Oklahoma State Bureau of Investigation

Criminalistics Services Division

QUALITY MANUAL

and

QUALITY PROCEDURES

OSBI CSD Quality Manual and Quality Procedures
Revision 02
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Approved By: Andrea Fielding, Director of Criminalistics Services Division

FOREWORD

The Oklahoma State Bureau of Investigation (OSBI) and the Criminalistics Services Division (CSD) are dedicated to providing quality service and results. Since 2001, the OSBI CSD has adhered to the accreditation requirements set forth by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) and now ANSI National Accreditation Board (ANAB).

ASCLD/LAB merged with the American National Standards Institute – American Society for Quality (ANSI-ASQ) National Accreditation Board (ANAB) in April, 2016 and is now part of the Forensic Business Unit within ANAB. In 2018, ANSI acquired full interests in the ANSI-ASQ National Accreditation Board, LLC, resulting in the ANAB becoming a fully owned subsidiary of ANSI and renamed the ANSI National Accreditation Board (ANAB). The OSBI CSD continues to adhere to accreditation requirements, which are established by ASCLD/LAB and ANAB.

OSBI MISSION

We exist to protect our citizens and support our public safety partners by providing Oklahoma's premier investigative, intelligence, information, and forensic services.

OSBI VISION

The OSBI's renewal and enhancement in the state's unmatched proactive 21st Century investigative agency.

CORE VALUES

Trust – "Trust is a function of two things: character and competence." –Stephen R. Covey. It is the full confidence that regardless of the circumstances or audience, performance is honest and reliable.

Integrity – Integrity consists of overlapping qualities of character where one adheres to moral and ethical principles. Integrity is demonstrated by consistency in actions, values, principles, and outcomes.

Respect – Respect is esteem or deference for the intrinsic value of people. Respect is developed by demonstrating integrity and trust.

QUALITY POLICY

The OSBI CSD management is committed to providing quality and professional service to our customers. It is the objective of the OSBI CSD to provide service that meets or exceeds the customer's needs and to ensure that quality and analytical practices meet or exceed the standards required for accreditation. The management system documents are provided to CSD employees to communicate the procedures which must be followed to provide this level of quality and service. As indicated in Section 1 below, all CSD personnel are responsible for knowing and implementing these policies. This manual and the laboratory practices will be reviewed regularly in order to maintain compliance with ISO/IEC 17025 standards and to continually improve the effectiveness of the management system.

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NOTE: Hyperlink and attachment maintenance (removal, addition, or correction of hyperlinks and attachments) shall not constitute a new document revision.

1.0 SCOPE (top ↑)

This manual sets forth the policies and procedures which govern the work performed by members of the OSBI CSD.

All members of the CSD are responsible for knowing and abiding by all management system policies and procedures. **It is the responsibility of every CSD employee to seek clarification from the Quality Manager BEFORE proceeding with testing activities if any portion of this manual is unclear or if testing activities arise which appear to be outside the scope of this manual.**

The OSBI CSD also participates and serves as the lead agency in the AT&T Digital Forensic Laboratory (ATTDFL), which is a collaboration between multiple agencies for the analysis of digital evidence. Solely for the purpose of reading and interpreting this Quality Manual and Procedures, any reference to the OSBI CSD also applies to the ATTDFL. Similarly, any reference to a Criminalist, OSBI CSD employee, staff or similar term in this manual applies to any examiner assigned to the ATTDFL by a participating agency.

2.0 REFERENCES (top ↑)

The following standards guide the requirements set forth in this policy manual. If the reference listed does not include a date, the most recent revision of the referenced document applies.
ISO/IEC 17025:2017
ANAB ISO/IEC 17025:2017 – Forensic Science Testing Laboratories Accreditation Requirements (AR 3125) - https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=12371

The FBI Quality Assurance Standards for Forensic DNA Testing Laboratories
The FBI Quality Assurance Standards for DNA Databasing Laboratories
The FBI Quality Assurance Standards Audit Document for Forensic DNA Testing Laboratories
The FBI Quality Assurance Standards Audit Document for DNA Databasing Laboratories

ANAB Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel Guidance Document (GD3150) located at
https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=6732
ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status (PR 1018) located at https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=12436
ANAB Accreditation Manual for Forensic Service Providers (MA 3033) -
https://anab.qualtraxcloud.com/ShowDocument.aspx?ID=7183

3.0 TERMS and DEFINITIONS (top ↑)

In addition to the terms and definitions listed below, any definition provided in one of the documents listed in Section 2.0 also applies.

ADMINISTRATIVE RECORDS: Records, whether electronic or hardcopy, that do not constitute data or information resulting from testing, such as case related conversations, test item (evidence) receipts,

chain of custody records, description of evidence packaging and seals, incident reports, service requests, correspondence received/sent, and other pertinent information.
ADMINISTRATIVE STAFF: The CSD Director and Criminalistics Administrators.
ADMINISTRATIVE SUPERVISION: The authority to monitor the day-to-day activities and perform traditional managerial duties of assigned units or laboratories.
CASE FILE: The file folder containing hard copy documentation relevant to a particular case or the electronic file contained within the BEAST that contains documentation relevant to a particular case.
CASE RECORD: The cumulative records which document the quality, technical, and analytical information relevant to a particular case.
COMPLAINT: The expression of dissatisfaction by any person or organization to a laboratory relating to the activities or results of that laboratory, where a response is expected. Examples may include dissatisfaction with the quality or timeliness of work products or services.
CONVENIENCE PACKAGE: Evidence which is properly sealed and marked for identification may be placed in unsealed containers such as boxes or bags for the purpose of grouping items of evidence or for the convenience of carrying the evidence without that container having to meet the "proper seal requirements," as long as evidence security requirements are otherwise met. These containers should be marked as a "convenience package."
CORRECTIVE ACTION: An action or actions implemented to correct circumstances which led to nonconforming work. Successful corrective actions should prevent a reoccurrence of the same type of nonconforming work. This is also referred to as "preventive measures taken" by QAS Standard 14.2.c.
CORRECTIVE ACTION PLAN: A plan to resolve a discrepancy identified in casework, database activities, or proficiency testing work which will correct the problem and prevent a future occurrence. (QAS based definition – Std. 14)
CRIMINALISTICS ADMINISTRATOR (CA): Individual who reports directly to the CSD Director and is responsible for supervising Criminalist Supervisors and/or Technical Managers.
CRIMINALIST SUPERVISOR: Individual who reports to a Criminalistics Administrator and supervises criminalists/technicians.
CRITICAL CONSUMABLE, SUPPLY, AND SERVICE: A consumable, supply or service which must meet one or more crucial specifications to ensure the quality of the test result. In this context, "crucial" means significant or important.
CUSTOMER (CLIENT): A person or organization that could or does receive a product or a service that is intended for or required by this person or organization. A customer can be internal or external to the forensic service provider. Examples may include recipients of the OSBI Criminalistics Services Division reports and/or services.
DERIVATIVE EVIDENCE: Material removed or derived from an evidence item already having an assigned item number. Examples are cuttings, debris collections, latent lifts, test fired casings and projectiles, and retained stain samples. Derivative evidence or containers will be marked with appropriate case number, item or sub-item numbers, analyst's initials and date, and listed in the case file.
EVIDENCE: For the purposes of this directive, evidence shall mean all materials submitted for scientific analysis during the course of an official criminal investigation.
EVIDENCE DESTRUCTION FORM: A form used to document permission for the destruction of evidence.
EVIDENCE RELEASE FORM: A form used to document the return or release of evidence to the courts, OSBI employees, or submitting agencies.
EVIDENCE TAPE: Tamper proof tape used in sealing evidence containers.

EXAMINATION RECORDS: The documentation, whether hard copy or electronic, of procedures followed, tests conducted, standards and controls used, diagrams, printouts, photographs, observations and results of testing and examinations; constitute part of "technical records."
FUNCTION VERIFICATION: A check to determine if a piece of equipment or instrumentation is working correctly within specified parameters.
MAJOR DEVIATION: A planned and approved modification to current policy or protocol which will apply for a set period of time or to a defined grouping of cases or samples.
MINOR DEVIATION: A planned and approved modification which will be applied to a single case, sample, or single batch of samples/cases.
NO ANALYSIS CASE: Evidence in cases submitted to the laboratory where charges have been dismissed or for some other reason no analysis is required can be returned to the submitting agency.
NONCONFORMING WORK: Testing work that does not meet the standards set forth in policy, procedure, protocol, or does not meet the needs of the customer. This may occur due to protocol drift or due to a quality or technical problem with a reagent, supply, or instrument.
ORIGINAL REQUESTING AGENCY: The agency having jurisdiction in the case that made the request for services. Evidence will be returned after analysis to the original requesting agency unless specified otherwise in this policy.
PERFORMANCE CHECK: Actions taken to ensure analysis methods still perform as intended. Performance checks are similar to validations, but more limited in scope.
PHYSICAL EVIDENCE TECHNICIAN: Individual responsible for the reception, storage, documentation, and handling of the physical evidence submitted to an Oklahoma State Bureau of Investigation Laboratory.
PREVENTIVE ACTION: Actions taken to improve circumstances which could lead to nonconforming work.
PROTOCOL DRIFT: Unintentional and/or unauthorized deviations from current protocol.
PROPER SEAL: An evidence container is "properly sealed" only if its contents cannot readily escape and only if opening the container would result in obvious damage/alteration to the container or its seal. Staples alone cannot provide a sealed condition on evidence packaging. A proper seal would constitute tape sealing, heat-sealing, or lock sealing and initialing the seal. A date on the seal is also recommended.
QUALITY: Adhering to generally recognized standards of good laboratory practice.
QUALITY ASSURANCE (QA): Those processes necessary to provide confidence that the results from OSBI Criminalistics Services Division analysis and testing will satisfy given requirements for quality.
QUALITY ASSURANCE AUDIT: A systematic examination and review to determine whether quality processes and related results comply with the protocols, policies, and procedures, and whether these practices are suitable and effective in achieving the quality objectives.
QUALITY ASSURANCE PROGRAM: OSBI Criminalistics Services Division guidelines describing recognized quality assurance requirements for forensic laboratory analysis and reporting.
QUALITY CONTROL (QC): The day-to-day operational techniques and activities used by the laboratory to consistently provide accurate analytical results that fulfill the requirements for quality.
QUALITY IMPROVEMENT COMMITTEE (QIC): An ongoing committee for the purposes of reviewing and implementing ways to improve the quality of laboratory services. This committee, which meets at least quarterly, is composed of all Regional and Unit Supervisors, discipline Technical Managers, and CSD Administration.
QUALITY MANAGER (QM): The Criminalistics Administrator assigned the responsibility of overseeing quality operations including proficiency testing, auditing, reviewing nonconforming work, etc.

QUALITY RECORDS: Records generated from quality assurance procedures. This includes, but is not limited to, proficiency tests, corrective and preventive actions, audits, training documentation, continuing education, and testimony review.
REFERENCE MATERIAL: A material for which values are certified by a technically valid procedure and accompanied by, or traceable to a certificate or other documentation, which is issued by a certifying body. Examples include known drug standards and NIST Standard Reference Materials (SRM's) which can include known values for a variety of substances, including DNA profiles.
REFERENCE STANDARD: A traceable standard, generally having the highest metrological quality available, from which measurements are derived. An example would be NIST traceable weights.
REMEDIATION: Steps taken to correct nonconforming work, such as issuing an amended report, re-testing, etc. This is also referred to as "corrective actions taken" by QAS Standard 14.2.b.
REQUESTING OFFICER: The individual, authorized by statute, requesting examination of the submitted evidence. Criminalists will not be listed as a requesting officer.
RFLE: Request For Laboratory Examination form.
SAMPLE SELECTION: The practice of selecting one or more samples from an item for testing based on training, experience, and competence. In sample selection, there is no assumption about homogeneity. Following analysis, results are reported clearly and unambiguously to indicate that the results reported apply to the sample, not the whole item.
SAMPLING: Selection of a sample for testing, according to a procedure. The approach to sampling can be either non-statistical or statistical.
SUBMITTING OFFICER: The person delivering evidence to an OSBI laboratory. Criminalists will be listed as the submitting officer when involved with the collection of evidence.
TECHNICAL MANAGER (TM): The individual assigned the responsibility and authority for the technical operations in a particular discipline.
TECHNICAL PROTOCOLS (PROCEDURES): Technical procedures are a key element in establishing and maintaining quality control within the laboratory. Written procedures will be prepared for those routine tests performed in the OSBI Laboratory. The procedures used may be those developed and adequately validated by an outside agency or laboratory or those developed and validated in-house.
TECHNICAL RECORDS: Documentation generated in the analysis of casework or database samples. This includes reports, examination records, quality control results, etc.
TEMPORARY EVIDENCE CLOSURE OR SEAL: Consists of a piece of tape across a box, a paper clip on a folded evidence envelope, or some other closure that would not normally constitute a proper seal on evidence. A temporary closure is acceptable when the analyst will be away from the work area for a short period of time or overnight as long as the evidence is secured in a locking drawer or controlled access evidence area.
TESTING: Analysis conducted at the request of OSBI CSD customers. This may include casework analysis, database sample analysis, or other work mandated for the OSBI CSD. This does not apply to training, research, etc.
TRACEABILITY: The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.
VALID COMPLAINT: A complaint that has been verified and that warrants action.
VERIFICATION: Provision of objective evidence that a given item fulfills specified requirements (ISO/IEC 17025:2017). A verification is a process of confirming information. The term verification is used in many

different contexts and may refer to a verification of findings, a verification that a process performed correctly (such as creation of an image of digital evidence), or confirmation a complaint is valid.

4.0 GENERAL REQUIREMENTS (top ↑)

4.1 IMPARTIALITY (top ↑)

4.1.1

The primary objective of the OSBI CSD is to provide quality forensic science services in an impartial manner. Within the CSD, impartiality is taken into account when making structural and management decisions and steps are taken to safeguard impartiality where necessary.

4.1.2 MANAGEMENT COMMITMENT to IMPARTIALITY

The OSBI CSD management, including the CSD Director, are committed to ensuring impartiality of CSD operations and testing.

4.1.3 RESPONSIBILITY for IMPARITIALTY

The OSBI CSD evaluates and minimizes potential risks to impartiality and conflicts of interest through a review of secondary employment (see **OSBI Policy 105**), the OSBI Code of Ethics, and through statutory limitations on gifting (refer to O.S. 257-20-1-9). The OSBI CSD will not allow commercial, financial, or other pressures to compromise impartiality.

4.1.3.1 All CSD personnel shall review annually the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel (See **Section 2.0 – References**). A record of this review shall be maintained as part of the management system review (see **Quality Procedure (QP) 18**).

All CSD employees are responsible for reporting circumstances they observe which may not adhere to the Guiding Principles to CSD management (Technical Manager, Supervisor, Criminalistics Administrator, and CSD Director). CSD management shall ensure appropriate actions are taken when necessary.

4.1.4 IDENTIFYING RISKS

The OSBI CSD continually evaluates potential risks to impartiality through routine activities, such as management reviews, policy revisions, and discussions with staff. Any CSD employee who becomes aware of a potential risk to impartiality or a possible conflict of interest shall notify his/her immediate Supervisor for guidance.

4.1.5 ELIMINATING RISKS to IMPARTIALITY

When risks to impartiality are identified, the steps taken to minimize or eliminate the risk shall be documented. This may occur through notes of a management system review or meeting, or in a case narrative when steps are needed in a specific case. For example, if an examiner identifies that he/she may have personal knowledge of individuals involved in a case (suspect,

victim, investigating officer, etc.), the examiner shall make the Supervisor aware of this potential risk. The Supervisor may determine that the examiner will not conduct testing, verifications or reviews in that case. In this circumstance, the decision should be documented in a case narrative.

4.2 CONFIDENTIALITY (top ↑)

4.2.1 RELEASE of INFORMATION

Confidential case information, including electronically stored and distributed reports and documentation, is protected. Refer to Oklahoma Statute Title 74, Section 150.5. Procedures for release of case information are located in **QP 33**. OSBI CSD staff shall not make case information publicly available, except as required through court testimony. All case related information is considered proprietary information and shall be regarded as confidential with the exception of information the customer makes publicly available, or when agreed (in writing) between the OSBI CSD and the customer (e.g. for the purposes of responding to complaints). Any exceptions to this shall be approved by the CSD Director and by the customer in advance.

4.2.2 LEGAL REQUIREMENTS to RELEASE INFORMATION

Confidential case records may be released pursuant to a valid discovery motion or order or a subpoena duces tecum. When responding to this type of legal requirement to release case information, a copy of the information released should be provided to both the prosecution and defense attorneys in the case.

4.2.3 INFORMATION ABOUT the CUSTOMER

In some circumstances, the OSBI CSD may be provided information about a customer from a source other than the customer. For example, complaints may be made against a submitting agency or personnel from a submitting agency. When the OSBI CSD receives information about a customer from a source other than the customer, the OSBI CSD shall keep this information confidential between the OSBI and the customer. In addition, the OSBI CSD shall not divulge the source of the information to the customer, unless agreed to by the source in writing.

4.2.4 EXPECTATION of PERSONNEL

All OSBI CSD personnel, including but not limited to, any contract employees, external reviewers, external auditors/assessors, ATTDFL participating examiners, or practicum students, shall keep confidential all information obtained or created during the performance of laboratory activities. Information shall only be released when required or appropriate based on applicable laws - see **QP 33.**

Any accreditation assessors shall likewise be bound to confidentiality through an agreement with the accrediting body.

5.0 STRUCTURAL REQUIREMENTS (top ↑)

5.1 LEGAL ENTITY (top ↑)

The OSBI CSD is a division of the Oklahoma State Bureau of Investigation, which has been granted legal authority by state statute. Refer to O.S. Title 74, Section 150.2. The CSD Director is appointed by the Director of the OSBI and has the responsibility and authority for all laboratory functions and personnel.

In addition, the OSBI CSD serves as the managing agency for the AT&T Digital Forensics Laboratory (ATTDFL) based on the Memorandum of Understanding signed by each participating agency.

5.2 MANAGEMENT STRUCTURE (top ↑)

The management positions which have overall responsibility for laboratory functions are identified in **QP 1** and in the OSBI CSD organizational chart.

5.2.1 LABORATORY DIRECTOR

The responsibilities and authority of as well as the education and experience requirements for the CSD Director are defined in **QP 1**.

5.3 RANGE OF LABORATORY ACTIVITIES (top ↑)

The range of laboratory activities in which the OSBI CSD is accredited are documented on the scope of accreditation issued by ANAB. A copy of the current scope of accreditation is located at http://search.anab.org/public/organization_files. OSBI CSD employees shall not infer accreditation in any area not included on the scope of accreditation. Refer also to **QP 28** regarding use of the accreditation symbol in OSBI reports.

5.4 OPERATING GUIDELINES (top ↑)

The OSBI CSD will provide forensic science service which meets or exceeds the needs of customers. OSBI CSD service will also meet or exceed the applicable requirements set forth by ANAB and regulating authorities.

The policies and procedures set forth in the management system apply to work within the OSBI CSD Scope of Accreditation performed by CSD personnel in any temporary, mobile, or permanent facility, and at sites away from the OSBI CSD's permanent facilities or at a customer's facility.

5.4.1 NDIS PARTICIPATION

The OSBI CSD DNA laboratories are NDIS participating laboratories. In order to continue participating in NDIS, the OSBI CSD DNA laboratories operate according to the NDIS Operational Procedures Manual and the FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and the FBI Quality Assurance Standards for DNA Databasing Laboratories.

5.4.2 USE of ACCREDITATION SYMBOL

The OSBI CSD shall conform to requirements located in ANAB's Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status (PR 1018). Refer to **QP 28** for further guidance on use of the accreditation symbol in reports.

5.4.3 AUTHORITY

As indicated above, the OSBI CSD is authorized to perform forensic testing in accordance with O.S. 74-150.2, which is available at http://oklegislature.gov/tsrs_os_oc.aspx.

5.5 ORGANIZATION (top ↑)

Organizational structure of the OSBI CSD, including the CSD's place within the OSBI and relationships between management, technical, and support personnel is defined through organizational charts. An agency wide organizational chart is available on the OSBI intranet and an OSBI CSD Organizational Chart is located in the Quality Management System (QMS) program.

The authority, responsibilities, and interrelations for personnel who manage, perform, or verify work which affects the results of laboratory testing are specified in organizational charts and **QP 1**. Current job descriptions are also located at https://omes.ok.gov/careers/job-family/criminalist.

The OSBI CSD management system documents the policies and procedures to be followed in order to ensure the consistent application of laboratory testing and the validity of results including analysis and data interpretation to arrive at a result, opinion, or interpretation. The OSBI CSD management system documents consist of the laboratory quality policy manual, the laboratory quality procedure manual, and discipline-specific quality, policy/protocol, and training manuals. The documents of the management system are available to all CSD employees in the QMS program. Refer to **QP 2** for distribution procedures.

5.6 AUTHORITY OF PERSONNEL (top ↑)

OSBI CSD personnel are provided sufficient authority and resources to complete their duties, including:

a) implementing, maintaining, and improving the management system,
b) identifying deviations/departures from policies, procedures, and protocols,
c) initiating actions to prevent or minimize deviations/departures,
d) reporting to management regarding the performance of the management system and needed improvement, and
e) ensuring the effectiveness of laboratory activities.

The authority and resources for these duties are outlined throughout the OSBI CSD Quality Procedures, including, but not limited to, **QP 1**, **QP 2**, **QP 3**, **QP 13**, **QP 14.1**, **QP 14.2**, **QP 14.3**, **QP 15**, and **QP 18**.

5.7 INTEGRITY OF THE MANAGEMENT SYSTEM (top ↑)

OSBI CSD management utilizes quarterly meetings of the Quality Improvement Committee (QIC) (defined in **QP 18**) to ensure effective communication regarding the effectiveness of the management system and the importance of meeting customer or other requirements. Supervisory staff are responsible for further disseminating this communication to all CSD staff - see **QP 18**. In addition to regularly scheduled QIC meetings, administrative staff meet with CSD personnel as needed to ensure adequate communication regarding laboratory objectives.

CSD management will preserve the integrity of the management system anytime changes to the system are planned and implemented. This is accomplished as all changes to the management system are authored and/or reviewed by individuals familiar with accreditation requirements as described by **QP 2** and **QP 3**. Changes to the management system will be monitored through regular discussion (meetings, etc.) to ensure changes to the management system are achieving the intended goals.

6.0 RESOURCE REQUIREMENTS (top ↑)

6.1 GENERAL (top ↑)

The OSBI CSD shall make available the necessary personnel, facilities, equipment, systems, and support services necessary to manage and perform laboratory activities.

6.2 PERSONNEL (top ↑)

6.2.1

All personnel working for the OSBI CSD, whether internal or external, who could influence laboratory activities, shall act impartially, be competent, and work in accordance with the OSBI CSD management system.

6.2.2

OSBI CSD management has established the competence requirements for each personnel function which influences the results of laboratory activities; such laboratory activities include the following:

a) developing, modifying, verifying and validating methods;
b) performing testing or sampling;
c) analyzing results;
d) reviewing results;
e) authorizing results;
f) verifying results;
g) technically reviewing casework or testimony;
h) expressing opinions or interpretations of testing;
i) reporting results; and
j) authorizing (signs) reports.

This includes documented requirements for education, qualification, training and technical knowledge, skills, and experience of employees. These requirements and the procedure for identifying training and conducting training are outlined in each discipline training manual. **QP 19** details how the effectiveness of the training program will be evaluated.

6.2.2.1 Educational requirements are located in the Criminalist Job Family Descriptor (JFD). Personnel who authorize results, opinions, and/or interpretations shall meet the educational requirements located in the ANAB Accreditation Requirements (**AR 3125** section 6.2.2.1). Any additional requirements necessary to comply with ANAB or QAS requirements will be added to the selective qualifications (SQ's) prior to posting a position for recruitment and are available and maintained by the OSBI Human Resources section.

6.2.2.2 Each OSBI CSD discipline shall have a documented training program which will be used to train employees in the knowledge, skills, and abilities necessary to perform analysis, handle evidence, and/or perform quality control processes. Requirements for discipline training manuals are outlined in **QP 19**. **QP 19** outlines general procedures for maintenance of skills and expertise in the sections for retraining and continuing education; discipline training manuals should include any additional requirements for maintenance of skills and expertise and retraining.

6.2.3

The OSBI CSD shall ensure all personnel have the competence to perform the activities for which they are responsible and to evaluate the significance of deviations/departures from policy and protocols.

OSBI CSD management shall ensure the competence of any individual who influences the results of testing activities.

