.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document control</td>
<td>The process for ensuring that controlled documents, including revisions, are reviewed, approved and released by authorized personnel (issuing authority), and only the latest approved revisions are available to personnel performing the prescribed activities.</td>
</tr>
<tr>
<td>Environmental conditions</td>
<td>Any characteristic of a laboratory facility that could impact the results of an examination (for example, lighting, heating, air conditioning, ventilation, plumbing, wiring, adequacy of exhaust hoods/bio-safety cabinets, etc.).</td>
</tr>
<tr>
<td>Evidence</td>
<td>Equivalent to “test item” as described in ISO/IEC 17025 / Section 5.8.</td>
</tr>
<tr>
<td>Examination</td>
<td>A process which uses approved technical procedures to characterize, quantitate or interpret evidence items.</td>
</tr>
<tr>
<td>Examination documentation</td>
<td>Referred to in the BFS Quality Manual as Technical Records.</td>
</tr>
<tr>
<td>Examination report</td>
<td>The formal results of a requested analysis provided to clients.</td>
</tr>
<tr>
<td>Examiner</td>
<td>An individual who conducts and/or directs the analysis of forensic casework samples, interprets data, and reaches conclusions. Used synonymously with analyst.</td>
</tr>
<tr>
<td>Field investigations</td>
<td>A forensic discipline which identifies, documents, collects, and interprets evidence at a location external to BFS laboratory facilities.</td>
</tr>
</tbody>
</table>
| Firearms / toolmarks | A forensic discipline which examines and compares evidence:  
  • Resulting from discharge and/or use of firearm.  
  • Resulting from marks made by tools. |
<p>| Focus group       | A small group of representative people, usually appointed by BFS Management, tasked with the study or analysis of a Quality Management System issue. For example, BFS Technical Advisory Groups are focus groups that oversee the technical aspects of BFS operations. |</p>
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement process</td>
<td>The process used by BFS to continuously evaluate and improve its Quality Management System. It encompasses the corrective action, preventive action and change processes.</td>
</tr>
<tr>
<td>Individual characteristic database</td>
<td>A collection, in computerized, searchable form, of unique and identifiable features associated with an object or person.</td>
</tr>
<tr>
<td>Individual characteristic database sample</td>
<td>A specimen of known origin from which individual characteristic information originates (e.g. reference blood or biological specimens, fingerprints of known individuals, electronic fingerprint records, test fired ammunition).</td>
</tr>
<tr>
<td>Intermediate check</td>
<td>A process used to verify the continued reliability of reagents or equipment. The procedures for intermediate checks are specified in each Discipline Manual.</td>
</tr>
<tr>
<td>Internal audit</td>
<td>A review conducted by BFS personnel to verify compliance of all elements of the Quality Management System including examinations.</td>
</tr>
<tr>
<td>Internal validation</td>
<td>Validation that occurs within BFS by qualified BFS personnel. Internal validations are performed to assess whether external procedures provide acceptable results within BFS facilities.</td>
</tr>
<tr>
<td>Issue Date</td>
<td>The date on which a Quality Management System document is posted to the Bureau document control system, and the date on which it is expected that BFS staff will fully comply with all policies and procedures therein.</td>
</tr>
<tr>
<td>Issuing authority</td>
<td>The person who authorizes a controlled document to be issued on the Bureau document control system. The issuing authority for all controlled documents in BFS is the Bureau Chief.</td>
</tr>
<tr>
<td>Key management</td>
<td>The key management includes the Bureau Chief, Assistant Bureau Chiefs, Bureau Quality Assurance Manager, Laboratory Directors, Assistant Laboratory Directors and any acting Assistant Laboratory Directors.</td>
</tr>
<tr>
<td>Laboratory Director (LD)</td>
<td>Under the direction of the Assistant Bureau Chief, the Laboratory Director fulfills BFS’s goals and objectives and directs the laboratory’s day-to-day services.</td>
</tr>
<tr>
<td>Laboratory Management</td>
<td>The personnel responsible for the administrative and technical management of BFS laboratories, which is usually comprised of Laboratory Director and Assistant Laboratory Director(s).</td>
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<tr>
<td>-----------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Latent Prints</td>
<td>A forensic discipline which develops and compares friction ridge impressions.</td>
</tr>
<tr>
<td>Management Review</td>
<td>A formal review of all elements of the Quality Management System by Laboratory Management done in addition to Internal Audits. The Management Review considers the overall system and assesses its effectiveness and relevance.</td>
</tr>
<tr>
<td>Minor Issue</td>
<td>Any issue that has minimal effect or significance, is not systemic, and does not significantly affect the fundamental reliability of the laboratory’s casework.</td>
</tr>
<tr>
<td>Non-conformance</td>
<td>Work that does not conform to the Quality Management System.</td>
</tr>
<tr>
<td>Non-standard procedures</td>
<td>Analytical methods developed by technical organizations, published in relevant scientific texts or journals, provided by instrument or reagent manufacturers, or analytical methods obtained from other laboratories that are not in the BFS Discipline Manuals.</td>
</tr>
<tr>
<td>Normative references</td>
<td>Quality standards that BFS adheres to in its policies, documentation, and services which it provides to the criminal justice system. BFS is evaluated against these standards during audits.</td>
</tr>
<tr>
<td>Objective</td>
<td>A measurable, definable accomplishment, which furthers the goals of BFS.</td>
</tr>
<tr>
<td>Opinion</td>
<td>A statement in an examination report which summarizes the interpretations of examination results in disciplines without established identification criteria. Reporting guidelines are in the discipline manuals.</td>
</tr>
<tr>
<td>Performance verification</td>
<td>A set of operations to determine if a piece of equipment produces examination results consistent with specified parameters. Performance verifications are done when:</td>
</tr>
<tr>
<td></td>
<td>• New equipment of the same technology is received in a laboratory for use with existing technical procedures.</td>
</tr>
<tr>
<td></td>
<td>• Existing equipment is moved to another physical location.</td>
</tr>
<tr>
<td></td>
<td>• Existing equipment is modified or undergoes maintenance which may change its performance.</td>
</tr>
<tr>
<td>Policy</td>
<td>A guiding principle, operating practice, or plan of action governing decisions made on behalf of BFS.</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Preventive action (PA)</td>
<td>An action to eliminate the cause of a potential nonconformance or other undesirable potential situation.</td>
</tr>
<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 employed.</td>
</tr>
<tr>
<td>Proficiency test</td>
<td>An internally or externally produced test used to evaluate the continuing capability of analysts and the performance of BFS.</td>
</tr>
<tr>
<td>Proper seal</td>
<td>A seal that prevents loss, cross transfer, or contamination while ensuring that attempted entry into the container is detectable.</td>
</tr>
<tr>
<td>Quality assurance</td>
<td>Those planned and systematic actions necessary to provide sufficient confidence that a laboratory’s product or service will satisfy given requirements for quality.</td>
</tr>
<tr>
<td>Quality assurance officer (QAO)</td>
<td>Under the direction of the Laboratory Director or Assistant Laboratory Director, the BFS Quality Assurance Officer (QAO) performs many duties related to the Quality Management System.</td>
</tr>
<tr>
<td>Quality control</td>
<td>Activities and processes used to monitor the quality of analytical data and ensure that it satisfies specific criteria.</td>
</tr>
<tr>
<td>Quality control check</td>
<td>A procedure used to ensure the continued reliability and accuracy of reagents, equipment, and analytical results. The checks may take the form of validations, performance verification, intermediate checks, or reanalysis of casework. The criteria for each of these checks are outlined in Section 5.1 (Reagents) and Section 5.5 (Equipment), as well as in any applicable technical procedures.</td>
</tr>
<tr>
<td><strong>Quality Management System (QMS)</strong></td>
<td>The organizational structure, responsibilities, procedures, processes and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly.</td>
</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td><strong>Quality Manager</strong></td>
<td>The individual who has the defined authority to ensure that the requirements of the Quality Management System are implemented and maintained. In most laboratories the Laboratory Director serves as the Quality Manager. In the Richmond DNA facility the Assistant Bureau Chief serves as the Quality Manager.</td>
</tr>
<tr>
<td><strong>Quality Manual</strong></td>
<td>The manual defining the BFS Quality Management System.</td>
</tr>
</tbody>
</table>
| **Quality records** | Quality records include:
- Reports from audits, management reviews, corrective, preventive, and change events.
- Validations, reagent checks, equipment performance verifications. |
| **Reagent** | A substance used because of its chemical or biological activity. |
| **Receiving party** | Regardless of who or where it comes from, the receiving party is the first BFS staff member who physically takes possession of the evidence package or shipping container. |
| **Records** | Documents or other data that are complete and unchangeable. BFS maintains quality, technical and administrative records. |
| **Reference material** | Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties.
- Reference material is typically used for:
  - Establishing the identity of an unknown substance
  - Comparison purposes
  - Performing quality control checks
  - Quantitative analysis (see **Certified Reference Material**)
  - Method validation and method development |
<p>| <strong>Reference standard</strong> | A measurement standard (e.g. a weight set or thermometer) that is routinely used in BFS to verify measuring equipment or instruments and, when necessary, is traceable to the international system of units (SI) through periodic calibrations. Also known as <strong>measurement standard</strong> or <strong>measurement reference standard</strong>. |
| Request for analysis | The submission of evidence to a laboratory of BFS by a customer with the anticipation that examinations will be performed that may be helpful in the resolution of a criminal matter. |
| Root cause analysis | A process of fact finding used to identify the root cause of a nonconformance. |
| Sample selection | A practice of selecting items to test, or portions of items to test, based upon training, experience and competence. In sample selection, there is no assumption of homogeneity. Sample selection may also be based on judicial requirements. |
| Sampling | Taking a part of a substance, material, or product for testing in order to reach a conclusion or make an inference about, and report on the whole. Sampling should only be used when there is a reasonable assumption of homogeneity of the whole. |
| Sampling plan | For an item that consists of a multi-unit population (e.g. tablets, baggies, bindles), a sampling plan is a statistically valid approach to determine the number of sub-items that must be tested in order to make an inference about the whole population. |
| Sampling procedure | A defined procedure used to collect a sample or samples from the larger whole, to ensure that the value obtained in the analysis is representative of the whole. The sampling procedure may include details about size and number of sample(s) to be collected, locations from which to collect the sample(s), and a method to ensure the homogeneity of the larger whole (or to make it so.) |
| Secure area | A locked space with limited access usually used for the storage of evidence. |
| Standard analytical method | An officially recognized analytical method published in international, regional, or national standards. Examples of standard analytical methods are contained in <em>Official Methods of Analysis of AOAC INTERNATIONAL.</em> |
| Subcontractor | An outside vendor utilized by BFS to conduct analytical work. |
| Subject matter expert (SME) | An individual with expertise in a certain area of the Quality Management System. TAGs are comprised of subject matter experts in their discipline. |</p>
<table>
<thead>
<tr>
<th><strong>Technical Advisory Group (TAG)</strong></th>
<th>A group of BFS personnel assembled to address technical issues in the specific disciplines utilized in BFS laboratories. The TAG is assembled and led by the TAG facilitator appointed by the Bureau Chief. TAGs are responsible for drafting and maintaining technical procedures and training curricula.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TAG Facilitator</strong></td>
<td>An individual appointed by the Bureau Chief to provide technical leadership and responsibility for specific disciplines utilized in BFS laboratories and has technical responsibility for the discipline manual. The TAG facilitator coordinates available subject matter experts to address any relevant issues.</td>
</tr>
<tr>
<td><strong>Technical leader</strong></td>
<td>The technical leader manages the technical operations of a specific discipline in a laboratory. BFS only has technical leaders in DNA laboratories.</td>
</tr>
<tr>
<td><strong>Technical procedure (TP)</strong></td>
<td>The course of action or technique followed in conducting a specific examination or comparison leading to an analytical result.</td>
</tr>
</tbody>
</table>
| **Technical records** | Technical records include:  
  • Case-specific documentation related to the examination of samples.  
  • Photographs, worksheets, observations, charts, diagrams, derived data  
  • When appropriate, reference to quality records such as validations, reagent checks, equipment performance verifications.  
  • Uncertainty of measurement, if applicable. |
<p>| <strong>Technical review (TR)</strong> | A review of the case record to ensure that proper technical procedures were used and documented, and that the results are supported by the notes. |
| <strong>Top management</strong> | Bureau top management consists of the Bureau Chief, Assistant Bureau Chiefs and Bureau Quality Assurance Manager. The Laboratory Director is the top management of a Laboratory. |
| <strong>Toxicology</strong> | A forensic discipline which analyzes biological samples for the presence of drugs. |
| <strong>Traceability</strong> | The property of a measurement result in which the result is related to the international system of units (SI) through an unbroken chain of comparisons (i.e. calibrations) with each comparison in the chain contributing to the overall uncertainty of measurement. Also known as measurement traceability, or metrological traceability. |</p>
<table>
<thead>
<tr>
<th>Trace Evidence</th>
<th>A forensic discipline which utilizes microscopic, chemical or instrumental techniques to examine trace evidence.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertainty of measurement</td>
<td>A quantitative estimate of the variability associated with a measurement result based on information that is known about the measurement process. Also known as measurement uncertainty or uncertainty.</td>
</tr>
<tr>
<td>Uncontrolled document</td>
<td>Documents that are not a part of the BFS document control system or copies of a controlled document provided for informational purposes only. Examples include copies provided to external inspectors or copies required for legal discovery.</td>
</tr>
<tr>
<td>Validation</td>
<td>A process used by the scientific community for acquiring the necessary information to assess equipment or a technical procedure to determine if it produces expected results.</td>
</tr>
</tbody>
</table>
4 Management Requirements

4.1 Organization

Policy

BFS provides publicly supported forensic services to law enforcement agencies in California.

Statutory authority (4.1.1)

The Bureau of Forensic Services (BFS) is a bureau within the Division of Law Enforcement (DLE) of the California Department of Justice (DOJ) deriving its statutory authority from California Penal Code section 11050.5.

Work for clients and accreditation requirements (4.1.2)

BFS laboratories provide forensic examinations, interpretations, and other forensic science services in accordance with standards set forth in the normative references.

BFS provides a broad range of impartial forensic services that are useful to law enforcement agencies submitting evidence for the purpose of accurate and objective examinations.
Work covered by Quality Management System (4.1.3)

The BFS Quality Management System covers all work carried out in its permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

BFS laboratories conduct forensic examinations across a broad range of physical evidence. The examinations fall within the following forensic disciplines and categories of testing:

<table>
<thead>
<tr>
<th>Drug Chemistry</th>
<th>Latent Prints</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Controlled Substances</td>
<td>• Latent Print Processing</td>
</tr>
<tr>
<td>• General Chemical Testing</td>
<td>• Latent Print Comparisons</td>
</tr>
<tr>
<td>• Clandestine Laboratory Analysis</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicology</th>
<th>Crime Scene</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Human Performance Forensic Toxicology</td>
<td>• Crime Scene Investigation</td>
</tr>
<tr>
<td>• Blood/Urine Alcohol</td>
<td>• Crime Scene Reconstruction</td>
</tr>
<tr>
<td>• Blood/Urine Drug</td>
<td>• Clandestine Laboratory Investigation</td>
</tr>
<tr>
<td>• Alcohol Beverage Analysis</td>
<td>Note: Crime scene reconstruction may include firearms trajectories, bloodstain pattern analysis, sequence of events, etc.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Biology</th>
<th>Digital and MultiMedia Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>• DNA (Nuclear)</td>
<td>• Computer Forensics</td>
</tr>
<tr>
<td>• DNA (Mitochondrial)</td>
<td></td>
</tr>
<tr>
<td>• Individual Characteristic Database</td>
<td></td>
</tr>
<tr>
<td>• Body Fluid Identification (including hair screening)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Trace Evidence</th>
<th>Firearms and Toolmarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Paint</td>
<td>• Firearms</td>
</tr>
<tr>
<td>• Fiber and Textiles</td>
<td>• Toolmarks</td>
</tr>
<tr>
<td>• Gunshot Residue</td>
<td>• Impression Evidence</td>
</tr>
<tr>
<td>• Glass</td>
<td>• Serial Number Restoration</td>
</tr>
<tr>
<td>• Hair</td>
<td></td>
</tr>
<tr>
<td>• Explosives</td>
<td></td>
</tr>
<tr>
<td>• Fire Debris</td>
<td></td>
</tr>
<tr>
<td>• General Physical/Chemical Analysis</td>
<td></td>
</tr>
<tr>
<td>• May include polymers, soil, analysis of unknowns, headlamp examination, and physical match comparisons</td>
<td></td>
</tr>
</tbody>
</table>

Note: Physical match comparisons are listed under the Trace Evidence discipline. However, these may be encountered in many of the disciplines listed.

Note: Disciplines are in **bold**, and categories of testing are listed as bullet points under each discipline.
Organizational structure and responsibilities
(4.1.4, 4.1.5.e, 4.1.4.1, and 4.1.4.1.1)

BFS is a part of the California Department of Justice. The authority for BFS technical operations resides within the management structure of BFS.

The BFS Bureau Chief coordinates all administrative and technical activities of the bureau through its headquarters consisting of an administrative unit and the Quality Assurance Unit.

The Bureau Chief delegates authority and responsibility to the Laboratory Director for the day-to-day activities of one or more laboratory locations. The laboratory director has the authority to make and enforce all decisions in their area of responsibility and act as the Quality Manager for assigned locations.

The specific programs provided at each laboratory are described in each laboratory’s operations manual. The laboratories of BFS are organized as follows:

- Regional laboratories providing distributed forensic services from Central Valley, Chico, Eureka, Fresno, Freedom, Redding, Riverside, Sacramento, Santa Barbara, and Santa Rosa.
- Specialized Laboratories
  - California Cyber Crime Center (C4)
  - Toxicology
- Jan Bashinski DNA Laboratory
  - CAL-DNA Data Bank
  - DNA Casework Program
  - Missing Persons DNA Program
  - DNA Method Development Section
- Support and Training Sections
  - Forensic Alcohol Instrument Repair Information Technology (FAIRIT) Unit
  - California Criminalistics Institute (CCI)

The organizational structure of DOJ is shown in the DOJ Organizational Chart, which includes all those with authority over BFS operations. For a detailed description of the reporting structure of BFS, see the BFS Organizational Charts posted on the Bureau’s document control system.

Personnel with authority and resources for management system (4.1.5a)

As specified in this Quality Manual:

- All BFS personnel are given adequate resources, are aware of the significance of any departure from the Quality Management System, and work to prevent or minimize such departures.
- Managerial and technical personnel have the authority and resources to carry out their duties, including implementing, maintaining, and improving the Quality Management System through the improvement process.
- Laboratory management or the DNA technical leader approves departures from standard technical procedures.
- Only the Bureau Chief can approve bureau wide departures from the Quality Management System.
BFS operates within an environment of uncompromising scientific independence and objectivity.

The BFS Quality Manual and Quality Management System build an environment of scientific competence, impartiality, judgment, and operational integrity. The financial compensation to an employee is not influenced by the quantity of work performed or the specific results of an analysis. Additionally, employees are also protected by adherence to the terms of the “Incompatibility Statement of the Department of Justice”.

BFS protects the confidentiality of client case-related information whether in paper or electronic format.

BFS emphasizes to employees the privacy of client information and notifies them that violation of client privacy may subject them to disciplinary action. The distribution of reports is controlled by the case security level required by the client agency. This is further addressed in Section 4.13.1.2 and 4.13.1.3 of this manual.