6.2.3.1 All CSD personnel who perform testing (including those that perform analysis, operate instrumentation, evaluate results, handle evidence or individual characteristic database samples, conduct quality control or other casework support processes, sign reports, review reports or testimony – see section 6.2.2 above) will be required to successfully complete a competency test, as outlined in **QP 19**, prior to performing testing or specific tasks that create items which could be used for testing. The competency test shall include a practical examination for the spectrum of tasks related to the testing. The competency test intended results shall be achieved prior to authorization to perform the tasks on test items.

NOTE: No supervised or unsupervised casework on evidentiary samples will occur prior to authorization for testing. Trainees will only perform work on training samples.

6.2.3.2 CSD personnel who perform technical review of results or testimony, shall meet the competency requirements as specified above in section 6.2.3.1 for the testing tasks being reviewed.

6.2.4
The duties, responsibilities, and authorities for each position in the CSD are listed in **QP 1**. Current job descriptions are available and maintained by the OSBI Human Resources section.

6.2.5 RECORDS RETENTION
In accordance with accreditation requirements, the OSBI CSD has procedures and retains record for the following as required:

a) Determining competence requirements (**QP 19**);
b) Selection of personnel (see **OSBI Policies 215.1** OSBI Recruitment Plan, **215.2** Interview and Selection Procedures, **215.3** Promotional Postings and the State of Oklahoma Human Capital Management regulations (https://omes.ok.gov/job-family-descriptor/g000-law-enforcement));
c) Training (**QP 19** and discipline quality/training manuals);
d) Supervision of personnel (see **OSBI Policies 214** Performance Evaluation (PMP), **115** Attendance and Leave, Human Resources Department);
e) Authorization of personnel (**QP 19** and discipline quality/training manuals);
f) Monitoring competence of personnel (**QP 30** Proficiency Tests, **OSBI Policy 214** Performance Evaluations, **QP 31** (and discipline quality manuals) Technical and Administrative Review, and **QP 32** Testimony Reviews).

6.2.6 AUTHORIZATION of PERSONNEL
Individuals will be authorized to perform specific laboratory activities as listed in **QP 19** – Training, including but not limited to:

a) development, modification, verification, and validation of methods;
b) analysis of results, including statements of conformity or opinions and interpretations;
c) reporting, review, and authorization of results.

The authorization should include all aspects of testing, including the use of equipment – see **QP 19**.

6.3 FACILITIES and ENVIRONMENTAL CONDITIONS (top ↑)

The range of laboratory activities for which each laboratory in the OSBI CSD laboratory system is accredited is documented on the Scope of Accreditation issued by ANAB. A copy of the current scope of accreditation is located at (http://search.anab.org/public/organization_files). OSBI CSD employees shall not infer accreditation in any area not included on the scope of accreditation.

6.3.1
OSBI CSD shall utilize laboratory facilities with proper energy sources, lighting, temperature, and other environmental conditions to ensure correct performance of tests and procedures. Employees should exercise caution when conducting sampling or analysis in a location other than

a permanent facility, such as a crime scene, to ensure that environmental conditions do not negatively impact the integrity of evidence or results.

6.3.2
Requirements for facilities, any accommodations necessary, and environmental conditions necessary for the performance of the testing activities or factors which could impact results shall be documented in the quality manual or technical protocols for each discipline.

6.3.3
When specific environmental conditions are required by the technical procedure or could impact the quality of results, the OSBI CSD shall monitor, control, and record the appropriate environmental conditions. Testing shall be stopped if the environmental conditions would negatively impact test results.

6.3.4
Measures to control facilities shall be monitored and periodically reviewed and shall include but not be limited to:

a) Access to laboratories and evidence rooms/lockers will be limited to employees assigned to the laboratory unit, evidence technicians assigned to the physical facility, Criminalistics Administrative personnel, and other personnel as authorized by the CSD Director on a limited or permanent basis.

b) Employees entering the walk-in freezer at the FSC facility shall wear proper personal protective equipment (PPE). This includes, but is not limited to, freezer gloves and a freezer jacket. All employees accessing the walk-in freezer shall notify a Physical Evidence Technician or other individual with direct access to the freezer prior to entering. Once the employee has finished accessing the freezer, they will report to the notified individual once again to ensure safety of the employee accessing the freezer.

c) Good housekeeping shall be maintained in OSBI CSD facilities. As applicable, discipline quality manuals and protocols will include procedures for cleaning and/or decontamination. If necessary, technical protocols will be prepared for sterilization procedures.

d) Incompatible testing activities shall be separated by time or space in order to prevent cross-contamination.

OSBI CSD follows the safety program detailed in **OSBI Policies 121.0** through **121.5**.

SAFETY COORDINATOR
The individual assigned as the OSBI Safety Coordinator (refer to the current organizational chart) has the responsibility and authority for implementing, updating, and ensuring compliance with the health and safety program.

6.3.4.1
Laboratory security procedures and alarm systems used during non-operational hours are located in **QP 20**. Access to testing areas is above in section 6.3.4.a. Identification badges and access by visitors is discussed in **OSBI Policy 104**.

Access to individual characteristic databases (ICD's) shall be limited to persons authorized by the CSD Director. ICD's are computerized, searchable collections of features, generated from samples of known origin from which individual characteristic information originates (*e.g.,* DNA profiles, friction ridge data, or firearm bullet/cartridge case images).

The CSD Director has delegated the authority to approve access to the Latent Evidence Technical Manager (AFIS), Firearms Technical Manager (IBIS), and the CODIS Administrator (CODIS). The Latent Evidence Technical Manager and the Firearms Technical Manager shall authorize individuals in the OSBI CSD to access and operate ICD's in the analysts' Authorization to Work memo (see **QP 19**). The Forensic Biology Technical Manager, in consultation with the CODIS Administrator, shall authorize individuals to access and operate the CODIS ICD in the analysts' Authorization to Work memos (see **QP 19**).

6.3.5
When CSD personnel perform laboratory activities in the Scope of Accreditation at sites or facilities outside its permanent control, the CSD personnel shall ensure that the accreditation requirements in section 6.3 related to facilities and environmental conditions are met.

6.4 EQUIPMENT (top ↑)

Equipment and software used to perform analysis or sampling will comply with specifications relevant to the test and shall be adequate to achieve the required accuracy. Calibration programs/procedures will be established as outlined in **QP 24**.

Equipment/Instruments will be operated by authorized CSD personnel. Authorization for use of equipment/instruments will be addressed in the authorization to work memo per **QP 19**. OSBI CSD trainees and technicians, practicum students, and interns are authorized to use equipment/instruments in the unit(s) they are assigned to **under the supervision of authorized CSD personnel**.

Current instructions for use and maintenance will be included in discipline protocols so that they are readily available for use by the appropriate CSD personnel. Alternately, manufacturers' manuals or use and maintenance instructions may be referenced in the protocol and placed in a designated location for easy access by authorized personnel.

6.4.1
Each laboratory and/or unit shall have the equipment (instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus)

necessary to ensure the correct performance of analytical tests conducted and that can influence results.

6.4.2
If equipment outside of the immediate control of the OSBI CSD is used for analysis of evidence samples, OSBI CSD management shall ensure that the equipment meets the requirements outlined in ISO/IEC 17025.
When equipment goes outside the direct control of the CSD, whether for repair or another purpose, the function and calibration status will be checked and shown to be satisfactory before the equipment is returned to service. This may also apply if instruments are taken out of casework service in order to conduct research. Refer to **QP 21.1**.

NOTE: Applies to equipment sent out or used externally by someone not trained in applicable procedures. This requirement does not apply to equipment that has service performed in-house (for example: annual service by a vendor). It is recommended that any required and/or necessary performance checks are successfully completed prior to use on casework.

6.4.3
Procedures for safe handling, transport, storage, use, and planned maintenance of equipment are located in **QP 24**.
NOTE: Software, Standard Reference Materials (SRMs), and consumables are included in this requirement.

6.4.3.1
Reagents prepared in-house will be labeled with the identity of the reagent, the lot number or date of preparation, and, as applicable, storage requirements. Records identifying who prepared the reagent and components used to prepare the reagent will be maintained.

Selection and purchasing of services and supplies will be made according to **OSBI Policy 208**. The purchase, receipt, and storage of reagents and consumable materials used for analysis will be conducted according to **QP 8.1**.

VERIFICATION of REAGENTS, SUPPLIES, and CONSUMABLE MATERIALS
Any supply, reagent, or consumable item that will affect the quality of analysis will not be used until inspected and/or verified according to **QP 8.1**.

EVALUATION of SUPPLIERS
The Technical Manager of each discipline will determine which reagents, consumables, supplies, and services are critical and affect the quality of testing. The Technical Managers will also oversee the evaluation of suppliers and may maintain a list of approved suppliers, as described in **QP 9**. At a minimum, reference standards, reference materials, and calibrations of equipment or reference standards used to establish or maintain measurement traceability shall be considered critical services and supplies.

RELIABILITY OF REAGENTS
The reliability of reagents will be verified according to **QP 8.1**.

6.4.3.2
Reference collections (data or materials of known origin maintained by the OSBI CSD for identification, comparison, or interpretation purposes such as mass spectra, motor vehicle paints, wood fragments, firearms, ammunition, DNA profiles) will have each entry documented, uniquely identified, and handled properly to protect the characteristic(s) of interest. Each discipline quality manual will address the discipline-specific reference collection(s) maintained.

Example: Biology discipline employee DNA profiles for comparison for contamination evaluation purposes may be documented in a controlled spreadsheet, uniquely identified, and verified for accuracy.

6.4.4
OSBI CSD instruments and equipment will be validated, performance checked, and/or verified for conformance to discipline policy requirements prior to being placed into or returned to service.

6.4.5
Measuring equipment used by the OSBI CSD for measurement uncertainty shall be capable of achieving measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6
Measuring equipment used by the OSBI CSD for measurement uncertainty shall be calibrated when the accuracy or uncertainty affect the validity of the reported results, and/or when the calibration is required to establish traceability for measurement uncertainty of reported results.

6.4.7
Any equipment used for testing which has a significant impact on the accuracy or validity of the test or sampling shall be calibrated before being placed in service. This includes any equipment used for subsidiary measurements such as environmental conditions, if it would have a significant impact on the validity or accuracy of results.

The requirements for equipment calibration procedures are outlined in **QP 24**. The calibration procedures will be reviewed and adjusted, as needed, in order to maintain confidence in the status of calibration.

As specified in **QP 24**, the procedures for checking the calibration of equipment are established based on the specific requirements of the tests being conducted. Under normal circumstances, a check of calibration will be conducted after any shut down and following service or other substantial maintenance. Calibration check intervals will not be less stringent than the

manufacturer's recommendations.

6.4.7.1
Each discipline quality/procedure manual will include a list of equipment requiring calibration which will include the specification for the calibration laboratory (as applicable), the requirements for calibration, and the interval of calibration. The list shall include specifications of the calibration laboratory, specified requirements for calibration, and the interval of the calibration.

NOTE: The OSBI does not provide calibration services as defined by ISO/IEC 17025.

6.4.8
Equipment which requires calibration shall be labeled to show the status of the calibration, including the date of the last calibration, and when recalibration is due. Depending on the equipment size and/or function, the labeling may need to be abbreviated and supplemented by providing the full information elsewhere (i.e. maintenance log).

6.4.9
Instruments and equipment which have been mishandled or have been shown to be outside acceptable limits will be taken out of service. Out of service instruments and equipment will be clearly labeled as out of service until repairs are made and the instrument/equipment is placed back in service following a successful function verification/calibration. Any associated maintenance log will reflect the date the instrument/equipment was taken out of service and will include a description of the issue and the steps taken to resolve the issue.

The impact of the defect or departure from acceptable limits will be evaluated and procedures outlined in **QP 13** will be initiated.

6.4.10 INTERMEDIATE CHECKS
If intermediate calibration checks (performance checks) are needed to maintain confidence in the calibration status of equipment, the checks will be done according to a written protocol approved by the appropriate Technical Manager.
When checks are needed to ensure confidence in the calibration status of reference, primary, transfer, or working standards and reference materials, these checks will be carried out according to defined procedures and schedules. Once established, the interval for intermediate checks shall not be extended without first obtaining supporting empirical data and evaluating the risk of such an extension.

NOTE: Evaluation of a need for an intermediate check will include consideration of factors such as calibration/performance check interval, use of equipment, stability, method specifications, and risks associated with a failure.

6.4.11 CORRECTION FACTORS
Where calibrations or performance checks result in correction factors that must be used, the

discipline shall implement a procedure to ensure that any copies (e.g. in computer software) are correctly updated and implemented.

6.4.12 UNINTENDED ADJUSTMENT of EQUIPMENT

Each discipline in the CSD will use practicable measures to safeguard against any unintended adjustments of equipment (including software) that could invalidate results.
Applicable controls, defined in discipline protocols, will be used to safeguard test equipment including hardware and software from adjustments which would invalidate the test results.

6.4.13 EQUIPMENT RECORDS

Whenever possible, equipment used for testing (measuring instruments, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus) and its software significant to the test result will be uniquely identified. At a minimum, unique asset numbers will be assigned to instruments, equipment, and software purchased by the OSBI in accordance with **OSBI Policy 209**.

For each instrument and its software significant to the analysis performed, the following records will be maintained according to **QP 24**:

a) the identity of the instrument (including software and firmware version, as applicable);

b) the manufacturer's name, type identification (model number), and serial number and/or asset number;

c) documentation of function verification;

d) the current location, if appropriate;

e) copies of all calibration and adjustment reports/certificates, including the date, result of calibration/adjustment, acceptance criteria, and the due date for the next calibration;

f) documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity;

g) the maintenance plan, if appropriate, and records of maintenance performed to date;

h) description of any damage, malfunction, modification, or repair of the equipment; and

i) the instruction manual, if available, or a reference to the location of the manual

6.5 METROLOGICAL TRACEABILITY (top ↑)

6.5.1

The CSD establishes and maintains metrological traceability of its measurement results as outlined in **QP 23** and **QP 24**. The OSBI CSD uses the procedure outlined in **QP 23** to ensure

adequate traceability of measurements where measurement uncertainty is estimated or when the measurement result has a significant impact on the final test result. As indicated in **QP 24**, the OSBI CSD will furnish CSD facilities with equipment and instrumentation which will provide the correct performance for the analysis conducted. **QP 24** will also be used to ensure safe handling, transport, storage, use, and maintenance of measuring equipment.

6.5.1.1 The OSBI CSD will use vendors for external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability as outlined in **QP 23.**

6.5.1.2 If a supplier that meets the requirements of **QP 23** is not available, the responsibility of the Technical Manager is listed in **QP 23**.

6.5.1.3 Per **QP 23**, The OSBI CSD shall not perform calibrations of equipment or reference standards without first obtaining accreditation in the necessary field of calibration from an accrediting body with an appropriate scope of recognition from IAAC or ILAC.

6.5.1.4 Certified reference materials, including alterations to traceable measurements, are discussed in **QP 26**.

Reference Standards **QP 25** outlines the procedures for the calibration of reference standards. Reference standards will be calibrated by an organization capable of providing traceability to SI units as described in ISO/IEC 17025 standard 6.5.1 and 6.5.2. Reference standards will only be used for calibration unless it can be demonstrated that other use will not invalidate their performance as a reference standard. Reference standards will be calibrated before and after adjustments.

Transport and Storage **QP 25** establishes the procedures for safe handling, transport, storage, and use of reference standards. These procedures prevent contamination and deterioration of the standards and protect their integrity.

Reference Materials As specified in **QP 26**, reference materials will be traceable to the International System (SI) units of measurement, or to certified reference materials, whenever possible. Accuracy of internal reference materials will be checked as far as is technically and economically practical.

6.5.2

As indicated in **QP 23** and **QP 24**, the calibration program for equipment is designed to ensure that calibrations and measurements are traceable to SI units, if possible. This is not required if the associated contribution of the calibration to the total uncertainty of the test results is negligible. In this situation, the OSBI CSD shall ensure that the equipment used provides the uncertainty of measurement needed.

6.5.3
Where traceability of measurements to SI is not possible and/or relevant, the OSBI CSD shall provide confidence in measurements by establishing traceability to appropriate standards such as certified reference materials, specified methods, and/or consensus standards.

6.6 EXTERNALLY PROVIDED PRODUCTS and SERVICES (top ↑)

6.6.1
The OSBI CSD shall ensure that only suitable externally provided products and services affecting laboratory services are used when such products and services:

a) are intended for incorporation into the OSBI CSD activities;
b) are provided, in part or in full, directly to the customer by the OSBI CSD, as received from the external provider;
c) are used to support the operation of the OSBI CSD.

NOTE: Products may include measurement standards, measurement equipment, and consumable materials. Service may include calibration services, testing services, facility and equipment maintenance, proficiency testing services, or assessment/auditing services. See also Evaluation of Suppliers in section 6.4.3.1 above.

In order to provide the best service possible, OSBI laboratories may choose to transfer work to another OSBI laboratory or subcontract to an outside vendor. However, when a customer (investigating agency, prosecuting agency, or defense attorney) requests evidence be sent out for further testing and specifies where to send the evidence it is not considered subcontracting. Similarly, when the laboratory does not have the capability, resources, or areas of competence to perform the requested testing, this is not considered subcontracting.

OSBI CSD shall use personnel employed by or under contract to the OSBI. If contract or additional support personnel are used, OSBI CSD will ensure that these personnel are also appropriately supervised and competent for the work they perform. Their work shall also be in accordance with the OSBI CSD Management System.

6.6.2 DETERMINING SUITABILITY of EXTERNAL PROVIDERS
The OSBI CSD will have procedures in each discipline quality/procedure manual and retain records for the following:

a) defining, reviewing, and approving requirements for externally provided products and services;
b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
c) ensuring that externally provided products and services conform to the CSD's established requirements, or when applicable, to the relevant requirements of ISO/IEC 17025, before they are used or directly provided to the customer;
d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

QP 30 lists requirements for external proficiency test providers.
QP 9 lists requirements for Evaluation of Suppliers.

6.6.2.1 SUBCONTRACT LABORATORY

QUALIFICATION of SUBCONTRACT LABORATORY

Any laboratory performing work for the OSBI must comply with the accreditation requirements in O.S. 74-150.37. If available, the subcontractor shall be accredited by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with a scope of accreditation that covers the service(s) being subcontracted.

CUSTOMER NOTIFICATION

The OSBI CSD shall notify customers in writing when subcontracting work to an outside vendor. The OSBI CSD will also obtain approval from the customer, preferably in writing.

REVIEW of SUBCONTRACTED WORK

The OSBI CSD maintains responsibility for subcontracted work, unless the customer or a regulatory authority specifies which subcontractor will be used.

RECORDS of SUBCONTRACTORS

The Quality Manager will receive and maintain a copy of the accreditation certificate for any laboratory which performs analysis on behalf of the OSBI.

6.6.2.2 PURCHASING SERVICES and SUPPLIES

Selection and purchasing of services and supplies will be made according to **OSBI Policy 208**. The purchase, receipt, and storage of reagents and consumable materials used for analysis will be conducted according to **QP 8.1**.

VERIFICATION of REAGENTS, SUPPLIES, and CONSUMABLE MATERIALS

Any supply, reagent, or consumable item that will affect the quality of analysis will not be used until inspected and/or verified according to **QP 8.1**.

DESCRIPTIONS of ITEMS AFFECTING QUALITY

Items that affect the quality of analysis will be identified on the Internal Purchase Request (IPR) with a description specific enough to ensure the appropriate quality of item is purchased. This description may be a product number, catalog number, a reference to a particular grade or purity, or other technical description. The description provided will be reviewed and approved with the IPR.

6.6.3 LABORATORY COMMUNICATION with EXTERNAL PROVIDERS

The OSBI CSD will communicate the following requirements to external providers:

a) products and services to be provided (using the procedures for submitting Internal Purchase Request (IPR) and other purchasing procedures outlined in **OSBI Policy 208** and in **QP 8.1**);
b) acceptance criteria (including reagent or equipment specifications);

c) competence, including qualification of personnel, as applicable (for example: for subcontractors or critical services);
d) activities that the CSD and/or customer intend to perform at external provider's premise (example: annual onsite visit for outsourcing cases).

7.0 PROCESS REQUIREMENTS (top ↑)

7.1 REVIEW of REQUESTS, TENDERS, and CONTRACTS (top ↑)

7.1.1

QP 4 establishes the procedures that will be followed for the review of requests, tenders, and contracts. This review process shall apply to work performed by any OSBI laboratory, regardless of which laboratory received the evidence and performed the review. It shall also apply to analysis that is subcontracted to a non-OSBI laboratory. This procedure ensures that:

a) The customer's requirements, which include the type of analysis or methods to be used, are well defined, documented, and understood.

b) The OSBI CSD is capable of meeting the customer's needs.

c) If external providers are used, the requirements outlined in section 6.6 above are applied. The CSD advises the customer of the specific laboratory activities to be performed by the external provider and gains customer approval.

d) The appropriate test method and procedures are selected and are capable of meeting the customers' requirements.

RECORDS

An electronic or hard copy of the RFLE received according to QP 5 will be maintained with the case file as a record of the request, review, and contract. In addition, any significant changes will be recorded in a narrative (conversation log, e-mail) or equivalent document. All records of changes to the contract will also be maintained with the case file (either electronic or hard copy).

7.1.2

CSD personnel shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date. This will be recorded in a narrative (conversation log, e-mail) or equivalent document and maintained in the case record if the case is accepted.

7.1.3 STATEMENTS of CONFORMITY

The OSBI CSD does not routinely provide states of conformity.

If the customer requests a statement of conformity to a specification or standard for the test (e.g. pass/fail, in tolerance/out of tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.

Example: barrel length of sawed off shotgun 18" with overall length of 26" – if analyst makes a statement re: legality in report / includes statute in report a statement of conformity would be required. If only stating length in report, this isn't required.

7.1.4 DIFFERENCES in REQUEST or TENDER and CONTRACT

Any differences between the request, tender, or contract will be resolved before work commences. Each contract should be satisfactory to both the OSBI CSD and the customer. Any deviations requested by the customer that could impact the integrity of the OSBI CSD laboratory or the validity of the results will not be approved.

7.1.5 DEVIATIONS from CONTRACTS

The customer will be informed of deviations from the contract. Refer to OSBI CSD **QMA 1.1** – Notice to Customers. If an analyst determines that requested analysis is not appropriate or recommends alternate or additional analysis, the customer will be contacted prior to modifying the contract, unless the modification has already been addressed through the general notice to customers, OSBI CSD **QMA 1.1**.

7.1.6 AMENDMENTS to CONTRACTS

Any amendment or modification to the contract after analysis begins will be reviewed in the same manner listed under **QP 4**. The person making the amendment will ensure the contract review is repeated and will notify the affected personnel.

7.1.7 COOPERATION with CUSTOMERS

The OSBI CSD will cooperate with OSBI customers to ensure that service provided meets customers' needs. This includes clarifying requests for analysis and monitoring the laboratory's work performance. This may be accomplished through a variety of methods including discovery requests, reports, tours, etc.

However, the OSBI CSD will ensure that cooperation with one customer does not compromise confidentiality of other customers. In addition, the OSBI CSD will ensure that the cooperation with a customer's request doesn't compromise the OSBI CSD integrity and is in line with the Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel. Refer to **QP 10** for procedures on customer assistance.

7.1.8 RECORDS of CONTRACT REVIEWS

Records of reviews, including any significant changes, shall be retained in the case record. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the CSD laboratory activities.

7.1.9 EXTENT of DATABASE SEARCHES

The extent of database searches is communicated to customers in OSBI CSD **QMA 1.1** and **QMA 4.1**.

7.2 SELECTION, VERIFICATION, and VALIDATION of METHODS (top ↑)

7.2.1 SELECTION and VERIFICATION of METHODS

7.2.1.1

The OSBI CSD shall use analysis methods and procedures, which meet the needs of the customer and which are appropriate for the testing conducted.

7.2.1.1.1

The OSBI CSD shall use appropriate methods and procedures for all associated data analysis and interpretation.

7.2.1.1.2

In order to minimize comparison bias, all test methods that involve the comparison of an unknown to a known shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations to the extent possible, prior to comparison to one or more known item(s).

NOTE: Such unknown items include alleles in DNA profiles, friction ridge detail in a latent print, striation detail on a bullet, or criteria for evaluation of mass spectrometry fragments and ratios in seized drug samples or toxicology sample extracts.

7.2.1.2

All methods, procedures, and supporting documentation relevant to testing activities, shall be kept up to date through review by the Quality Manager and/or discipline Technical Managers. Current versions are made available to personnel in QMS.

7.2.1.3

The OSBI CSD uses the latest valid versions of standard methods when appropriate and possible.

7.2.1.4

The OSBI CSD reserves the right to select the most appropriate method and to select the item(s) most appropriate for analysis (see **"Notice to Customers" – OSBI CSD QMA 1.1**). If a particular test method or service is desired for a specific item, a Criminalist from the discipline in question will be contacted for assistance with the review of the request.