Additionally, BFS protects examination results and reports by electronically storing them in multiple locations as well as securing the primary hard copy case record in the laboratory.

The authorities, responsibilities, and interrelationships of BFS personnel are specified in these documents:
- State Personnel Board job descriptions
- Duty statements, defined in the employee’s personnel folder
- Employee performance expectations and work plans, included in the employee’s training folder
- Quality Manual, section 4.2
- DOJ and BFS organizational charts

BFS technical staff are accountable to one supervisor per category of testing.

As shown on the BFS organizational chart, each employee has only one administrative supervisor. An employee may be performing casework in multiple categories of testing; however, each employee is accountable to only one supervisor per category of testing.
Forensic staff, including those in training, are managed and supervised by persons familiar with the content and purpose of technical procedures and the assessment of analytical results through the processes specified in this Quality Manual.

This technical management and supervision is provided by:

- Criminalist Manager (Laboratory Director)
- Criminalist Supervisor (Assistant Laboratory Director)
- Latent Print Supervisor (Assistant Laboratory Director)
- Questioned Document Supervisor (Assistant Laboratory Director)
- DNA Technical Leader
- TAG Facilitator

These positions have the overall responsibility for technical operations and to provide the resources needed to ensure the required quality of laboratory operations.

The TAG Facilitator is designated as having the technical responsibility for their respective discipline with one exception. In the Biology discipline, the DNA Technical Leaders are designated as having technical responsibility for testing involving DNA and Data Bank.

All TAG Facilitators and DNA Technical Leaders have the appropriate technical experience in their respective disciplines.

A list of currently appointed TAG Facilitators is located on SharePoint.

Each laboratory has a Laboratory Director whose responsibilities and authorities are defined in Section 4.2 of this manual.

The Laboratory Director is the laboratory Quality Manager except in the Richmond DNA Laboratory, where the Assistant Chief is the Quality Manager.

BFS appoints deputies for key managerial personnel.

BFS headquarters, as well as each laboratory, provides a written, posted chain of command to ensure continuity of management responsibilities, including those responsibilities specified in the Quality Management System. The chain of command establishes who will be in charge of the Bureau, Laboratory and any unit.
Personnel awareness of Quality Management System – communication (4.1.5k and 4.1.6)

BFS ensures that personnel know their role in the achievement of quality service through the Quality Management System.

Staff is informed through the following methods:
- Periodic management meetings convened by the Bureau Chief
- Periodic staff meetings held at the local laboratory level
- Written communications, including electronic mailings
- Formal and informal training
- Focus groups chartered with specific issues
- Form entitled Annual Employee Performance Expectations and Work Plan
- Review of QMS documentation as documented on the Document Review Form.

Meeting agendas

To develop personnel’s awareness of the Quality Management System, BFS will integrate into laboratory staff and management meetings the following topics:
- Bureau activities
- Operations:
  - Personnel
  - Training
  - Administration
  - Casework
- Quality Management System issues
- Health and safety
- Client agency and employee concerns and feedback
- Other topics as needed

Documentation of the meeting and topics discussed is maintained in the laboratory.

Health and safety program (4.1.7)

The responsibility for implementing and maintaining the health and safety program rests with the Laboratory Director, who supervises an appointed laboratory Safety Officer.

The safety officer is responsible for ensuring that the health and safety program is implemented and followed. Safety officers inform laboratory management of deviations from the health and safety program and have the authority to rectify safety violations.

The safety related responsibilities of BFS staff, including appointed laboratory Safety Officers, are defined in the BFS Safety Manual.
Key and top management (4.1.8)

The laboratory system defines key and top management.

Bureau top management consists of the Bureau Chief, Assistant Bureau Chiefs and the Bureau Quality Assurance Manager. The Laboratory Director is the top management of a laboratory and reports to an Assistant Bureau Chief or the Bureau Chief. The Assistant Laboratory Directors report to the Laboratory Director. One of the Assistant Bureau Chiefs or Bureau Quality Assurance Manager will be designated as Acting Bureau Chief when the Bureau Chief is unavailable.

Key management includes the Bureau Chief, Assistant Bureau Chiefs, Bureau Quality Assurance Manager, Laboratory Directors, Assistant Laboratory Directors and any acting Assistant Laboratory Directors. One of the Assistant Laboratory Directors will be designated as the Acting Laboratory Director when the Laboratory Director is unavailable.

Laboratory Directors are key management in Bureau-wide matters and top management in their respective laboratories.

The top or key management also includes any employees designated as acting management.
## 4.2 Quality Management System

| Quality Management System scope (4.2.1 and 4.2.5) | The BFS Quality Management System (QMS) applies to all forensic services, and is available to all staff for their review and use. The Quality Management System  
• is defined in the documents outlined in Section 1,  
• is communicated as described in sections 4.1.5k and 4.1.6, and by bureau-wide QMS documents distributed by the document control system, and  
• incorporates audits and reviews to assess understanding and practice of its content. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality manual (4.2.2)</td>
<td>Policies and objectives of the Quality Management System are defined in the Quality Manual, issued under the authority of the Bureau Chief. The Quality Management System objectives are reviewed annually as part of the management review process.</td>
</tr>
<tr>
<td>Professional responsibility (4.2.2.1 and 4.2.2.2)</td>
<td>BFS provides annual training to all laboratory personnel on forensic science professionalism as a part of our commitment to good professional practice. BFS Laboratory Directors (or their designee) review the ASCLD/LAB <em>Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists</em> WITH all laboratory personnel annually. All laboratory personnel are expected to abide by those principles in the performance of their duties, to include courtroom testimony. Documentation of the review is located in the laboratory.</td>
</tr>
<tr>
<td>Continual improvement of Quality Management System (4.2.3)</td>
<td>BFS is committed to developing, implementing, and continually improving the Quality Management System. BFS staff members, under the authority of the Bureau Chief, developed the Quality Management System in alignment with normative references. The mechanism to effect change in the Quality Management System is the process entitled “Improvement” defined in this manual (section 4.10).</td>
</tr>
</tbody>
</table>

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+++ALL PRINTED COPIES ARE UNCONTROLLED+++
The process for Quality Management System Improvement may be triggered by the following:

- Annual management reviews and internal audits at each laboratory
- Monitoring of client agency communications and surveys to assess positive and negative feedback and forecast trends
- Proficiency testing
- Regular review of manuals by subject matter experts
- Monthly quality checks
- Regular training programs, including continuing education
- Testimony monitoring
- Staff and management meetings

### Meeting client needs (4.2.4)

The importance of meeting client needs as well as statutory and regulatory requirements is emphasized in the Quality Policy Statement (section 1).

### Quality Management System roles and responsibilities (4.2.6)

Every employee is responsible for ensuring compliance with the Quality Management System including the normative references listed in Section 2 of this manual. The roles and responsibilities of technical management and the quality manager, including their responsibility for compliance with the normative references, are defined below.

Employees must report quality issues to their immediate supervisor. If the supervisor is non-responsive or a conflict of interest seems to exist, the employees are empowered and encouraged to elevate the issue to the next level in the chain-of-command.

### Bureau Chief (BC)

The Bureau Chief, responsible for the compliance with the Quality Management System, provides leadership consistent with the mission statement and coordinates BFS activities to achieve measurable objectives.

The Bureau Chief is responsible for the following duties within the Quality Management System:

- Provides overall direction and resources for the Quality Management System
- Evaluates annual internal audits and management reviews
- Issues all Quality Management System documents
Assistant Bureau Chief (ABC)

The Assistant Bureau Chiefs, under the direction of the Bureau Chief, help formulate and implement policy and procedures essential to the BFS mission. The Assistant Bureau Chief coordinates with management of the individual laboratories to deliver day-to-day services to the criminal justice system.

The Assistant Bureau Chiefs are responsible for the following duties within the Quality Management System:

- Approves the outcome of all aspects of the improvement process
- Monitors compliance
- Guides the improvement process in conjunction with the Quality Assurance Manager
- Oversees the Quality Management System in the absence of the Bureau Chief

Bureau Quality Assurance Manager (BQAM)

The Bureau Quality Assurance Manager, under the direction of the Bureau Chief, ensures that the Quality Management System is consistently applied in accordance with the Bureau’s mission statement, goals and objectives and the normative references.

The Bureau Quality Assurance Manager is responsible for the following duties within the Quality Management System:

- Collaborates with the Bureau Chief, Assistant Bureau Chiefs and Laboratory Directors to achieve Quality Management System compliance
- Approves all Quality Management System controlled documents
- Supervises the Quality Assurance Unit
- Coordinates and administers:
  - The external proficiency testing program
  - Monthly quality assurance checks of casework
  - Internal investigations into nonconformance
- Provides administrative guidance to the technical advisory groups
- Continually reviews the Quality Management System
- Monitors the improvement process
### Quality Manager (laboratory)

The laboratory Quality Manager ensures compliance of their laboratory with the BFS Quality Management System and that it is consistently applied in accordance with the Bureau’s mission statement, goals and objectives and the normative references. In most cases, the local Laboratory Director acts as the Quality Manager for the laboratory or region*.

The laboratory Quality Manager is responsible for:
- Implementing the Improvement processes
- Directing the internal audit and management review process
- Communicating regularly with the laboratory Quality Assurance Officer(s) to remain up to date on laboratory quality issues.
- Reviewing monthly quality checks

*Note: The Quality Manager for the Jan Bashinski DNA Laboratory is the Assistant Bureau Chief.

### Laboratory Director (LD)

The Laboratory Director, under the direction of the Assistant Bureau Chief, directs the laboratory’s day-to-day activities. The Laboratory Director* is the Quality Manager of the laboratory, responsible for implementing the Quality Management System.

Working with the Assistant Laboratory Directors and Quality Assurance Officer(s), the Laboratory Director performs the following duties within the Quality Management System:
- Monitors the adequacy, safety, and security of the laboratory facility
- Monitors:
  - Casework assignments to ensure efficiency and maximize productivity
  - Casework, reports, and testimony for quality
- Reviews and evaluates proficiency test results
- Evaluates staff’s training needs to improve quality of the work product
- Recommends personnel action to the Assistant Bureau Chief, as necessary
- Conducts periodic staff and management meetings
- Reviews monthly quality checks
- Prepares the Laboratory Operations Manual
- Implements the:
  - Improvement processes
  - Internal audit and management review process

*Note: The Quality Manager for the Jan Bashinski DNA Laboratory is the Assistant Bureau Chief.
### Assistant Laboratory Director (ALD)

Under the direction of the Laboratory Director, the Assistant Laboratory Director fulfills BFS’s goals and objectives and directs the day-to-day operations of the laboratory.

The Assistant Laboratory Director is responsible for the following duties within the Quality Management System:

- **Ensures:**
  - Staff awareness and compliance with the Quality Management System
  - Performance of technical and administrative reviews
  - Adherence to quality control processes
- **Monitors:**
  - Casework assignments to ensure efficiency and maximize productivity
  - Testimony
- **Administers** the proficiency-testing program.
- **Reviews** client requests as specified in section 4.4
- **Notifies** the Laboratory Director of any nonconformance or deviation from the Quality Management System
- **Makes recommendations** to the Laboratory Director for potential improvements
- **Maintains and prepares** training files, workplans, and annual evaluations

### Quality Assurance Officer (QAO)

Under the direction of the Laboratory Director, the Quality Assurance Officer performs the following duties within the Quality Management System:

- **Performs** periodic quality checks and creates monthly quality-check reports
- **Reports** to the Laboratory Director any trends that may lead to the improvement process
- **Participates in** annual internal audits, inspections, and other quality surveys
- **Supports the BFS proficiency testing program**
- **Briefs laboratory management monthly** on quality issues

### Analyst / Examiner

Under the direction of the Laboratory Director or Assistant Laboratory Director, the Analyst/Examiner is responsible for the following duties within the Quality Management System:

- **Informs laboratory management immediately** of any issue affecting quality
- **Remains current** in areas of expertise through continuing education
- **Participates in** proficiency testing
- **Seeks approval from** laboratory management before any case-mandated deviations from the technical procedures
- **Participates in focus groups** in areas such as technical disciplines, quality matters, and operational and administrative matters, as directed by laboratory management
The roles and responsibilities of the DNA Technical Leader are outlined in the DNA Casework and DNA Data Bank Discipline Manuals, and comply with the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and DNA Databasing Laboratories.

Under direction of laboratory management, the Property Controller is the main custodian of evidence submissions, and may receive and monitor evidence submitted to the crime laboratory to include establishing the chain-of-custody. The Property Controller is also responsible for retrieving evidence for laboratory staff, as well as returning evidence to client agencies. The Property Controller is additionally responsible for the acquisition and tracking of other laboratory property such as vehicles, equipment, and supplies. Laboratory management may designate property controller duties to other staff depending on the needs of the laboratory.

Administrative or technical support staff helps achieve the Bureau’s goals and objectives within the Quality Management System. The responsibilities of the administrative or technical support staff are as follows:

- Informs management immediately of any issue affecting quality
- Remains current in areas of expertise through continuing education
- Seeks approval from laboratory management before any deviations from the Quality Management System
- Participates in focus groups in areas such as technical disciplines, quality matters, and operational and administrative matters, as directed by laboratory management

BFS encourages suggestions for improvements to the Quality Management System.

All BFS personnel are made aware of the need for continual improvement in the Quality Management System. Improvements to the Quality Management System are implemented without compromising the integrity of the Quality Management System.

Suggestions for improvement are made through the improvement process (section 4.10) and the management review process (section 4.15).
4.3 Document Control

BFS maintains procedures to control all documents forming its Quality Management System. These procedures are referenced in this section.

The Bureau Chief is the issuing authority for all BFS-controlled documents.

A master document list identifying the current revision and distribution of Quality Management System documents has been established. Approved controlled documents are maintained by the document control system (SharePoint), and are available to all staff through https://caljries1.doj.ca.gov/sites/bfs/.

- Current Quality Management System (QMS) documents are available at all locations where essential laboratory operations are performed. When QMS documents are needed at locations away from the laboratory (e.g. crime scene response), it is the responsibility of BFS staff to ensure they have access to the current versions.
  - Examiners may access controlled versions of QMS documents through the document control system located on the BFS SharePoint portal.
  - Printed and electronic copies of QMS documents are not controlled, but are working copies. Before using a working copy, staff must verify that it is the current version.

Examples of methods that can be used to access current QMS documents off-site:

  - Remote access via the BFS SharePoint portal using mobile devices equipped with internet access.
  - Transfer current electronic copies onto portable electronic storage media to view on a mobile device.
  - Print the documents prior to leaving the laboratory.

- Quality Management System documents are reviewed to remain responsive to requirements of both clients and accreditation.
  - The controlled documents are reviewed in response to changes in client needs, normative references, or trends in forensic science as part of the improvement process. Periodic formal review of controlled documents is scheduled by the BQAM.

- Obsolete documents are promptly removed from all points of issue or use, and are archived to ensure against unintended use.

- Obsolete documents are suitably marked.

All BFS-controlled documents are retained indefinitely.
BFS forms distributed to clients for their convenience, such as the BFS-1 Physical Evidence Submittal Form, will be accepted regardless of revision and may be included in case records.

All Quality Management System documents generated by BFS are uniquely identified.

**Manuals are formatted as follows:**

Header:
- Unique document title
- Section number (if multiple-section document)
- Page number in the format of page X of X (total number of pages)
- Section title (if applicable)
- Name of issuing authority
- Document number

Footer at a minimum shall contain:
- A statement “ALL PRINTED COPIES ARE UNCONTROLLED”
- The revision number and issue date of the document

**Forms are formatted as follows:**

The header contains the document title. The footer contains:
- Document number
- Page number in the format of : “Page X of Y” including single page documents
- The revision number and issue date of the document.
- Issuing authority

Changes to quality management system documents are reviewed and approved by the Bureau Chief.

All changes to existing controlled documents are identified in red font for the review and implementation period. The final document changes are summarized in the manual history, if applicable.

BFS does not allow amendment of the Quality Management System by alteration of printed copies.

Any changes to the Quality Management System are made using procedures documented in this manual.
### Changes to computerized documents (4.3.3.4)

The BQAM designates staff that have administrative rights to the document control system.
4.4 Review of Requests, Tenders, and Contracts

Review of client requests for analysis (4.4.1)

BFS is responsive to clients, meeting their specific investigative requests* with timely and effective service. Client requests are evaluated in light of the laboratory’s resources and bureau wide capabilities.

**BFS selects the forensic approach and procedures responsive to client needs.**

When necessary laboratory personnel discuss the request with the client to clarify case information and client expectations. BFS may triage evidence items to establish which will be examined and notify the client of any substantial change to previously agreed conditions. Differences are resolved before any work commences.

BFS adheres to the following case review procedure whenever a client requests criminalistics, digital evidence, or latent print analysis:

• The type of evidence submitted, including the question to be answered, is defined by the client and documented on a BFS-1.
• An Assistant Laboratory Director or designee evaluates the ability to meet the client request by determining the following:
  − Is the laboratory able to perform the analysis on site, or are external resources required? The laboratory communicates to the client work not within the scope of BFS, and documents suggested and/or selected alternatives in the case record.
  − Is the evidence properly packaged and suitable for the examination to be performed?
  − For evidence requiring multiple disciplines, in what order should the evidence be analyzed?
  − Can the laboratory reach conclusions within the client’s timelines?
• For time sensitive cases, the laboratory will reach an agreement with the client on the items to be examined and the time of completion.

Evidence submitted in high volume evidence programs, such as blood alcohol, toxicology, or controlled substances, do not routinely require review by laboratory management before analysis.

*The term request is used generically and does not equate with a JusticeTrax “Request”.

Subcontracted work (4.4.3)

The review process in section 4.4.1 also applies to work submitted to a subcontracted laboratory.

Deviations (4.4.4)

The laboratory informs the client whenever it is necessary to deviate from the agreed-upon analysis.
Any time the needs of the client agency or the laboratory change, laboratory management reviews, documents, and, if appropriate, accommodates the request as stated in section 4.4.1.
4.5 Subcontracting of Tests

**Qualifying and documenting subcontractors (4.5.1 and 4.5.4)**

BFS employs only competent subcontractors.

Subcontractors demonstrate competency through the following criteria:

- Training and experience
- Accreditations or certifications
- Process review including audits and testing

Accreditation to ISO/IEC 17025:2005 is not required.

Subcontractors meeting these criteria are added to a list of acceptable providers and their qualifications retained on file at the laboratory.

The discipline manuals for the DNA programs detail the competencies of DNA subcontractors according to the FBI Quality Assurance Standards.

Transferring evidence between BFS laboratories is not considered subcontracting.

**Notice to client (4.5.2)**

The laboratory advises the client of the subcontracting arrangement in writing and, when appropriate, gains the approval of the client, preferably in writing.

**Responsibility for work (4.5.3)**

BFS is responsible to the client for any work performed by BFS-specified subcontractors. BFS is not responsible for the work performed by any client-specified subcontractor.
4.6 Purchasing Services and Supplies

BFS purchases supplies and services that comply with the quality requirements as specified in each discipline manual. BFS maintains records of compliance.

Supplies and services determined to affect the quality of tests have quality requirements specified in the discipline manual. Therefore, if no quality requirement exists then the supply or service has not been deemed as one which significantly affects the quality of tests.

BFS ensures that purchased supplies and services determined to affect the quality of tests are not used until they have been verified as complying with the quality requirements defined in each discipline manual. Laboratory specific procedures are defined in the Laboratory Operations Manuals.

In addition to routine state-mandated processes, the general procedure for purchasing, receipt, verification, and storage of supplies and services that affect the quality of tests are below.

**Records of compliance with these procedures must be maintained.**

**Purchases**

Prior to purchase, the following actions are necessary to assure that supplies and services are not ordered until it is confirmed that the vendor can meet the specified quality requirements:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Determine if any quality requirements are specified by the discipline manuals for the intended use of the supply or service to be purchased.</td>
</tr>
<tr>
<td>2</td>
<td>Verify that the supply or service to be purchased meets the stated quality requirements. Document this review, affirming that the quality requirements have been met. For example, write “Quality requirements met, initials/date” on the purchase order. Refer to the Laboratory Operations Manual for laboratory specific procedures regarding documentation.</td>
</tr>
</tbody>
</table>
Receipt, Verification, and Storage of Supplies
Upon receipt, the following actions are taken to assure that supplies are not used until quality requirements have been met:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Verify that the quality of each supply received matches what was ordered from the vendor. Note any discrepancies and remedy with the vendor.</td>
</tr>
<tr>
<td>2</td>
<td>Document that the quality requirements for the supply have been met. For example, write “initials/date” on the supply container. Refer to the Laboratory Operations Manual for laboratory specific procedures for documentation.</td>
</tr>
<tr>
<td>3</td>
<td>Store supplies according to the manufacturer’s recommendations.</td>
</tr>
</tbody>
</table>

Receipt and Verification of Services
The following steps are taken to assure that equipment being serviced is not used until quality requirements are met:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Verify that the service received, meets the quality requirements specified in the discipline manual or other QMS document (ex: Balance Technical Procedures).</td>
</tr>
<tr>
<td>2</td>
<td>Note any discrepancies, and remedy them with the vendor.</td>
</tr>
<tr>
<td>3</td>
<td>Record the service in the equipment maintenance log. The initials/date of the staff making this entry signifies that the service requirements for the equipment have been met. Without this verification, equipment may not be put back into service.</td>
</tr>
</tbody>
</table>

Each discipline manual identifies CRITICAL supplies and services. Vendors of critical supplies and services are evaluated and approved prior to use.

Specific quality requirements for vendors of critical supplies and services are listed in each discipline manual. The vendor must be capable of meeting these requirements in order to receive approval.

A list of approved vendors of critical supplies and services is maintained on the document control system. To add vendors to the approved list the following procedure is followed:
- The laboratory evaluates the vendor according to the criteria listed in the applicable discipline manual.
- The laboratory completes the Vendor Evaluation Form which is signed by an individual authorized to sign purchase orders.
- The laboratory maintains the original of the form along with any documentation supporting compliance with the quality requirements as specified in the applicable discipline manual.
• A copy of the form is forwarded to the Quality Assurance Unit who will add the vendor to the approved vendor list.

• Prior to using an approved vendor, the laboratory must verify the approval is still current. For example, if a quality requirement for a vendor includes specific accreditation requirements, the applicable scope of accreditation for that vendor will have an expiration date and will need to be approved again.

• In the event that there are issues with an approved vendor (e.g. poor customer service, supplies or service did not meet requirements, late shipments), the Quality Assurance Unit should be contacted promptly. The QA Unit will suspend the vendor from the approved master list until the issues are resolved.
4.7 Client Agency Service

Client agency service (4.7.1) BFS communicates regularly with client agencies regarding laboratory services in order to ensure that client needs are being met. This communication is done with sensitivity to client confidentiality.

Awareness of the investigative circumstances and the questions that need to be answered comes about through open communication between the laboratory and client agency. Case-specific client communications are documented in the case record.

Seeking feedback from client agencies (4.7.2) BFS management routinely seeks client input as part of a coordinated effort to improve the Quality Management System and forensic services.

Laboratory management is responsible for gathering client agency feedback, both positive and negative, from which to learn the client’s opinions about both case-specific issues as well as issues affecting bureau-wide goals and objectives. These feedback results are included as part of the annual management review process and are used to refine goals and objectives.

Client feedback may be gathered through a number of methods:
- Client surveys
- Meetings
- Testimony review
- Compliments and complaints
- Conversations
### 4.8 Complaints

**BFS records complaints and compliments related to the Quality Management System from any source including clients and employees. Records are maintained of the complaints and actions taken to resolve them are documented.**

Complaints or compliments from clients, employees, and the public are referred to laboratory management to be addressed promptly. BFS seeks to resolve all complaints at the Laboratory Director level. Complaints affecting bureau wide goals and objectives are forwarded to the next level in the chain of command.

**Complaint Procedure:**

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The Laboratory Director documents complaints in the Complaint log and initially assesses its merit.</td>
</tr>
</tbody>
</table>
| 2    | The Laboratory Director:  
  - Conducts and documents an investigation to determine the validity of the complaint.  
  - Completes section II of the Complaint form summarizing the investigation and proposed solutions. A copy of the form and any related documentation is placed in the laboratory’s complaint binder.  
  - If the Laboratory Director’s scope of authority is sufficient to address the complaint, then solutions are implemented. Complaints with Bureau-wide implications or outside local scope of authority are forwarded to the Bureau Quality Assurance Manager (BQAM) within 30 days of the Laboratory Director being informed. |
| 3    |  
  - The BQAM reviews the submitted documents with the Assistant Bureau Chief (ABC) summarizing comments in Section III of the complaint form.  
  - The BQAM and ABC evaluates the Bureau-wide impact of the complaint and its solution, informing the Bureau Chief as appropriate.  
  - The ABC approves the solution to the complaint and forwards the form to the Bureau Chief for implementation. |
| 4    | The Bureau Chief directs the implementation of the solution to the complaint. |
| 5    | After implementation, the effectiveness of the solution is evaluated as part of review and audits. |

**Compliments**

Compliments regarding laboratory service or staff efforts are conveyed to the appropriate employee(s) and documented in the employee(s) personnel file or communicated at staff meetings. When appropriate, the Bureau management is informed.
4.9 Control of Nonconforming Work

Nonconforming work (4.9.1)

Nonconforming work is evaluated by laboratory management, and an appropriate response is made based on the evaluation.

Responsibilities and authorities (4.9.1a and 4.9.1e)

The Laboratory Director or DNA technical leader is responsible for all examinations and resolutions of nonconformances as appropriate:
- The Laboratory Director has the authority to halt or resume non-DNA casework.
- The DNA technical leader has the authority to halt or resume DNA casework.

Ensuring quality is the responsibility of every employee; therefore, it is the duty of each employee to report suspected nonconformance to laboratory management.

Nonconformance may be detected by:
- Technical review, administrative review, and Laboratory Director case review
- Notification of nonconformance in a proficiency test
- Employee or client communication
- Routine quality audits, annual internal audits, management reviews, and external reviews

Evaluation and correction of nonconformance (4.9.1b and 4.9.1c)

The Laboratory Quality Manager evaluates each nonconformance to determine its significance.

Nonconformances are classified as Level I or Level II.

- **Level I** – Pervasive nonconformances broadly affecting the quality of casework. The nature and cause of the nonconformance raises immediate concern regarding the quality of the laboratory’s work product. Repeated instances of Level II nonconformances may be classified as a Level I.

- **Level II** – Nonconformances due to a problem that may affect the quality of the work, but are not serious enough to cause immediate concern for the overall quality of the laboratory’s work product.

*Note:* The nature or cause of a Level II nonconformance does not, to any significant degree, affect the fundamental reliability of the work product of the laboratory or the integrity of the evidence. The nature, or cause, is of the type that allows the laboratory to complete the required corrective action over an extended period without raising an immediate concern about the laboratory’s overall work product.

**Level I** and **Level II** nonconformances are subject to the corrective action process as described in section 4.11.
### Minor Issues

All issues not rising to either a Level I or Level II nonconformance will be considered minor in nature. A minor issue has minimal effect or significance, is not systemic, and does not significantly affect the fundamental reliability of the laboratory’s casework.

Examples of minor issues may include the following:
- Administrative or transcription errors, which may require corrected reports.
- An apparent Level I or Level II nonconformance, which upon review does not require formal corrective action.

Minor Issues are not subject to the corrective action process. However, upon evaluation, repeated instances of a minor issue may be classified as a Level II nonconformance.

Minor issues will be documented at the laboratory level in a Minor Issue Log and are reviewed annually by the Laboratory Director at the time of the management review to determine if repeated issues need to be elevated to a nonconformance.

### Notification to client agencies (4.9.1d)

If the laboratory’s reported results are found to be inaccurate, the work is corrected, and the client is notified. BFS does not recall reports issued to clients.

If an examination report is released with results later determined to be nonconforming, the client is notified in writing (e.g., corrected report, letter to agency, etc.).

### Initiating the corrective action process (4.9.2)

Any nonconformance that could recur or raises doubt about compliance with the Quality Management System initiates the corrective action process (Section 4.11), which shall be promptly followed.

Non-casework related nonconformances involving the Quality Management System may also initiate corrective actions.

Correction of an issue at the time of case review, and prior to the release of a report or the laboratory’s work product, generally does not trigger the formal corrective action process.
4.10 Improvement

**Improvement (4.10)**

BFS continually improves the effectiveness of the management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Improvements of the Quality Management System are often triggered as the result of laboratory management functions, such as:

- Evaluating client needs, the appropriateness of BFS quality objectives, and the use of instrumentation and methodology.
- Monitoring productivity, daily operational issues and corrective and preventive actions.
- Encouraging staff feedback, communication between laboratories, and staff development.
- Reviewing staffing levels, work product, proficiencies, audits and management reviews.

The resulting improvements to the QMS are incorporated into QMS documents through the change process.

**Change process**

Changes to subject matter, content, policies and/or procedures in Quality Management System (QMS) documents are initiated and tracked through the use of the Change Form. Any BFS staff may initiate the change process by opening a Change Form. Changes are made by the appropriate BFS staff as a result of the change process described below:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
</table>
| 1    | The laboratory submits an approved Change Form to the BFS QA Unit.  
*Note: The approval must be from the Laboratory Director, or designee. When DNA issues are involved, approval of the Technical Leader is also required.* |
| 2    | The applicable subject matter experts (SME), for example the TAG:  
- evaluate the proposed changes.  
- may accept, deny, or make modifications to the suggested changes  
- will incorporate their recommended changes into the relevant QMS documents. |
| 3    | The QA Unit:  
- Reviews the submitted documents  
- Evaluates the Bureau-wide impact of the proposed action, informing the Bureau Chief as appropriate.  
- Prepares final documents for approval. |
| 4    | The BQAM either:  
- denies the change, or  
- approves the change and forwards the documents to the Bureau Chief for review. |
<p>| | |</p>
<table>
<thead>
<tr>
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</table>
| 5 | The Bureau Chief either:  
- denies the change, or  
- directs the implementation of the change by approving and issuing the revised QMS document(s).  

*Note: All BFS Staff are notified by email when such changes are made to QMS documents.*  
|
| 6 | If implemented, the laboratory evaluates the effectiveness of the change as part of their management review and audits.  

### Administrative changes to QMS documents

Administrative changes to QMS documents (e.g. formatting, typographical, spelling or grammatical errors etc.) do not have any substantive effect on work instructions or policies. These changes can be made by the Bureau Quality Assurance Unit (QA Unit).

Users of QMS documents are encouraged to notify the QA Unit of needed changes and proposed corrections.

Administrative changes may also be made as part of the change process described above.

### Critical Action Bureau Policy

**The Bureau Chief has the authority to implement a Critical Action Bureau Policy.**

Occasionally, in response to a situation that requires immediate action, a Critical Action Bureau Policy may be issued by the Bureau Chief.

The Critical Action Bureau Policy will remain in effect:  
- for the duration stated (if any),  
- until revoked and/or archived, or  
- until it is incorporated into an appropriate QMS document

### Lab Policies

Occasionally, supplementary QMS policies and procedures are implemented in a specific laboratory location by the Quality Manager, and are not necessarily applied Bureau-wide.

The Laboratory Policy and/or Procedure will remain in effect:  
- for the duration stated (if any),  
- until revoked and/or archived  
- until it is incorporated into an appropriate QMS document (e.g. Laboratory Operations Manual).
### 4.11 Corrective Action

**Evaluation Criteria for the Classification of Nonconformances (4.11.1)**

BFS requires and authorizes the Laboratory Director to follow the Corrective Action Process for all level I and level II nonconformances.

The corrective action process for Level I and Level II nonconformances is as follows:

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
</table>
| 1    | The Laboratory Director notifies the Bureau Quality Assurance Manager (BQAM) and the Assistant Bureau Chief (ABC) of a potential Level I or II nonconformance, providing basic information and preliminary classification.  
– The BQAM opens a Quality Assurance Inquiry, creates a Quality Assurance Inquiry File (QAIF), and provides the QAIF number to the Laboratory Director.  
– The BQAM notifies the Bureau Chief.  
• The Laboratory Director documents the nonconformance in the laboratory’s Corrective Action Log. |
| 2    | The Laboratory Director, or designee (in collaboration with the DNA Technical Leader, where DNA issues are involved):  
• Conducts and documents an investigation to determine the root cause and extent of the nonconformance and confirm its classification.  
• Develops and recommends corrective actions.  
• Completes the first section of the Corrective Action Form summarizing the investigation, the root cause determined in the process, any preliminary actions taken, and potential corrective actions with recommendations.  
• Keeps a copy of the Corrective Action Form and related documentation in the laboratory.  
• Forwards the form and supporting documentation to the BQAM.  
Note: This step is to be done in consultation with the BQAM, who will provide advice and guidance. This will facilitate consistent application of the Corrective Action process across the Bureau. |
| 3    | The BQAM reviews the submitted documents with the ABC and may accept the Laboratory Director’s recommended actions or seek additional information. If accepted, the Laboratory Director is directed to proceed with the corrective actions. Approval of the corrective action(s) is documented by the BQAM on the Corrective Action Form.  
• For DNA-related corrective actions, the BQAM and DNA Technical Leader will work together and the Technical Leader’s approval of the corrective action is also documented on the Corrective Action Form.  
• The BQAM updates the Bureau Chief, as appropriate. |
4. The Laboratory Director implements the approved plan and upon completion, submits copies of all supporting documentation to the BQAM.

5. The BQAM evaluates the remediation documents ultimately forwarding the documentation to the Bureau Chief for closure.

6. The Bureau Chief reviews and closes the completed corrective action.

The effectiveness of any corrective action is assessed during the annual internal audit and management review process. The standard by which any corrective action is measured is its success in preventing the recurrence of the nonconformance.

Note: All correspondence (instructions, notices, etc.) regarding a corrective action must be in writing.

**Root cause analysis (4.11.2)**

For every nonconformance the Laboratory Director conducts an investigation to determine the root cause.

An in-depth investigation of all potential causes of the nonconformance will be performed to develop the most effective corrective action.

**Identification, selection, implementation, and documentation of corrective action (4.11.3)**

The Laboratory Director identifies potential corrective actions based upon a root cause analysis of the nonconformance. The selected corrective action shall be appropriate to the magnitude and risk of the problem and prevent its recurrence.

If the root cause analysis leads to an action defined by the Department of Justice as a “personnel action,” BFS management decides whether to proceed with a corrective action or a confidential personnel action.

The laboratory documents nonconformances and all documentation related to subsequent corrective actions in the laboratory’s Corrective Action binder or equivalent.

**Monitoring corrective action (4.11.4)**

BFS monitors the results of corrective actions to ensure that the corrective actions taken are effective and compatible with the Quality Management System.

Laboratory management monitors the corrective action to ensure that the recommendations are followed and that they will prevent future occurrences. The effectiveness of the corrective action is evaluated during the annual management review process.
Additional audits (4.11.5) The Bureau Chief has the authority to call a special audit under section 4.14 if any condition affects quality compliance.

Conditions can include concerns about:
- Quality product to client
- Compliance with the normative references
- Compliance with the BFS Quality Management System
4.12 Preventive Action

Preventive action policy (4.12.1)

BFS scrutinizes examination processes, client relations, and the Quality Management System to proactively identify potential nonconformances and improve client service.

The preventive action process is one form of the improvement. Solutions are developed to reduce the possibility of future nonconformances.

Preventive action process (4.12.2)

The preventive action process follows the change process described in section 4.10.
4.13 Records Management

Managing records (4.13.1.1 and 4.13.1.2)

BFS requires records to be thorough and legible, meeting defined standards for identification, collection, access, filing, storage, maintenance, and disposal.

BFS defines three types of records, outlined below: quality records, technical records, and case-specific administrative records.

- **Quality records:**
  - Records of audits, management reviews, and corrective, preventive, and change requests
  - Validations, intermediate checks, and performance verifications

- **Technical records:**
  - Case or analysis-set specific documentation sufficient to reproduce the examination, such as photographs, worksheets, and notes
  - Reference to quality records specific to the case, when appropriate
  - Uncertainty of measurement, when applicable

- **Case or analysis-set specific administrative records:**
  - Chain of custody
  - Client investigation reports
  - Service requests and records of all client communications
  - Technical and administrative reviews

Case and Data Bank records are collections of technical and case-specific administrative records and are kept as hard copy or electronic data. The records enable the examination to be interpreted and reproduced.

Records management

The following applies to all case records generated by BFS:

- **Records are identified** by the author’s initials or name, date, subject identifier, and, when appropriate, page number.
- **Records are generated** at the time of the observation.
- **Record access** is limited to BFS personnel. The Laboratory Director or Bureau Chief may grant exemption as required by court processes, accreditation, or client request.
- **Record filing** depends on the source and subject matter of the document.
  - All hard-copy records (e.g. case files) are filed locally as stated in the laboratory operations manual.
  - All electronic records are maintained on the DOJ network, or stored on a suitable digital storage media.
  - Appropriate electronic case and data bank records are maintained in LIMS systems, following data system requirements.
**Records retention policy**

- **Record storage** depends on the media and subject matter.
  - Case file hard copy records and case related quality records are locally-retained for a minimum of 5 years, after which their disposition is as follows:
    - Hard-copy records may be converted to electronic files and when verified, the hard copy may be destroyed and the electronic form used as the original.
    - All retained electronic data is stored and backed up on a secure network, or suitable digital storage media.
    - Quality records that are not case related (e.g. internal audits, management reviews, records of corrective and preventive actions) are retained under BFS control for at least one ASCLD/LAB- International accreditation cycle, or five years, whichever is longer, after which time they may be destroyed.

  *Copies of records involved in criminalistics cases will be filed with the criminalistics case file after analysis.*

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criminalistics (all service types not listed below)</td>
<td>Indefinitely retained off site in State Records Retention Office</td>
</tr>
<tr>
<td>DNA Casework</td>
<td></td>
</tr>
<tr>
<td>Digital Evidence</td>
<td></td>
</tr>
<tr>
<td>Felony Toxicology</td>
<td></td>
</tr>
<tr>
<td>Clandestine Labs</td>
<td></td>
</tr>
<tr>
<td>Latent Prints</td>
<td></td>
</tr>
<tr>
<td>Data Bank analysis sets</td>
<td></td>
</tr>
<tr>
<td>All DUIs</td>
<td>Destroyed by secure means unless client requests retention</td>
</tr>
<tr>
<td>Non-felony Toxicology</td>
<td></td>
</tr>
<tr>
<td>Controlled Substances</td>
<td></td>
</tr>
</tbody>
</table>

- All case and data bank records are held in confidence and secured in a location defined in the laboratory operations manual. Records should be stored in such a way as to prevent damage or deterioration and to prevent loss. Readily retrievable access is restricted to BFS personnel unless authorized by the Laboratory Director or Bureau Chief.