OSBI CSD uses appropriate methods for all testing, including test data analysis and interpretation, and evidence handling. Evidence handling procedures are included in **QP 6.1** through **QP 7**. Technical procedures, estimations for uncertainty of measurement,

and any statistical techniques for analysis of testing data are included or referenced in discipline-specific quality manuals and/or protocols. Instructions on the operation of instrumentation, sample handling, and preparation will also be included or referenced in the discipline-specific quality manuals and/or protocols, if written instructions are necessary to ensure the quality of test results. Any deviations to these procedures occur only as outlined in **QP 3**.

All analytical protocols shall be documented and issued according to **QP 2**.

Appropriate controls and standards shall be specified in the analytical records and the results of controls and standards tested shall be documented in the case record.

7.2.1.5 STANDARD METHODS
The OSBI CSD shall verify that it can properly perform standard methods before introducing them to casework by ensuring that it can achieve the required performance (e.g. successful validation, performance verification). Records of this verification shall be retained. If the method is revised, the verification shall be repeated to the extent necessary.

7.2.1.6 METHOD DEVELOPMENT
When method development may be necessary, it shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review by the discipline Technical Manager shall be completed to ensure that the needs of the customer are being fulfilled. Any modifications to the development plan shall be approved and authorized by the discipline Technical Manager or appropriate Criminalistics Administrator. See **QP 21.1** and **QP 21.2**.

7.2.1.7 DEVIATION from METHODS
Deviations from methods for all OSBI CSD laboratory activities shall occur only if the deviation has been documented, approved by the discipline Technical Manager, authorized and accepted by the customer. The customer agreement can/may be included in the initial contract. See OSBI CSD **QMA 1.1**.

7.2.2 VALIDATION of METHODS
Validation of a method shall provide objective evidence that the method meets the particular requirements for a specific intended use. The reliability of any new method will be internally validated and the results of the validation study documented prior to implementing the procedure for use in casework. The procedure for suggesting, conducting, documenting, and maintaining records of a validation are outlined in **QP 21.2**.

Validation of new methods developed by the OSBI CSD shall be planned and conducted by qualified personnel authorized per **QP 19** who have the necessary resources. Effective communication shall be maintained and the validation plan shall be updated as

the method development proceeds.

7.2.2.1
All methods (laboratory-developed methods and standard methods used outside their intended scope or otherwise modified) used by the OSBI CSD shall be validated to ensure that the methods are fit for the intended use and given application.

7.2.2.1.1
QP 21.2 covers the procedures for the Evaluation of Methods, Instruments, Equipment, and Software.

In order for a method to be determined fit for an intended use, the range and accuracy of the values obtained from the method must be relevant to the customer's needs.

7.2.2.2
When changes are made to a method previously validated by the OSBI CSD, the influence of the intended changes shall be determined using the appropriate procedures in QP 21.2. If the modification is found to affect the parameters set forth in the original validation, a new method validation shall be performed per QP 21.2.

NOTE: The associated data analysis and interpretation is considered part of a validated method. If considering a change to data interpretation, section 7.2.2.2 above applies, including consideration of the influence and need for re-validation per QP 21.2.

7.2.2.3
The performance characteristics (e.g. measurement range, accuracy, limit of detection, repeatability/reproducibility, cross-sensitivity, bias, etc.) of validated methods used by the OSBI CSD, as assessed for their intended use, shall be relevant to the customers' needs and consistent with specified requirements.

7.2.2.4
The OSBI CSD will retain the following records of validation obtained per QP 21.2:
a) the procedure used,
b) the results obtained,
c) any specific sample and/or analysis requirements,
d) the range and accuracy of the values obtainable by the method (e.g. limit of detection, selectivity, repeatability, reproducibility), and
e) a conclusion indicating whether the method is fit for the intended use.

Before implementing a validated method new to the OSBI CSD, the reliability of the method will be demonstrated against any documented performance characteristics (such as sensitivity or specificity) of the method using the procedures outlined in QP

21.2. Records of the performance check, which may be incorporated into the validation work, shall be retained per QP 21.2 and any applicable discipline quality or protocol manuals.

7.3 SAMPLING (top ↑)

The OSBI CSD will not report results based on a statistical sampling method. The OSBI CSD may report results for a whole based on testing a portion in limited circumstances using sample selection which include toxicology analysis and the identification of controlled substances.

The Toxicology Quality Manual and protocols will specify the necessary steps to ensure homogeneity of toxicology samples and the amount of sample to be used for analysis.

For the Forensic Chemistry discipline, state statute (Title 63, Chapter 2, article 2, section 2-204 (Schedule I) and section 2-206 (Schedule II)) states: "Any material, compound, mixture, or preparation that contains any quantity of the following hallucinogenic substances, their salts, isomers, and salts of isomers, unless specifically expected, when the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation."), which establishes a legal basis for homogeneity for the identification of controlled substances. The Forensic Chemistry Quality Manual and protocols will specify any necessary steps for documentation of the sample selection and the amount of sample to be tested will be based on the analyst's training, experience, and competency.

NOTE: The intent of ISO/IEC 17025 is that the activity of sampling occurs prior to the item being submitted to the OSBI CSD. The OSBI CSD can choose to perform further sampling after the receipt of the item, in which case the requirements for sampling in ISO/IEC 17025 are applicable.

7.4 HANDLING of TEST or CALIBRATION ITEMS (top ↑)

7.4.1

The procedures for transportation, receipt, handling, protection, storage, retention, return and/or disposal of all evidence items received by the OSBI CSD are included in QP 5 through QP 7. These procedures include all provisions necessary to protect the integrity of evidence and the interests of the OSBI CSD and our customers.

QP 6.1 details the procedures for preventing loss, deterioration, contamination, or damage to evidence items during storage and handling. This includes ensuring the security and proper environmental conditions of evidence storage locations. Requirements for monitoring refrigerators and freezers used to store evidence are located in QP 6.4.

7.4.1.1

Through compliance with the evidence handling procedures outlined in QP 5 through QP 7, the OSBI CSD documents the chain of custody for all test items (evidence) received by the laboratory. The minimum components of a chain of custody record include the person (by signature or electronic equivalent) or location receiving evidence,

the date of receipt or transfer, and a description or unique identifier of the evidence item.
In order to ensure a complete and accurate chain of custody, all employees will document evidence transactions in the LIMS at the time evidence items are physically moved from one location to another, unless exceptions are provided for in evidence handling procedures. In addition, employees shall not share LIMS passwords with anyone. Failure to comply with this policy will result in progressive discipline.

Failure to comply with evidence handling procedures may also result in progressive discipline.

As detailed in **QP 6.1**, when evidence is subdivided in the laboratory, the OSBI CSD requires the same chain of custody documentation for any sub-items created.

Items that are collected or created and preserved as evidence for future testing (e.g. test fired ammunition, latent print lifts, trace evidence, DNA extracts, retained sample vials in seized drug unit) shall require the same chain of custody documentation. These items shall be reported to the customer as described in **QP 28**.

NOTE: Not all items created during testing are considered evidence – some may be considered work products. This delineation will be included in each disciplines' quality manual.

As described in **QP 5**, all evidence accepted and stored by the OSBI CSD will be properly packaged and sealed, if practicable. Examples of items that may not be able to be properly packaged may include bicycles and automobiles.

NOTE: Consultation with the appropriate Technical Manager(s), or designee, is recommended.

All evidence will be stored in a secured, limited access storage area when not in the process of examination.

Each discipline quality manual shall specify whether individual characteristic database (ICD) samples will be treated as evidence, reference materials, or examination records.

All evidence items will be re-sealed as soon as practicable.

QP 6.1 details how to secure unattended evidence in the process of examination.

QP 6.1 also clearly defines when evidence is considered to be in the process of examination.

When evidence, such as latent prints or impressions, can only be recorded or collected by photography and the image itself is not recoverable, the photograph or negative of the image shall be treated as evidence.

OSBI CSD personnel collecting evidence at a crime scene will ensure that the evidence is protected from loss, cross-transfer, contamination, and deleterious change, whether in a sealed or unsealed container, during transport to the laboratory. Crime scene evidence shall be appropriately identified, packaged, and entered into the LIMS as soon as practical.

The OSBI CSD maintains ICD's in the CODIS Unit and Firearms Unit. Procedures for the operation of ICD's in the Latent Evidence Unit, CODIS Unit, and Firearms Unit are located or referenced in the appropriate discipline/unit quality manuals and/or protocols. ICD samples under the control of the OSBI CSD will be protected from loss, cross transfer, contamination and deleterious change.
NOTE: The Latent Evidence Unit conducts searches of samples in AFIS but does not maintain the ICD. It is maintained by the Information Services Division of the OSBI.

OSBI CSD **QMA 1.1** addresses communication to the customer regarding the disposition of all items received. **QP 28** addresses the communication to the customer regarding items collected or created and preserved for future testing.

7.4.2
The OSBI CSD utilizes the "BEAST" Laboratory Information Management System (LIMS) to identify all evidence items received while they are in OSBI CSD custody. This system, in conjunction with the evidence handling procedures, ensures that evidence cannot be confused physically or when referred to in the case record or other documentation. The system allows for sub-dividing groups of evidence items, transfer of evidence within the laboratory, and receipt and return of evidence.

OSBI CSD personnel collecting evidence at a crime scene will ensure that the evidence is protected from loss, cross-transfer, contamination, and deleterious change, whether in a sealed or unsealed container, during transport to the laboratory. Crime scene evidence shall be appropriately identified, packaged, and entered into the LIMS as soon as practical.

ICD samples under the control of the OSBI CSD will be uniquely identified.

7.4.2.1 Each item of evidence shall be marked with the case number and item number. If it is not possible to mark the evidence or if marking the evidence with the item number could affect the integrity of the evidence, then the proximal container or tag shall be labeled.

7.4.3
When evidence is received, any abnormalities regarding the packaging or condition of evidence will be recorded. If there is doubt whether the item is suitable for testing or if the item does not match the description provided, the customer will be consulted for clarification and the

conversation recorded using the "Narrative" button on the "Case Info" tab in the LIMS before proceeding.

Examples may include but are not limited to solidified toxicology sample or an arson can with the lid popped open.

Reasonable effort /attempts to consult with the customer will be made by the analyst or their Supervisor/TM. If contact is unsuccessful after 10 calendar days of attempts, the analyst will proceed with the analysis in the case sans the item(s) with the discrepancy. If analysis proceeds without the affected item, the report will indicate wording similar to "Evidence description(s) on the Request for Laboratory Examination (RFLE) did not match the evidence received. Clarification is necessary from the customer prior to proceeding with this analysis. Attempts to obtain clarification were unsuccessful; therefore, Item X was not analyzed at this time. Please re-submit the item(s) with the appropriate description and request for analysis should you require analysis of the affected item(s) in this case."

This requirement for customer consultation does not apply to items received that cannot be tested. Examples include but are not limited to used field test kits, extra packaging, waste.

Analysts should work with their Supervisor and/or discipline Technical Manager regarding any issues that may arise as a result of this requirement.

7.4.3.1 If testing the items is possible and the customer agrees to continue with testing the item, the report shall include a disclaimer indicating which results may be affected by the abnormality.

7.4.4

QP 6.1 details the procedures for preventing loss, deterioration, or damage to evidence items during storage and handling. This includes ensuring the security and proper environmental conditions of evidence storage locations. Requirements for monitoring refrigerators and freezers used to store evidence are located in **QP 6.4**.

When items need to be stored or maintained under specific environmental conditions (e.g. refrigerated), these conditions shall be maintained, monitored, and recorded.

7.5 TECHNICAL RECORDS (top ↑)

7.5.1

The OSBI CSD will retain records of examination documentation and supporting documentation, such as quality assurance/quality control documentation, and copies of reports for the period of time defined in **QP 16.1**. Each case record will contain enough information to identify factors affecting uncertainty of measurement, if possible and applicable, and to enable re-analysis to be conducted under conditions as close to the original as possible. The date and identity of the individual(s) responsible for each laboratory activity and for checking data and results will be reflected in the case record. Dates may be reflected as a range of dates or the date of each test.

Original observations, data, and calculations must be recorded at the time they are made and must be identifiable to the specific case/task involved.

Examination documentation must include at a minimum, the start and end dates of examination.

Each page of hard copy examination documentation will bear the case number and examiner's handwritten initials. Electronic examination documentation added to the image vault of the BEAST does not require case number or initials, as the BEAST displays the case number and the analyst who attached the documentation. However, each document added to the image vault must contain enough information to verify that the document was added to the correct case record.

If a technician or other individual prepares examination documentation which another analyst interprets, reports, or testifies to, the person who prepares the examination documentation must sign/initial (or electronically sign/initial) the page(s) he/she prepares.

All administrative documentation, received or generated by the OSBI CSD, must be labeled with the laboratory case number. This may be accomplished via hand-written initials on the hard copy documentation prior to scanning or by ensuring the BEAST displays the case number and identifies the analyst who attached the documentation.

When multiple cases are analyzed simultaneously, the case number of each case must be appropriately recorded on the printout if the data is recorded on a single printout.

Examination documentation should be one-sided. Each side of any two-sided examination documentation will be treated as a separate page.

7.5.1.1 Documents maintained as part of the case record are identified in **QP 16.2**.

7.5.1.2 The meaning of any abbreviations or symbols specific to the OSBI CSD will be documented either in the case record or in discipline quality manuals or protocols.

7.5.1.3 Operating parameters used during instrumental analysis shall be recorded in the examination documentation, protocol, or another suitable and appropriate location. Examination and supporting documentation must be sufficient for another examiner possessing the relevant knowledge, skills, and abilities to determine what was done and to independently interpret the data.

7.5.1.4 Examination documentation will be permanent in nature.

7.5.1.5 If an observation, data, or calculation is rejected, the reason, the identity of the individual(s) taking the action and the date shall be recorded in the technical record **per QP 16.2 II.A.2.d.**

7.5.1.6 If an adjustment or repair is performed to testing equipment due to a calibration that does not meet specifications, pre and post adjustment/repair data shall be retained. Example: As found / as left for scale calibration certificates.

7.5.2 TRACKING CHANGES TO TECHNICAL RECORDS

The documentation associated with amendments to technical records must be sufficient to be tracked to previous versions or to original observations. Both the original and the amended data and files shall be retained, including the date of alteration, an indication of the altered aspects, and the personnel responsible for the alterations.

NOTE: Contemporaneous revisions are not considered amendments.

In order to maintain the original data, non-contemporaneous alterations/changes in examination documentation (technical records) will be crossed out with a single line, initialed, and dated with the correct value added alongside. Erasing, obliterating, or otherwise making the original data illegible is not permitted.

Examination documentation is considered complete when it is submitted for administrative and/or technical review.

Any changes made to completed examination documentation, shall be tracked.

7.6 EVALUATION of MEASUREMENT UNCERTAINTY (top ↑)

7.6.1

The procedure for estimating the uncertainty of measurement is located in **QP 22**.

7.6.1.1

The OSBI CSD method for evaluation of measurement uncertainty will be included in discipline-specific quality/protocol manuals and shall:

a) Require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method; when specific environmental conditions are required by the technical procedure or could impact the quality of results, the OSBI CSD shall monitor, control, and record the appropriate environmental conditions. Testing shall be stopped if the environmental conditions would negatively impact test results.

b) Include the process of rounding the expanded uncertainty;

c) Require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and

d) Specify the schedule to review and/or recalculate the measurement uncertainty.
Example: Upon getting a new analyst, including the new individual in the calculations may be necessary if their work doesn't fall into the current window.

7.6.2
The OSBI CSD does not perform its own calibrations.

7.6.3
The procedure for estimating the uncertainty of measurement is located in **QP 22**.

7.6.3.1 Measurement uncertainty shall be evaluated, or estimated when applicable, for all quantitative results reported by the OSBI CSD.

7.6.4
The requirement for retention of records to be maintained for each evaluation and estimation of measurement uncertainty is listed in **QP 22**.

7.7 ENSURING the VALIDITY of RESULTS (top ↑)

7.7.1
The OSBI CSD procedures for monitoring the validity of tests are located in technical protocols as appropriate. Results of each quality control activity shall be recorded in order to demonstrate capabilities and confirm competence. In addition, procedures for proficiency tests, re-examination, and reviews are referenced below. Data will be recorded in a way to allow trends to be detected and whenever practical, statistical techniques will be used to review the data. OSBI CSD quality control monitoring is planned and reviewed according to the procedures referenced. Monitoring includes the following:

a) use of appropriate controls and standards, which are specified in protocols and recorded in case records

b) regular use of certified or secondary reference materials, as appropriate

c) the use of alternative instrumentation that has been calibrated to provide traceable results

d) functional check(s) of measuring and testing equipment

e) use of check or working standards with control charts, where applicable

f) intermediate checks on measuring equipment

g) replicate tests using the same or different methods

h) re-analysis of casework
Verifications of analytical findings, such as latent print or firearms identifications, will be conducted by currently qualified examiners. Verifications will be documented to include what was verified, whether the second examiner agrees, and when the verification was

conducted. If the verification does not agree with the original test result, planned action shall be taken to resolve the discrepancy and the resolution of any discrepancy shall be recorded in the case record.

i) correlation of results for different characteristics of an item

j) internal and external proficiency testing

k) review of reported results

l) intralaboratory comparisons

m) testing of blind sample(s)

n) Technical review of casework will be conducted according to **QP 31** in order to routinely verify that conclusions reported are accurate and supported by the examination documentation. **QP 31** further defines the qualifications of a technical reviewer, scope of a technical review, how technical reviews will be documented, and what actions will take place if a discrepancy is noted.

Administrative review of casework will be conducted according to **QP 31** to ensure that reports and case records are accurate and complete. All OSBI CSD reports, with the exception of no analysis reports, will be administratively reviewed prior to release.

o) Testimony provided by OSBI CSD analysts will be monitored according to **QP 32**. Technical Review of Testimony performed by individuals previously or currently qualified in the method(s) used in the case will utilize the Qualified Testimony Review Form **OSBI CSD QPA 32.4**.

7.7.2
The OSBI CSD shall monitor its performance by comparison with results of other laboratories and intra-laboratory results through involvement in external and internal proficiency testing. The OSBI CSD proficiency testing program is located in **QP 30**.

7.7.2.1 The OSBI CSD will ensure successful completion of at least one external proficiency test for each discipline prior to accreditation being granted in that discipline and ensure each location on the Scope of Accreditation successfully completes, per calendar year, at least one proficiency test for each discipline in which accredited services are provided. The Quality Manager, or designee, will authorize the release of the proficiency test results to ANAB from the test provider.

7.7.3
Quality control data shall be analyzed and planned action will be taken to correct the problem if the quality control data is outside the predefined window for acceptability.

The Quality Manager or discipline Technical Managers may monitor for any variances between analysts and/or facilities by reviewing proficiency testing results.

7.7.4
All personnel that perform testing will be monitored by completing at least one internal or external proficiency test per calendar year in each discipline on the Scope of Accreditation in which the individual conducts work.

Analysts and Technicians qualified in DNA analysis shall complete two external proficiency tests annually in accordance with the FBI's Quality Assurance Standards.

If an internal or external proficiency test is not available, the Quality Manager, or designee, will assign the individual an intra-laboratory comparison (re-analysis item or case as outlined in **QP 30**) or an observation-based performance monitoring will be documented by the discipline Technical Manager.
NOTE: The monitoring should be varied over time to cover all aspects of the assigned job functions but does not have to include all aspects of the work performed each time.

An individual whose sole function is verifications or reviewing/authorizing results is considered to be performing testing and is subject to the requirements listed in 7.7.4 above.

7.7.5
The OSBI CSD proficiency testing program is listed in **QP 30**.

7.7.6
The Quality Manager, or designee(s), maintains a spreadsheet documenting annual proficiency testing plans, distribution, and results. The Technical Managers of each discipline will ensure there are representative samples of the components/parameters and equipment/technologies within each discipline listed on the Scope of Accreditation.

7.7.7
The OSBI CSD shall use a proficiency test provider that is accredited to ISO/IEC 17043 by an accrediting body that is a signatory to the APLAC MRA or IAAC MLA and has the applicable proficiency test(s) on its scope of accreditation or gain approval from ANAB for alternative means by which the OSBI CSD performance may be assessed. All external proficiency test results will be submitted to the test provider by the Quality Manager, or designee, on or before the due date provided by the test provider.

7.7.8
The OSBI CSD will retain the following records for intralaboratory comparison, interlaboratory comparisons, proficiency tests, and observation-based monitoring:

a) discipline(s) completing the monitoring;
b) design of monitoring activity;
c) expected results;
d) location;
e) records submitted to a proficiency test provider, when applicable;
f) appropriate technical records;
g) evaluation of results and action taken for unexpected results; and
h) results of the test/monitoring provided to the individual.

7.8 REPORTING of RESULTS (top ↑)

7.8.1 GENERAL

7.8.1.1
All results from the OSBI CSD shall be reviewed and authorized prior to release in accordance with **QP 31**.

7.8.1.1.1 The authorizer of the results shall review the technical record associated with the case and document the review.

NOTE: Any OSBI CSD analyst who issues a report or testifies based on the examination documentation generated by another individual shall complete and document a review of all relevant pages of documentation in the case record.

7.8.1.2
The results of testing and examinations of evidence items, and any evidence collection not inherent to a reported result that is conducted by OSBI CSD personnel will be reported accurately, clearly, unambiguously, and objectively in a written Criminalistics Examination Report. Additional instructions on ensuring the clarity of reported results are located in **QP 28**.

The procedure for reporting of results in each discipline quality or policy manual shall identify what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for partial work performed.

All initial database entries (e.g. CODIS, AFIS, NIBIN) will be included in the report. Any associations made from database searches (e.g. CODIS, AFIS, NIBIN) will be reported to the customer.

The reporting of results does not include testing of known origin samples for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.

In the event that a request for analysis is canceled, no-analysis or partial analytical reports will be issued according to **QP 28**.

7.8.1.3
When agreed with the customer, the results may be reported in a simplified way. Any information not reported to the customer shall be available in the case record and is available upon request. The agreement shall specify the content of the simplified report – see **QP 28** and OSBI CSD **QMA 1.1**.

7.8.2 COMMON REQUIREMENTS for REPORTS

7.8.2.1
Analytical reports will be prepared and issued according to **QP 28**.

When analysis is subcontracted, the subcontractor shall provide a case record and report which meet the same requirements as OSBI reports and case records. The OSBI shall maintain a copy of the case record, and after reviewing the case record and report, the subcontractor's report will be sent to the customer.

OSBI CSD reports shall be formatted in a manner to accommodate the types of tests conducted and to minimize the possibility for misunderstanding or misuse.

7.8.2.2
The OSBI CSD is responsible for the information provided in each Criminalistics Examination Report, except when information is provided by the customer. Any data provided by the customer shall be clearly identified in the report. Reports with information provided by the customer that can affect the validity of the results shall include a disclaimer identifying this information. When the OSBI CSD is not responsible for the sampling stage (e.g. sample provided by the submitting agency), the OSBI shall state in the report that the results apply to only the sample received.

7.8.3 SPECIFIC REQUIREMENTS for TEST REPORTS

OSBI CSD reports and/or case records will include the following information:

a) Deviations from, additions to, or exclusions from the protocol and specific test conditions as necessary for interpretation of the test results shall be recorded in the case record.

b) When relevant, a statement of compliance with requirements or specifications should be included in the case record.

c) Where applicable, a statement on the estimated uncertainty of measurement should be included in the test report (or in an annex to the test report) when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement. Under most circumstances, records for

uncertainty of measurement will be maintained by the laboratory and available on request. A statement should be included in the report when it is relevant to the validity of the test result, the customer requests the statement, or if the uncertainty affects compliance to a specification limit. The measurement uncertainty shall include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability, and be in the format of y +/- U. The measurement uncertainty shall be limited to two significant digits, unless there is a documented rationale for reporting additional significant digits, and be reported to the same level of significance (i.e. same number of decimal places or digits) as the measurement result. **QP 22** and discipline-specific quality and policy manuals further address uncertainty of measurement.

d) Opinions and interpretations shall be included in the report when necessary. For example, expert opinions regarding comparison of latent prints or interpretations of DNA profiles.

e) Additional information shall be included in the report and/or case record as required by the method or by the customer.

7.8.4 SPECIFIC REQUIREMENTS for CALIBRATION CERTIFICATES

The OSBI CSD does not issue calibration certificates.

7.8.5 REPORTING SAMPLING – SPECIFIC REQUIREMENTS

If a sampling plan is used to analyze evidence, the following information shall be included in the case record in addition to the requirements in section 7.8.2 above:

a) the date of sampling;

b) unique identification of the item sampled;

c) location of sampling (including any diagrams, sketches, photographs);

d) reference to the plan and procedures used;
   a. If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population.

e) details of any environmental conditions during sampling that may affect the test results;

f) any standard or other specification for the sampling method and any deviations, additions to, or exclusions from the specification;

g) information required to evaluate measurement uncertainty for subsequent testing.