Client-determined case-security levels are used to restrict the release of examination results. These levels are assigned to cases in JusticeTrax as follows:

<table>
<thead>
<tr>
<th>Security Level</th>
<th>Disposition of Results/Examination Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine (Unrestricted)</td>
<td>Communicated to agency and district attorney</td>
</tr>
<tr>
<td>Agency Only</td>
<td>Communicated to client agency only</td>
</tr>
<tr>
<td>Agent Only</td>
<td>Communicated to selected agent in agency and not available on BFSInfo</td>
</tr>
</tbody>
</table>

Case discussions with outside agencies must comply with the agency-assigned security level.
Electronic records control (4.13.1.4)

BFS electronic records are protected and backed-up and access is limited by the following procedures:

- Jan Bashinski DNA Laboratory Computer Security Policy located in the laboratory operations manual.
- Department of Justice, Hawkins Data Center Security Policies

Instrument data system records are exported to a network server, or suitable electronic media, or printed out for retention in case files.

Case or data bank records, content and purpose (4.13.2.1, 4.13.2.2, 4.13.2.1, 4.13.2.4, 4.13.2.5 and 4.13.2.5.2)

BFS retains detailed technical and administrative documentation prepared at the time of original observations. This documentation is retained in case or data bank analysis records for a period of time defined in the records retention policy in this section. These records are sufficient for independent interpretation or reproduction of the original examination.

To permit independent interpretation or reproduction of the original examination, these case records include:

- A copy of the examination report
- Unique identifiers and descriptions of the items analyzed
- Observations leading to conclusions reached
- Instrument operating parameters, if not documented in the technical procedure(s)
- As appropriate, the identification of factors affecting uncertainty
- Sufficient information to establish an audit trail:
  - Identification of personnel performing each examination
  - Identification of personnel performing a second interpretation (date and opinion), where required by the procedure
  - Identification of personnel performing technical and administrative reviews
- Dates associated with each step of the audit trail
- The reason a test result or observation is rejected.
- Examination documentation will reflect, at a minimum, the starting and ending dates of the testing performed.
  - Examination documentation is dated at the time observations, data, calculations or conclusions are recorded. The earliest and latest dates in the examination documentation are therefore the starting and ending dates of the testing performed.
  - When examination documentation contains only a single date, that date is both the starting and ending date of testing.

Batch case records need not include a copy of the examination report since a secure electronic version is available through BFSInfo.
Any change to hard-copy case or data bank records are initialed by the person making the change. Nothing is obliterated or erased.

Changes to hard-copy case or data bank sample set records shall be made in the following manner:

- Any additions, including interlineations, must be initialed by the person making the addition.
- Corrections are made with an initialed strikeout by the person making the correction.

Technical records, except for Data Bank files, are stored as hard copies and considered complete when submitted for technical and administrative review.

Data Bank records are considered stored after being submitted for administrative review.

Any additions or corrections, including interlineations to completed technical records generated and/or maintained in an electronic form shall be made on a hard-copy printout of the original data or shall be electronically tracked by a means sufficient to determine what was changed, when it was changed and by whom it was changed.

Technical records are considered complete when submitted for technical and administrative review.

Hard-copy case and Data Bank analytical file information meet the following requirements:

- Documentation is securely fastened.
- Examination documentation is of a permanent nature and written in ink.
  - Exceptions may be made when conditions at crime scenes prevent the use of inks.
  - Pencil (including color) may be appropriate for diagrams and tracings.
- Administrative records are identified by the laboratory case number or data bank-analytical file number.
  - The case or data bank-analytical file number appears on the first page of bound, multi-paged records.
- Each page of technical records is marked and identified by the unique laboratory identifier, page number, date(s), and analyst’s handwritten initials or secure electronic equivalent.
  - For casework involving multiple analysts, the reporting analyst will initial and date each page of technical records prepared for this specific request.
  - Analysts who prepare such technical records, but do not interpret findings, prepare the test report, and/or testify concerning the records, shall put their initials and date on the page(s) of examination records representing their work.
- The first and last pages of a specific request are numbered 1 of N and N of N.
  - Intervening pages are numbered in sequence.
  - Inserted pages are numbered using an alpha-numeric sequence (for example, 14A, 14B, etc.)
  - Each side of a double-sided document is considered a separate page.
Testimony on work prepared by other analysts:

- If an analyst testifies to the work reported by another analyst, the witness documents the page numbers of the pertinent technical records used to form the basis of his or her testimony, including the date of review and initials within the case file.

Identifying multiple cases on a single printout (4.13.2.9)

When data from multiple cases or Data Bank files is recorded on a single printout or worksheet, the unique laboratory number of each case or data bank analytical file is appropriately recorded on the document.

The printout may be kept in a central file if it is referenced in all applicable case files.

Examination documentation, such as instrumental data from a batch analysis, that bears the appropriate identification on an original document may be copied for filing in multiple places without placing original identifiers on each copy. The appropriate identification is specified above.

Abbreviations (4.13.2.13)

Abbreviations or symbols used in records are clearly documented in one or more of the following locations:
- Discipline manuals
- Laboratory operations manuals
- Case and data bank records

Abbreviations widely accepted by the scientific community do not require further definition.

Latent print records (4.13.2.5.1)

Latent print examinations comply with BFS record-keeping procedures and the requirements of the Appendix C of the “ASCLD/LAB - Latent Print Examination Records.”

Independent check on a critical finding (4.13.2.12)

When an independent check on a critical finding (second read) occurs, it shall be conducted by an individual having expertise gained through training and casework experience in the category of testing.

The individual conducting the independent check on a critical finding shall document the check in the pertinent section of the case file by:
- Indicating the critical finding has been checked and agreed to,
- Indicating who performed the check (signature, initials, or electronic equivalent), and
- Indicating the date that the check was performed.
4.14 Audits

The Laboratory Director plans and organizes an internal audit at least annually to verify compliance with all elements of the Quality Management System.

The Laboratory Director will:

• Allocate sufficient resources to ensure a thorough and objective internal audit.
• Provide auditors with documented training included in their training records.
• Ensure that the audit is scheduled and carried out according to the audit procedure.
• Provide assigned auditors advance notice and sufficient time to conduct the audit.
• Assign and supervise a lead auditor who plans, organizes, and directs the audits.
• Ensure that, whenever possible, auditors are independent of the activity to be audited.

Internal Audit procedure

The audit procedure to be followed is set out below:

• The lead auditor initially:
  − Assigns auditors areas of responsibility to audit.
  − Selects documents to be used for the audit.

• The auditors:
  − Seek objective evidence of compliance with the Quality Management System by utilizing the Internal Audit Checklist, or equivalent.
  − Review and refer to the following documents before and during the audit:
    ▪ Normative references
    ▪ Administrative and laboratory operation manuals
    ▪ Periodic quality assurance-check records and monthly summary reports
    ▪ Previous audit records
    ▪ BFS internal audit checklist
    ▪ The records of all improvement procedures
  − Perform the audit tactfully, and with an open mind.
  − Reference the internal audit findings to the specific audit standard.
  − Present their findings to the lead auditor.

• The lead auditor:
  − Reviews and analyzes each auditor’s findings.
  − Collates the team’s findings into the internal audit report template.
  − Presents, along with the audit team, the internal audit checklist and reports to the Laboratory Director.

• The Laboratory Director:
  − Receives and reviews the internal audit report.
  − Implements the improvement process as required.
  − Submits a copy of the internal audit report to the Bureau Quality Manager.

Records of audit findings and any associated corrective actions that arise from them are retained for at least one accreditation cycle of ASCLD/LAB-International or five years, whichever is longer.

The records stored at the laboratory include:
- Auditor’s notes
- A copy of the internal audit report

Performance Declaration (4.14.5)

Each laboratory submits a written self-evaluation report, called a Performance Declaration, to ASCLD/LAB in accordance with a schedule assigned by ASCLD/LAB.

The required elements of the Performance Declaration are listed in the most current version of ASCLD/LAB-International Program Overview document. This report was previously called the Annual Report.

Maintaining ASCLD/LAB accreditation

Additionally, the following requirements must be met to maintain ASCLD/LAB-International accreditation:

- **Surveillance Visits**
  - During the first accreditation cycle, an annual surveillance visit will be made to ASCLD/LAB selected BFS laboratories. These visits will be carried out annually, at about twelve (12) month intervals from the date of accreditation, but no greater than eighteen (18) months between visits.
  - The frequency of surveillance visits after the first successful reassessment will be at the discretion of ASCLD/LAB.

  *Note*: BFS will receive notice from ASCLD/LAB of an upcoming surveillance visit no less than ninety (90) calendar days prior to arrival.

- **Reassessments**
  - Each laboratory must submit a new application to maintain accreditation prior to the end of their accreditation cycle, and subsequently, must undergo another full on-site assessment.
FBI DNA Quality Assurance audits

In addition to the audit requirements outlined within the BFS Quality Manual, BFS laboratories with DNA programs must abide by the following:

- FBI Quality Assurance Standards:
  - DNA laboratories are audited annually according to the FBI Quality Assurance Standards for Forensic DNA Testing and/or DNA Databasing Laboratories. The audits shall:
    - Occur every calendar year, and shall be at least six (6) months and no more than eighteen (18) months apart.
    - Consist of an external audit at least once every two (2) years.

Note: All external audit documentation and laboratory responses shall be provided to the FBI within thirty (30) days of laboratory receipt of the completed audit documents from the auditors. All audit documentation and laboratory responses will be retained according to the requirements of the FBI Quality Assurance Standards.

Corrective action (4.14.2 and 4.14.4)

Audit findings that cast doubt on compliance with the Quality Management System or on examination validity trigger the corrective action process. The effectiveness of any corrective action is assessed during the annual internal audit and management review process.

Clients are notified in writing if corrective action investigations show that the laboratory results may have been affected.
4.15 Management Review

The Laboratory Director conducts an annual management review. BFS management meets annually to review the management reviews of each laboratory and to assess any bureau-wide impact.

The management review is performed after the annual internal audit is completed. This review seeks to continually improve the Quality Management System in an effort to deliver the highest standards of client service.

The management review:
• Serves as an evaluation of the Quality Management System based upon input by clients, employees, and management.
• Serves as the basis for identifying improvements in client service.
• Takes account of:
  − The suitability of policies and procedures as well as recommendations to change these documents to improve or maintain the quality of client services
  − Reports from managerial and supervisory personnel of problems and solutions encountered regarding client service
  − The results of current and past internal and external audits
  − Improvement processes, including review of corrective and preventive actions, and change actions and their effectiveness and influence on client services
  − Any assessments by external bodies
  − The proficiency test program
  − Changes in volume, type of work, technologies, new client agencies, or funding
  − Client feedback
  − Complaints and compliments
  − Other relevant factors, such as quality control activities and changing resources
  − Suitability of controlled documents as well as recommendations to change these documents to improve or maintain the quality of client services
  − Training given or received in light of present and anticipated tasks

Management reviews are documented, and the records are retained by the laboratory through one ASCLD/LAB-International cycle of accreditation or five years, whichever is longer.
Management review findings (4.15.2 and 4.15.1.2)

Laboratory management responds to the review findings with timely appropriate action.

Based on the findings of the review, the Laboratory Director produces:
- A management review report
- Corrective, preventive, or change forms resulting from the review

The management review report will include an appropriate and agreed upon timescale for all action items identified during the Management Review. These action items and their status will be documented in either management meeting notes or in a Management Review Spreadsheet.

The management review report and proposed improvements are forwarded through the chain of command to the Bureau Quality Assurance Manager. These documents are retained in the laboratory for at least one ASCLD/LAB-International accreditation cycle. They are used in the bureau-wide annual review of the Quality Management System.
5 Technical Requirements

5.1 General and Reagents

Factors relating to reliability of testing (5.1.1 and 5.1.2)

BFS takes into account all critical factors affecting the reliability of test results.

These critical factors affecting the reliability of test results are considered when developing technical procedures, training curricula, equipment specifications, and competency testing:

- Personnel (section 5.2)
- Facility Security, Safety, and Environmental conditions (section 5.3)
- Technical procedures (section 5.4)
- Equipment (section 5.5)
- Measurement traceability (section 5.6)
- Sampling and Sample Selection (section 5.7)
- Evidence handling (section 5.8)

Reagent checks (5.1.3)

BFS ensures the reliability of its reagents.

The discipline manuals specify all reagents used in technical procedures and their requirements for initial quality control and intermediate checks. The nature, frequency and documentation of these checks are specified in the discipline manuals.

Reagents not meeting quality control criteria are removed from service and affected casework is reviewed. Reagents or chemicals past their assigned expiration dates are either discarded, or clearly marked for training and/or research use only.

Reagent labeling (5.1.3.1)

Reagents prepared in the laboratory are properly labeled and documented.

Labeling

Labeling of laboratory prepared reagents includes at a minimum the name of the reagent and the date of preparation. Labeling of neat reagents includes at a minimum the name of the reagent and the lot number. Safety labeling follows BFS Safety Manual guidelines.

Documentation

Reagents prepared for a single service request are documented in the case record. Reagents that will be applied to multiple service requests are documented in a log which will include:

- Name of the reagent
- Name of preparing analyst
- Date prepared
- Lot numbers
- Expiration date (if any)
- Date and results of initial quality checks
Reliability Testing
Reliability testing of laboratory prepared reagents shall be performed prior to use, or if appropriate, concurrent with the test.
5.2 Personnel

Personnel as the key to quality

Quality begins with qualified employees who are continually encouraged to improve and develop professionally.

A motivated and engaged staff, supported by adequate facilities, training, technology, and professional development, is fundamental to delivering quality services to the client agency.

Prior to performing critical tasks, BFS personnel demonstrate competency through education, training, and competency testing.

Critical tasks are those skills or duties related to the collection and examination of samples, including conducting visual and chemical examinations, operating equipment, interpreting results, providing opinions, and generating reports. The knowledge and skills required to perform critical tasks and demonstrate competency are defined in each discipline manual.

The pathway to competency in a discipline, category of testing, or critical tasks is as follows:

• Supervised training is provided as defined in each discipline manual.
• The training is documented in an individual’s discipline-specific training binder.
• Mastery of the training curriculum is demonstrated by successful completion of a competency test as outlined in each discipline manual.
• Minimum requirements for competency tests for employee’s whose job responsibility includes report writing is as follows:
  – Examination of sufficient unknown samples to cover the anticipated spectrum of assigned duties
  – A written test report to demonstrate the employee’s ability to properly convey results and/or conclusions
  – A written or oral examination to assess the employee’s knowledge of the discipline, category of testing, or task being performed
• After an employee’s successful completion of all training criteria, the Laboratory Director, or designee, issues the Certificate to Perform Casework or Data Bank Work form, which is stored in the employee’s administrative training file.
  – If the employee is authorized to perform casework in limited portions of a discipline, then the Laboratory Director ensures that they clearly indicate on the Certificate to Perform Casework or Data Bank Work which skills or duties the employee has been approved to perform.

Competency is evaluated annually through the proficiency testing program (Section 5.9.3).
A technically qualified analyst following the standards set forth in the BFS Quality Management System may review, interpret, report, or testify to the examination of another analyst.

Refer to section 4.13 for documentation requirements.

BFS provides a documented training program to train employees in the knowledge, skills, and abilities needed to perform critical tasks.

- The discipline-specific training curriculum, presents an overall introduction and a list of critical tasks. Each critical task includes a training curriculum containing the following sections:
  - Introduction provides a brief overview of the specific critical task.
  - Applied scientific knowledge includes the scientific principles, required readings, and written exercises to assess and document comprehension.
  - Laboratory analysis contains task-specific laboratory exercises to develop knowledge, skills, and abilities. Mentors document completion of these exercises with their signatures.
  - Assessment occurs as the mentor documents the trainee’s successful completion of the task-specific curriculum.
  - Competency testing may be required by the discipline manual or the laboratory management at various intervals throughout the training curriculum. A competency test is required before the Laboratory Director issues the Certificate to Perform Casework or Data Bank Work.

- Employee training binders, specific to the discipline and retained by employees, document progress in the training curriculum sections.

- Administrative training files/binders for each employee contain:
  - The Certificate to Perform Casework or Data Bank Work
  - Employee Performance Expectations and Work Plan
  - List of proficiencies
  - Course certificates
  - Training to re-establish competency
  - A copy of the Authorization to Perform Technical or Administrative Review form
  - Transcripts or reference to their storage location if required by discipline
  - Documentation of Bureau required training

At least once a year, the employee reviews his or her administrative training file/binder. This review is documented on the file access roster by both the employee and his or her supervisor. If the employee transfers to another BFS laboratory, the file is transferred to that facility.

Administrative training files/binders are retained indefinitely.
Retraining and continuing education (5.2.1.1)

Laboratory management will determine when an analyst is in need of retraining (for example, due to an unacceptable proficiency, nonconforming work, etc.). The applicable discipline specific training curriculum, or portions thereof, may be used for retraining. Successful completion of a competency test documents completion of this additional training.

BFS requires all proficiency-tested examiners to undergo a minimum of eight hours a year of continuing technical education.

Records of continuing education are retained indefinitely.

Court training (5.2.1.2)

Employees subject to subpoena complete training in courtroom testimony.

This training will include the following:

- Completion of the Judicial Process and Testimony Training Curriculum and
- Any discipline-specific training from the laboratory operations or discipline manual

Additional training requirements (5.2.1.3)

Additionally, BFS provides training in the application of ethical practices in forensic sciences, a general knowledge of forensic science, and applicable criminal and civil law and procedures.

- Ethical practices:
  - All laboratory personnel read the BFS Ethics Document,
  - Technical staff and Property Controllers also complete the CCI Ethics in Forensic Science course, or equivalent.

- Training in general knowledge of forensic science is accomplished through a combination of CCI coursework and training curricula.

- Applicable legal procedures are addressed in the Judicial Process and Testimony Training Curriculum. When needed, discipline manuals address relevant legal issues.
### Training plans and goals (5.2.2)

Laboratory management identifies training needs and implements training programs in response to present and anticipated workload demands.

Training goals are formulated as follows:

- Individual goals for developing education and skills are formulated as part of each employee’s Employee Expectations and Work Plan. Laboratory management and the employee meet annually to:
  - Ensure that knowledge, skills, and abilities are aligned with workload demands.
  - Formulate the employee’s annual training plan.
  - Promote individual competency.
  - Promote professional development and long-term career growth by:
    - Attending formal courses.
    - Attending scientific seminars and meetings.
    - Acquiring professional certification.
  - Ensure that mandated training is provided.

- Laboratory training goals are evaluated in light of present and future workload demands during annual management review to:
  - Align competencies with changing client needs and laboratory capabilities.
  - Promote professional development and long-term career growth in all staff.
  - Ensure that mandated training is provided.

BFS evaluates the effectiveness of individual training through competency and proficiency testing.

### Contracted personnel (5.2.3)

Only BFS employees perform critical tasks in the laboratory. BFS does not use contracted employees.

### Job descriptions (5.2.4)

All BFS personnel have a duty statement and current workplan on file.

Formal job descriptions for each classification are maintained by the State Personnel Board and are available online. The specific assignments of an employee are contained in a duty statement and the Employee Expectations and Work Plan form. The workplan is reviewed and revised annually.

### Educational requirements (5.2.6.1.1 to 5.2.6.1.5)

BFS employees meet the minimum educational requirements for critical tasks.

BFS continually recruits the most qualified applicants meeting or exceeding the prerequisites set by BFS and hires only the most qualified. BFS recruits through advertising and presentations at academic institutions or professional meetings. These recruitment efforts result in internship or employment.
Applicants meeting the state-mandated minimum requirements must:
• Complete a state application to present their education, training, and experience.
• Undergo a structured interview to present their character, education, training, and experience, allowing BFS to evaluate their potential for competency and excellence.

BFS hires the most qualified candidates, those who desire to become a part of an organization of excellence, innovation, and service.

BFS analysts meet the education requirements listed in the most current ASCLD/LAB-International Supplemental Requirements document.

<table>
<thead>
<tr>
<th>Literature resources (5.2.7)</th>
</tr>
</thead>
</table>
BFS makes literature resources, relevant to services and disciplines provided by the laboratory, available to all staff.
In addition to the local laboratory library, the California Criminalistics Institute (CCI) maintains a library containing books and journals.
5.3 Facility Security, Safety, and Environmental Conditions

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**Laboratory facilities maintenance (5.3.1 and 5.3.2)**

BFS maintains laboratory facilities so that they are conducive to the examination of samples. Examinations shall be stopped when environmental conditions jeopardize test results.

Environmental conditions may affect sample storage, instrumentation, and testing:
- Environmental conditions affecting sample storage, such as refrigerator temperatures, are monitored. The procedures for this monitoring are specified in the laboratory operations manual and/or applicable discipline manuals.
- Environmental conditions critical to an analysis are specified within its technical procedure. Internal controls are used to monitor the performance of an analysis which may be affected by environmental factors.
- Field investigations occur in various environments. Environmental conditions that may adversely affect evidence collected by BFS staff are documented in the case record.

---

**Separation of incompatible activities (5.3.3)**

BFS separates, by space or time, incompatible activities to prevent cross-contamination in the laboratory.

During the examination of evidence, care is taken to prevent cross-contamination:
- As much as possible, suspect and victim items are physically separated by physical distance, time, or container.
- Work surfaces and examination implements are cleaned.
- Evidence remains out of its protective container only as long as necessary to complete the examination.

Discipline manuals contain any specific requirements to prevent contamination.

---

**Laboratory security (5.3.4 and 5.3.4.1a to f)**

BFS limits access to examination and sample storage areas to personnel authorized by the Laboratory Director.

Procedures in each laboratory’s operations manual ensure that:
- Access to laboratory operational areas is controlled. Visitor access to analytical areas is restricted and supervised.
- Exterior exit and entrance points and the entire outer perimeter of the laboratory, have adequate security control.
- Laboratory management grants staff access to designated operational areas.
- Each access key assignment is documented and all access keys are accounted for.
- The laboratory is monitored during vacant hours by an alarm or by security personnel.
- Evidence storage areas are controlled to prevent loss or alteration of the evidence before and after examination.
Housekeeping requirements (5.3.5)

As much as possible, BFS laboratories are maintained in a clean and orderly condition to provide a contaminant-free environment.

Any discipline-specific storage or environmental requirements are discussed in the discipline manuals.

Safety program (5.3.6)

BFS requires the highest level of safety possible during all activities. Safety is a primary concern of all laboratory employees.

BFS has established and implemented a health and safety program for the reduction of injuries, illnesses, and accidents. As appropriate for their positions and work assignments, all employees participate in the health and safety program and are responsible for implementing and adhering to its policies.

The following documents are part of the health and safety program:

- The BFS Safety Manual containing:
  - Injury and Illness Prevention Program
  - Fire Prevention Plan
  - Hazard Communication Program
  - Chemical Hygiene Plan
  - BFS Bloodborne Pathogen Exposure Control Program
  - Respiratory Protection Program
  - Radiation Protection Program
  - Laboratory Safety Inspection Report Template
- BFS Laboratories that provide Clandestine Laboratory Scene response utilize the Clandestine Laboratory Manual of Instruction and Procedures (CLMIP)
- The laboratory operations manual may contain safety requirements that are specific to the site.
- Safety concerns specific to each discipline are delineated in each discipline manual.

The Laboratory Director appoints a health and safety program officer who:

- Is properly trained.
- Monitors compliance.
- Performs monthly safety checks.
- Recommends suspending examinations when health and safety are jeopardized.
- Periodically reviews the BFS safety program.
5.4 Technical Procedures

General (5.4.1)  BFS uses scientifically valid procedures accepted by the forensic community to perform critical tasks in casework and in the Data Bank.

Technical procedures are a part of the discipline manuals developed by technical advisory groups (TAGs) or the DNA Technical Leaders. These procedures are periodically reviewed as part of the Bureau-wide management review process. Technical procedures are readily available through the document control system for use and review by all personnel. Instrument manuals are available to all technical personnel.

These procedures include, where appropriate:
- Sample selection, sampling procedures, and/or sampling plans, following the specifications of section 5.7
- Procedures for the handling, transport, storage, and preparation of evidence, in addition to the procedures mentioned in section 5.8
- Procedures for determining the uncertainty of measurement
- Any statistical techniques used for the analysis of data
- Instructions on the use and operation of all relevant equipment where the absence of such instructions could jeopardize the results of examinations
- Controls and standards, including the use of any reference materials

Deviations to technical procedures must be first justified by examiners to laboratory management and authorized using the Deviation from Procedure form. The completed form is stored in the case record. Clients are notified of any deviations that impact the investigative approach (section 4.4).

Selection of procedures (5.4.2)  BFS uses validated procedures to meet the analytical needs of its client.

The client does not specify the procedure to be used; however, BFS consults with the client at the time of request to determine the investigative approach (section 4.4.1). The procedures used are documented in the case record and available to the client upon request. Procedures are selected from the following:
- International, national, or regional standards of analysis
- Technical organizations
- Scientific texts or journals
- Equipment manufacturers
- Laboratory-developed technical procedures
The technical procedures used are:

- The latest valid edition.
- Supplemented with additional details to ensure consistent application.
- Validated by the laboratory to ensure reliability when necessary.
- Revalidated after any significant change to the technical procedure.

---

Validation of new technical procedures

The reliability of any new procedure is documented before its implementation.

New technical procedures are validated to demonstrate that they produce the desired results using the reagents and equipment in the laboratory. Requirements for validation are specified in the discipline manuals, and validation results are stored in the laboratory.

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Laboratory-developed technical procedures (5.4.3)

New technical procedures may be recommended or developed and documented by qualified personnel using adequate resources provided by BFS.

To continually improve the quality of examinations BFS utilizes two approaches to the development of new technical procedures:

- Selected subject matter experts working as “Technical Advisory Groups (TAG)” evaluate new technologies and make recommendations using the improvement process of the Quality Management System (section 4.10) which involves continuous updates and communications to all involved personnel.
- The Jan Bashinski DNA Laboratory Research/Training group is responsible for the development of technical procedures relevant to DNA.

---

Use of nonstandard procedures (5.4.4)

The Laboratory Director authorizes the use of nonstandard procedures in the examination of evidence once such procedures have been validated.

Requests for the use of nonstandard procedures follow the chain of command. Nonstandard procedures are used when mandated by the client agency’s investigative needs or the nature of the evidence. These technical procedures are validated, approved and documented in the case record using the BFS Deviation from Procedure form before being used.

As stated in Section 5.4.2, the client does not specify the procedure to be used. This also applies to the use of nonstandard procedures.

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Technical procedure validation (5.4.5.1, 5.4.5.2, 5.4.5.3, and 5.4.5.4)

BFS uses only scientifically valid technical procedures.

BFS uses validated procedures to meet the client agency’s investigative needs. The use of validated procedures ensures that the results are scientifically acceptable and reproducible and that the procedure is fit for its intended application.
Two types of validation are required to implement or modify scientific technical procedures for forensic analysis:

- A developmental validation requires a complete understanding of the theoretical basis for the technical procedure or technology. With this understanding, the forensic analyst can demonstrate the specificity, accuracy, precision, detection limits and reproducibility of the technical procedure or technology. A BFS laboratory or an outside organization may perform developmental validation.

- An internal validation demonstrates that established technical procedures perform as expected in each laboratory’s environment or with new technology. Internal validation is required:
  - Before using a procedure or technology that has undergone developmental validation
  - When a new technology is applied to an existing technical procedure
  - When there is a significant change to a technical procedure

BFS retains validation documentation to include the following:

- Procedure used for the validation
- Results obtained
- A statement as to whether the technical procedure is fit for the intended use

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**Uncertainty of measurement for calibration laboratories (5.4.6.1)**

BFS is not a calibration laboratory and does not perform its own calibrations.

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**Uncertainty of measurement (5.4.6, 5.4.6.2 and 5.4.6.3)**

Uncertainty of measurement is addressed in each applicable discipline manual.

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**Control of data (5.4.7.1)**

BFS calculations and data transfers are checked through the technical and administrative review process.
Use of computers in analysis (5.4.7.2)

Computers, automated equipment, and software used for acquiring, processing, recording, reporting, storing, or retrieving examination data meet the following conditions:

- Internally developed computer software is validated and documented prior to use
- The integrity and confidentiality of data are protected according to sections 4.3 and 4.13.
- Computers and automated equipment are installed and operated in compliance with manufacturer’s recommendations. Intermediate checks verify the proper functioning of automated equipment and their controlling computers. The environmental and operating conditions of stand-alone personal computers are not monitored.

Commercially-developed software, such as word processing, database, or instrument data system software, is considered sufficiently validated.

Computers used in digital evidence examination (5.4.7.2.1)

- Access to the areas containing computer systems used for examining digital evidence will be limited to the laboratory management and staff authorized by the laboratory director.

- The digital evidence computer areas will be secured by electronic key access or manual locking mechanism, and the areas will be locked when vacant.
5.5 Equipment

BFS laboratories are furnished with the analytical equipment necessary for the examinations performed.

The equipment required to examine evidence is documented in the appropriate discipline manual.

BFS laboratories do not use any equipment outside BFS’s permanent control that has not been validated or otherwise checked to ensure consistently reliable results.

BFS equipment meets the requirements of the relevant examinations listed in the discipline manuals.

Equipment that significantly affects the quality of an examination requires regular quality control through internal validation, performance verification, and intermediate checks. The equipment and associated quality control procedures are defined in each discipline manual.

BFS ensures that analytical equipment meets the requirements of relevant examinations by:

- Performing or accepting outside developmental validation of technology with a theoretical basis significantly different from equipment currently in use.
- Conducting internal validation of new equipment technology applied to existing technical procedures.
- Conducting performance verification for the following:
  - New equipment of existing technology for use in existing technical procedures
  - Equipment returning to the control of BFS
  - Equipment that has undergone a change of location
- Performing intermediate checks of equipment at regular intervals according to specifications in the discipline manuals.

Equipment in BFS is operated by authorized personnel.

Personnel are authorized to operate equipment through the completion of the training program specified in section 5.2.

Up-to-date instructions on the use and maintenance of equipment are provided by the manufacturers and are stored in close proximity to each piece of equipment.
Identification of equipment (5.5.4)

**Equipment and its software are uniquely identified.**

The State of California assigns a number for inventory purposes. The laboratory may assign another unique identifier to the equipment to allow for easier tracking of examination documentation, quality control checks, and maintenance.

Equipment records (5.5.5 a to h)

**Equipment records are stored in electronic or hard copy form.**

The records include at least the following:

- The unique identity of the item of equipment and its software, as specified in section 5.5.4
- The manufacturer’s name, type identification (model number), and serial number or other unique identification
- Quality control check records, which may consist of:
  - Internal validations
  - Performance verifications
  - Intermediate checks
- The current location
- The manufacturer’s instructions, if available, or reference to their location
- Calibration certificates and the due date of next calibration if applicable
- The maintenance schedule, if appropriate, and the maintenance carried out to date
- Any damage, malfunction, modification, or repair to the equipment

Each piece of equipment has a corresponding instrument maintenance log containing the above information. The log is located close to the instrument. All maintenance, repairs, or performance verifications are recorded as soon as possible after completion.

Equipment maintenance (5.5.6)

**BFS has procedures for safe handling, transport, storage, use, and planned maintenance of equipment to ensure proper functioning and to prevent contamination or deterioration.**

Guidelines for handling, transporting, and storing instruments are normally designated by the instrument’s manufacturer. Any exceptions to the manufacturer’s instructions are specified in the appropriate discipline manual. Equipment requires performance verification before being moved and before subsequent use in its new location.

Maintenance of critical equipment is performed by laboratory personnel authorized to operate the specific equipment (section 5.5.3) or people certified by the instrument’s vendor.

Maintenance procedures document:

- The frequency and type of maintenance to be performed.
- Any scheduled maintenance contract information, if applicable.
Equipment that does not meet predefined quality control criteria and that cannot be immediately repaired is removed from service.

Equipment that is removed from service is clearly labeled “Out of Service” until the problem has been rectified.

The removal of equipment is documented in the appropriate instrument maintenance log, with the date and reason for removal. The date the instrument is returned to service is written in the log.

If appropriate, the laboratory examines the effect that the removed equipment may have had on previous examinations and institutes any necessary corrective action.

Calibrated equipment is labeled with the date that calibration is next due.

Records are kept of the calibration status of instruments, as specified in section 5.6.2.2.1, including the date last calibrated and the date recalibration is due. These records are kept in the instrument maintenance log.

If equipment leaves the direct control of the laboratory, the laboratory ensures that the function and, if applicable, calibration status of the equipment are checked and shown to be satisfactory before use in examinations. Visual inspections, quality control procedures, and intermediate checks are examples of equipment checks. Specific details for equipment requiring traceability are located in the appropriate discipline manuals.

Intermediate checks are carried out to ensure the continued performance of equipment.

The continued reliability of examination equipment is verified through the use of intermediate checks. The nature and frequency of intermediate checks are specified in the discipline manuals and the results documented. Equipment that does not pass intermediate checks is removed from service and affected casework is reviewed.

BFS is not a calibration laboratory and does not perform its own calibrations.

If an instrument calibration by an approved vendor gives rise to a set of correction factors, the affected equipment is removed from service.
Adjustments of calibrated equipment (5.5.12)

Examination equipment is safeguarded from adjustments that would invalidate the examination results.

To safeguard from adjustments that would invalidate the test results, all equipment used for examinations is located in limited access areas. This equipment is only used by qualified personnel as specified in section 5.5.3.

All analytical equipment is periodically checked to ensure proper function as designated in the appropriate discipline manual.
5.6 Measurement Traceability

General traceability policy (5.6.1)

All equipment requiring measurement traceability is calibrated before being put into service. The program and procedure for the calibration of equipment is specified in the appropriate discipline manuals.

General calibration check requirements (5.6.1.1)

Each discipline manual includes quality control check procedures for each piece of equipment that significantly affects the quality of examinations.

Calibration laboratory requirements (5.6.2.1 and 5.6.2.1.1)

BFS does not provide calibration services. This standard does not apply.

Calibration requirements (5.6.2.1.2)

BFS does not provide calibration services. This standard does not apply.

Traceability requirements (5.6.2.2.1)

Although BFS testing laboratories are not calibration laboratories, they do report measurements that require traceability. The traceability of these measurements is assured by the use of external calibration laboratories that can demonstrate competence, measurement capability and traceability. The program and procedure for the calibration of equipment is specified in the appropriate discipline manuals.

BFS reports the following measurements that require traceability:
- The weight of a controlled substance submission (grams)
- The alcohol concentration in a biological sample (weight per volume)
- The barrel length of a rifle or shotgun (inches)
- The overall length of a rifle or shotgun (inches)
- The concentration of a drug in a blood sample (weight per volume)
Equipment Requiring Measurement Traceability

Equipment requiring measurement traceability is calibrated by an external vendor in order to ensure that measurements made by the laboratory are traceable to the International System of Units (SI). The calibration and external vendor requirements are specified in the appropriate discipline manuals:

- Balance Technical Procedures (TP-22)
- Calibration of Measuring Equipment Used in the Alcohol Technical Procedures (TP-15-2)
- Calibration of Measuring Equipment used in Firearms/Toolmarks for the Determination of Barrel and Overall Length (TP-08-2)
- Toxicology Technical Procedures (TP-11-2)

Calibration Certificates

Calibration certificates issued for equipment requiring measurement traceability by external calibration laboratories are to contain the measurement results, including either the measurement uncertainty or a statement of compliance with an identified metrological specification. Each laboratory maintains records related to the calibration of equipment by external vendors.

Documentation requirements

In instances when multiple items of equipment requiring traceability are available for use, the case record shall reflect the unique identification of the equipment used. For example, multiple pipettor diluters may be used for forensic alcohol casework. The case notes will document identifying information of the pipettor diluter that had been used for the analysis.

Traceability of qualitative measurements (5.6.2.2.2)

Where traceability to SI units is not possible and/or relevant, BFS uses reference materials, agreed methods, or consensus standards for quality control checks of equipment that significantly affects the quality of examinations.

BFS laboratories provide confidence in examination results by establishing traceability to appropriate standards through the use of:

- Reference materials (Section 5.6.3.2) to give a reliable physical or chemical characterization of a material. These materials are provided by a competent supplier.
- Clearly specified procedures that are described in the discipline manuals.
Reference standards are used to check the calibration status and proper function of equipment.

Reference standards are procured from vendors that can provide certificates of measurement traceability to the International System of Units (SI). Reference standards are used in the following manner:

<table>
<thead>
<tr>
<th>Reference Standards</th>
<th>Used to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weights</td>
<td>Perform scheduled intermediate checks for all balances</td>
</tr>
<tr>
<td>Thermometers</td>
<td>Check temperature measurements in instruments and equipment, as defined in specific discipline manuals</td>
</tr>
</tbody>
</table>

The calibration of reference standards are defined in the appropriate discipline manual.

When appropriate, reference material may be used for equipment quality control checks where traceability to SI units is not possible or relevant.

The discipline manuals specify the reference material used for equipment quality control checks.

Reference material used for measurement traceability, called certified reference material (CRM), must be purchased from a vendor accredited as a reference material producer that provides a certificate documenting that the material meets specific property values (e.g. concentration or purity) and includes information on the associated traceability and uncertainty.

Certain BFS technical procedures must meet additional requirements, which are established by external regulatory agencies such as California Department of Public Health. These agencies may require names for solutions that differ from those in Section 5.6.3.2, but fit the definition of reference materials. This exception is specifically allowed in the following instances:

- The terms “Secondary Alcohol Standard” and “Internal Standard” may be used in the following procedures:
  - TP-14 GC Headspace Technical Procedure
  - TP-15 Direct Oxidation Method
Reference collections (5.6.3.2.1)

BFS controls collections of reference materials or data to ensure reliability of examination results.

Fully documented, uniquely identified and properly controlled reference collections are maintained for identification, comparison, quality control, or interpretation purposes.

Reference collections may be comprised of:
- Items of known origin not meeting the traceability requirements for reference materials or reference standards such as:
  - Laboratory collected materials such as soils, paints, fibers, construction materials, firearms, etc.
  - Purchased materials such as automotive paint collections, insect collections, ammunition, minerals, etc.
- Data of known origin from reliable sources.
  - Internally developed mass spectral databases
  - Purchased mass spectral databases from authenticated sources.