7.8.6 REPORTING STATEMENTS of CONFORMITY

The OSBI CSD does not routinely report statements of conformity – see section 7.1.3.

7.8.7 REPORTING OPINIONS and INTERPRETATIONS

The OSBI CSD issues reports including opinions and interpretations only for forensic disciplines which have been appropriately validated and documents the training of each analyst issuing reports with opinions and interpretations to ensure release of this information by authorized personnel only.

Opinions and interpretations shall be based on the results obtained from the tested item and shall be clearly identified in OSBI CSD reports. Any additional requirements for each discipline will be addressed in the discipline-specific quality and/or policy manuals.

When opinions and interpretations are directly communicated by dialogue to the customer, a record of the dialogue shall be maintained in the case record.

Examples: pre-trial conferences, phone conversations.

7.8.8 AMENDMENTS to REPORTS

Modifications to OSBI CSD reports shall be handled according to **QP 28**. Analysis conducted subsequent to the issuance of a report will be included in a separate, uniquely identified report. Corrections to an issued report will be made by issuing a corrected report and indicating which report it replaces.

7.9 COMPLAINTS (top ↑)

Complaints will be resolved and documented according to **QP 12**.

7.10 NONCONFORMING WORK (top ↑)

Any work related to casework or individual characteristic database analysis that does not conform to the requirements set forth in this manual, the Quality Procedures, or in OSBI discipline quality manuals or technical protocols shall be addressed according to **QP 13**. By following the procedure detailed in **QP 13**, OSBI CSD shall ensure that:

a) Responsibilities and authorities for managing nonconforming work are specified and appropriate actions are defined and taken when nonconforming work is identified. Actions taken shall be based upon the risk levels established by the OSBI CSD.

b) The nonconforming work is evaluated to determine the significance.

c) A decision regarding the acceptability of nonconforming work is made and correction is done immediately.

d) The customer is notified and work is recalled when necessary.

e) The responsibility for authorizing work to resume is defined.

The OSBI CSD shall retain records of nonconforming work and actions taken as a result of the evaluation of risk as specified in **QP 13**.

IMPLEMENTATION of CORRECTIVE ACTION
If the evaluation of the nonconforming work indicates a significant possibility that the problem could recur, or there is an indication that lab operations do not comply with OSBI policy and procedures, then corrective action procedures outlined in **QP 14.2** or **QP 14.3** will be followed.

7.11 CONTROL of DATA and INFORMATION MANAGEMENT (top ↑)

7.11.1
The OSBI CSD shall have access to the data and information needed to perform laboratory activities.

7.11.2 and 7.11.3
For the computer software or automated equipment used for the collection, processing, recording, reporting, storage, or retrieval of test data (e.g. Laboratory Information Management System (LIMS), software used for testing), the OSBI CSD management shall ensure that:

a) Computer software is validated for functionality, including proper functioning of interfaces within the LIMS by the OSBI CSD before introduction. Whenever there are changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented, and validated prior to implementation.

1. When OSBI CSD employees develop software for use in testing or documenting testing results, the software shall be validated in accordance with **QP 21.2**.

2. Commercial off-the-shelf software (e.g. word processing, database and statistical programs) in general use within their designed application range are considered to be sufficiently validated.

b) Procedures are used to protect the data; such procedures shall include, but are not limited to, integrity and confidentiality of data entry or collection, protection from unauthorized users, safeguards against tampering or loss, data storage, data transmission, and data processing.

c) Computers and equipment are maintained to ensure proper functioning and are provided with environmental and operating conditions necessary to maintain the integrity of the data.

d) System failures will be recorded along with the appropriate immediate and corrective actions.

7.11.2.1
There shall be a plan for validation of computer software developed by the OSBI CSD and records of the successful validation shall be maintained.

7.11.4
The LIMS system "BEAST" is managed and maintained on-site. If a system is used that will have data maintained off-site or through an external provider, the OSBI CSD will ensure that the provider or operator of the BEAST database complies with all applicable requirements of this document.

7.11.5
The OSBI CSD ensures that instructions, manuals, and reference data relevant to the LIMS are readily available to personnel through the BEAST LIMS program and the LIMS Administrator.

7.11.6
Calculations and data transfers shall be subject to appropriate checks in a systematic manner, such as the administrative and technical review process. If an additional check is required, it should be included in the appropriate discipline protocol(s).
When calculations and data transfers are checked, the test record shall indicate the check was performed and who performed the check. When possible, this check shall not be performed by the person who performed the calculation(s) or data transfers. This check may be part of the technical review.

NOTE: This requirement does not apply if the calculation or data transfer is secure and not subject to human error.

8.0 MANAGEMENT SYSTEM REQUIREMENTS (top ↑)

The OSBI CSD management system documents the policies and procedures to be followed in order to ensure the quality of laboratory services provided. The OSBI CSD management system consists of the quality policy manual, the quality procedure manual, and discipline quality, protocol, and training manuals. The documents of the management system are available to all CSD employees in the QMS program. Refer to **QP 2** for distribution procedures.

Management communicates the importance of meeting customer, statutory, and regulatory requirements during regular meetings of the Quality Improvement Committee (QIC).

8.1 OPTIONS (top ↑)

8.1.1 GENERAL

The OSBI CSD uses the policies and procedures outlines in the Quality Manual and Quality Procedures to establish, document, implement, and maintain the management system which is capable of supporting and demonstrating the consistent achievement of the accreditation requirements and to ensure the quality of the OSBI CSD laboratory results.

8.1.2 OPTION A

The OSBI CSD Management System addresses the following:

a) Management system documentation (QM 8.2);
b) Control of management system documents (QM 8.3);
c) Control of records (QM 8.4);
d) Actions to address risks and opportunities (QM 8.5);
e) Improvement (QM 8.6);
f) Corrective actions (QM 8.7);
g) Internal audits (QM 8.8);
h) Management reviews (QM 8.9).

8.1.3 OPTION B

The OSBI CSD does not establish or maintain a management system in accordance with ISO 9001.

8.2 MANAGEMENT SYSTEM DOCUMENTATION (OPTION A) (top ↑)

8.2.1

The policies and objectives associated with each of the sections listed in section 8.1.2 above shall be acknowledged and implemented at all levels of the OSBI CSD.

8.2.1.1 The following words (including forms of the same word) require addressing the requirement in writing: agreed, appoint, authorize, define, instructions, method, plan , procedure, program , record, schedule, and specify.

8.2.2

The OSBI CSD policies and objectives address the competence, impartiality, and consistent application of the analysts and management within the OSBI CSD.

8.2.3

Management is committed to developing, implementing, and continually improving the effectiveness of the management system. This is evident through management's involvement in quality procedures including audits, proficiency testing, management system review, etc.

The OSBI CSD ensures the effectiveness of the management system through the following steps:

a) Activities which would bring question to the competence or integrity of the agency and its employees are prohibited. Refer to the **OSBI Code of Ethics** and **OSBI Policy 105**.

b) No employee is accountable to more than one Supervisor per function.

c) Several functional titles are used in the organizational chart and in policy to refer to Criminalists assigned to different responsibilities. However, there is a single job description which encompasses all Criminalist positions.

d) Testing staff, including trainees, will be supervised by individuals who are familiar with the methods and procedures used. This may be accomplished through the Supervisor's own experience in the methods and procedures used by staff or through the Supervisor's coordination with Technical Managers and/or Criminalistics Administrators familiar with the methods used. Refer to **QP 19** for additional information on training.

e) Each discipline has a Technical Manager who has the authority, responsibility, and resources required to ensure the appropriate quality of work. Refer to the current organizational charts and **QP 1** for additional information regarding responsibilities and authority.

f) One Criminalistics Administrator (CA) will be appointed as the Quality Manager for the CSD. Refer to the current organizational chart and **QP 1**.

g) Key managerial personnel (as defined below) are responsible for naming a designee and notifying employees during planned absences. If a designee is not named, or there is an unplanned absence, the individual's Supervisor will be responsible for assigning a designee and notifying employees. Deputies for key managerial personnel are responsible at a minimum, for the critical duties of the position which cannot be delayed until the individual returns.

Key management personnel include the following positions:
CSD Director
Quality Manager
Criminalistics Administrators
Safety Coordinator
LIMS Administrator
FSC Facility Manager
Administrative Programs Officer for Evidence
Technical Managers
Supervisors

Top Management is the OSBI CSD Director.

h) Through routine unit and discipline meetings, all employees are informed of the importance of their activities and how those activities help ensure that the CSD meets the objectives of the management system.

8.2.4
SUPPORTING PROCEDURES
Quality policies are included in the Quality Manual, which follows the same outline as the ISO/IEC 17025 standards. Procedures governing the implementation of these policies which apply to multiple disciplines are included in the Quality Procedures. Quality policies and technical procedures which apply to a single discipline are included in the discipline quality and

protocol manuals. Discipline-specific manuals may amplify but shall not contradict the CSD Quality Manual or Quality Procedures.

8.2.5
All OSBI CSD personnel involved in laboratory activities shall have access to the parts of the management system documentation and related documentation that are applicable to their responsibilities. The documents of the management system are available to all CSD employees in the QMS program. Refer to **QP 2** for distribution procedures.

8.3 CONTROL of MANAGEMENT SYSTEM DOCUMENTS (OPTION A) (top ↑)

8.3.1 GENERAL

The OSBI CSD controls all documents included in the management system to ensure the documents are appropriate to the work conducted. The management system consists of internally and externally generated documents. Documents as referenced in this policy include policies, procedures, regulations, standards, software, manuals, etc. Refer to **QP 2** for document control procedures.

8.3.2 APPROVAL and ISSUE

8.3.2.1 Any technical protocol or discipline quality manual documents will be reviewed by the Technical Manager or his/her designee. Technical protocols and discipline quality manuals will be approved by the Technical Manager and the CSD Director or designee, in his/her absence.

Management system documents including quality policies and quality procedures will be reviewed by the Quality Manager and will be approved by the Quality Manager and the CSD Director or designee, in his/her absence.

8.3.2.2 **QP 2** describes the steps taken to ensure that:

a) The current authorized version of management system documents is available at all OSBI work locations.

b) Management system documents are periodically reviewed and revised as appropriate.

c) Documents which are no longer valid are removed from use promptly.

d) Retired documents that are retained for legal or knowledge preservation purposes are marked appropriately to prevent unintended use.

8.3.2.3 Each internally issued document will be identified with the information specified in **QP 2**.

8.3.3 DOCUMENT CHANGES

8.3.3.1 Changes to documents can be made in two ways. Documents are revised following **QP 2**. In addition, changes to documents can be documented using a major deviation, as described in **QP 3**. Both methods follow the same review and approval method.

8.3.3.2 Each internally issued document will identify new or altered text as described in **QP 2**.

8.3.3.3 Documents will only be amended as indicated under section 8.3.3.1 above. Amendments may not be made by hand writing on documents.

8.3.3.4 **QP 2** details how changes are made and controlled for documents issued through QMS.

8.4 CONTROL of RECORDS (OPTION A) (top ↑)

8.4.1 GENERAL

QP 16.1 describes the procedure for maintaining quality and technical records. Quality records and technical records are defined in the glossary.

Records will be legible and stored in a manner that they are readily retrievable and protected from damage and loss. Retention times for records are also reflected in **QP 16.1**. If an original record will be scanned and the original record destroyed, the scanned copy will be verified to ensure it is complete and legible prior to destroying the original record.

Records will be kept in secure locations and are confidential.

Procedures for records stored electronically are detailed in **QP 16.1.**

NOTE: Contractual obligations for records retention include legal requirements and customer expectations.

8.5 ACTIONS to ADDRESS RISKS and OPPORTUNITIES (OPTION A) (top ↑)

Needed improvements or potential sources of nonconformity will be identified and routed as indicated in **QP 15**. Risks related to impartiality will be monitored by the OSBI CSD management. Preventive action plans will be developed, implemented, and monitored for effectiveness in order to ensure that opportunities for improvement are exploited and nonconforming work is prevented.

8.5.1 RISK and OPPORTUNITY ASSESSMENT

Continual risk and opportunity assessment by OSBI CSD personnel is necessary in order to reassure that the CSD management system is continually achieving its intended results, to increase opportunities to achieve the objectives of the OSBI CSD, prevent (or help reduce) undesired impacts and potential failures in the OSBI CSD activities (including health and safety

considerations), and to achieve overall improvement of the quality of the CSD laboratory system.

8.5.2
Any OSBI CSD member that recognizes a potential risk or opportunity shall notify his/her immediate Supervisor. Depending on the level of the risk and/or opportunity, the Supervisor shall notify the discipline Technical Manager, the CSD Administrator, and/or the Quality Manager. The management system will be continually improved using information gained during audits (**QP 17**), analysis of statistical data, corrective (**QP 13**, **QP 14.1**, **QP 14.2**, **QP 14.3**) and preventive actions (**QP 17**) taken, management review (**QP 18**), etc. Additionally, expanding the scope of the laboratory activities, addressing new customer needs, using new technologies and/or methods, can also be addressed using the appropriate procedures outlined in **QP 21.1** Research and **QP 21.2** Evaluation of Methods, Equipment, Instrumentation, and Software.

8.5.3 ACTION TAKEN to ADDRESS RISKS and OPPORTUNITIES
The actions taken to address risks and opportunities shall be proportional to the identified issue and the potential impact on the validity of laboratory results. Actions taken may include general discussions/reminders, formal notification of customers, corrective action, re-training, etc.

8.6 IMPROVEMENT (OPTION A) (top ↑)

8.6.1
The OSBI CSD identifies and selects opportunities for improvement and implements any actions necessary using information gained through management review, review of technical procedures, audit/assessment results, corrective and preventative actions taken, etc.

8.6.2
SOLICITING FEEDBACK from CUSTOMERS
The OSBI CSD will seek feedback from customers, primarily through the use of surveys. Feedback will be utilized to improve the management system, analytical procedures, and customer service. **QP 11** details the procedure for soliciting general customer feedback. **QP 32** details the procedure for soliciting feedback specific to testimony provided.

8.7 CORRECTIVE ACTIONS (OPTION A) (top ↑)

8.7.1
When nonconforming work is identified, it will be addressed according to **QP 13**. This procedure and the procedures for corrective action, **QP 14.2** and **QP 14.3**, detail the appropriate authorities for implementing corrective actions. **QP 14.2** and **QP 14.3** also require establishing reasonable timeframes for completion of corrective actions.

CAUSE ANALYSIS
As indicated in **QP 14.2** and **QP 14.3** the first step of corrective action will be to investigate the cause of nonconforming work.

SELECTION of CORRECTIVE ACTION
After the completion of the cause analysis, potential corrective actions will be evaluated. The goal of the corrective action is to correct the problem and prevent the problem from recurring. The corrective action plan will also be appropriate to the magnitude and risk of the problem. The corrective action plan most likely to succeed in these areas will be selected and implemented. Any changes necessary as a result of the corrective action investigation will be implemented and documented.

MONITORING CORRECTIVE ACTIONS
For each corrective action plan, the results of the corrective action will be monitored to determine effectiveness. During the monitoring period defined in the plan, the effectiveness of the executed corrective action plan will be assessed. If the desired results are not being achieved, the risks and opportunities will be updated and adjusted, as needed.

TIMEFRAMES for CORRECTIVE ACTION
The timeframes set forth shall establish reasonable timeframes for completion of the associated tasks and for the period of monitoring (as applicable).

8.7.2 SUITABILITY of CORRECTIVE ACTION
The corrective actions shall be appropriate to the effects of the nonconformities identified during the process.

ADDITIONAL AUDITS
When the nonconforming work indicates that there is a failure to comply with ISO/IEC 17025 standards or CSD policies and procedures, an audit of the areas of activity in question will be conducted as soon as possible. In addition, an audit may be used following the implementation of a corrective action plan in order to assess the effectiveness of the corrective action.

8.7.3 RECORD RETENTION for CORRECTIVE ACTIONS
The records retained for corrective actions shall be sufficient to document the nature of the nonconformity, the cause(s) identified, and any subsequent action(s) taken. In addition, the documentation shall include the results of any corrective action.

8.7.4 PREVENTIVE ACTION
Needed improvements or potential sources of nonconformity will be identified and routed as indicated in **QP 15**. Preventive action plans will be developed, implemented, and monitored for effectiveness in order to ensure that opportunities for improvement are exploited and nonconforming work is prevented.

8.7.3.1 PROCEDURE
QP 15 details how to initiate preventive actions and how to utilize controls or other measures to ensure the preventive action is effective.

8.8 INTERNAL AUDITS (OPTION A) (top ↑)

The OSBI CSD shall conduct internal audits as described in **QP 17** in order to assess the conformance to the laboratory's own requirements as well as accreditation standards and requirements, competence, and effectiveness of the laboratory's activities.

Internal audits will be conducted annually and will include direct observation of accredited services within each laboratory discipline. The scope of each internal audit will be determined by the Quality Manager, or designee, as listed in **QP 17**.

Documentation of internal audits will be retained as quality records according to **QP 16.1**.

If audit findings identify nonconforming work or indicate that the effectiveness of operations or validity of test results may be questionable, then procedures outlined in **QP 13**, if applicable, and **QP 14.2** and/or **QP 14.3** will be promptly followed as necessary.

An audit report will be completed according to **QP 17**. The audit report information addresses whether the OSBI CSD management system conforms to the ISO/IEC 17025 requirements. The audit of the management system will be performed in conjunction with each internal audit.
Implementation and effectiveness of any corrective actions generated as a result of an internal audit will be verified and recorded according to **QP 14.2** or **QP 14.3.**

8.9 MANAGEMENT REVIEWS (OPTION A) (top ↑)

8.9.1

OSBI CSD management will conduct a review of the management system and casework activities, at least annually, to ensure their continued effectiveness, suitability, and adequacy, and to introduce changes or improvements as needed. The procedure for management system reviews is detailed in **QP 18**.

8.9.2

Records of management system reviews will be retained as a quality record according to **QP 16.1**. Management system reviews will include the following topics:

a) changes to internal and external issues relevant to the laboratory;

b) fulfillment of objectives;

c) suitability of policies and procedures;

d) reports from managerial and supervisory personnel (status of actions from previous management reviews);

e) outcome of recent internal audits;

f) corrective and preventive actions;

g) external assessments;

h) proficiency test results;

i) changes in volume and type of analysis;

j) customer feedback;

k) testimony review and other personnel feedback;

l) complaints;

m) recommendations for improvement including the effectiveness of implemented improvements;

n) adequacy of resources;

o) results of risk identification (may also include identification and mitigation of risks);

p) outcomes of the assurance of the validity of test results;

q) any other relevant factors.

Findings from management reviews and the actions taken will be recorded according to **QP 18**. CSD management will ensure that actions are carried out according to an appropriate timetable.

8.9.3 MANAGEMENT REVIEW OUTPUT

The effectiveness of the OSBI CSD management system and its processes, the improvement of the laboratory activities related to the fulfillment of the accreditation requirements, the provision of required resources, and any need for change will be documented as required in **QP 18**.

I. Scope (top ↑)

This procedure explains the responsibilities and authority of key CSD personnel.

II. Procedure

A. Responsibilities of CSD Personnel

1. CSD Director

The CSD Director will promote and direct the quality system and ensure that the policies and objectives are documented, as well as communicated to, understood by, and implemented by CSD personnel. The CSD Director serves as the laboratory director for the Forensic Science Center (FSC) and is an ex officio member of all CSD committees. The CSD Director has the responsibility and authority for all laboratory functions and personnel.

Any individual designated as the CSD Director shall meet the following education and experience requirements:

a) Bachelor's or advanced degree from an accredited college or university in chemistry, biology, forensic science, criminalistics, toxicology, a closely related natural science, criminology, law enforcement, or criminal justice, and;

b) At least five years of experience as a forensic laboratory analyst, and;

c) At least two years of experience supervising and directing others in work involving scientific and technical analysis of forensic evidence or DNA databasing samples, and;

d) At least two years administrative experience involving the direction of a major section of a forensic laboratory system, including administrative coordination of certain forensic disciplines, projects, and programs, and developing and implementing goals and objectives.

2. Criminalistics Administrators

Criminalistics Administrators (CA) will be assigned the administrative supervision of specific laboratories and/or laboratory units. Each CA will also be assigned additional responsibilities as indicated below.

a) The CA responsible for the administrative supervision of the Forensic Science Center (FSC) Toxicology Unit, FSC Firearms/Toolmarks Unit, FSC Physical Evidence Unit, FSC Chemistry Unit, and the Digital Evidence Unit is responsible for the statewide coordination of these forensic disciplines and units/laboratories. This position is also responsible for overseeing or coordinating CSD drug destruction activities and coordinating the Coverdell grant. All activities will comply with quality standards set forth by the OSBI CSD. This position serves as a back-up to the FSC Facility Manager.

b) The CA assigned the administrative supervision of the FSC Forensic Biology Unit, FSC Cold Case Unit, FSC Latent Evidence Unit, and the Northeast Regional Laboratory is responsible for the statewide coordination of these disciplines/units/laboratories. This position will also be responsible for responding to Open Records Requests and will be primarily responsible for applying for and managing grants related to the Forensic Biology Unit and/or DNA analysis. He/She will work in conjunction with his/her Biology Supervisors (Forensic Biology and Cold Case Units) as well as the other CA with oversight of biology-focused units (SFBU and CODIS Units). All activities will comply with quality standards set forth by the OSBI CSD.

c) The CA assigned the administrative supervision of the FSC CODIS Unit, FSC Specialized Forensic Biology Unit, Eastern Regional Laboratory, Northwest Regional Laboratory, and the Sexual Assault Kit Tracking System Administrator is responsible for the statewide coordination of these forensic disciplines and units/laboratories/program. This position is also responsible for overseeing the Laboratory Information Management System (LIMS) as described below in the LIMS Administrator section. All activities will comply with quality standards set forth by the OSBI CSD. This position serves as a back-up to the Quality Manager.

d) The fourth CA position is responsible for the administrative supervision of the Forensic Biology, Latent Evidence, Digital Evidence, Toxicology, and Forensic Chemistry Technical Managers. This position will also serve as the Division Quality Manager and will be responsible for coordinating CSD activities in the area of quality control/quality assurance. This includes, but is not limited to, ensuring compliance with accreditation standards and requirements, proficiency testing, laboratory accreditation, testimony monitoring, and audits. The CA assigned to this position will also be responsible for lab surveys and complaints. All activities will comply with quality standards set forth by the OSBI CSD.

3. LIMS Administrator

The LIMS Administrator is responsible for the statewide administration and coordination of the CSD's Laboratory Information Management System (LIMS) known as the BEAST. This includes:

a) Implement programs or procedures.

b) Troubleshoot and upgrade the system as needed.

c) Approve users/access.

d) Train users.

e) Develop and/or modify management and Crystal reports as needed.

f) Ensure security of the data maintained in the BEAST.

g) Monitor, manage, and procure the resources necessary for employees to access and utilize the BEAST.

h) Prepare monthly, quarterly, and yearly statistical reports and other management reports as needed for the CSD Director.

i) Oversee the external user access to OSBI online lab reports.

4. NIBIN Program Administrator

The NIBIN Program Administrator is responsible for communication with all parties (i.e. submitting law enforcement agencies, ATF Crime Gun Intelligence Centers (CGICs), etc.), involved in the NIBIN process.

a) The NIBIN Program Administrator must be a qualified NIBIN user and full-time employee of the NIBIN site and meet the following requirements:
   i. Be a full-time employee of the agency operating the site.
   ii. Minimum experience requirements: a qualified NIBIN user that has completed acquisition and correlation training.

b) The NIBIN Program Administrator is responsible for:
   i. General Duties and Authority:
      1. Oversee the operations of the site and success of the NIBIN program;
      2. Authority to initiate, suspend, and resume NIBIN Operations for the site or an individual.
   ii. Minimum Specific Duties:
      1. To evaluate and document approval of all methods used by the site and to propose new or modified procedures as needed;
      2. To review the training records for newly qualified NIBIN Users and approve their qualifications prior to performing NIBIN acquisitions or correlations, and to document such review.;
      3. To coordinate with audit personnel for NIBIN site audits.
   iii. Accessibility: The NIBIN Program Administrator shall be accessible to the site and ATF NIBIN Unit to provide onsite, telephonic, or electronic consultation as needed.
      1. In the event the NIBIN Program Administrator position is vacated and there is no individual at the site who meets the requirements and can serve as a NIBIN Program Administrator, the site shall immediately contact the ATF and submit their contingency plan within 14 days to the ATF for its approval. Work in progress by the site may be completed during this 14 day period but no new casework shall be started until the plan is approved by the ATF.
   iv. The NIBIN Program Administrator shall ensure personnel operating within the NIBIN system shall have the proper levels of training and experience for

their position and that all individuals performing acquisitions and/or correlation reviews are qualified NIBIN users.

v. The NIBIN Program Administrator shall maintain records on the relevant qualifications, training, skills, and experience of the NIBIN Administrator and qualified NIBIN users.

vi. The NIBIN Program Administrator is responsible for implementing and directing policies and procedures of the NIBIN site.