All BFS reference collections are:
- Fully documented on the material, its container or in a computer database. Documentation should include:
  - The source of the item
  - Date acquired and by whom
  - Method of authentication (if applicable)
- Uniquely identified by an alpha-numeric code, vendor lot number, or the name of the item.
- Properly controlled by Laboratory Management in a manner to protect the integrity of the reference standards, reference materials and reference collections.

Intermediate checks (5.6.3.3)

Intermediate checks used to maintain confidence in the calibration status of reference, primary, transfer or working standards are referenced in the appropriate discipline manual.

Transport and storage of reference standards and materials (5.6.3.4)

To protect their integrity, BFS stores and packages reference materials and reference standards in order to prevent contamination or deterioration during transport, long-term storage, and use.

When necessary, BFS specifies requirements for the handling, transport, storage, and use of reference materials and standards used to perform quality control checks on equipment. BFS specifies these requirements on the item, on its container, in the database used to track it, or in the appropriate discipline manual.
5.7 Sampling and Sample Selection

Evidence sampling and sample selection (5.7.1)

BFS uses either sampling or sample selection in order to test items of evidence. When necessary, procedures for sampling, and/or sample selection, are documented in the appropriate discipline manual.

BFS selects samples based upon:
- The training and experience of the examiner
- Statutory implications of the analytical results

*Note:* BFS does not use sampling plans.

Documentation of deviations from sampling and sample selection procedures (5.7.2)

BFS documents client-requested deviations from sampling, and/or sample selection procedures, in the case records.

Recording of sampling and sample selection data (5.7.3)

BFS records any relevant data related to sampling, and/or the sample selection, of evidence in the case records.

Documentation may include the following:
- The location of the sample, including any diagrams, sketches, or photographs
- The date sampled and by whom sampled
- Description of the item sampled
- Details of any environmental conditions during sample selection that may affect the interpretation of examination results
5.8 Evidence Handling

BFS laboratories ensure the integrity of evidence, from receipt to disposition, to protect the interests of the client and the laboratory.

Each BFS laboratory provides a controlled environment that allows for evidence to be securely received from clients. Sample packaging is evaluated for evidence integrity and for suitability of examination. Evidence and its chain of custody are tracked in JusticeTrax (JT), the laboratory’s information management system. Evidence is stored in secure, limited access locations.

Evidence submitted to BFS laboratories is to be accompanied by a Physical Evidence Submission Form (BFS-1) which includes case-related information, a listing/description of evidence submitted, information regarding the services being requested, and an initial chain of custody. In lieu of the BFS-1, evidence in volume programs (e.g. Alcohol, Controlled Substance, Toxicology, and RADs) may be submitted in an evidence envelope which contains the essential administrative information and chain of custody. When necessary, a BFS-1 form will be created by laboratory staff.

BFS assigns a case number that is a combination of the BFS laboratory identifier, year and sequential number (e.g. RD-15-001234). This case number is a link to the case records associated with the client’s investigative request and the laboratory analysis. Each evidence submission on a case is given a unique identifier which includes the BFS case number.

Entry of evidence into JusticeTrax is to be done in a timely manner, typically the day of receipt. If entry does not occur by the end of the next business day, the reason for the delay will be documented in the case record.

Program Differences

Some programs address samples/evidence differently than described above. These include:

<table>
<thead>
<tr>
<th>Program</th>
<th>Distinctions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing Persons DNA Program</td>
<td>• In lieu of BFS1, uses the BFS 810 or BFS 900</td>
</tr>
<tr>
<td></td>
<td>• In lieu of JusticeTrax, uses Laboratory Information Systems Applications (LISA)</td>
</tr>
<tr>
<td></td>
<td>See the DNA Casework Technical Procedures – Volume II for further information.</td>
</tr>
<tr>
<td>CAL-DNA Data Bank Program</td>
<td>• Samples received are not considered evidence and are not subject to these guidelines. See the Data Bank Discipline Manual for details on sample handling.</td>
</tr>
<tr>
<td>California Cyber Crime Center (C4)</td>
<td>• Manuals addressing evidence handling are in development.</td>
</tr>
<tr>
<td></td>
<td>• This program is not accredited at this time.</td>
</tr>
</tbody>
</table>
General evidence receipt process (5.8.1 and 5.8.1.1.2)
The general process for the receipt of evidence is described below. The chain of custody and other relevant information will be documented throughout the process.

<table>
<thead>
<tr>
<th>Submission</th>
<th>Evidence is submitted by a client agency into the BFS Laboratory.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A client agency submits evidence to the BFS Laboratory for analysis. Evidence submission generally occurs either in-person via an agency representative or through delivery via a common courier (e.g. UPS, FED/EX, US Mail, etc.). It is the responsibility of the agency to submit evidence that is properly packaged (to prevent damage, loss, and transfer) and properly sealed (with an identifying mark on the seal).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Receipt and evaluation</th>
<th>Evidence is received into the BFS Laboratory and evaluated by the BFS Staff.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Evidence is considered received into the laboratory when a BFS Staff member physically takes possession of the evidence package or shipping container, regardless of the method of submission.</td>
</tr>
<tr>
<td></td>
<td>BFS Staff then evaluates the evidence packaging in order to ensure the evidence is:</td>
</tr>
<tr>
<td></td>
<td>• properly packaged to prevent damage, loss and transfer, and</td>
</tr>
<tr>
<td></td>
<td>• properly sealed with an identifying mark on the seal (e.g. initials, badge number, etc.).</td>
</tr>
<tr>
<td></td>
<td>Any issues are to be corrected by the agency when possible or by BFS Staff as soon as practicable after the issue has been identified.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Entry in JusticeTrax</th>
<th>Evidence is entered into JusticeTrax.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Key elements for the maintenance of evidence integrity include:</td>
</tr>
<tr>
<td></td>
<td>• assignment of a unique identifier to the evidence</td>
</tr>
<tr>
<td></td>
<td>• recording the chain of custody for the evidence, starting with submission to the laboratory</td>
</tr>
<tr>
<td></td>
<td>• BFS staff using their PIN to secure all of their chain of custody entries</td>
</tr>
<tr>
<td></td>
<td>Refer to the JusticeTrax Manual for specific procedures regarding the above.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage</th>
<th>Evidence is securely stored awaiting analysis.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Evidence awaiting analysis must be stored securely and in a manner appropriate to its evidence type.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documentation of chain of custody</th>
<th>The chain of custody of the evidence is accurately documented.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>When an agency submits evidence in-person, both the agency representative and the BFS staff member are to sign and date the chain of custody section of the Physical Evidence Submission Form (BFS-1) or BFS evidence envelope. For any other method of submission, the BFS staff member receiving evidence will sign the chain of custody on the BFS-1 or BFS evidence envelope, also noting the method of submission (e.g. name of courier company, mail unit, drop box) and the date of receipt.</td>
</tr>
<tr>
<td></td>
<td>Regardless of how the evidence is submitted, this chain of custody is also duplicated in JusticeTrax, along with record of the storage location of the evidence.</td>
</tr>
</tbody>
</table>
### Variations to the evidence receipt process

Occasionally there may be variations to the above process depending on circumstances and available staff. When these occur it is important to ensure that the following principles are followed:

- The evidence packaging must be evaluated in order to ensure the evidence is properly packaged and sealed. In some instances, the staff receiving the evidence may not open the shipping container. In these instances:
  - The receiving staff must at least verify the shipping container is sealed and initial/date the container.
  - The staff opening the shipping container is responsible for ensuring the evidence is properly packaged and sealed as described above.

- The evidence must be stored in a manner that protects the integrity of the evidence (e.g. Blood alcohol samples are to be placed in refrigerated storage if there is an overnight delay in entry into JusticeTrax).

- The chain of custody documentation must include:
  - A written record of the receipt, as evidenced by the receiver’s signature and the date on the BFS-1 or evidence envelope, and
  - An electronic record of receipt and of all internal transfers to persons or storage locations, as evidenced by secured transactions in JusticeTrax.

---

### Chain of custody (5.8.1.1 and 5.8.1.1.1)

**BFS maintains a complete chain of custody for every item of evidence from receipt to disposition, including items internally transferred.**

All examined evidence items, their containers, or identification tags are marked with a unique identifier that:

- Associates it to a particular external agency investigation
- Tracks it from receipt to disposition
- Aids in linking examination results to a particular evidence item within a container.

JusticeTrax, as the primary chain-of-custody system used by BFS, performs the following functions:

- Tracks evidence from laboratory receipt to disposition
- Records the internal transfers of evidence packages, including subdivided items, within the laboratory
- Records the transfer of evidence from a person to another person or from a person to a location
Evidence identification and labeling (5.8.2, and 5.8.4.3)

Each submission container and each examined item of evidence is assigned a unique identifier.

This unique identifier is used to:
- Track the chain of custody within and from the laboratory.
- Ensure that evidence items cannot be physically confused.
- Ensure that evidence items cannot be assigned erroneous examination results.

The following procedure is used to establish unique identifiers:
- Case-related information entered into JusticeTrax generates a case number specific to that investigation. This case number becomes a part of the unique identifier assigned to each submission container or examined item.
- Examined items are described and assigned a unique identifier in JusticeTrax. This unique identifier is retained throughout the item’s life in the laboratory. This unique identifier and inherited chain are passed to sub-items in a parent-child relationship.
- The unique identifier is applied to all evidence submissions, its proximal container or its attached tag.
- The unique identifier of sub-items, including splits, is a combination of its parent’s identifier and a numeric or alpha-numeric character.
- Sub-items, including splits, inherit the historical chain of custody of its parent and are subsequently tracked through its own chain of custody.

Evidence evaluation (5.8.3)

BFS evaluates evidence packaging, labeling, and sample descriptions for any abnormalities that could affect admissibility, staff safety, or the viability of examination results.

In addition to guidelines specified in section 4.4, the laboratory generally consults the client agency before beginning an examination when:
- There is doubt that the evidence is suitable for the requested examination.
- Initial examination may result in consumption of all of the evidence.
- An item does not conform to the description provided.
- The required examination is not specified in sufficient detail.

Evaluation of the evidence occurs at the time of receipt as well as during the examination process in order to detect any abnormalities that may affect the ability of the laboratory to receive or examine the evidence.
Abnormalities are resolved as follows:

- Sealing or labeling abnormalities that affect the ability to receive the evidence are recorded and corrected by the submitting party or laboratory staff.
- If abnormalities affect the ability to examine the evidence:
  - The submitting agency is informed.
  - The abnormality is recorded in the case record.
  - Agreement is reached with the client as to what examinations are appropriate.
  - If no agreement is reached, the evidence is returned without examination.

---

**Storage of evidence (5.8.4)**

**BFS provides security and storage to protect the integrity of samples in its control.**

The procedures detailed in section 5.8 are designed to routinely protect evidence from deterioration, loss, or damage during storage, handling, and preparation.

Special temperature requirements for evidence storage are specified in the appropriate discipline manual. Procedures for temperature monitoring are maintained in the laboratory operations manual.

Any non-routine evidence is handled as follows:

- Any special instructions provided by the client about the handling of the evidence or case security are adhered to or further discussed with the client.
- Large items of evidence, a portion of which will be examined, are stored securely in the laboratory and protected from deleterious change or contamination.

---

**Evidence not in the process of examination (5.8.4.1)**

**Evidence not in the process of examination is securely stored in a properly sealed container to protect it from loss, cross-transfer, or contamination.**

Evidence not in the process of examination is stored under proper seal in a secure location to maintain its integrity, preserve the chain of custody, and protect the evidence (sections 5.3.4 and 5.3.4.1).

**Proper Sealing of Evidence**

These general guidelines apply to the proper sealing of evidence:

- Evidence containers are tape- or heat-sealed and marked with an identifier such as initials.
- Exceptions to normal sealing requirements are:
  - Potential evidence contained on a large item not suitable for normal packaging (such as bullet holes, impressions, fingerprints, or blood) is isolated to protect its integrity.
  - Properly labeled firearms may be secured in an unsealed condition when appropriate.
- Whenever possible the examiner opening the evidence leaves the original seal intact. Prior to its return to the vault the evidence is resealed.
- Containers designated to transport evidence do not require sealing.
Unattended evidence in the process of being examined
(5.8.4.2)

BFS secures evidence in the process of being examined.

Evidence that is actively being examined may be left unattended in limited-access examination areas during business hours if the evidence is protected from loss, cross-transfer, contamination, or deleterious change.

During non-business hours, in progress evidence should be in a personal storage unit, vault, secure storage room, or in a secure laboratory area as long as it is protected from deleterious change or contamination.

Evidence in the possession of an analyst is “in the process of examination” until the related request is administratively reviewed.

Evidence will not be kept in a personal storage area for longer than 60 days after the related request is administratively reviewed, with the exception of DNA extracts, which may be stored in short-term storage for up to six months pending additional testing. To protect the integrity of the evidence, personal evidence storage areas are not to be used for long term evidence storage.

Photographic evidence
(5.8.4.4)

Agency-submitted negatives, prints, or digital images are evidence. BFS field-generated negatives or digital images are evidence.

In the course of an examination, an analyst may capture images of evidence or examination results. The images are treated as evidence if the examination results cannot be reproduced, the evidence item no longer exists, or the characteristics examined no longer exist. Otherwise, they are treated as examination documentation.

Evidence negatives, prints, or digital images are:
• Handled according to section 5.8, including packaging, storage, and disposition.
• Indicated as released to “a representative” of any external photo-processor in the chain of custody.
• Labeled with a unique identifier to associate the appropriate request or item number.
• Not altered.

BFS-generated copies of evidentiary images may be treated as examination documentation once they are clearly labeled as copies. The copies may be enhanced for viewing but not altered to change their meaning.
Evidence in transit to the laboratory by laboratory personnel from crime field investigations is protected from loss, cross-transfer, contamination, or deleterious change.

Any field processing to preserve, evaluate, document, or render evidence safe is accomplished before final packaging. Evidence collected from a field investigation is appropriately identified, packaged, and listed on a BFS-1 submittal form initiating the chain of custody and then entered into JusticeTrax following the evidence receipt guidelines (section 5.8.1.1).

Procedures for the operation of CAL-DNA databanks are found in the Data Bank discipline manual.

BFS has established definitions for which individual characteristic database samples are treated as evidence, reference materials, or examination documentation.

Samples submitted to BFS for entry into the following externally controlled individual characteristic database programs are defined as evidence or reference as follows:

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Database</th>
<th>Sample Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latent Prints</td>
<td>Cal-ID AFIS/IAFIS</td>
<td>Evidence</td>
</tr>
<tr>
<td>DNA Data Bank</td>
<td>CODIS</td>
<td>Reference</td>
</tr>
<tr>
<td>DNA CW/MP</td>
<td>CODIS</td>
<td>Evidence</td>
</tr>
</tbody>
</table>

Individual characteristic database samples treated as evidence meet requirements of chain of custody (section 5.8.1.1), evidence sealing and protection (section 5.8.4.1), evidence storage (section 5.8.4.2), and evidence marking (section 5.8.4.3).

Individual characteristic database samples not treated as evidence are:
- Uniquely identified.
- Protected from loss, cross-transfer, contamination, or deleterious change.
- Restricted in access to those authorized by the Laboratory Director as designated in the Laboratory Operations Manual.
- Treated in a manner that reasonably ensures its utility as comparison materials.

Access to individual characteristic database samples under the control of the laboratory is restricted to those authorized by the laboratory director.

A completed Certificate to Perform Casework or Data Bank Work form, signed by the laboratory director, serves as authorization for access to database samples within that discipline.
Guidelines for evidence retention and destruction (5.8.1)

Evidence subject to long-term storage or destruction is outlined below:

<table>
<thead>
<tr>
<th>Case Type</th>
<th>Storage Conditions</th>
<th>Retention Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-felony Alcohol and Toxicology evidence</td>
<td>Refrigerated*</td>
<td>Minimum of one year, then destroyed</td>
</tr>
<tr>
<td>Felony Alcohol and Toxicology evidence</td>
<td>Refrigerated*</td>
<td>Minimum of one year, then returned to agency</td>
</tr>
<tr>
<td>Biological evidence retained as Long-term storage (LTS) samples</td>
<td>Frozen</td>
<td>Minimum of five years, then returned to agency</td>
</tr>
<tr>
<td>DNA extracts**</td>
<td>Frozen</td>
<td>Minimum of five years, then returned to agency</td>
</tr>
</tbody>
</table>

*All Alcohol and Toxicology evidence is stored under refrigeration until first analyzed. Samples may be stored at room temperature after the evidence has been analyzed and reported, unless otherwise specified in the technical procedures.

**Only DNA extracts and laboratory-prepared slides are considered to be evidence. All other material generated as a function of DNA analysis, including amplified product, is considered to be work product.

Note: Portions of Data Bank samples, although not evidence, may require reanalysis to confirm hits, type additional loci or conduct quality control testing and are retained indefinitely.

Documentation of evidence release, destruction and storage (5.8.1)

When evidence is released from the possession of the laboratory or its staff (e.g. to agency or to court), the chain of custody documentation must include:

- A written record of the release on the BFS-1 or evidence envelope, and
- An electronic record of release in JusticeTrax.

When evidence is to be retained for long-term storage in the laboratory, the JusticeTrax chain of custody is updated with the long-term storage location.

When evidence is to be destroyed, the JusticeTrax chain of custody is updated by transferring the evidence to “Destroyed,” and a list of destroyed items is retained.
5.9 Ensuring the Quality of Examination Results

BFS has quality control procedures to ensure that accurate results are generated and reported.

BFS quality control procedures used to validate examinations are recorded and monitored and, where practical, statistically evaluated for trends. These procedures include the use of:

- Certified reference materials and/or internally generated reference materials as specified in section 5.6.3.
- A proficiency test program
- Replicate examinations using the same or different methods.
- Adherence to quality control procedures outlined below.

Controls and standards (5.9.1.1)

All controls and standards are specified in the technical procedures and their use documented in the case record.

Use of quality control data (5.9.2)

BFS uses quality control data to monitor the examination process, detect inconsistencies and ensure the accuracy of results.

Quality control procedures and their acceptance criteria are documented in the appropriate discipline manual. Quality control records may:

- Affect reagents and equipment related to multiple cases—these are documented in log books (Sections 5.1 and 5.5.7).
- Affect examinations conducted within a single case—these are documented in the case record.

Examination results are not released if quality control data does not meet acceptable criteria as evaluated by the individual performing the check. If necessary, the appropriate reagent or equipment is removed from service until the problem is corrected.

Quality control records are retained to show that all appropriate quality measures have been taken.
BFS proficiency testing program (5.9.3, 5.9.3.1, 5.9.3.2, 5.9.3.3, 5.9.3.3.2 and 5.9.3.4) BFS maintains a documented program of proficiency testing. BFS is committed to an effective proficiency testing program as part of its Quality Management System, one which meets all relevant standards of the normative references.

Purpose of Proficiency Testing Program
The proficiency testing program is used to:
• Monitor the performance of individual examiners annually in each discipline.
• Scrutinize the laboratory as a whole in all disciplines.
• Identify areas for improvement.
• Comply with the ASCLD/LAB Proficiency Testing and Review Program.
• Evaluate the administrative flow of the proficiency test, the handling of related evidence, documentation, and report conclusions.

Proficiency Tests Treated as Casework
The proficiency testing program consists of samples that are:
• Treated as normal casework or data bank samples, including all aspects of the Quality Management System.
• Representative of normally encountered examinations.
• Analyzed using BFS-approved technical procedures.

Types of Proficiency Tests
Two types of proficiency tests are used to satisfy laboratory and individual testing requirements:
• External proficiency tests are created and evaluated by a source outside of BFS. Whenever available, an ASCLD/LAB-approved external provider is used. If an approved provider is not available, other external sources are used.
• Internal proficiency tests are created and evaluated within BFS. This may include the use of re-examination or blind tests.

Requirements for Proficiency Testing
The requirements for proficiency testing are as follows:
• Laboratories must successfully complete at least one external proficiency test each year for each discipline in which it provides services.
• Individuals must successfully complete:
  − An initial proficiency test, demonstrating competency to perform casework in a discipline
  − At least one proficiency test each year for each discipline in which he or she performs examinations
  − At least one proficiency test in each category of testing in which he or she performs examinations within an accreditation cycle. In order to meet this requirement, the laboratory shall have a documented schedule of proficiency testing which is being followed by each individual.
All DNA analysts and technical support personnel performing DNA analysis comply with proficiency test requirements of both the Quality Assurance Standards for Forensic DNA Testing Laboratories and the Quality Assurance Standards for DNA Databasing Laboratories.

Details of proficiency testing for data bank analysis team members are included in the DNA Data Bank Discipline Manual.

For DNA proficiency tests, the date the test is performed is defined as the date the test is submitted.

BFS maintains proficiency test records for all examiners.

Records of proficiency testing contain, at a minimum, the following:

- The test set identifier
- The way samples were obtained or created
- The identity of the person taking the test
- Dates of analyses and completion (may be the start or finish date)
- Originals or copies of all examination records including those supporting the conclusion
- The proficiency test results
- Any discrepancies noted
- Records of technical and administrative review
- Any feedback provided to the analyst including a review of results provided by the test provider.
- Details of any corrective actions taken

The record requirements listed above are retained at the local laboratory or the BFS Quality Assurance unit for at least one full ASCLD/LAB-International accreditation cycle or five years, whichever is longer.

Technical review (5.9.4, 5.9.4.1, and 5.9.4.3)

BFS performs a technical review of all case and Data Bank records where analysis was performed. This review shall be done by an authorized individual that did not participate in the analysis.

NOTE: The person who performs an independent check of a critical finding (See 4.13.2.12) is still permitted to perform a technical review of that case.
BFS performs technical reviews to ensure that:

- The conclusions, opinions or interpretations expressed in the report:
  - Are reasonable, within the constraints of scientific knowledge.
  - Are based upon objective reasoning and a demonstrable analytical approach.
  - Address the questions posed by the client.
  - Are accurate and supported by the examination documentation.
  - Are consistent with approved technical procedures.
  - Are consistent with applicable bureau and laboratory policies and procedures.
  - Associations are properly qualified in the report.
  - The report contains all required information.
- The electronic version of the report matches the reviewed hard-copy version.

The documentation of an accepted technical review is done as follows:

- The reviewer’s handwritten identification, date, and number of pages reviewed (including any inserted pages) are placed:
  - On the technical review checklist for criminalistics, digital evidence, latent prints, clandestine laboratory analysis, and field investigation cases.
  - On the Blood Alcohol Review Checklist for alcohol case files, if used.
  - On the first page of the notes for batch or individual toxicology and controlled substance case files.
  - On the DNA Data Bank technical review checklist for Data Bank folders.
- The technical reviewer updates the technical review milestone in the appropriate electronic database.
- The technical reviewer initials the examination reports of criminalistics, digital evidence, latent prints, clandestine laboratory analysis, and field investigation cases.

**Technical Review: Differing Opinions**

If differing opinions exist between the examiner and technical reviewer:

- Laboratory management confers with the parties to discuss and resolve the differences.
- If the differences are unresolved, laboratory management determines what further actions are needed, such as reanalysis or additional review.
- If no agreement can be reached, the Laboratory Director issues a report stating that different interpretations of examination results have not been resolved and that the results are not conclusive for this item of evidence.

**Laboratory management approves those qualified to perform technical review.**

Technical review is performed by employees who have gained expertise through training and experience in the discipline or category of testing, and have knowledge of the laboratory’s technical procedures. Authorization to perform technical review is documented on the Authorization to Perform Technical Review form, which is retained in the employee’s training file.
Administrative review (5.9.5 and 5.9.5.1)

BFS performs administrative review of all case and Data Bank records by an authorized individual that did not participate in the preparation of the test report.

BFS performs administrative reviews to verify that:

- The conclusions expressed in the report:
  - Address the client’s questions in the BFS-approved reporting format.
- Result from the use of approved and documented technical procedures.
- The case-related information meets the following:
  - Case security controlling the dissemination of reports is in place.
  - All supporting information meets the requirements of the Quality Management System.
  - Any client communications are documented.
- The electronic version of the report matches the reviewed hard-copy version.
- All spelling and grammar in the report are accurate.
- All administrative and examination records are uniquely identified
- All key information is included in the report.

An accepted administrative review is documented as outlined in the technical review section (section 5.9.4) using the administrative review checklist for criminalistics, digital evidence, latent prints, clandestine laboratory analysis, field investigation cases, and the Blood Alcohol Review Checklist for Alcohol cases (if used). The administrative reviewer updates the administrative review milestone in the appropriate electronic database.

Authorization to perform administrative review is documented on the Authorization to Perform Administrative Review form, which is retained in the employee’s training file.

Note: Data Bank records do not result in a test report; therefore, for the purpose of administrative review, the analyst who interprets the DNA profile is considered the author of the test report.

No work reports

Although “No Work” reports only require administrative review, the reviewer shall update the technical and administrative review of the written report and the milestones in the appropriate electronic database.
BFS annually monitors the testimony of all testifying personnel.

**Key Terms**

**Testifying personnel**: Any BFS employee called to testify regarding work performed during the normal course of BFS business. This may include analysts, property controllers, or other support staff that handle evidence, as well as anyone who performs a technical or administrative review of casework. Henceforth referred to as the **witness**.

**Evaluator**: Any individual who observes and evaluates the testimony of the witness. This includes BFS technical staff, BFS management, or officers of the court, such as prosecuting attorneys, defense attorneys, or judges.

**Testimony monitoring**: The entire process, which involves the following components:
- Observation and evaluation of witness testimony
- Review of the evaluation with the witness
- Remedial action (if applicable)
- Retention of records

**Witness Evaluations**

Direct observation by laboratory management, or technical staff, is the preferred method of witness evaluation. All feedback is documented using the **BFS Witness Evaluation Form**. This form is filled out directly by the evaluator, or by laboratory management, who has been in communication with the evaluator, or by reviewing court transcripts of the testimony. The **BFS Witness Evaluation Supplemental Form** may also be used by lab management in order to document any additional feedback for the witness.

The **BFS Witness Evaluation Form** is reviewed by laboratory management in order to determine if the witness performed satisfactorily. Laboratory management will discuss the evaluation with the witness, and that discussion is documented on the form. Disagreements with evaluations may be handled as described below.

**Remedial Action**

Remedial action will occur when:
- any rating is marked Poor or Unacceptable, or
- laboratory management deems it appropriate.

Laboratory management determines the type of remedial action the witness should perform, and will meet with the witness to discuss the remedial action.
Examples of remedial action may include, but are not limited to:

- Repeating selected portions of the Judicial Process and Testimony Training Curriculum
- Moot court or additional discussions
- Additional reading and/or written exercises
- Observation of other witnesses

Laboratory management will use the *BFS Witness Evaluation Supplemental Form* to document the remedial action, completion of the remedial action, and whether or not the remedial action was successful. If the remedial action was not successful then laboratory management will determine if the remediation will be expanded or the corrective action process will be initiated.

In instances where BFS laboratory management is not the evaluator, they should communicate with the evaluator in order to determine if a less than satisfactory evaluation is justified. If laboratory management determines that the evaluation was not justified, then no remedial action is needed. The communication with the evaluator and the rationale behind denying the remedial action shall be documented.

**Disagreements**

In the event that a witness disagrees with an evaluation, he or she may submit a memorandum to laboratory management documenting his or her disagreement. It is the responsibility of laboratory management to respond to the disagreement.

**Record Retention**

Documentation of annual testimony monitoring is retained not less than one ASCLD/LAB-International cycle of accreditation or five years, whichever is longer.
## 5.10 Reporting the Results

### General report guidelines (5.10.1 and 5.10.1.1)

BFS reports the results of its examinations objectively, accurately, and clearly, in accordance with the Quality Management System.

Accurate and unambiguous analytical results are provided in writing to the client. All reports, including internal reports, such as proficiency test reports, meet the following specifications:
- Is based upon scientifically valid technical procedures
- Objectively interprets results in the context of the investigation
- Accurately correlates results to uniquely identified samples
- Thoroughly addresses questions developed in the course of the investigation

A written report will be generated for every client request, including those for which no work is performed. Reports are not required when evidence is transferred from one BFS laboratory to another BFS laboratory for analysis.

BFS examination reports and case records include the information specified in sections 5.10.2 and 5.10.3.

CODIS offender hit notifications include the information specified in the Data Bank Technical Procedures, Section 6 (TP-07-05).

### Examination report contents - required (5.10.2 a to k)

The examination report contains the information listed below.
- Title of the report
- The name and address of the laboratory
- The BFS case and request number on each page (for example, RD-15-001234-0001).
- The name, address, and case number of the submitting agency
- Subject names
- A description and unambiguous identification of the evidence being examined.
- A summary of conclusions and the units of measurement, when appropriate
- A reference to the procedure used for sampling and/or sample selection, when it is necessary for the interpretation of test results
- Where relevant, a statement verifying that the results relate only to the evidence examined
- Evidence disposition
- The date of the report
- The name, title, and signatures, or electronic equivalent identification, of the examiner
- Signature, initials or electronic equivalent identification of the technical and administrative reviewer will appear at the end of the main body of the report (and may be in advance of any attachments or appendices).
### Examination report contents - optional (5.10.2 a to k)

The following information is included in the case record.

- The date of receipt of evidence being examined.
- The date of the examination.
- Identification of the technical procedure used, for example: Biology, Firearms.
- The condition of the evidence if it has bearing on the examination.

The author may elect to include any of the above in the examination report.

### Additional requirements (5.10.3.1 a to e)

The following information is included in the case record, as necessary for the proper interpretation of the examination result.

- Deviations from the technical procedure
- When relevant, any deviation from any examination agreed upon with client
- Information on specific examination conditions that may affect the validity of results
- The uncertainty of measurement associated with any applicable measurements
- Opinions and interpretations, where appropriate and needed
- Additional information required by the technical procedure or client

The author may elect to include any of the above in the examination report.

### Reporting of sampling and sample selection (5.10.3.2 a to f)

**BFS examination reports do not routinely include information regarding sampling or sample selection.**

Sampling and sample selection are only included on the report when it is necessary for the interpretation of test results. When reporting the results of sampling and/or sample selection, the examination report shall include the following:

- The date of sample acquisition
- Unambiguous identification of the item
- Location of the sample
- Reference to the procedure for sampling and/or sample selection
- Environmental factors that may affect the interpretation of results
- Any deviations from the specified sampling and/or sample selection procedure
Policy for release of case information (5.10.3.3)

BFS controls the release of case report information.

Release of case information is controlled by the following factors:
- JusticeTrax security levels as described in sections 4.13.1.2 and 4.13.1.3.
- Oral results of laboratory examinations are not released until the examination has undergone technical review.
- Written examination results are not released until the report has been technically and administratively reviewed.
- Observations and preliminary interpretations formed at crime scenes and provided to client agencies must be documented in the case record and subjected to review prior to formal reporting.

Agencies authorized to receive case-related information and reviewed reports may access them through a password-protected web-based application called BFSInfo.

Reporting the results based on the work of multiple analysts (5.10.3.4)

Analysts who issue findings, including writing test reports and providing testimony, based on examination records generated by another analyst shall document their review of all relevant pages of examination documentation in the case file.

Details regarding compliance with this standard are addressed in section 4.13.

Associations (5.10.3.5)

The significance of any associations is clearly communicated and properly qualified in the report.

In addition to documentation required in sections 5.10.1 and 5.10.2, the following applies to all examination reports:
- When conclusive associations are made, they are clearly communicated and properly qualified in accordance with contemporary forensic science.
- When results are inconclusive or associations are not made, they are clearly communicated and properly qualified in accordance with contemporary forensic science.

Comparative examination (5.10.3.6)

Elimination of an individual or object is clearly communicated in the examination report.

No definitive conclusion (5.10.3.7)

When no definitive conclusion can be reached, the reason is documented in the examination report.
Author participation

The author of a laboratory report must be competent in the corresponding discipline or category of testing, and must have conducted, been involved in, observed, supervised, directed, or evaluated the technical data or observations.

Accredited calibration laboratories (5.10.4.1 to 5.10.4.4)

BFS does not currently have any accredited calibration laboratories. The requirements set forth in these sections do not apply.

Opinions and interpretations (5.10.5)

Case records contain the basis for any conclusions, opinions, and interpretations included in the examination report.

Each BFS report contains an affidavit similar to the following which identifies the adherence to BFS policies on identifying opinions and interpretations and the laboratory’s accreditation status.

“I the undersigned, declare under penalty of perjury: (1) I am employed by the State of California, Department of Justice (DOJ), Bureau of Forensic Services; (2) I conducted an examination of the material described below in the ordinary course of my work as a qualified examiner, according to the standard laboratory procedures that include creation of contemporaneous documentation and technical review of my work; (3) The observable data is set forth in the associated laboratory case record; (4) Any opinions, interpretations, or conclusions in this report are based upon data in the associated laboratory case record and findings listed below.

Note: This laboratory report has been prepared and retained by DOJ in the normal course of business according to DOJ’s regular practices and procedures. The Department of Justice Laboratory is accredited by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB).
BFS examination reports clearly identify results, opinions, or interpretations related to testing that are not covered by the laboratory’s Scope of Accreditation.

<table>
<thead>
<tr>
<th>When…</th>
<th>Then…</th>
</tr>
</thead>
<tbody>
<tr>
<td>None of the tests performed are covered by the Scope of Accreditation.</td>
<td>Reference to ASCLD/LAB accreditation may not be used on the report, or attachments (including any written correspondence). See also QM, section 5.10.5.</td>
</tr>
<tr>
<td>Multiple tests were performed, and at least one of the tests is not covered by the Scope of Accreditation.</td>
<td>Reference to ASCLD/LAB accreditation may be used, but test results not falling within the Scope of Accreditation must be clearly identified. Example: “The opinions/interpretations expressed in this report regarding XYZ are outside the scope of this laboratory’s accreditation.”</td>
</tr>
</tbody>
</table>

If a BFS report contains results of examinations performed by subcontractors, those results are clearly identified in the examination report.

Subcontractors submit their results in writing or by secure electronic means.

The electronic release of case information is restricted to the intended client.

To ensure the confidentiality appropriate to a client report the following measures are taken:
- Adherence to sections 4.13.1.2, 4.13.1.3, and 5.10.3.3 of this Quality Manual
- Compliance with “result release security requirements” of the JusticeTrax manual (Section 2)
- Facsimile or electronic mail sent to client-confirmed locations in compliance with the “result release security level” of the case.

The format of examination reports minimizes the possibility of misunderstanding or misuse.

BFS uses standardized report formats responsive to the requests of the agency. These formats include manually-generated and JusticeTrax-generated laboratory examination reports and field investigation reports.

The standardized BFS report header and footer contain much of the administrative information listed earlier in “Examination report contents - required (5.10.2 a to k)” along with the affidavit regarding opinions, interpretations, and accreditation as described in “Opinions and interpretations (5.10.5)”
The body of the standardized BFS report format varies slightly based upon the examination type, as described below. When relevant, specific details of report content are included in Technical Procedures.

<table>
<thead>
<tr>
<th>Basic Components for all Examination Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Summary OR Results</strong></td>
</tr>
<tr>
<td>A clear and concise statement of significant conclusions.</td>
</tr>
<tr>
<td>• Not required for Field Investigations</td>
</tr>
<tr>
<td><strong>Evidence</strong></td>
</tr>
<tr>
<td>A description and unambiguous identification of the evidence being examined.</td>
</tr>
<tr>
<td>• May also include additional information such as date received and from whom.</td>
</tr>
<tr>
<td>• For Field Investigations, will be a list of specific evidence collected at the scene.</td>
</tr>
<tr>
<td><strong>Examination</strong></td>
</tr>
<tr>
<td>Statements that provide additional facts relevant to the examination and summary/results.</td>
</tr>
<tr>
<td>• May not be necessary in all cases.</td>
</tr>
<tr>
<td><strong>Disposition</strong></td>
</tr>
<tr>
<td>A description of the status of the evidence, either retained or returned.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Components for Field Investigation Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background</strong></td>
</tr>
<tr>
<td>Administrative information detailing agency contact information, location, date and time of contact on scene, subject names, and circumstance-specific background information</td>
</tr>
<tr>
<td><strong>Field Activities</strong></td>
</tr>
<tr>
<td>A summary of processing activities or opinions and conclusions provided to the agency and supported by notes</td>
</tr>
</tbody>
</table>

**Notification format – Data Bank (5.10.8)**

The format of CODIS offender hit notifications is specified in the Data Bank Technical Procedures, Section 6 (TP-07-05).
Amendments to test reports (5.10.9)

BFS does not amend or edit issued reports. All BFS reports bear a unique identifier.

Any report related to a case is identified with the same case number but is assigned a unique request number. Therefore every BFS request/report has a unique identifier (Section 5.10.2). This includes:

- The first report
- Subsequent reports of additional examination
- Corrected reports

Reports which correct a previously issued report bear the heading of “Corrected Report” centered on the line above the subject name.

Note: All corrected reports must contain a reference to the initial report.

All BFS reports meet all of International Standard requirements for test reports as specified in this Quality Manual.
Manual History

This manual’s history is recorded in this section.