5. Sexual Assault Kit Tracking System Program Administrator

a) Oversee and manage the state's computerized Statewide Sexual Assault Tracking System that will be designed to track all sexual assault kits distributed by forensic labs and used to collect evidence of sexual assault.

b) Train users of the Tracking System and manage all log-in/passwords for users.

c) Manage the ordering, supply, and distribution of the state's standardized sexual assault evidence collection kit. Work closely with medical facilities and law enforcement to ensure that facilities are properly equipped with kits.

d) Develops and maintains congenial, professional, and effective working relationships and liaison with OSBI Administration, agency investigators, CSD Director, lab employees, accrediting bodies, courts, attorneys, regulatory agencies, the forensic laboratory community, professional associations, civic groups, our client criminal justice agencies, crime victims, etc. by promptly providing reliable responses and services that meet their needs.

e) Serves as a back-up to the LIMS Administrator.

6. Administrative Programs Officer – Evidence Discipline

The administrative programs officer over the evidence unit at FSC is the Technical Manager for the physical evidence discipline of the CSD. Responsibilities of this position include:

a) Oversee the storage, maintenance, archival, and destruction of technical records.

b) Oversee and coordinate statewide activities of the physical evidence technicians/units.

c) Assist with Laboratory Information Management System (LIMS) administration by correcting custody record and deleting incorrect items/sub-items when needed.

d) In coordination with the Quality Manager, develop, draft, and revise policies and procedures related to the acceptance, handling, tracking, storage, return, and destruction of evidence.

e) Perform supervisory duties for the Physical Evidence Unit at FSC.

7. Safety Program Coordinator

The OSBI Safety Program Coordinator will be identified on the Organizational Chart (located on the OSBI Intranet). The responsibilities of the Safety Program Coordinator are listed in **OSBI Policy 121.0**.

8. Technical Managers

Each discipline in the OSBI CSD shall have a Technical Manager. The Technical Managers will be identified on the most current organizational chart. Each OSBI CSD Technical Manager shall:

a) Oversee implementation of the OSBI CSD Quality System within the discipline, ensuring compliance with accreditation standards and requirements.

b) Communicate with CSD Administrator(s) and CSD Director when technical issues arise that may result in a work stoppage.

c) Assist with management reviews as described in **QP 18**.

d) Review and approve all technical procedures within the discipline.

e) Implement and review quality documentation within the discipline.

f) Stay abreast of recommendations made by Scientific Working Groups and/or the NIST Organization of Scientific Area Committees (OSAC) for the discipline and incorporate appropriate recommendations.

g) Educate all discipline members in the implementation of the quality assurance program and confirm that all members of the discipline understand the importance of the program.

h) Participate in audits and inspections when requested.

i) Oversee training, competency testing and evaluation of analysts.

j) Issue and update Authorizations to Work as needed.

9. Criminalist Supervisors

Each OSBI CSD Criminalist Supervisor shall:

a) Assist with management reviews as described in **QP 18** and disseminate information regularly to members of their unit.

b) Ensure that members of the unit understand and follow all quality assurance procedures.

c) Know and follow the CSD Quality Assurance Program.

d) Make recommendations to improve quality within the discipline and division.

e) Educate all unit members in the implementation of the quality assurance and safety programs and confirm that all members of the discipline understand the importance of the program.

f) Approve Time and Leave.

g) Manage Productivity of the Unit / Analysts.

h) Case Assignment and Management, as applicable.

i) Serve as laboratory director, if assigned to a regional laboratory.

j) Supervisors are to be knowledgeable regarding the quality of casework produced by their staff.

10. Criminalists

Each Criminalist shall:

a) Know, understand and apply quality procedures that pertain to their specific discipline.

b) Ensure completeness of laboratory reports, notes and essential documentation and make recommendations and suggestions for improvements of procedures used for the examination of forensic evidence.

c) Advise Technical Manager and Supervisor of any technical problems or questionable results and make recommendations for improvements.

11. Physical Evidence Technicians

Each physical evidence technician shall:

a) Know, understand and apply all quality procedures that apply to proper evidence handling including evidence submission, transfer, return, or destruction.

b) Notify the Technical Manager and Supervisor of any concerns relating to the quality assurance program of the Division.

12. Laboratory Analysts and Technicians

Each laboratory analyst, laboratory technician, or part time employee shall:

a) Know, understand, and apply quality procedures that apply to their specific discipline or job task.

b) Notify the Technical Manager and Supervisor of any concerns relating to the quality assurance program of the Division.

B. Authority of CSD Personnel

1. CSD Director

The CSD Director has the authority to make and enforce decisions impacting any and all work produced by the division.

2. Criminalistics Administrators

Under the administrative direction of the CSD Director, the Criminalistics Administrators have the following authority:

a) The Quality Manager (QM) will have the authority to halt any laboratory activity that fails to exhibit the required levels of accuracy, specificity, reliability, or validity with respect to the OSBI CSD Quality System, after consultation with the CSD Director.

b) Technical decisions made by each Criminalistics Administrator responsible for the coordination of a forensic discipline will apply to all personnel engaged in any capacity within the affected forensic discipline. These decisions will be made after consultation with the Technical Manager for the discipline.

c) Authority of each Criminalistics Administrator shall include but not be limited to the assignment of specific duties or responsibilities to specific personnel and the review of the activity of those personnel engaged in these duties including all quality practices adopted by the OSBI CSD.

3. Safety Program Coordinator

The Safety Program Coordinator has the express authority to immediately halt any laboratory activity which is determined to fall outside established safety policies and procedures and applicable laws.

4. Technical Managers

The Technical Manager of each discipline has the following authority:

a) Technical Managers will assign and approve forensic procedures. All procedures will address and include practices consistent with the quality standards.

b) Technical Managers, in consultation with the QM and CSD Director, have the authority to suspend any work which does not comply with the OSBI CSD Quality System or any applicable quality standards.

5. Criminalist Supervisors

Criminalist Supervisors, in consultation with the QM, CSD Director, and discipline Technical Manager, have the authority to suspend any work which does not comply with the OSBI CSD Quality System or any applicable quality standards.

III. Attachments

None

I. Scope (top ↑)

All management system documents will be approved, issued, modified, and controlled according to this procedure. Management system documents include policies/procedures developed internally, externally prepared documents or standards which are referenced or used (user's manuals, applicable standards, etc.), and software (internally or externally developed) used for testing purposes.

II. Procedure

A. Control

1. All current approved, internally generated CSD management system documents (policies, procedures, protocols, training manuals, quality manuals, major deviations, forms, etc.) will be placed in QMS. Any hard copy or other electronic copy is considered an uncontrolled document.

2. Archived versions of approved, internally generated CSD management system documents (policies, procedures, protocols, training manuals, quality manuals, major deviations, forms, etc.) will be maintained on the Quality Server.

3. Uncontrolled copies may be made, if necessary, to reference at a work area that doesn't have easy access to QMS. However, CSD employees creating or using uncontrolled copies must verify the uncontrolled copy is still current <u>before each use</u> and immediately dispose of any uncontrolled copy that is not current.

4. Uncontrolled copies may also be made for the purpose of responding to discovery requests/orders.

5. External documents, software, and any other management system documents which are not distributed through QMS will be referenced in the CSD or appropriate discipline quality manual, protocol, or an attachment to the appropriate document. The reference must identify the current revision/version approved for use and the distribution or location of the document.

6. The individual responsible for the initial approval of internally generated documents (Quality Manager or appropriate Technical Manager) shall maintain a copy of the current version that can be edited when the document requires revision (see below).

B. Approval

1. Technical protocols/procedures, discipline quality manuals, and related attachments and references will be approved by the appropriate Technical Manager and the CSD Director or designee.

2. The CSD Quality Manual, Quality Procedures, and related attachments and references will be approved by the Quality Manager (QM) and the CSD Director or designee.

3. CSD documents distributed through QMS will include the signature of the individuals who have approved the document.

C. Issue

Once approved, the document(s) shall be distributed to the designated point(s) of issue. When a document is replaced or rescinded, it shall be removed from the point(s) of issue at the time it is replaced or no longer effective (e.g. moved to an archived/rescinded folder on the Quality Server and removed from QMS). In addition, when changes to documents are made, the updated documents should be stored or archived as indicated in section II.E below. Current laboratory policies and procedures may also be posted to the OSBI Internet to facilitate access by customers.

1. The naming scheme of documents uploaded to QMS will follow the guidelines listed below in section II.E.

2. Approved CSD documents distributed through QMS, with the exception of forms, will be scanned or otherwise converted to pdf format prior to placing the documents in QMS.

3. Documents may be added to QMS by the QM, appropriate Technical Manager (TM), or designee.

4. Documents referenced by the CSD or discipline quality manuals will be added to or removed from the designated point(s) of issue by the QM, appropriate TM, or designee.

5. Externally generated management documents will be available at each location where related work is conducted. For example, any externally generated management documents referenced by analysts conducting drug analysis will be located at each regional laboratory providing drug analysis.

D. Notification

For internally generated management documents, an e-mail will be sent to the appropriate individuals indicating that the document has been issued, revised, or rescinded. The e-mail will be sent by the QM, appropriate TM, or designee.

A copy of the notification will be archived to the appropriate folder in the following directory: \\pm-fsc13000s\qa\Lab-System_Records\Management_System_Docs\Notifications.

E. Storing and Archiving Controlled Documents

1. Discipline TM's and the QM shall save current and archived controlled documents which

they draft, revise, and approve, as described below. Controlled documents shall be saved in the appropriate folder in the following directory: \\pm-fsc13000s\qa\Lab-System_Records\Management_System_Docs\.

2. All controlled documents will be saved as PDF files and will be named in the following format: DC###_REV##_MM-DD-YY. DC### refers to the document number (e.g. LP-001, QP-028, etc.) and REV## is the document revision number (e.g. Rev00, Rev10). MM-DD-YY is the effective date of the protocol. Once a controlled document has been replaced by a new revision or rescinded, the date it is replaced by a new revision or rescinded shall be added to the file name. For example, LP-001_Rev08_12-03-09_05-07-10 would be the archive file name for the 8th revision of LP-001 and would reflect that the document went into effect on 12-03-09 and was replaced on 05-07-10. If LP-001, Rev 8 was rescinded (see section II.I), the original file (LP_001_Rev08_12-03-09) would be replaced by the rescinded file (LP-001_Rev08-R_12-03-09_05-07-10).

3. Once a new revision of a document has been issued, the prior revision and applicable deviations shall be moved to the appropriate archive folder on the Quality Server.

4. All controlled documents will be retained indefinitely.

5. Major deviations shall be stored and archived in the same manner as controlled documents. When naming major deviations, the file name should include an identification that the file is a deviation, the policy number and revision it modifies, and the date(s) the deviation is/was effective. For example, "LP-001_Rev08_Deviation_(02-13-10)" would represent an active deviation that went into effect on 02-13-20. Once deviations have been replaced by a revised version of the appropriate policy, they will be archived by adding the last effective date to the file name (e.g. LP-001_Rev08_Deviation_(02-13-10_05-07-10).

6. In addition to retaining the PDF file for all versions of controlled documents, the current version of every document needs to be retained in Word format. Each individual responsible for maintaining controlled documents (e.g. Technical Managers and Quality Manager) may store the most current revision in Word format on his/her hard drive. However, a copy of the most current version shall also be stored in the appropriate folder on the Quality Server (\\pm-fsc13000s\qa\Lab-System_Records\Management_System_Docs\). When revising documents, care should be taken to name working documents in a manner that identifies the most current draft to avoid confusion. For example, QM_QP_Rev2_DRAFT_11-19-19 could be used to name the draft revision 2 that was created or updated on 11-19-19. **Once a document has been issued, any prior revisions and drafts should be moved or deleted to avoid creating a future document from an obsolete version.** Word documents must be locked, stored in a limited access folder, password protected, or otherwise protected from unintentional modifications.

F. Identification

Internally generated CSD management system documents will be uniquely identified and include the following:

1. document number

2. title

3. revision number

4. page numbering

5. total number of pages or mark indicating the end of the document

6. issuing authority

Forms or other attachments to management system documents will be identified in the following manner:

1. unique form number

2. revision number

3. page number and total number of pages (e.g. page X of Y) or the designator "AΩ" may be used to indicate a one-page form

Revision numbers for forms and attachments may be tracked independent of the document revision number. The current attachment revision number (if applicable), changes made to attachments, and approval of attachments will be included in the attachment, history, and approval section of the document to which it is attached.

G. Format

All OSBI CSD controlled documents shall be formatted as described below.

1. Each document shall have a history page or history section which will be located following the approval page or section. The history may be saved electronically as a separate file.

2. Each policy and protocol must include an effective date which indicates when the policy will go into effect. Issue dates (when the document was provided to employees) and revision dates (when the work of modifying the document was conducted) will not be required and do not need to be referenced.

3. Document revision numbers and the effective date for the document will be located in the

header and/or footer of the document.

4. A list of required forms and any other externally issued controlled documents which are required to be used for a protocol or policy (e.g. user's manual, etc.) will be located in either the header of the parent document or in a section that follows the main text of the policy. Other references (e.g. journal articles or textbooks used as a basis for the protocol) may be listed in a "references" section, but are not required.

5. Protocols should include the following information, as applicable:

a) Appropriate identification;

b) Scope;

c) Description of the type of item to be tested;

d) Parameters or quantities and ranges to be determined;

e) Apparatus and equipment, including technical performance requirements;

f) Reference standards and reference materials required;

g) Environmental conditions required and any stabilization period needed;

h) Description of the procedure, including

i. Affixing of identification marks, handling, transporting, storing and preparation of items,

ii. Checks to be made before the work is started,

iii. Checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,

iv. The method of recording the observations and results,

v. Any safety measures to be observed;

i) Criteria and/or requirements for approval/rejection;

j) Data to be recorded and method of analysis and presentation;

k) The procedure for estimating uncertainty.

H. Review and Revision

1. Management system documents will be reviewed annually.

2. Internally generated CSD documents will include a history section or attachment which will be used to document the completion of revisions and, when possible, identify modifications made during revision. Management system documents which are reviewed and found not to need revision should be documented in the history section/attachment.

3. If desired, a track changes version of each revision of policy can be maintained and the history page can reference this version instead of restating all changes made. In this event, the document shall be named in the same format as the controlled document, with an addition to the file name to indicate that it is a track changes version. In addition, the track changes version should be saved to QA server folder designated for this purpose and not in the folder with the current controlled copy.

4. Temporary deviations or modifications implemented between revisions will be documented and issued according to **QP 3**.

I. Rescinding Controlled Documents

When a controlled document needs to be rescinded and will not be replaced by a new revision, the following actions shall occur:

1. The history page or section will be updated to show the date that the policy will no longer be in effect.

2. The approval page will be modified to show "date rescinded" instead of "date approved" and signed by the appropriate authorizing individuals.

3. The revision number of the document will be modified to add an "R" at the end to show the document is rescinded. For example, if the 9th revision of a document is rescinded, the revision number would be "Rev. 9-R."

4. Notification of personnel will be conducted in the same manner used for document revisions.

III. Attachments

None

I. Scope (top ↑)

This procedure explains the process to follow when a CSD employee believes that a deviation from a current CSD-authored, controlled document is necessary. This procedure does not apply to any policies or procedures issued from outside the CSD. Any deviations from CSD policy, procedure, or protocol which do not comply with this procedure are considered protocol drift and must be evaluated as potential nonconforming work according to **QP 13**.

II. Procedure

A. Requirements and recommendations

In order to ensure the quality of analysis conducted and services provided, written policies, procedures, and protocols have been established and issued to all appropriate CSD personnel. However, due to the variability of evidence and circumstances encountered, many protocols, procedures, and policies are worded to include **recommendations** (indicated by "should") instead of **requirements** (indicated by "shall", "will", or "must"). All CSD personnel are expected to follow both requirements and recommendations set forth in CSD policies, procedures, and protocols, with the following exceptions:

1. Planned deviations from **requirements** can be requested and conducted following approval of a minor or major deviation as indicated below.

2. CSD employees may deviate from **recommendations** stated in protocol, procedure, or policy, provided the employee can articulate a legitimate reason which warrants the deviation.

3. CSD employees should make a notation explaining the deviation from **recommended** procedure.

4. If an employee is not certain whether circumstances warrant a deviation from **recommended** procedure, he/she should consult the Technical Manager for assistance.

B. Minor deviations

CSD employees will complete the following steps to request, approve, and document authorization to deviate from current policy, procedure, or protocol for an individual sample, case, or batch of samples/cases.

1. The employee will describe the proposed deviation to his or her Technical Manager (TM), or designee, and obtain approval before implementing the deviation.

2. The TM, or designee, will evaluate the benefits and risks of the proposed deviation to

determine if the circumstances warrant the deviation. The TM, or designee, will consult with any appropriate individual (e.g. CSD Quality Manager or TM (if a designee is the approving individual)), if necessary, to thoroughly evaluate the benefits and risks of the deviation.

3. If approved, the deviation will be documented in the case record when applicable to case work and documented in a relevant location for non-case work activities.

4. The approval will be documented by initialing a short description of the deviation in the case record or applicable materials in non-case work activities.

5. Alternately, a description of the requested minor deviation may be documented electronically by the analyst in the narrative section of the electronic case file. The TM, or designee, may document his/her approval electronically by logging into the case and entering a narrative indicating his/her approval.

6. When a TM needs to request a minor deviation, he/she will request the deviation from the Quality Manager (QM) and provide the rationale for the deviation. The QM will consult with an appropriate Supervisor, Criminalistics Administrator, or designee, if necessary prior to approving or denying the deviation.

C. Major deviations

CSD employees will complete the following steps to request, approve, and document authorization to deviate from current policy, procedure, or protocol for a defined period of time or grouping of cases or samples. These steps will also be used to initiate, approve, and document permanent changes to policies, procedures, and protocols in between issued revisions of controlled documents.

1. The requesting individual will complete Section I of the Deviation Request Form (OSBI CSD **QPA 3.1**) and specify on the form:

   a) the applicable protocol, procedure, or policy

   b) a description of the requested deviation

   c) the specific instance(s) for which the deviation is requested

   d) the reason for the deviation

2. The requesting individual will then forward the form for approval as indicated below.

3. Prior to implementation, all major deviations must be approved by the same authorities

responsible for approving the document being modified.

a) Section II must be completed by the appropriate TM for any deviation impacting a discipline quality manual or protocol approved by the TM.

b) Section III must be completed by the QM for any deviation impacting the CSD Quality Manual, any Quality Procedure, attachment, or any other management system document initially approved by the QM.

c) Section IV must be completed by the CSD Director, or designee, for all major deviation requests.

d) Any deviation request for a document which was also originally approved by another individual must be routed to that individual for evaluation and approval. This additional evaluation and approval should be documented on an attached memo or e-mail.

4. Individuals responsible for reviewing a deviation request will evaluate the request in the same fashion as the document being modified. This review includes an evaluation of the merit and risk of the deviation and whether the proposed modification complies with any and all applicable standards.

5. Major deviations which are approved will be issued in the same fashion as the controlled documents affected by the deviation.

6. Deviation requests which are not approved will not be disseminated or retained. The individual denying the deviation request should notify the requestor of the decision.

7. Approved deviations may be effective once signed by the CSD Director or designee. When necessary to delay the implementation of a deviation until employees have had an opportunity to be notified of the deviation, the CSD Director, QM, or TM's may indicate an effective date on the bottom of the form. If the effective date is left blank, the deviation is effective on the date it was signed by the CSD Director.

8. Major deviations should be routed and approved/disapproved by the appropriate persons within two weeks of the date of request.

III. Attachments

OSBI CSD QPA 3.1, Rev03 Deviation Request Form
(Available in QMS Forms Folder)

I. Scope (top ↑)

This procedure will be used to evaluate all requests for laboratory examination and provide response to the customer requesting analysis. Whenever OSBI CSD personnel accept evidence for analysis, the entry of the evidence into the OSBI CSD system constitutes a contract with the customer.

II. Procedure

A. Review of Requests

The following steps shall be taken to review all requests for analysis. This includes requests made at the time of evidence submittal (see **QP 5**) and subsequent requests or amendments made after evidence has already been received by the OSBI CSD.

1. ☐ Verify that the individual requesting the analysis is authorized by statute to request services from the OSBI CSD. The agencies and individuals authorized to request services are listed in Title 74, Sections 150.2 and 150.5.

2. ☐ Verify that the type of evidence being submitted falls within the acceptance requirements described in **QMA 2**.

3. ☐ Verify that the OSBI CSD is capable of providing the type and degree of service requested. A list of available services/methods is listed in OSBI CSD **QMA 4.1**. If external providers are used, the requirements outlined in section 6.6 of the Quality Manual above must be applied. The OSBI CSD shall advise the customer of the specific laboratory activities to be performed by the external provider and document customer approval.

4. ☐ Verify that requests for digital evidence examination are accompanied by a completed Digital Evidence Examination Request Form (OSBI CSD **QPA 5.2**).

5. ☐ Check to see if the request is for a service that has any specific limitations as listed in OSBI CSD **QMA 4.2**. If so, ensure that the submission meets the appropriate limitations or that approval for an exception is documented by the appropriate individual.

6. ☐ If necessary, consult the appropriate Supervisor or Criminalistics Administrator to determine that the request meets the criteria listed above.

B. Tenders

Based on the results of the review conducted, one of the following responses will be given to the customer.

1. If the request meets the applicable criteria listed in II.A.1 through II.A.5, the analysis will be conducted.

2. Requests for digital evidence examinations which are not accompanied by a completed Digital Evidence Examination Request Form (OSBI CSD **QPA 5.2**) will be refused.

3. If the request does not meet the criteria but can be modified to meet the criteria, the modification will be proposed to the customer. If the customer agrees, then the analysis agreed to in the modification will be conducted. This agreement regarding the modification will be documented in the case record. For example, if a customer requested blood typing, DNA analysis could be proposed as an alternative.

4. If the request does not meet the criteria and cannot be modified to meet the criteria, the requested analysis will not be conducted and the evidence will not be accepted. In this situation, the customer will be notified of the reason why the analysis cannot be conducted.

5. Under most circumstances, the customer will be notified of the inability to conduct analysis in the same fashion that the request was received. For example, if the request is made in person, the customer will be informed in person at the time the request is made.

6. The customer may be notified in a different fashion when the alternate method provides for better or more direct communication or when the customer cannot be reached by the same method that the request was received.

C. Contracts

When the OSBI CSD agrees to conduct analysis for a customer, a contract is established between the OSBI CSD and the customer. This contract is established in the following ways.

1. For requests received for evidence that has not yet been submitted, the contract is established by following the evidence intake procedure in **QP 5**. The electronic submission record or a printed copy of the submission represents the contract established.

2. Requests received for evidence that has been submitted constitute an amendment to the original contract. Once an amendment has been agreed upon by the OSBI CSD and the customer, it will be documented in the narrative section located on the "Case Info" tab or by placing a copy of the communication (e-mail, letter, etc.) in the case record.

3. The OSBI has published a Notice to Customers (OSBI CSD **QMA 1.1**) regarding some deviations which may be made in the normal course of analysis. When necessary, additional notifications may be made. A record of any notification made will be maintained in the case record.

III. Attachments

None

I. Scope (top ↑)

These procedures shall be used by any OSBI CSD employee when receiving evidence.

II. Procedure

A. Review of the Request

Conduct a review of the request as described in **QP 4**. With the exception of blood alcohol kits and cases submitted using pre-log, each request for examination shall be submitted on the Request for Laboratory Examination (RFLE) form (OSBI CSD **QPA 5.1**). Requests for digital evidence examination must also be accompanied by a completed Digital Evidence Examination Request Addendum (OSBI CSD **QPA 5.2**).

1. If the OSBI CSD does not have the capability or resources to provide the service requested, return the evidence to the submitter. If possible, provide assistance to the customer in locating a laboratory that can provide the services needed. A list of potential service providers is located in OSBI CSD **QMA 5**.

2. If the OSBI CSD can provide the needed service, accept and log-in the evidence as described below.

3. For in person submissions, check that the RFLE has been signed by the submitting officer. If it has been signed, verify that the identity of the officer submitting the evidence matches that of the signature. If it has not been signed, ask the officer to sign the RFLE before proceeding. The signature on the RFLE/affidavit indicates agreement to the terms listed in **QMA 1.1** Notice to Customers.

    a. If a customer does not agree to the terms listed in **QMA 1.1** Notice to Customers, a narrative describing the dissentions and/or additional requests of the customer (e.g. addition of methods used for testing in the Examination Report) will be included in the case record. It is the case analyst's responsibility to ensure the requests of the customer are addressed appropriately when analyzing the case. Any issues during this process will be brought to the attention of the Supervisor and appropriate Criminalistics Administrator(s).