<table>
<thead>
<tr>
<th>Section &amp; Comment</th>
<th>Manual Issue Date</th>
<th>Change No.</th>
<th>Revision</th>
<th>Author/Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous manual history entries archived with revision 11 of M-1. From this date</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td>forward, all revision dates listed in the manual history will be the date of</td>
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<td>issue of the document as opposed to the past practice of documenting the various</td>
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<td>dates of revision by the author(s).</td>
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<tr>
<td>Throughout entire document – minor formatting and clarifications were made.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 1 (Quality Management System) – Clarifications added as to what documents</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td>define the QMS, and what units are within the scope of the QMS.</td>
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</tr>
<tr>
<td>Section 2 (Normative References) – Updated Normative Reference list.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 3 (Definitions) – Made various updates, as well made additions to the</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td>definitions listed in this section.</td>
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<tr>
<td>Section 3, and throughout remainder of manual – Clarified difference between case</td>
<td>5/1/2014</td>
<td>CR-13-027</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td>file and case record.</td>
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<tr>
<td>Section 3 – Clarified definition of “Quality Control Check”</td>
<td>5/1/2014</td>
<td>CR-13-106</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td>Section 3 – Updated definitions of Technical Advisory Group, and TAG facilitator.</td>
<td>5/1/2014</td>
<td>CR-14-032</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td>Section 4.1.3 (Work covered by Quality Management System) – Updated list of</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td>examinations that fall within the BFS Quality Management System, to include</td>
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<tr>
<td>categories of testing.</td>
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<tr>
<td>Section 4.1.5.1 (One supervisor per function) – Changed block title to “One</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td>supervisor per category of testing”. Updated wording from “function” to “category of testing” to correspond with current ASCLD/LAB requirements.</td>
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<tr>
<td>Section 4.1.5.g, etc (Technical management and supervision of examination staff)</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td>– Eliminated obsolete positions, and clarified that TAGs are not management.</td>
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<tr>
<td>Section 4.1 (Technical Advisory Groups (TAGs)) – Deleted block.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<tr>
<td>Section 4.1 (Meeting Agendas) – Deleted requirement to keep staff and management</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<td>QA Unit</td>
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<td>meeting minutes. Not an</td>
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<tr>
<td>ASCLD/LAB or ISO 17025 requirement to keep meeting minutes.</td>
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<tr>
<td><strong>Section 4.2.2.1, etc. (Professional responsibility)</strong> – Deleted mention of ethics training, as section 5.2.1.3 is a more appropriate location in the QM to discuss ethics training requirements. Clarified where documentation is to be located.</td>
<td>5/1/2014</td>
<td>CR-13-066</td>
<td>12</td>
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<tr>
<td><strong>Section 4.2.3 (Continual improvement of Quality Management System)</strong> – Clarified the various ways that the QMS improvement process may be triggered by.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<td><strong>Section 4.2 (Laboratory Director)</strong> – Updated duties.</td>
<td>5/1/2014</td>
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<td>QA Unit</td>
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<tr>
<td><strong>Section 4.3.2.1 (Controlled documents approval and issue)</strong> – Deleted redundant text.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<td>QA Unit</td>
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<tr>
<td><strong>Section 4.3.2.2 a-d (Approved documents)</strong> – Re-organized text to directly correspond to ISO/IEC 17025 requirements, as well as made minor clarifications.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<td>QA Unit</td>
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<tr>
<td><strong>Section 4.3.2.3 (Uniquely identified documents)</strong> – Updated to reflect current document identification practices.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<td>QA Unit</td>
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<tr>
<td><strong>Section 4.3.3.1 and 4.3.3.2 (Document preparation and changes)</strong> – Changed block title to “Document changes”. Moved section 4.3.3.2 to a new block, deleted redundant text, and made other minor clarifications.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<tr>
<td><strong>Section 4.3.3.4 (Changes to computerized documents)</strong> – Clarification made as to who may designate staff with administrative rights to the Document Control System.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 4.8 (Compliments)</strong> – Clarified how compliments are conveyed to BFS staff.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 4.9.1 (Nonconforming work)</strong> – Clarification to statement describing nonconforming work.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.9.1b and c (Evaluation and correction of non-conformance)</strong> – deleted text regarding minor issues and moved to its own block. Added text that was moved from section 4.11.1 in order to keep all non-conformance evaluation criteria within the same location of the QM. Deleted requirement to keep a Corrected Report Log.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.9.1d (Notification to client agencies)</strong> – Clarified how clients may be notified when reports are released with nonconforming results.</td>
<td>5/1/2014</td>
<td>CR-13-036</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 4.10 (Changes to QMS documents)</strong> – Changed title of block to “Administrative changes to QMS documents”. Clarified the process of making administrative changes.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 4.10 (Change process)</strong> – Updated section to</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
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<td>reflect current and new practices, and to more closely follow the sections outlined in the Change Form.</td>
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<tr>
<td>Section 4.10 (Critical Action Bureau Policies and Procedures) – Updated title of block to “Critical Action Bureau Policy”, and updated entire section to allow for more flexibility in policy format, etc.</td>
<td></td>
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<tr>
<td>Section 4.10 – added block of information, titled “Lab Policies” to reflect current practices.</td>
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<tr>
<td>Section 4.11.1 (Evaluation Criteria for the Classification of Nonconformances) – Deleted majority of text regarding classification of nonconformances, and moved to 4.9.1b.</td>
<td></td>
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<tr>
<td>Section 4.11 (Corrective action process for Level I and Level II non-conformances) – Updated step/action table to current practices.</td>
<td></td>
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<tr>
<td>Section 4.11.2 (Root cause analysis) – deleted “with the assistance of the BQAM”.</td>
<td></td>
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<tr>
<td>Section 4.12.2 (Preventive action process) – Updated step/action table to reflect current practices.</td>
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</tr>
<tr>
<td>Section 4.13.1.1, 4.13.1.2, and 4.13.2.4 (Managing records and Records defined) – Moved text relating to 4.13.2.4 to section 4.13.2.1, etc. regarding Case or data bank records, content and purpose, to keep case record info together. Clarified that records may be kept as hard copy or electronic data, and removed redundant text.</td>
<td></td>
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<tr>
<td>Section 4.13 (Records management and Records retention policy) – minor clarifications to records management text. Records retention (storage) policy text was modified to delete redundant wording, and adjusted the flow of the section.</td>
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<tr>
<td>Section 4.13.1.2 and 4.13.1.3 (Records storage, access, and retention time) – Added statement that records should be stored in such a way to prevent damage, deterioration, and to prevent loss.</td>
<td></td>
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</tr>
<tr>
<td>Section 4.13.2.6, etc (Case or Data Bank files requirements) – clarified documentation requirements for reporting analysts and analysts who prepare technical records but do not interpret findings, prepare the test report, and/or testify concerning the records.</td>
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</tr>
<tr>
<td>Section 4.13.2.7 and 4.13.2.12 (Documentation prepared by other analysts) – deleted this entire block of information. Some information was moved to other locations (with slight modifications, as needed) within section 4.13, and other information was deleted due to redundancy.</td>
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<tr>
<td><strong>Section 4.14 (Internal audit procedure)</strong> – clarified text to reflect current practices.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.14.2 and 4.14.4 (Corrective action)</strong> – Clarification made regarding when clients are notified.</td>
<td>5/1/2014</td>
<td>CR-13-036</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.15.2 and 4.15.2.1 (Management review findings)</strong> – Deleted requirement to use a management review tracking spreadsheet. Added option to track action items in either the management meeting notes or in a Management Review Spreadsheet.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.1.3 (Reagent checks)</strong> – Allowed for an option to use expired reagents if they are clearly marked for training and/or research use only.</td>
<td>5/1/2014</td>
<td>CR-13-030</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.1.3.1 (Reagent labeling)</strong> – clarified that the information is in regards to reagents prepared in the laboratory.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.2.1, etc. (Determination and documentation of competence)</strong> – Added clarification regarding the minimum requirements for competency tests, and other minor clarifications.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.2 (Review, interpretation, reporting or testifying to examination of another analyst)</strong> – Added new block of information and included information that was moved from 4.13.2.7 and 4.13.2.12 section.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
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<tr>
<td><strong>Section 5.2.1.1 and 5.2.1.3 (Training program)</strong> – Added clarifications regarding ethics training requirements.</td>
<td>5/1/2014</td>
<td>CR-13-066</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 5.2.2 (Training plans and goals)</strong> – deleted “and communicates laboratory training plans in the monthly report”, as this is no longer the practice.</td>
<td>5/1/2014</td>
<td>CR-12-184</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.4.5.1, etc. (Technical procedure validation)</strong> – clarified what was to be included with the validation documentation.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
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<tr>
<td><strong>Section 5.5.9 (Equipment checks before return to service)</strong> – Clarifications to what is required when equipment leaves the direct control of the laboratory.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.6.1 (General traceability policy)</strong> – Deleted all text and replaced with a general statement regarding traceability and directs reader to discipline manuals.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.6.2.1 and 5.6.2.1.1 (Calibration laboratory requirements)</strong> – Deleted all text and replaced with statement that BFS does not provide calibration services and this standard does not apply.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 5.6.2.2.1 (Calibration and traceability for examination equipment with SI unit output)</strong> – changed title of block to “Traceability requirements”.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
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<td>Section &amp; Comment</td>
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<tr>
<td>Clarified requirements to better meet ASCLD/LAB traceability requirements.</td>
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<tr>
<td><strong>Section 5.6.3.1 (Reference standards), Section 5.6.3.2 (Reference materials), Section 5.6.3.3 (Intermediate checks), and section 5.6.3.4 (Transport and storage of reference standards and materials)</strong> - Clarified requirements to better meet ASCLD/LAB traceability requirements.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.8 (Evidence sample splits)</strong> – deleted entire block of information as it is redundant to information found elsewhere within this manual.</td>
<td>5/1/2014</td>
<td>CR-13-131</td>
<td>12</td>
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</tr>
<tr>
<td><strong>Section 5.9 (Technical review)</strong> – added note to clarify that a person who performs an independent check of a critical finding is still permitted to perform a TR of that case.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.9 (Nepotism policy)</strong> – Deleted entire block of information as this information is located within the DOJ administrative manual.</td>
<td>5/1/2014</td>
<td>CR-14-030</td>
<td>12</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.10.3.4 (Case reports based on the work of multiple analysts)</strong> – Changed title of block to “Reporting the results based on the work of multiple analysts”. Clarified where to document a review of all relevant pages of examination documentation.</td>
<td>5/1/2014</td>
<td>CR-11-150</td>
<td>12</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 5.10.8 (Report format)</strong> – add formatting minimum for DNA Casework hit reports, remove “attached copy of the CODIS match detail report from the CODIS hit notification sub-section</td>
<td>5/1/2014</td>
<td>CR-13-030</td>
<td>12</td>
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<tr>
<td><strong>Section 5.10.9 (Reporting additional work or correcting previously issued work)</strong> – changed title of block to “Amendments to test reports”. Clarified that corrected reports must contain a reference to the initial report.</td>
<td>5/1/2014</td>
<td>CR-12-137</td>
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<td><strong>Section 3</strong> – Added commonly used abbreviations to various terms.</td>
<td>5/1/2014</td>
<td>CR-14-055</td>
<td>12</td>
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<tr>
<td><strong>Minor corrections to include grammar, misspellings, etc. throughout document. This also includes changing any reference to a “five-year accreditation cycle” to only state generically “accreditation cycle” without listing the number of years.</strong></td>
<td>10/24/2014</td>
<td>CR-14-112</td>
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<tr>
<td><strong>Section 3 (Definitions)</strong> - Deleted definition for “critical reagent” and added a new definition for “critical supply and service.”</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 3 (Definitions)</strong> – Changed definition for “critical task” to match the Section 5.2.1 definition.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
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<tr>
<td><strong>Section 3 (Definitions)</strong> - Changed definition of TAG Facilitator that explains the TAG Facilitators have technical responsibility for their discipline and discipline manuals.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.1.3 (Work covered by Quality Management System)</strong> – Updated list of Disciplines/Categories of Testing to the most current ASCLD/LAB wording.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.1.5.h.1 (Technical responsibility for the discipline)</strong> – Added a new section (4.1.5.h.1) that explains the TAG Facilitator has technical responsibility for discipline except for tests involving DNA and Data Bank, where the DNA Technical Leaders have responsibility.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.1.8 (Key and Top Management)</strong> – Added the following statement: “Laboratory Directors are key management in Bureau-wide matters and top management in their respective laboratories.”</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.2.2.1 and 4.2.2.2 (Professional responsibility) and Section 5.2.1.1 and 5.2.1.3 (Training program)</strong> – Updated section to make it clear that the Lab Director or designee reviews the ASCLD/LAB Guiding Principles of Professional Responsibility... WITH all laboratory personnel. And that personnel are expected to abide by those principles in the performance of their duties, to include courtroom testimony.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.3.2.1(Controlled documents approval and issue)</strong> – Added link to BFS document control system, SharePoint.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.6 (Purchasing Services and Supplies)</strong> - Many changes to this section to include that quality requirements must be checked prior to purchasing, only “critical” items as identified in the Technical Procedures (TP) need an evaluation and to be on the approved vendor list, any vendor requirements are in the TP, and to ensure that any vendor on the Approved list is still current.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 4.9.2 (Initiating the corrective action process)</strong> – Added the words “…which shall be promptly followed” to the end of the first sentence.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 4.11 (Corrective action process for Level I and Level II non-conformances)</strong> – Updated the corrective action process.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<tr>
<td>Section &amp; Comment</td>
<td>Manual Issue Date</td>
<td>Change No.</td>
<td>Revision</td>
<td>Author/Reviewer</td>
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<tr>
<td><strong>Section 4.13.2.1, 4.13.2.2, 4.13.2.2.1, 4.13.2.4, 4.13.2.5 and 4.13.2.5.2 (Case</strong>&lt;br&gt;</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>or data bank records, content and purpose) – Added specifics regarding what</td>
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<td>constitutes the “Starting” and “Ending” dates for testing.</td>
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<tr>
<td><strong>Section 4.14.5 (Performance Declaration) – This was</strong></td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>previously titled “Audit report and accreditation.” The section was changed to</td>
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<td>update to new ASCLD/LAB wording as well as their new requirements for declaring</td>
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<td>continued conformance with all accreditation requirements.</td>
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<td><strong>Section 5.2.1, 5.2.6.2.1, 5.2.6.2.2 and 5.2.5 (Determination and documentation</strong>&lt;br&gt;</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>of competence) – Clarifies how analysts demonstrate competency and adds</td>
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<td>clarification that if an analyst is only authorized to perform a limited portion of</td>
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<td>the discipline, then it must be clearly indicated on the authorization certificates.</td>
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<td><strong>Section 5.2.6.1.1 to 5.2.6.1.5 (Educational requirements) – Deletes any specific</strong>&lt;br&gt;</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>educational requirements and just states that all BFS analysts meet the education</td>
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<td>requirements listed in the ASCLD/LAB-International supplemental requirements.</td>
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<tr>
<td>**Section 5.3.1 and 5.3.2 (Laboratory facilities maintenance) – Added that</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>temperature monitoring may also be in the “applicable discipline manuals.”</td>
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<tr>
<td><strong>Section 5.3.6 (Safety program) – Clarified what documents are a part of the BFS</strong>&lt;br&gt;</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>Safety Manual. Also deleted the statement: “The laboratory operations manual will</td>
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<td>detail the location of these documents in the laboratory.”</td>
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<td><strong>Section 5.8.1 and 5.8.1.1.2 (Procedures for evidence receipt, transport and</strong>&lt;br&gt;</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>disposition) – Added a note about Missing Persons DNA Program evidence.</td>
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<td><strong>Section 5.8.4.2 (Unattended evidence in the process of being examined) – Deleted</strong>&lt;br&gt;</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>“During non-business hours, evidence is stored in a personal evidence storage area</td>
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<td>or vault.” And added “During non-business hours, in progress evidence should be in</td>
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<td>a personal storage unit, vault, or secure storage room, or in a secure laboratory</td>
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<td>area as long as it is protected from deleterious change or contamination.”</td>
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<tr>
<td><strong>Section 5.8.4.6.4 (Access to individual characteristic database samples) – Added</strong>&lt;br&gt;</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
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<td>“or Data Bank Work” to the type of authorizations needed.</td>
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<tr>
<td>Section 5.9.3, 5.9.3.1, 5.9.3.2, 5.9.3.3, 5.9.3.3.2 and 5.9.3.4 (BFS proficiency testing program) – Added sentence stating the laboratory shall have a documented schedule of proficiency testing.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 5.9.1.1 (Controls and standards) – Originally this was section 5.4.1.2, but moved to this section to correspond to the actual ASCLD/LAB requirement number.</td>
<td>10/24/2014</td>
<td>CR-14-112</td>
<td>13</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 5.2.1.1 (Continuing Education) – Addition of language regarding retraining.</td>
<td>1/16/2015</td>
<td>CR-14-129</td>
<td>14</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 4.3.2.2 (Approved Documents) – Updates made regarding access to Quality Management System documentation at locations away from the laboratory (ex: crime scene response).</td>
<td>3/2/2015</td>
<td>CR-15-032</td>
<td>15</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 1 (Introduction) – Added templates, software and databases to list of QMS documents</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 3 (Definitions) – Added definition for receiving party, corrected spelling of principle. Added abbreviation for subject matter expert (SME). Changed style of definition title so they do not show in table of contents.</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 4.1. (Organization) – Added Alcohol Beverage Analysis as category of testing (4.1.3); updated listing of labs and units (4.1.4 etc); restated means by which personnel protected from influence (4.1.5 b and 4.1.5 d); added statement that TAG Facilitator list is on SharePoint (4.1.5.h.1), miscellaneous administrative updates (4.1.3, 4.1.5a, 4.1.7)</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 4.2 (Quality Management System) – Reworded QMS Scope (4.2.1 and 4.2.5); added role of Property Controller, added common abbreviations for roles; adjusted title of Forensic Examiner to Analyst/Examiner.</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 4.6 (Purchasing Services and Supplies) – Significant revision with emphasis that quality requirements for supplies and services that affect the quality of tests are verified prior to purchase and prior to use. Also, stated that specific procedures related to this are Laboratory Operations Manuals.</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
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<tr>
<td>Section 4.10 (Improvement) – Streamlined Improvement block (4.10); clarified language in Change Process although process itself was not changed; moved location of Administrative Changes to QMS Documents, reworded and removed extraneous detail.</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
</tr>
<tr>
<td>Section 4.12 (Preventive Action) – Edited Preventive</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
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<td>action policy explanation (4.12.1); edited preventive action process (4.12.2) to indicate that it follows the change process in 4.10; removed step/action table as it is no longer relevant. Note: The Change Form was also updated to capture that it was initiated as a Preventive Action.</td>
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<tr>
<td><strong>Section 5.2 (Personnel)</strong> – From Training program (5.2.1.1 and 5.2.1.3), moved and edited info relating to 5.2.1.3. Now in block labeled Additional training requirements (5.2.1.3).</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 5.4.7.2 (Use of computers in analysis)</strong> – added software to opening line and clarified that validation is prior to use.</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
</tr>
<tr>
<td><strong>Section 5.6 (Measurement Traceability)</strong> – Added block for Documentation requirements.</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 5.8 (Evidence Handling)</strong> – Significant rewrite and reorganization of General evidence guidelines (5.8.1); replaced Procedures for evidence receipt, transport and disposition (5.8.1 and 5.8.1.1.2) with General evidence receipt process (5.8.1 and 5.8.1.1.2) and Variations to the evidence receipt process. Reordered and edited Documentation of evidence release, destruction and storage (5.8.1) and minor edits to Guidelines for evidence retention and destruction (5.8.1). Reordered Chain of custody (5.8.1.1 and 5.8.1.1.2) and eliminated Chain of custody definitions (5.8.1.1) as these are in other blocks or should be addressed in JusticeTrax Manual.</td>
<td>7/16/2015</td>
<td>CR-15-086 CR-15-028</td>
<td>16</td>
<td>QA Unit</td>
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<tr>
<td><strong>Section 5.10 (Reporting the Results)</strong> – Introduced new policy in General report guidelines (5.10.1 and 5.10.1.1) that reports are not required when transferring evidence from one BFS to another for analysis. Clarified what we require in reports versus case records for 5.10.2 a to k and 5.10.3.1 a to e. Updated Opinions and interpretations (5.10.5), primarily to reflect current affidavit. Added Reporting results not covered by the Scope of Accreditation. Edited Report format – casework (5.10.8) including new explanations paragraphs, different presentation of report content. Clarified where to find CODIS offender hit notification reporting guidelines and formats.</td>
<td>7/16/2015</td>
<td>CR-15-086</td>
<td>16</td>
<td>QA Unit</td>
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