B. Evaluation of Evidence Integrity Concerns

Inspect the evidence to ensure that it is packaged in a manner that will preserve the integrity of the evidence.

1. Evaluate each package to ensure that it is appropriate for the type of evidence it contains. For example, arson samples should be in arson cans while evidence with dried biological stains should be in packaging that will prevent mold or bacterial growth. If evidence is inappropriately packaged, advise the submitter of the proper packaging and ask them to repackage the evidence. The evidence shall not be accepted until packaging concerns are resolved.

2. Evaluate the seals on each package to ensure that they protect the evidence from loss, cross-transfer, contamination, and deleterious change. Ensure that the officer's initials or other identifying mark are on each seal. Ask the officer to add his/her initials or identifying mark if initials are not present. Refer to OSBI CSD **QMA 3** for more information regarding proper seals. When evidence is received which has an acceptable seal, but does not bear the officer's initials, and the officer is not available to add his/her initials or identifying mark, the seal(s) should be marked, when practical, to indicate it was received in this fashion using one of the following methods:

    a. The individual receiving the evidence can place a piece of red evidence tape at an approximate 90-degree angle to the seal and add his/her initials to the red evidence tape.

    b. The individual receiving the evidence can mark the seal with "RITC" or "received in this condition" and his/her initials.

3. Evaluate each package and its seal to ensure the evidence is packaged and sealed in a manner that is conducive to the analyst opening and resealing the package, preferably without destroying or obscuring the original seal. If this is not feasible due to the package containing too much evidence or being over-sealed (excess amount of tape sealing the package), request the submitting officer re-package the evidence.

4. Determine whether there are any special storage conditions (e.g. store refrigerated) which need to be observed to protect the evidence.

5. Evaluate the items grouped together in each package and the types of analysis requested. If necessary, have the officer re-package items to ensure more efficient flow of evidence. For example, if a projectile which needs Firearms analysis is packaged with clothing which needs Biology analysis, have the officer repackage the projectile into a new container.

C. Evaluation and Identification of Safety Concerns

Inspect the evidence submitted to ensure that the evidence is packaged and labeled in a manner which ensures the safety of CSD personnel.

1. When firearms are submitted, have the officer indicate on his/her RFLE and the evidence

package whether the weapon is unloaded, by labeling the RFLE and evidence package "unloaded" and initialing next to the notation. (Officers should be instructed to indicate unloaded only if they have direct knowledge that the weapon is unloaded.) If there is no indication that the weapon has been rendered safe and the submitting officer does not have direct knowledge of the weapon's status have a qualified individual verify that the firearm(s) has/have been unloaded or otherwise rendered safe. Have the qualified individual document that the firearm is unloaded/rendered safe on the evidence package and on the RFLE by adding "unloaded" and his or her initials.

2. Ensure that chemicals, including any known carcinogens, mutagens, toxic substances, and volatile or foul smelling compounds are properly labeled and packaged according to safety policy and SDS recommendations.

3. Ensure any sharp item (syringe, knife, glass, etc.) is packaged in a fashion that prevents the item from puncturing the package and potentially injuring CSD personnel.

4. Ensure that proper warning labels are on each package. This includes biohazard, sharps, and any other necessary hazard label.

5. Liquid evidence, with the exception of toxicology blood kits, must be double packaged in such a manner that the outer package would contain liquid in the event that the inner package was broken or leaked. For example, a properly sealed evidence package that contains liquid evidence could be placed into a bucket for storage and transport to prevent breaks and contain any liquid in the event of a break or leak. The bucket can be a convenience container and does not need to be properly sealed.

D. Data Entry

Transfer information provided on the RFLE (or other submission paperwork for cases such as DUI) into the BEAST by creating a new case using manual creation or by creating a new submission on an existing case. If it is not certain whether the submission is the first submission in a case, a search should be done with the information provided to ensure there will not be duplicate OSBI lab numbers assigned to the same case. Fields in the BEAST which have a question mark in the box have a drop down menu available which can be used as needed.

1. Use the "Type of Offense" from the RFLE to select the most appropriate case type in the "Case Type" field.

2. Enter the County of Offense in the "County" field.

3. For a rush request, select "1" for the case priority. For a routine/normal request, select "2" as the case priority.

4. If a report should not be sent to the DA, check the box for "DA Case Restriction."

5. Select the appropriate agency in the "Department" field. Verify that the appropriate county of offense has been entered (#2 above), keeping in mind that some agencies have jurisdiction which covers more than one county.

6. The name of the officer requesting analysis shall be entered in the "Case Officer" field **using the drop down menu**. The case officer is listed on the RFLE as the "Requesting Officer." If the officer's name is not present in the drop down menu, contact the LIMS Administrator, the APO for Evidence, or another individual with authorization to add officers to this menu.

7. Select the appropriate submission method in the "Submission Type" field.

8. For items received by mail, enter the shipping or mailing tracking number in the "Tracking Number" field by scanning the barcode or typing the number. For blood alcohol kits, if the tracking number is entered manually or if there is an agency barcode number/label on the mailing container, make a copy of the mailing container to capture the tracking labels. Scan the copy of the mailing container into the BEAST (see II.F).

9. In the "Department Case" field on the top half of the screen, enter the appropriate department case number or "NONE*" if an agency case number is not provided. Agency case numbers will be recorded as shown on the RFLE. If the case number appears to include additional information (e.g. property receipt number), it will be entered as shown, unless the officer instructs otherwise.

10. **Using the drop down menu**, enter the name of the officer bringing evidence to the lab in the "Submitted By" field. If the officer's name is not present in the drop down menu, contact the LIMS Administrator, the APO for Evidence, or another individual with authorization to add officers to this menu.

    If the submitting officer works at a different agency than the case officer, select the submitting officer's agency first from the second field on the "Submitted By" line and then select the submitting officer from the drop down list in the first field. If the evidence is not submitted in person (e.g. mail, UPS, evidence locker, etc.) the name of the individual listed on the RFLE as "Submitting Officer" shall be listed in the "Submitted By" field. If the "Submitting Officer" line on the RFLE is blank, then the name of the requesting officer should be entered into the "Submitted By" field.

11. On the “Offense / Date” line, leave the first three fields blank and record the date of offense in the fourth field.

12. For OSBI Agent cases, in the “Orig Req Agency” field, use the drop down menu to select the original requesting agency. This will be the agency that requested OSBI assistance. This field is not required for non-OSBI Agent cases.

13. On the “Names” tab, use the drop down menu to select name type.

    a) Select “S” for suspect(s).

    b) Select “V” for victim(s).

    c) Select “K” for subjects that have known samples being submitted for elimination/identification purposes and are not considered suspects/victims (e.g. buccal swabs from parents to identify unknown homicide victim).

    d) Select “O” for cases that do not have a suspect or victim (e.g. controlled buy).

        i. For cases that do not have a suspect or victim, enter the agency case number in the “Last” name field.

14. Enter other available applicable information in the remaining fields on the “Names” tab.

15. Enter each outer package of evidence on the “Containers” tab.

    a) Enter a letter designation for each outer package in the “Cont. #” column.

    b) Select a description of the evidence package that most closely describes the package from the drop down list in the “Package” column. If an appropriate description is not in the list, select “miscellaneous.”

    c) Assign one item number to each container of evidence.

    d) Select the analysis needed from the “Service Req(s) F4” column.

16. Enter item specific information on the "Items" tab.

    a) In the "Pkg." column, enter ITEM or the type of evidence collection kit (DUI, SAKIT, etc.).

    b) In the "Type" column, select "EVIDENCE" or the appropriate evidence code from the drop down list. For evidence collection kits, such as blood alcohol, sexual assault, or gun-shot residue kits, select the appropriate kit type. The sexual assault kit type should reflect the agency that provided the kit (OKKIT, OCPD, OSBI, or TPD).

    c) For blood alcohol kits, highlight the "Attribute F4" column, press the F4 key, and enter the blood kit and citation number in the window that opens. For sexual assault evidence collection kits, highlight the "Attribute F4" column, press the F4 key, and enter the SA kit tracking number.

    d) In the "Description F7" column, enter the description of what is in each package based on the information provided by the officer and/or the labeling on the package.

17. If another agency or individual needs to receive a copy of the report, enter the appropriate information on the "Distribution" tab.

E. Finalize Case Creation

Finish creating the case by completing the following steps.

1. For all cases, once the information has been entered into the BEAST, click the "Quick Create" button.

2. For in person submissions, type the name of the individual submitting the evidence and capture his/her signature using the signature pad. Click on "Save Signature" when he/she has finished signing.

3. For in person submissions, offer the submitting officer a copy of the BEAST generated submittal receipt.

4. For mail, courier, and evidence locker submissions, the BEAST generated submittal receipt is available in the law enforcement report portal (report system).

F. Scan Any Necessary Documents

Scan a copy of blood alcohol kits, officer RFLE's, officer affidavits, and any other necessary documentation and save them to the Image Vault. This can be done by completing the following steps:

1. Insert the document into the scanner in the proper orientation, according to the scanner instructions.

2. Open the case within the BEAST.

3. With the “Case Info” tab selected, hit the F11 key or click on the “Documents F11” button.

4. Click on the “Scan_Doc” button in the lower right corner of the window that opens.

5. Select “black and white picture or text” and set the page size to “Letter” in the window that opens and click “Scan”.

6. When prompted for a document description, include the case number and “BA kit”, “affidavit”, or an appropriate description of the document scanned and then click “ok.”

G. Label Evidence and Folder

Ensure the evidence and, if applicable, case file(s) are properly identified by completing the following steps:

1. Apply the appropriate barcodes to the package(s) and file folder(s) or RFLE.

2. If the county and agency are not displayed on the barcode, label the evidence package(s) with this information.

3. If the evidence packaging does not have the department/agency case number or suspect and victim information, ask the officer to add the appropriate information if his/her agency will need it to identify the evidence when it is returned.

H. Transfer Evidence and Folder Barcode to Proper Storage Location

Transfer evidence to the appropriate vault by performing the following steps. Then, use the same process to transfer the folder barcode to an appropriate location (file system or electronic file, etc.).

1. Scan the barcode representing the location to which the evidence will be transferred.

2. Scan the barcode for each evidence package/folder being transferred.

3. Either scan the barcode representing “Process Transaction” or select enter.

I. E-mail Submissions – Latent Evidence Unit

For evidence received by e-mail by the Latent Evidence Unit, similar steps as those outlined in sections D through H will be used to create an evidence submission. Transfer information provided on the RFLE into the BEAST by creating a new case using manual creation or by creating a new submission on an existing case. If it is not certain whether the submission is the first submission in a case, a search should be done with the information provided to ensure there will not be duplicate case numbers assigned to the same case.

1. In the "Case Type" field use code 94-Unidentified Deceased.

2. Enter the County of Offense in the "County" field.

3. For a rush request, select "1" for the case priority. For a routine/normal request, select "2" as the case priority.

4. Uncheck the box for "Print Receipt."

5. Select the appropriate agency in the "Department" field.
   7891, State Medical Examiner-OKC
   7892, State Medical Examiner-Tulsa

6. The name of the officer requesting analysis shall be entered in the "Case Officer" field **using the drop down menu**. The case officer is listed on the RFLE as the "Requesting Officer."

7. In the "Submission Type" field select "Email."

8. In the "Department Case" field, enter the ME's case number.

9. **Using the drop down menu**, enter the name of the individual emailing evidence to the lab in the "Submitted By" field.

10. On the "Offense / Date" line, leave the first three fields blank and record the date of offense in the fourth field.

11. If another agency involved with the case has a case #, enter that information in the "Location" section.

12. Enter information in the "Names" tab.

    a) If you have information for a tentative identification, select "O" in the "Type" field on the "Names" tab and add the appropriate information for the tentative identification.

b) Select “V” in the “Type” field and enter “unidentified deceased” in the “Last” field.

13. In the “Containers” tab:

a) Enter a letter designation for each package in the “Cont. #” column, starting with “A.”

b) Enter “ITEM” in the “Package” column.

c) Assign one item number to each container of evidence.

d) Select the analysis needed from the “Service Req(s) F4” column. (LP-C for examination of images from unidentified deceased prints)

14. Enter item specific information on the “Items” tab.

a) In the “Description F7” column, enter the description of the evidence based on the information provided on the RFLE.

15. In the “Remarks” Tab, put a statement of the date and time the e-mail submission was received and by whom. Ex. “Received by (your name) via e-mail on 8/16/16 at 1500.”

16. If another agency or individual needs to receive a copy of the report, enter the appropriate information on the “Distribution” tab.

17. Check that all of the entered information is correct. When you are ready to create the submittal, click the “Quick Create” button.

18. Two barcodes will be printed. Place the barcode for the case file in the box on the RFLE labeled “OSBI Laboratory Number.” Place the container barcode in the Item Description area on the RFLE.

19. Scan the RFLE and save it to the Image Vault.

20. Upload the e-mail submission to either the “Narrative” section or to the Image Vault.

21. Label the submitted digital images with the Case # and Item # in front of the original file name.

22. Upload the submitted images to the Image Vault.

23. Using the container barcode on the RFLE, scan the evidence to the “Image Vault.”

24. Using the file barcode on the RFLE, scan the file to "Electronic Case File."

J. Linking Cases

In some cases, there may be a request or a need to compare items from one OSBI CSD case to one or more other cases. When this occurs, the cases can be linked in the BEAST to facilitate the cross-case comparison. Prior to linking cases, it is advisable to contact the respective District Attorney's Office(s) and ensure that linking the cases is acceptable. In some circumstances, the DA may feel it is necessary to leave cases unlinked in order to ensure the reference to (an) additional case(s) in a report does not create the potential to prejudice the jury.

1. Determine which case is primary and which case(s) is/are secondary. When linking cases, a copy of the item description and submission information for linked items from a secondary case will be put into the primary case record. Linking cases does not copy information from the primary case into the secondary case(s).

2. Before linking cases, verify that all items of evidence are within the custody of the OSBI CSD. If a request has been received to make a comparison to items which are no longer in OSBI CSD custody, determine whether the items will be resubmitted or whether the request needs to be declined. Do not link items which are not in OSBI CSD custody in order to avoid creating an assignment that cannot be completed.

3. Open the primary case in the BEAST.

4. Click on the "Items" tab.

5. Click on the "Link" button on the right side of the screen.

6. In the window that opens, click on the "Select Items Manually" button. This will open a "Find a Case" window.

7. Use the "Find a Case" window to open the case record for the secondary case.

8. Select the item(s) to link and click ok. If a sub-item will be linked, the associated parent item must also be selected.

9. Click on the "Link Items" button to complete the linking process.

10. Once the linking process is completed, navigate to each secondary case and edit the item description for each linked item to include "*LINKED ITEM_XX-XXXXX*" (XX-XXXXX is the primary linked case number) at the beginning of the item description. This additional identification of the linked item should be used to help ensure that a linked item is not released prior to the completion of the analysis on the primary case.

In the event it is necessary to link to a legacy case (one which pre-dates the BEAST and LETS evidence tracking systems), contact the Evidence APO for assistance.

III. Attachments

OSBI CSD QPA 5.1, Rev07 Request for Laboratory Examination
OSBI CSD QPA 5.2, Rev03 Digital Evidence Examination Request Addendum
(Available in QMS Forms Folder)

I. Scope (top ↑)

This procedure outlines the process for handling evidence within the OSBI CSD. Evidence handling procedures include uniquely identifying evidence, labeling evidence items and/or packaging, and preventing contamination.

II. Procedure

A. Evidence Inventory

1. An initial inventory of evidence containers (packages) is created during the evidence intake process. Refer to **QP 5**.

2. During the examination of evidence, analysts will create an inventory of evidence items contained within any package or container of evidence that is opened for analysis (see II.B.2). Discrepancies between evidence received and the labeling on the officer's RFLE or evidence packaging should be noted and handled according to section 7.4.3 as appropriate to the significance and potential impact of the discrepancy. A more significant discrepancy (e.g. a mislabeled reference sample) may require contacting the submitting agency for verification and/or submission of a new reference sample. The action taken to verify the correct information shall be noted in the case record.

3. The inventory of evidence should include a unique item number or sub-item number for each evidence item or package (if package not opened) observed by the analyst and a description of the item or package.

4. Analysts creating an inventory of evidence which may be forwarded for latent evidence analysis should be cautious when assigning sub-item numbers, since latent evidence analysis may often be conducted on the packaging of an item tested by another discipline (e.g. the packaging is an item for analysis). Whenever possible, the analyst creating the inventory should communicate with a latent evidence analyst to ensure that the inventory is created in a manner which facilitates analysis and reporting by both disciplines.

B. Itemizing Evidence

The following procedure will be used to assign a unique item number or sub-item number to each piece of evidence analyzed.

1. Selecting an Item or Sub-Item Number:

    a) Item numbers will be assigned using the default item numbering system currently in effect in the "BEAST" Laboratory Information Management System (LIMS). Item numbers are a numerical integer, with each subsequent item assigned the next

consecutive integer. Each "parent" container or package is assigned an item number at the time of intake.

b) Parent item numbers will not be added, edited, deleted, or otherwise modified without prior approval of the Administrative Programs Officer responsible for the FSC Evidence Unit, or designee.

c) Sub-item numbers will also be assigned using the default numbering system in effect in the BEAST. Sub-item numbers are assigned by the BEAST alternating letters and numbers. For example, if the item number is 1, the first sub-item number will be 1A. Each sub-item number will progress alphabetically. If there are more than 26 sub-item numbers (1A through 1Z) subsequent sub-item numbers are assigned by the BEAST in the following fashion: 1AA through 1AZ, followed by 1BA through 1BZ, etc. Sub-item numbers may be edited, but only under the following circumstances:

i. Sub-item numbers may be edited in order to match a sub-item number previously assigned for evidence that has been re-submitted.

ii. In addition, sub-item numbers may be edited if necessary to maintain consistency with a legacy numbering system. For example, if a case was analyzed prior to the BEAST and additional evidence is submitted, the sub-item numbers can be changed to the item numbers that would have been assigned under the original numbering system.

2. Creating an Inventory:

Analysts will use the following method to create, <u>on the "Items" tab</u>, an inventory of evidence items and/or packages contained within each container of evidence that is opened for analysis.

a) Upon opening each container of evidence, the analyst will determine how many items or packages are present in the container. Analysts may exercise some discretion to determine what is an item.

b) Multiple physical pieces of evidence may be considered a single item, provided that results can still be reported clearly and unambiguously and that the chain of custody for all evidence is still recorded accurately. Examples of multiple physical pieces of evidence which may be handled as a single item include:

i. Multiple tubes of blood from the same individual, collected at the same time as part of a toxicology case.

ii. Multiple tablets bearing the same markings, with one or more tablets selected, subjected to testing, and yielding the same results.
iii. Items which were packaged together and are not intended for analysis (e.g. box labeled as containing victim clothing).

c) If only one item is present in the package, analysis should be completed and documented using the parent item number assigned to the package. However, if the item has been previously itemized or was submitted in relation to a case that was previously analyzed using a different numbering method, a sub-item should be created in order to maintain consistent numbering. See above.

d) If more than one item is present in the package, the analyst will use the sample button to create the correct number of sub-items. Alternately, the parent package can be sampled once, and the sub-item can be "duped" to create the correct number of sub-items.

e) Sub-Item numbers should not be assigned in a manner that they refer to a package or container alone, unless that package or container will be analyzed (e.g. for latent prints). Analyst discretion may be used on sub-itemizing containers if it is an evidence kit (e.g. sexual assault kits, GSR kit (kit is Item 1, with contents being 1A, 1B, etc.)).

3. Sub-Divided Evidence and Work Product:

Sub-item numbers or item numbers will also be assigned to evidence which has been sub-divided or to work products <u>as necessary to accurately document the chain of custody and report results</u>.

Evidence has been sub-divided anytime a portion of an evidence sample is removed and is not consumed in testing or returned to the original package.

Work product refers to items generated from evidence, such as sperm cell search slides, DNA cuttings, extracts and dilutions, and digital evidence exhibit reports.

a) Selecting an Item or Sub-Item Number:

i. Sub-item numbers will be used when the sub-divided evidence or work product originates from a single parent item.

ii. However, if sub-divided evidence or a work product is created which originates from more than one parent item (e.g. multi-well slides with stains from more than one item, Digital Evidence Exhibit Reports generated from more than one item of evidence, etc.), then the next available item number may be assigned. When a new item number is used in this fashion, the description of the item number shall

clearly identify the item or sub-item numbers it originated from or is associated with.

b) Recording Sub-Divided Evidence and Work Products:
In most cases, item numbers and sub-item numbers assigned to evidence will be created on the Items tab in the BEAST in order to ensure an accurate chain of custody and clear reporting. However, there may be some exceptions. The following guidelines should be used when determining how to create or record an item or sub-item number.

i. Item and sub-item numbers assigned to evidence will be created on the items tab when there may be further sub-item numbers assigned later which are related to the same parent item of evidence. This will ensure there are not reports issued which reference the same sub-item number for different pieces of evidence.

ii. When there is no potential for duplication of sub-item numbers and when all sub-items are maintained within the same container as the parent item, the sub-item may not need to be created on the Items tab. In these circumstances, the sub-item numbers should be added to the description of the parent item, unless the evidence will not be returned or retained (e.g. such as a blood alcohol kit).

C. Labeling Evidence

1. The first CSD employee examining a piece of evidence will mark the item with the laboratory case number, assigned item or sub-item number, date, and his/her handwritten initials. Any CSD employee who subsequently examines the evidence will mark the item with the date and his/her handwritten initials.

2. If the evidence itself cannot be labeled or labeling the item itself could compromise the integrity of the evidence, or a subsequent evidence processing method could remove labeling information (for example latent print processing), an alternate labeling method should be used. Possible ways of labeling and preserving labeling of such items may include one or more of the following methods:

a. Labeling a tag which can be attached to the item, after processing if necessary.

b. Labeling the proximal container.

c. Including a photo of the item with the labeling information visible in the photo as part of the case notes.

d. Using a thin-tipped marker in an appropriate area.

e. Taking a photo after marking, to record the markings, if necessary.

3. Cell phones and their component parts are not required to be labeled directly on the item, as this type of evidence is often obtained based on consent and will be returned to the owner upon completion of analysis. Cell phones and any sub-items assigned to the component parts shall be clearly labeled on the proximal container.

4. All evidence items and/or their proximal containers will be legibly marked in such a way that the examiner's identifying marks or entry into the container does not cover, obliterate, or substantially alter another examiner's or officer's seal or markings whenever possible. In this way a traceable chain of seals is maintained.

5. When evidence is re-sealed after analysis, the examining Criminalist will ensure the outer container is marked, next to the barcode label if possible, to indicate the item and sub-item number(s) contained within the evidence package, his/her initials, and if desired, the date. The item and sub-item number labeling should clearly convey what items are contained in the evidence package, including any items or sub-items which have been added to or removed from the package. Additionally, outer evidence containers should bear the county of offense and the submitting agency. This requirement does not apply to blood specimen collection kits that will not be returned to the submitting agency.

D. Evidence Recovered by Photography

1. When evidence, such as latent prints and impressions, can only be recorded or collected by photography (including digital images) and the evidence in the image is not recoverable, the photograph must be treated as evidence.

2. Photos such as these, that are treated as evidence, must be handled in the following manner:

   a) The photographs must be labeled with, or contain in the image, the case number, date taken, analyst initials, and a unique photo number (i.e. Photo 1) or an item/sub-item evidence number. Whenever possible, this information should be included in the image.

   b) The photographs must be listed in the case file, in either hard copy or electronic format.

   c) In latent evidence cases, photographs and negatives can be retained in the case file.

E. Evidence Handling

Each analyst is responsible for ensuring that all evidence examined is protected from loss, contamination, cross transfer, and deleterious change.

1. Evidence will be handled taking precautions to prevent any unauthorized alteration, cross-contamination, or deleterious changes by the following method or combination of methods:
   a) Analysts shall obtain approval from the Technical Manager (TM) and/or Quality Manager (QM) prior to combining samples of evidence which may originate from a different source, even if located on or submitted as a single item (e.g. multiple biological stains on a single item, multiple tablets or syringes submitted as a single item).

   b) Generally, open and examine only one container of evidence at a time.

   c) Suspect and victim evidence will be searched in separate areas or at different times after decontamination measures are employed to prevent cross-contamination.

   d) Every reasonable attempt will be made to maintain and preserve informative samples of biological evidence in serology related cases. Analysis of consumption samples will be documented according to **QP 16.2**. Requests for additional documentation or observation will be handled according to **QP 10**.

   e) Representative samples of all informative biological material will be preserved in a manner to minimize degradation of the material and allow for future testing as required. These items may be retained, if necessary, or returned to the submitting agency.

2. All evidence received of insufficient quantity to allow a representative sample after testing should be photographed and documented according to **QP 16.2** prior to examination. In addition, any work product of the analysis, such as DNA extracts, that may permit retesting, will be preserved and retained in such a way as to prevent degradation.

F. Evidence Storage

1. Temporary closure of evidence is encouraged for evidence in overnight lockup to prevent the possibility of loss, cross transfer, contamination, or deleterious change. Locking cabinets, drawers, etc. will be provided and used by Criminalists, when practical, for securing evidence overnight or when the Criminalist will be away from the laboratory. It is recognized that there are times when it may not be practical to secure evidence in locking cabinets, drawers etc. Examples may include when an examiner needs to leave for a brief period of time (e.g. lunch hour or shorter) or if the evidence is in process and needs to be left out as part of the analysis procedure (e.g. latent print processing). In the event it is not practical to put evidence in a temporary locked storage, evidence being examined may be

left out if it is in a secure area (e.g., a limited-access laboratory room). It is the responsibility of every CSD employee to ensure that evidence is always stored in the most secure manner practical.

2. Large items or boxes of evidence in the process of being examined will not be required for lock-up as long as they are closed and/or sealed in a secured restricted access lab area when the Criminalist will be away for short periods of time.

3. Evidence shall be re-sealed as soon as practical after requested testing has been completed.

   a. Evidence such as fingerprints and/or projectiles in unsolved cases that are subject to frequent requests for comparison may be treated as "evidence in the process of examination." "Evidence in the process of examination" may be stored unsealed in a secure, limited access area, as long as the evidence is protected from loss, cross-transfer, contamination, and/or deleterious change. After 30 consecutive days of no analysis or new requests for comparisons, a case is no longer considered "in the process of examination." Cases no longer in the process of examination should be closed and the evidence sealed properly until analysis resumes or a new service request is received.

   b. Similarly, digital evidence such as cell phones, computers, hard drives, etc. may be treated as "evidence in the process of examination." Due to the length of time it may take to image and analyze digital evidence, it is acceptable for this type of evidence to be stored unsealed in the examiner's secure, limited access work area until the examination is complete. However, if examination is delayed and 30 consecutive days have passed with no active examination, the evidence must be re-sealed and returned to an evidence room until examination resumes.

4. Evidence will be stored in conditions which prevent degradation or other deleterious change. Blood and urine samples submitted for Toxicology analysis will be stored refrigerated upon receipt and until they are disposed of according to statute or returned to the appropriate agency.

5. DNA extracts, including those in the process of examination, must be stored refrigerated or frozen.

6. Evidence should not be returned to a property room or other physical location for return to the requesting agency until after technical review has been completed. This practice ensures that evidence is available for further inspection or testing, if a question or concern arises during the review process.

G. Transporting Evidence

1. Evidence collected from a crime scene must be protected from loss, cross transfer, contamination, and/or deleterious change, whether in a sealed or unsealed container, during transportation to an evidence facility. Where appropriate, further processing to preserve, evaluate, document, or render evidence safe shall be accomplished prior to final packaging. Evidence collected from a crime scene must be appropriately identified, packaged, and entered into the secured electronic evidence tracking system as soon as practical.

2. Evidence that has been received into the custody of the OSBI CSD that must be transported to another facility should be sealed prior to transport.
3. Evidence being transported to another facility should not be left in an unoccupied vehicle overnight.

4. Transportation of evidence will be documented using the evidence transaction procedures outlined in **QP 7**.

III. Attachments

None

I. Scope (top ↑)

When evidence is needed for purposes other than casework analysis, this procedure shall be followed to ensure that the non-casework use of evidence is documented and communicated to OSBI customers, **if the non-casework use would consume a portion of the evidence or could potentially damage the evidence**.

II. Procedure

A. Approved Non-Casework Use of Evidence

There are several different circumstances other than casework analysis when the use of evidentiary samples is essential to further the mission and goals of the OSBI CSD. These include:

1. Research or validations which improve the quality or types of services the OSBI CSD can provide.

2. Training of CSD employees, practicum students, or interns.

3. Quality control purposes, such as re-analysis casework.

B. Preferred Sources of Evidence for Non-Casework Use

In order to ensure that non-casework use of evidence does not conflict with the OSBI CSD's responsibility to preserve and protect the integrity of evidence, the following sources of evidence will be used in the order listed if practical. With the exception of evidence returned for destruction, **at least half of all samples must be retained or returned to the submitting agency**.

1. Evidence which has been resubmitted to the OSBI CSD for destruction or which is eligible for destruction based on state statute (e.g. toxicology samples).

2. Evidence from a no-analysis case, where there is no possibility for a later request for analysis. For example, evidence from a no-analysis case where the suspect has pled guilty.

3. Evidence from adjudicated cases or no-analysis cases with a potential that a request for analysis will be received later.

4. Evidence from active, non-adjudicated cases.

C. Notifying Customers of Non-Casework Use of Evidence

1. Notifications may be handled in the following manner:

a) All customers will be notified of the OSBI's policy regarding non-casework use of evidence by the posting of this policy and the attachment (OSBI CSD **QPA 6.2.1**) on the OSBI website.

b) For evidence samples retrieved from destruction evidence, no further notification is required.

c) When a second sample of an evidence item is taken for non-casework purposes and consumed concurrent with analysis of the case, no further notification is required. The consumption of a second sample shall be documented in the case record, as indicated below.

d) When a portion of evidence is **retained** for non-casework purposes from adjudicated cases, no-analysis cases, or cases with no expectation of future analysis requests, a second notification will be sent to the investigating agency or the prosecuting agency, at a minimum. This notification may be through a letter, memo, or e-mail. Alternately, this notification may be done by adding a statement to the Criminalistics Examination Report which states that a portion of the evidence is being retained in accordance with OSBI CSD QP 6.2 and the notification posted on the OSBI website.

e) When a portion of evidence is **retained** for non-casework purposes from non-adjudicated cases, the second notification must be sent to the prosecuting agency and defense counsel. Including a statement in the report like that described in II.C.1.d above will be considered notification of both prosecution and defense.

2. As indicated in OSBI CSD **QPA 6.2.1**, authorization will be documented through the submittal of evidence for analysis or destruction.

D. Documenting Non-Casework Use of Evidence

When evidence is used for non-casework purposes it will be documented as indicated below.

1. Re-analysis of casework samples will be documented according to **QP 30** and all applicable discipline protocols.

2. Use of destruction evidence will be documented on the destruction form.

3. Use of no-analysis, adjudicated, or non-adjudicated casework will be documented in the case record.

   a) The information may be recorded in a case narrative or as part of the examination documentation, whichever is most appropriate.

b) The amount and item/sub-item numbers of samples taken and the purpose of sampling will be documented. The amount of sample taken may be recorded by a specific size, weight or other measurement. Alternately, if additional samples or aliquots are taken which are the same size as that used in casework analysis, the documentation could simply reflect "1 additional test sample taken for training purposes" or a similar notation.

III. Attachments

OSBI CSD QPA 6.2.1, Rev02 Notification Regarding Non-Casework Use of Evidence

I. Scope (top ↑)

This procedure outlines the process for maintaining property rooms and evidence vaults/lockers within the OSBI CSD. Supervisors are responsible for ensuring that property rooms designated for their unit/lab are properly maintained, according to the requirements listed below.

II. Procedure

A. General Maintenance

1. All CSD employees who have access to evidence rooms or handle evidence are responsible for ensuring that evidence is properly sealed, labeled, and stored. Any employee who observes a problem with an evidence seal, packaging, labeling, or storage shall notify the appropriate Supervisor(s) and correct the problem.

2. Problems noted with evidence handling, sealing, packaging, labeling, or storage will be evaluated according to **QP 13**. The Administrative Programs Officer (APO) for Evidence will have the final authority to determine which level of response is warranted (simple correction, corrective action, or nonconforming results). The Evidence APO will be responsible for tracking evidence-related simple corrections and notifying other Supervisors as needed so that issues are addressed quickly and do not grow in scope. If necessary or desirable, discipline Supervisors and/or Technical Managers may record evidence related Class II nonconforming work on the nonconforming work record spreadsheet.

3. Property rooms will be neat and organized. Locations for varying types of evidence (pending analysis, ready for return, retain, etc.) will be clearly identified. Evidence lockers should be cleaned after each use.

4. The primary method for organizing evidence will be to sort evidence in numerical order based on laboratory case number. When necessary, alternate organization methods may be used in addition to or in place of the primary method. For example, evidence pending return to agency may be more appropriately sorted based on agency or county. Similarly, units with evidence that cannot be feasibly grouped due to discrepancies in packaging size or storage requirements will need to modify their organization method accordingly.

5. The organization method will be communicated to all who access and use the property room or vault. All individuals accessing the vault will be responsible for maintaining the organization. For example, analysts pulling evidence for analysis will adjust the packaging so that there are not random “gaps” between cases. Likewise, evidence technicians bringing new evidence will place evidence neatly in the appropriate area.

B. Evidence Room Inventory Schedule

Periodic evidence room inventories will be conducted to monitor for and correct any discrepancies. Evidence inventories will be scheduled based upon the frequency of turn-over or movement of evidence for that particular location.

1. Locations with **evidence pending analysis** will be inventoried at least **once per quarter** (January – March, April – June, July – September, October – December).

2. Locations with **evidence pending return to agency** will be inventoried at least **once per quarter**.

3. Locations with **retained or long-term storage,** with the exception of the FSC Long Term Storage Property Room, will be inventoried at least **annually**.

4. All locations within the FSC Working Property Room will be inventoried at least annually.

C. Conducting Evidence Room Inventories

The following procedure may be used as a guide to conducting an evidence room inventory, using the Physical Inventory in the BEAST:

1. Log in to the BEAST program using your regular BEAST User ID and password.

2. Select “Phy Inventory”.

3. Scan the barcode of the location to be inventoried.

4. Scan the barcodes for all evidence in the location being inventoried.

5. Check the “Missing Items” and “Mismatched Items” tabs to verify all evidence has been scanned correctly.

6. Click on the “Save” button.

7. Click on the “Finalize” button.

8. The following categories are tracked by the inventory report:

   a) Misplaced/Mismatched Items – Items which are scanned but the computer records indicate should not be in the location inventoried.

   b) Missing Items – Items which were not scanned, but the computer records indicate they should be in the location inventoried.

c) Deleted/Invalid Items – Items which were scanned but there is no computer record found in the database. Items may have been deleted and re-entered. This invalidates the barcode. A new label should be printed.

d) Not in Container Items – These items were scanned. The computer records indicate that these items should be in a container.

e) Found Items – These items were scanned and are in the correct location.

D. Reporting Evidence Room Inventories

Unit/Laboratory Supervisors, or designee, will be responsible for ensuring the inventory report is saved in the BEAST. In addition, Supervisors will be responsible for reporting inventory results as follows:

1. Upon completion of the inventory, Unit/Lab Supervisors shall provide written notification detailing the completion of the inventory to the Evidence APO and the Criminalistics Administrator over the Evidence section.

2. Any problems identified as a result of the inventory will be listed individually in the report, along with any steps taken to correct the problem and then addressed appropriately according to **QP 13**.

3. Information detailing the status of evidence room inventories will also be reported as part of the management system review quarterly and reports as outlined in **QP 18**.

E. Custody Inquiry Personal Inventories - Schedule

In order to ensure that any incorrect evidence transactions are identified promptly, each employee who routinely has evidence in his/her possession will conduct a check of his/her personal inventory by running a custody inquiry as described below. This helps ensure that any mistakes identified can be corrected prior to evidence leaving CSD custody.

1. Evidence Technicians shall conduct a custody inquiry at the close of business each day provided that evidence transactions were conducted on that day.

2. Analysts shall conduct a custody inquiry at least once per week provided that evidence transactions were conducted during the week.

F. Conducting a Custody Inquiry

The following procedure should be used to conduct a personal evidence inventory, or custody inquiry:

1. Click the “Custody Inquiry” button at top of the BEAST home screen.

2. Type “AN” in the “Custody Of” box on the screen that appears.

3. Type your user name in the “Location” box on the same screen.
4. Click the “Search” button or hit Enter.

5. Review the list and compare to all evidence in your physical custody.

6. Notify the Evidence APO if any custody corrections need to be made. The Evidence APO may make corrections or may instruct the employee how to make the appropriate correction.

III. Attachments

None

I. Scope (top ↑)

Refrigerators and freezers used to store evidence shall be monitored to ensure each unit is maintained in a fashion that protects the evidence from degradation, cross contamination, or other deleterious change. This procedure shall be used to properly maintain all refrigerators and freezers used to store evidence. This includes refrigerators and freezers which are used intermittently for evidence storage. Refrigerators/freezers purchased for evidence storage which have not yet been placed into service may be exempted from this procedure, provided they are clearly and appropriately labeled.

II. Procedure

A. Temperature Ranges

The following temperature ranges are guidelines to be used when determining the high and low point for temperature monitoring systems:

1. Standard refrigerator compartments: 1˚C to 10˚C

2. Small refrigerator/freezer units: -20˚C to 10˚C*

3. Refrigerator/freezer combination (with probe located in freezer): -30˚C to 5˚C

4. Standard freezer compartments: 0˚C or below

   * The high/low point for combination units shall be set in a fashion that ensures frozen items are maintained at or below 0˚C and refrigerated items are maintained from 1-10˚C.

B. Guidelines for Proper Operation

1. Contents of each refrigerator/freezer should be arranged and reasonably limited to allow proper air circulation to allow for effective cooling.

2. Thermometers should be placed in an easily visible location.

3. Thermometer bulbs, sensors, and probes should be free from contact with evidence, shelving, and other materials.

4. "Frost-free" refrigerator/freezer units have short duration defrost cycles which will create some temperature variation. This should be taken into account when recording temperatures, placing temperature probes, and setting the high and low points on the alarm monitoring pad. For proper monitoring, the alarm probe must be placed in a position where the temperature does not fluctuate enough during defrost cycles to set off the alarm.

5. Care should be taken when placing evidence into freezers which require manual defrosting. Additional steps should be taken to protect evidence from water damage that could occur due to an unintended defrost during a freezer failure or power outage. For example, avoid placing evidence on the very bottom of the freezer and consider draping plastic over evidence to divert any drips.

C. Alarm Monitoring

1. All refrigerators and standalone freezers used to store evidence will have a remote alarm monitoring device installed.

2. The OSBI maintains a contract with an alarm monitoring company. If a refrigerator or freezer temperature falls outside the acceptable range outside of business hours, the alarm company will notify the OSBI according to contract specifications. The appropriate Supervisor, or designee, will then be notified to investigate the source of the alarm.

3. The Supervisor, or designee, will be responsible for taking appropriate actions as indicated in section II.E below.

D. Manual Monitoring

1. Thermometers will also be used to regularly check the temperature of refrigerators and freezers. Thermometers used will measure in ˚C and must have a range that spans the temperature range designated for the unit being monitored.

2. At least once per week, the temperature will be recorded on the Temperature Monitoring Form (OSBI CSD **QPA 6.4.1**) or an alternate temperature log which records the same information included on OSBI CSD **QPA 6.4.1**. The person recording the temperature shall check previous readings to monitor for any trends which would indicate the performance of the refrigerator or freezer may be declining. If a single reading appears to indicate a negative trend (concern that unit is not operating properly), a second reading will be taken later in the day and the Supervisor will be notified.

3. When the temperature is checked and logged, the refrigerator or freezer will also be inspected for mold, mildew, excess frost/ice buildup, or any other possible deleterious condition that may require maintenance. Appropriate and immediate action will be taken to remedy any deleterious condition, if possible. For maintenance that cannot be performed immediately (e.g. manual defrosting or maintenance that requires a service technician) the Supervisor will be notified so the maintenance can be scheduled as soon as practical.

E. Out of Range Temperature

When a refrigerator or freezer temperature falls outside the acceptable range, the following actions shall be taken to investigate and correct the issue.

1. The unit shall be inspected to attempt to determine the cause of the variance. If the cause is readily identified (e.g. a door not properly closed, evidence stacked in a fashion that prevents air circulation, etc.) then appropriate steps will be taken to correct the issue and the temperature will be closely monitored to ensure that the steps taken corrected the problem.

2. If the cause cannot be easily determined or corrected by in-house personnel, the unit shall be emptied. The contents shall be transferred to a working unit (if possible) or to a temporary storage until expedient arrangement can be made for proper storage. The unit shall be marked with an "Out of Service" sign. The date shall be recorded both on the sign and in the maintenance record. The unit Supervisor, or designee, shall arrange to have the unit repaired or replaced.

F. Power Outages

Power outages may periodically occur due to inclement weather or utility maintenance work. The following steps should be taken to ensure a power outage does not damage evidence stored in refrigerators and freezers.

1. Whenever practical, refrigerators and freezers used to store evidence should be placed on a properly maintained backup generator.

2. Staff should be trained on the proper operation of any backup system or generator in use.

3. Staff should also be trained on appropriate steps to take in the event that a power failure occurs and a backup generator is not available. This includes methods to identify and triage the most critical evidence (e.g. whole blood, tissue, bone samples should be prioritized above more stable evidence such as DNA extracts; freezers with frost buildup should be handled before frost free units, etc.), alternate storage locations and methods, etc.

4. Training provided shall be documented in the employee's training folder (see **QP 19**).

III. Attachments

OSBI CSD QPA 6.4.1, Rev01 Temperature Log
(Available in QMS Forms Folder)

I. Scope (top ↑)

The security and integrity of all evidence in the possession of the OSBI CSD will be preserved. Transfer, return, and/or destruction of evidence will be conducted according to the specifications of this procedure.

II. Procedure

NOTE: Scanning evidence for any custody transaction must be performed accurately to ensure proper chain of custody. It is vital when transferring, returning, or destroying evidence to ensure all packages have been scanned properly. Packages should be counted manually and compared to the count on the screen to ensure no package is overlooked.

A. Documenting Chain of Custody for Evidence Transfers

The following process will be used to document evidence transfers at the time of the transfer:

Scan the appropriate barcodes as indicated below.

1. Location (the person receiving the evidence or the vault/storage area where the evidence will be placed)

2. Item (the barcodes associated with all items being moved)

3. Process chain of custody (or hit enter/click save)

B. Documenting Chain of Custody for Legacy Evidence

Occasionally, the need arises to transfer evidence which has been retained by the OSBI CSD. When legacy evidence (evidence which pre-dates the BEAST and LETS evidence tracking systems) needs to be transferred, the chain of custody may be documented using a legacy method (e.g. hard copy tracking, release, and destruction forms, etc.) if the transfers are intended to release the evidence out of OSBI CSD custody. For example, if retained evidence associated with cases that are past the statute of limitations is being returned to the original requesting agency, the transfers may be documented using the legacy method.

However, if evidence transfers are necessary to facilitate additional analysis, the evidence shall be added to the BEAST so that subsequent chain of custody transfers and analysis can be tracked using the current system.

The Evidence APO shall be consulted when transfers are conducted of legacy evidence to ensure all evidence transactions are documented correctly.

C. Evidence Transfers

The following method will be used to transfer evidence between individuals or locations. For the purposes of this section, an evidence transfer refers to evidence that has been analyzed in one unit or laboratory and is being routed to another unit or laboratory for additional analysis. Evidence which has been received (but not analyzed) by one laboratory which must be transported to another laboratory for analysis does not constitute an evidence transfer as described in this section. Evidence transports must be documented according to section II.A above.

1. Routing Evidence

a) The individual initiating an evidence transfer will verify that an assignment for the target unit exists in the BEAST. If there is no assignment for the target unit, the individual initiating the transfer will create the assignment.

b) Evidence transfers can be done directly from analyst to analyst. This should be done whenever necessary to ensure the efficient and timely analysis of evidence.

2. Prepare Evidence Packaging

a) Create a new container, if necessary, for the item(s) to be transferred.

i. From the items tab, click on the barcode button located next to the “Cont#” field.

ii. In the window that opens, click on “New.”

iii. Select the appropriate package type.

iv. Select the item(s) that are being placed in the new container.

v. Click on “OK” and enter password when prompted.

vi. Click the barcode button again, ensure that the newly created container is selected, and then click on print label.

vii. Attach the barcode label to the container.

b) Verify that the package(s) is/are properly sealed and labeled. At a minimum, packages should be labeled with the following information:

i. case number;

ii. item number(s) included;

iii. analyst initials;

iv. barcode label;

v. county and agency (this information should be on the barcode label);

vi. any applicable hazard labels.

c) For evidence that will be physically transferred by another individual (such as an evidence technician) the following steps will be taken to identify evidence pending transfer:

i. Complete the evidence transfer form (OSBI CSD **QPA 7.3**). Attach the form to the evidence with a staple or paper clip. Do not use tape, unless the evidence container is a bucket or other container which requires tape in order to securely attach the form.

ii. Move the evidence to a location specified for evidence transfers.

d) Following transport of the evidence (if applicable) to the target lab, the following actions will take place:

i. The individual receiving the evidence at the target lab will remove the transfer form from the evidence and forward the transfer form to the appropriate unit or an appropriate location designated for this purpose.

ii. The evidence being transferred will be placed in the target unit's property room or vault in the location designated for pending evidence.

iii. The Supervisor, or designee, of the target unit will review the information on the transfer form and ensure that the case is assigned to an analyst or prioritized as necessary.

iv. The transfer form may be retained in the case file while the assignment is in progress, but will be shredded prior to the assignment being closed.

D. Evidence Returns

With the exception of evidence samples which require or warrant retention or which are authorized for destruction, evidence will be returned to the appropriate submitting or requesting agency.

1. Evidence will generally be returned in person, but may be returned by certified mail (with return receipt requested) or private courier (UPS, FedEx).

2. For evidence returned at an OSBI CSD facility, perform the following steps:

   a) Scan the barcode for "return to agency."

   b) Scan the barcode(s) for the item(s)/container(s) being returned.

   c) Type the agency receiving the evidence and any comments necessary in the "Comments" field. For example, if evidence is returned to an agency other than the requesting agency, an explanation or comment should be entered.

   d) Scan the barcode for "process chain of custody" or click on "Save."

   e) Enter your password and click "OK."

   f) Type in the name of the individual receiving the evidence, have them sign on the signature pad, and click "Save Signature."

   g) Give a printed copy of the evidence receipt to the individual.

3. For evidence returned at remote locations, perform the following steps:

   a) Transfer the evidence to the custody of the individual that will be returning the evidence.

   b) Prepare (a) hard copy evidence release form(s) (OSBI CSD **QPA 7.2**).

   c) Deliver the evidence to the appropriate agency and have the individual receiving the items print and sign his/her name on each form and date the form(s).

   d) Document the date and time of the transfer.

   e) After returning to a CSD facility, attach an imaged copy of the signed release form to the appropriate BEAST case file.

   f) Update the chain of custody record to reflect the return to agency. This can be done by coordinating with the Administrative Programs Officer over the Evidence discipline.

E. Evidence Destruction

The following procedure for evidence destruction applies to items that are currently in the

custody of the OSBI CSD or that are brought to the OSBI CSD specifically for destruction. This can include dog drugs, provided that the agency has already had a property officer weigh the dog drugs and record the weights on the DEA form 41. If an agency needs to submit dog drugs for destruction but has not weighed the dog drugs and recorded the weights on DEA form 41, then they must submit these drugs for destruction only at FSC and only during a scheduled appointment with the OSBI CSD Dog Drug Coordinator, or designee.

1. Toxicology evidence submitted in relation to an impaired driving case shall not be destroyed until after 60 days from the date of collection, in accordance with O.S. Title 47, Section 752.

2. Drug and other evidence will be destroyed after receiving written authorization from the OSBI Case Agent, the submitting agency, the district attorney having jurisdiction in the case, or by applicable statutes. OSBI CSD **QPA 7.1** must be completely filled out by a law enforcement representative for the proper destruction.

3. Completed destruction forms should be attached to the electronic case file in the BEAST using the same procedure described in **QP 5**, section II.F. The file name for the electronic copy of the destruction form should include the case number and an indication that the file is a destruction form.

4. Destruction forms do not need to be imaged for any evidence that has been returned to the agency and is then brought back to the OSBI solely for destruction.

5. The Criminalistics Administrator over the FSC physical evidence unit will coordinate the destruction of evidence.

6. Any laboratory facility may accept drug items for destruction. Items received for destruction should be maintained under seal, if possible. Destruction items are not considered evidence. Guidelines for accepting items for destruction can be found in the appropriate section of the OSBI Physical Evidence Technician Training Manual, located on the intranet.

7. To update the chain of custody for destruction of evidence still in the custody of the OSBI CSD, perform the following steps.

   a) Scan the barcode for the evidence disposition “destroyed.” If the destruction form is received by mail, scan the barcode for “destroyed, no signature”;

   b) Scan the barcodes for the item(s)/container(s) being destroyed;

   c) Enter the destruction number in the comments field, if applicable;

   d) Scan the barcode for “process chain of custody”;

e) Enter your password and then click on “OK”.

III. Attachments

OSBI CSD QPA 7.1, Rev02 Evidence Destruction Form
OSBI CSD QPA 7.2, Rev03 Evidence Release Form
OSBI CSD QPA 7.3, Rev01 Evidence Transfer Form
(Available in QMS Forms Folder)

I. Scope (top ↑)

The OSBI CSD recognizes that the quality of reagents, supplies, consumables, and services used are an integral part of providing quality and reliable test results. This procedure will be used to guide the purchase, receipt, and verification of reagents, supplies, consumables, and services required for testing procedures, with the exception of Digital Evidence Unit (DEU) analysis. Procedures for the purchase, receipt, and verification of supplies and consumables used for DEU analysis shall be addressed in DEU policy and procedure.

II. Procedure

A. Identification of Necessary Quality of Products/Services

1. All reagents, supplies, or consumable materials used in analysis will be identified in analytical protocols proportional to the degree to which they impact the quality of the test. For example, a reagent or supply which does not impact quality may not be specifically listed or may be listed with no clarifying information (e.g. "methanol"). A reagent which does impact the quality of the testing will be described in fashion that ensures the proper quality of reagent or supply is ordered and used for the test (e.g. "methanol – 95% purity" or "methanol – reagent grade").

2. Technical Managers (TM's) <u>may</u> choose to consolidate this information into a single list to make it easier to identify reagents and supplies affecting quality of analysis as they are received.

3. Critical reagents or supplies, which must be tested to confirm the purity or quality prior to use, must be identified by the discipline TM in analytical protocols or another suitable location.

B. Purchasing Quality Reagents, Supplies, and Consumables

1. An Internal Purchase Request (IPR) will be filled out with sufficient detail to identify the quality of reagent or supply needed.

2. If a substitution is necessary, the discipline TM should be consulted to determine if the substitution is acceptable.

3. IPR's for items that affect the quality of the tests shall be reviewed and approved for technical content. This review may be done by the individual(s) with approval responsibility according to **OSBI Policy 208**, provided he/she has sufficient technical knowledge to ensure the appropriate quality product has been requested. If the approving individual does not have sufficient technical knowledge to conduct an appropriate review, he or she should

consult with the TM.

4. When consultation with the TM is necessary for a review of technical content or for a substitution, it may be documented in one of the following ways, or an equivalent method:

   a) by summarizing the consultation with TM in the comments field in the IPR system during the approval process;

   b) by adding a memo or e-mail as an attachment to the electronic IPR.

5. When a purchase requires the creation of an invitation to bid, request for proposal, or another mechanism to allow for competitive bidding, the evaluation process submitted with the IPR shall include the process for evaluating items of added value as outlined below.

C. Evaluation of "Added Value" Items

In the event a vendor responds to an invitation to bid (ITB), request for proposal (RFP), or a related solicitation and indicates they will include an additional item or service at no charge as an added value, the following steps must be taken to evaluate the added value item or service prior to accepting it.

1. The CSD employee responsible for the bid evaluation process shall notify his/her TM and Criminalistics Administrator (CA) if a bid response includes items of added value. The TM shall then determine if the proposed added value item or service is a service or supply which will affect the quality of testing and if the item or service is a critical service or supply. If it is not, the item or service may be accepted with no further evaluation.

2. If the added value item or service will affect the quality of testing, the TM will verify that the item or service meets any relevant specification or requirements defined in protocol.

3. If the added value item or service is also a critical supply or service, the TM will ensure that the vendor has been evaluated and approved to provide the offered service or supply in accordance with QP 9. If no evaluation has been performed for the vendor for the offered service or supply, the TM may conduct and document such an evaluation. If the TM approves the vendor as a provider of the critical service or supply, then the added value item or service may be accepted. If the TM does not approve the vendor as a provider of the critical service or supply or chooses not to perform the appropriate evaluation, then the added value item or service shall not be accepted.

D. Receiving Reagents, Supplies, and Consumables

1. Upon receipt, all reagents will be marked with the date the item is received. In addition,

upon opening a container of a chemical or reagent for the first time, the analyst opening the container will initial and date the container. Date of receipt and date opened should also be marked on supplies or consumables if the age of the supply will impact the quality of the product.

2. In some circumstances (such as reagent kits with multiple components within each kit) it may not be feasible to mark each reagent container with the date received and/or the date opened. In these circumstances, an alternate labeling or tracking method may be established, provided that the method implemented facilitates effective trouble shooting, corrective action and identification of potentially impacted cases in the event reagent failure or contamination is suspected. If an alternate labeling or tracking method is necessary, it shall be included in an appropriate discipline-specific quality manual or protocol.

3. All containers will indicate a lot number and expiration date, if applicable.

E. Storage of Reagents, Supplies, and Consumables

1. Once reagents, chemicals, reference materials, and supplies are received, they should be stored at an appropriate temperature, using the manufacturer's recommendations or the Safety Data Sheet (SDS) as a guide. For example, a reagent labeled "Store at 2-8˚C" or "1-5˚C" will be stored refrigerated. Likewise, reagents, chemicals, or reference materials labeled for storage at a temperature at or below 0˚C will be stored frozen. In the event that a reagent, chemical, or reference materials does not have labeling which indicates an appropriate storage temperature, the item may be stored at room temperature, refrigerated, or frozen.

2. Refrigerators and freezers used to store reagents, chemicals, or reference materials will be monitored in the following manner in order to ensure they are functioning properly:

   a) A thermometer or other temperature monitoring device will be placed in the refrigerator or freezer. Combination refrigerator and freezer units should have a thermometer or other temperature monitoring device in both compartments if each compartment is used to store reagents.

   b) Refrigerator and freezer temperatures will be checked and recorded weekly.

   c) Freezer temperatures should be at or below 0˚C.

   d) Refrigerator temperatures should be at or between 0˚C and 10˚C.

   e) In the event a freezer or refrigerator temperature falls outside the accepted range, the temperature should be checked and recorded again after a short period of time.

i. If the temperature on the subsequent check is within the expected range no further action is required.

ii. If the temperature still falls outside the expected range, actions should be taken to try to adjust the temperature setting of the unit and the additional check repeated at least one more time to see if the adjustment has corrected the issue. If the unit still fails to reach the appropriate temperature range, the unit will be taken and labeled out of service and reagents will be moved to an appropriate alternate location. The Unit Supervisor and Technical Manager shall be notified in the event a refrigerator/freezer will be taken out of service.

iii. When an initial temperature reading falls outside the accepted range, a notation shall be made on the temperature log to indicate the action(s) taken to address the observation.

f) Temperatures can be recorded using form OSBI CSD **QPA 6.4.1.**

3. Reagents and supplies affecting the quality of analysis that have not been inspected or verified must be stored either in a separate location from those that have been inspected and approved, or in another manner which prevents uninspected materials from being used in casework.

4. If specific storage conditions are required for reagents which are prepared in-house, the appropriate storage condition should be referenced in an appropriate discipline-specific protocol.

F. Inspection of Quality Reagents and Supplies

1. At a minimum, the reagent or supply will be inspected to ensure that it meets the quality criteria established in the protocol. This may be as simple as comparing the part number, described quality (e.g. % purity, or grade), or other relevant information on the reagent or supply received to that included in the IPR and/or the appropriate technical protocol.

2. In addition to inspecting reagents or supplies upon receipt to ensure the proper quality of product was received, the quality of reagents and supplies will also be continually monitored through the evaluation of standards and controls established in discipline protocols. Any quality concern identified through the use of standards and controls will be handled according to **QP 13** thru **QP 15** as appropriate.

3. All reagents prepared in-house must demonstrate proper function. Function verification should include testing the reagent or item in the same manner it will be used in testing. Function verification should be completed prior to using the item for testing samples which

could not be retested.

4. Reagents used for DNA analysis will be evaluated in a method which complies with the current Quality Assurance Standards.

G. Documenting Preparation and Inspection of Reagents/Supplies

1. If the reagent or product is inspected to verify that the proper purity or quality of reagent was received (in lieu of conducting a function verification test), a copy of the packing slip, invoice or other document should be marked to indicate the quality was verified, the date, and the initials of the person verifying the item. This documentation must be maintained if it is the only record that the quality of the reagent or product was verified.

2. Any product inserts (or Certificates of Analysis) received, which indicate the quality or purity of a reagent, should be retained. Unit Supervisors are responsible for ensuring these are properly retained and communicating to staff where the inserts and/or certificates will be retained. The lot number(s) and date received should be noted on the document.

3. The following information will be recorded, as applicable, when reagents are prepared and/or their function is verified by OSBI staff:

   a) Name of reagent

   b) Lot number

   c) Expiration date

   d) Name, amount, supplier, lot number, and expiration date of each component

   e) Brief narrative detailing method for preparation

   f) Identity (e.g. initials, signature, or electronic equivalent) of analyst preparing the reagent

   g) Date of preparation

   h) Procedure used to verify the function of the reagent

   i) Indication whether the reagent was acceptable or not

   j) Identity (e.g. initials, signature, or electronic equivalent) of analyst verifying the reagent

k) Date verification conducted and/or reagent approved for use

4. When a reagent is prepared only for use as a component of another reagent, the verification information should be recorded for the combined reagent and is not needed for the individual component reagents.

5. Reagents such as Takayama which are made and used in small quantities and expended or discarded within a short time frame (~ one week) should have the preparation and verification information listed in II.G.3 recorded for the initial preparation. Subsequent preparations using the same component lot numbers and amounts do not need to be recorded. However, function verification and/or control results must be recorded in the case record for each preparation.

6. Records of reagent preparation and verification must be retained and available for inspection. These records should be maintained in a reagent logbook for each discipline or in the Chemical Inventory system in the BEAST (see **QP 8.2**). The Supervisor of each unit is responsible for maintaining any archived hard copy reagent records.

7. The reagent container must, at a minimum, bear the name of the reagent, the identity of the individual preparing the reagent (for reagents prepared in-house), and the lot number. The preparation date will be used for the lot number for in-house reagents. For example, a reagent prepared on July 20, 2003 would have the lot number 72003. Expiration dates should be placed on the front of the container if applicable.

8. Documentation of reagent preparation and evaluation of reagents used for DNA analysis will be maintained according to the Forensic Biology and CODIS Quality Manuals.

III. Attachments

None

I. Scope (top ↑)

The BEAST LIMS provides a laboratory asset manager system that can be used to organize chemical inventory, reference collections, and general laboratory assets such as computers or instruments. This policy outlines the procedure for utilizing the Chemical Inventory/Laboratory Asset Manager Program on the LIMS System. The chemical inventory program can be started by running the cheminv.exe program in the labora folder of your laboratory. Your user ID and password are the same ones you currently use to login to the BEAST.

II. Procedure

A. Definition of Asset Classes

The following categories of assets are available in the Chemical Inventory program. The OSBI CSD is not currently using the "Other Asset" class:

1. *Chemical/Purchased Reagent:* Chemical or a reagent that is purchased from an outside source.

2. *Prepared Reagent:* Reagent that is prepared in house.

3. *Instrument:* Laboratory instruments.

4. *Other Asset:* Assets that do not fit into any of the other categories.

B. User Permissions

There are three levels of permissions set up for Chemical Inventory Users which are described below. The Technical Manager for each discipline will be responsible for determining which level of permission will be given to individuals within the discipline.

1. **Chemical Inventory Manager (CHMGR)** – This group code provides the highest level of permissions, including the authority to delete records when needed.

2. **CHM_3** – This group code provides the user permission to access Setup, however users in this level are restricted from deleting records.

3. **CHM_2** – This group code is the basic level for Chem Inventory users. Users in this group cannot access Setup and cannot delete records.

4. **CHM_1** – This group code provides users permission to view records only.

C. Viewing an Asset Record

1. Select your laboratory location and section in the top left hand corner of the screen.

2. In the "Work With" box, choose which class of assets you would like to view.

3. All currently available chemicals/assets of that class will appear as a list under "Name."

4. Click on the item you would like to view, and the window will automatically populate with that chemicals/assets information.

5. There are several tabs which can be viewed. These include "Chemical Info", "Manufacturer/Vendor", "Safety Info", "Lab Status Info", and "History of Custody."

6. If the "Images" button is red, there are images that have been uploaded which can be viewed by clicking this button.

D. Adding an Asset Record

1. Select your laboratory location and section in the top left hand corner of the screen.

2. In the "Work With" box, choose which class of assets you would like to add.

3. Click the "Add" button on the bottom, left side of the main screen.

4. Enter or select the Asset Type Code. Any default information for this type code will automatically be filled in. If you do not find the Asset Type Code you are looking for, please contact your designated Chemical Inventory Manager.

5. It is important to choose the correct Asset Type Code as the BEAST uses this code to pull the lot numbers into the matrix or reagent panel.

6. Click on the "Lab Status Info" tab and verify the "Date Received" is correct. This automatically fills in with today's date. Fill in the expiration date if required. Once the date listed in expiration date has passed, this lot number should not be able to be selected as a chemical used in casework in the BEAST. If an asset is showing up in the BEAST past this date, please notify your designated Chemical Inventory Manager.

7. Enter any additional information about the asset on any of the tabs (Chemical Info, Manufacturer/Vendor, Safety Info, Lab Status Info, or History of Custody) and hit save.

8. A barcode label for the new chemical/asset that was added will print automatically.

9. Transfer the new asset to its proper location (see section II.J).

10. Upload any documents/images that will be attached to this asset (see section II.F).

E. Editing an Asset Record

1. Select your laboratory location and section in the top left hand corner of the screen.

2. In the "Works With" box, choose which class of assets you would like to edit.

3. Select the asset record that needs to be modified.

4. Click the "Edit" button, which can be found on the bottom of the main screen beside the "Add" button.

5. Make any necessary changes and hit "Save."

F. Uploading Document/Images

SDS, QA/QC documents, packing receipts, certificates of analysis, or other documents can be uploaded and attached to individual chemical/asset records. This can be done when a new asset record is added or by editing an asset record at a later time.

1. Locate and select the asset record to which you want to attach an image/document.

2. Hit the "Images" button to bring up the "SDS Viewer" box.

3. Click on the "Attach Doc" button and choose the document/image that you want to attach.

4. To change the title of the image/document that is displayed in the list under description, click on the "Edit Desc" box and enter the new description in the "Enter Description" box.

5. The document/image that is attached to the asset record can be viewed by clicking on the "Images" button or by going to the "Safety Info" tab for that record.

G. Deleting an Asset Record

In the event an asset record is deleted, it will **no longer be able to be viewed**. This is different than disposing of an asset if it is expired or expended (see Section II.I below). If a record needs to be deleted, contact your designated Chemical Inventory Manager.

H. Searching for an Asset Record

After logging into Chemical Inventory, you can scan the barcode of the asset to view the asset record. To find it without scanning the barcode, follow this procedure:

1. Select your laboratory location and section in the top left hand corner of the screen.

2. In the "Work With" Box, choose which class of assets you would like to search.

3. Click on the "Search" button, which can be found on the left hand side, under the "Work With" box. The Search Record window will display.

4. Fill in the search criteria in the appropriate box. For example, to find Methanol, you would type "Methanol" into the Name box. Alternately, existing reagents or assets can be searched by clicking on the question mark in the "Type" Field.

5. On the bottom left hand corner of this screen is a box titled "Disposed". Choose "No" to search currently available chemicals/assets only, choose "Yes" to search only chemicals/assets that have been transferred to expended, or choose "Both" to search currently available as well as expended chemicals/assets.

6. The results of your search will be displayed in a list in the box on the bottom left hand side of the screen, under "Name".

7. Clicking on the "View All" button, located beside the "Search" button will clear the search results.

I. Expended/Expired Chemicals

1. Expended/Expired Chemicals should not show up as available for use in the BEAST after the date that is listed on the "Lab Status Info" tab in the "Expiration Date" box. (If an expired/expended lot is showing up, please contact your designated Chemical Inventory Manager). If no date was originally entered, the asset record should be edited and the date entered that reflects the expended/expiration date.

2. The Expended/Expired Chemical Asset Record must **NOT** be deleted.

3. The Expended/Expired Chemical will be transferred (see section II.J) to Expended Chemicals of the appropriate laboratory.

J. Transferring Custody

1. In the "Work With" Box, choose which class of assets you would like to transfer.

2. Click on the Transfer button, found at the center bottom of the main page. The items currently displayed in the list under "Names" will appear in the "Process Chain of Custody" window.

3. Select the item(s) that are being transferred, by checking the box to the left of the asset. If you want all items selected, you can hit the "Select All" button.

4. Select the location where the items are being transferred to.

   a) Hit the "?" box to the right of "Transfer To". This brings up a "Select Custody Location" box.

   b) Hit the "?" to the right of "Custody Of" to open the "Custody Of" box.

   c) Choose your storage location depending on if the chemical is currently in use or is expended/expired.

   d) If the asset is currently in use, choose the appropriate laboratory Chemical Storage, then click OK. Alternatively, you can double click on the appropriate laboratory Chemical Storage and not have to click OK. Now choose the unit where the chemical is utilized, and click OK (or double click).

   e) If the asset has been expended or is expired, choose "Chemical Disposition" and then "Expended Chemicals" for the appropriate laboratory.

5. Click on the "Transfer Items" button. If prompted, enter your password and click OK. If the transfer is successful, "Update O.K." will flash across the screen.

6. When items are transferred to expended, the asset will no longer be shown on the list of assets under the "Name" on the main page of chemical inventory. However, the information is available to view by using the search button.

III. Attachments

None

I. Scope (top ↑)

Critical reagents, supplies, and services which affect the quality of testing will be obtained from reliable suppliers. The following process will be used to evaluate suppliers to determine the reliability of services and/or supplies they provide.

II. Procedure

A. Evaluation

One of the following methods will be used to evaluate suppliers of critical reagents, supplies, and services.

1. The first time a new supplier is used, an in-house verification process will be performed to verify the quality of reagent supplied. If the reagent/supply ordered does not already have a verification process established, the Technical Manager (TM) will be responsible for determining the method appropriate for verification and determining what documentation must be maintained as a record of the verification. This verification should be performed using non-probative or non-casework samples before the reagent/supply is used for testing purposes and should verify that the reagent/supply is free from contamination and yields the expected results.

2. For suppliers used prior to the original issue of this document, historical data can be reviewed to confirm the supplier's reliability.

B. Documentation

1. The evaluation process will be documented in the following manner.

   a) Examination documentation and results of an in-house verification process will be maintained in a location determined by the TM.

   b) Evaluation of suppliers which is based on historical data will be documented by the TM.

The approved suppliers may be documented in the following manner. The approved supplier list is not a lab-wide requirement, but some disciplines may choose to include this requirement in the discipline-specific quality manuals after a risk assessment.

2. The TM for each discipline may maintain a list of all approved suppliers for critical reagents, supplies, and services. The list may include the name of the supplier and the reagents, supplies, or services obtained from the supplier.

C. Handling Quality Problems with Reagents, Supplies, and Services

When quality concerns are identified with reagents, supplies, or services, the following response will be taken.

1. If the quality concern potentially impacts or did impact testing, the nonconforming work will be reported and documented according to **QP 13** and **QP 14.1** through **QP 14.3**, as applicable.

2. The supplier will be removed from the list of approved suppliers if, based on the severity of the quality concern, the supplier's response to the concern, and the record of past transactions with the supplier, such action is appropriate.

3. Any significant quality concern will be documented and a copy of the documentation will be forwarded to the OSBI purchasing office.

4. If a supplier is removed from the list of approved suppliers, the purchasing office will be notified and steps taken to file a vendor complaint with the OMES according to **OSBI Policy 208**.

III. Attachments

None

I. Scope (top ↑)

The OSBI CSD will cooperate with customers to clarify service requests and allow monitoring of CSD progress and/or testing as necessary. This procedure outlines methods to ensure this service while protecting the confidentiality of other customers.

II. Procedure

A. Consultations with Customers

1. In order to ensure that both OSBI CSD employees and the customer understand the services that will be provided and the customer is informed of the progress, CSD employees shall be available for consultation. These consultations will be included in the case record in accordance with QM section 7.1.1.

   a) Analysts and/or Supervisors will be available to consult with customers at the time evidence is submitted. Individuals receiving evidence will contact an analyst/Supervisor when necessary.

   b) Analysts and/or Supervisors will contact customers when significant changes (e.g. projected completion dates, additional analysis possible/recommended, etc.) occur.

   c) Analysts will be available to meet in person with officers or attorneys to review evidence or explain testing results.

   d) CSD employees will provide updates on the progress or status of work as requested. For open assignments which have been given to an analyst, status inquiries will be forwarded to the appropriate analyst.

2. Locations for Consultations

   a) Consultation rooms are available at the FSC to allow for private discussion and examination of evidence.

   b) Consultation may also be conducted in an alternate lab space or location, but CSD employees will ensure that customers are not given access to confidential information from other cases. This includes case files and evidence packaging with suspect/victim information on it.

B. Requests to Monitor/Observe Analysis

In order to ensure confidentiality of case information, limit potential for contamination, ensure security of evidence and case records, and to provide the best service possible to all customers,

the OSBI CSD will not permit the practice of outside observers in laboratory spaces during analysis. However, under certain circumstances, such as the analysis of consumption samples, allowing some form of monitoring or observation of analysis may be necessary. The following steps may be used to facilitate monitoring.

1. The OSBI CSD may elect to send the samples to an independent laboratory for analysis.

2. The analysis may be videotaped (using a single video camera) and a DVD documenting the analysis provided to the customer. Under these circumstances, the customer will be expected to reimburse the OSBI CSD for the cost of videotaping and providing the DVD's.

3. If possible and equipment is provided by the customer, a closed circuit feed may be set up to enable the observer(s) to monitor analysis from a separate room or location.

NOTE: This restriction does not apply to witnessing activities conducted in order to maintain accreditation.

C. Requests for Assistance with Verifications or Technical Reviews

In some circumstances, some customers (such as local police laboratories) may request assistance conducting verifications or technical reviews of work they've performed. These requests may be met by performing work in-house or by conducting work as if a contract employee of the customer's lab. All requests for assistance with verifications or technical reviews must be forwarded through the chain of command to the CSD Director, who will coordinate necessary discussion with the customer and determine whether assistance will be provided.

Specific Requirements for External Verifications and Reviews:

External verifications and reviews shall be considered critical. Therefore, the qualifications of an external verifying analyst or reviewer shall be evaluated prior to performance of service. Services under the scope of this section include:

1. Technical review of laboratory test reports,
2. Technical review of controlled documents, and
3. Verifications of identifications or positive associations.

If the external verifying analyst or reviewer is employed by an accredited laboratory, the evaluation will include verifying the individual is employed by a laboratory that meets the accreditation requirements specified in OSBI CSD Quality Manual section 7.7.4 and is currently qualified to perform work within the scope of the requested service (i.e. review and retention of the authorization to work).

Requirements for Documentation:
The following records will be maintained by the CSD Quality Manager:

1. Accreditation certificate from the laboratory employing the individual and
2. A letter or memorandum from the external individual's Supervisor, authorization to work, or a current curriculum vitae (CV) confirming their qualification to perform the requested service.

External verifying analysts or reviewers who do not meet the above requirements may still be used if the Technical Manager determines that have adequate experience based on any or all of the following records:

1. CV or resume of training and experience,
2. Copies of certificates for relevant training courses,
3. Letter(s) of qualification or competency from previous employment in an accredited laboratory,
4. Past and/or current proficiency test results, and/or
5. Any additional records the Technical Manager deems important.

Requirements for Documentation:
Records used by the Technical Manager to determine adequate experience shall be maintained by the CSD Quality Manager.

1. <u>In-House Analysis</u>

   A request for verification may be handled by analyzing the case in the same fashion as any other case, following all applicable discipline and CSD policies and procedures for chain of custody and documentation.

2. <u>Conducting "Contract" Work</u>

   Prior to approving OSBI employees to conduct verifications or technical reviews as unpaid "contract" employees of another laboratory, the CSD Director may direct a review of the applicable policies and procedures of the requesting laboratory. This review may be conducted to ensure that any OSBI CSD employee is protected from reviewing or verifying work which may not be in compliance with accreditation standards and/or good laboratory practice.

   Alternately, verifications can be conducted by OSBI employees working as "contract" employees of the customer's laboratory. In order to do this, the OSBI employee must receive training from the customer regarding the applicable policies and procedures. The OSBI employee will then perform and document the requested verification(s) according to the customer's policies. Any request for assistance performing technical reviews for another laboratory must be handled in this same fashion.

Prior to conducting this type of work, OSBI employees must prepare a Memorandum of Understanding (MOU) detailing the work to be done. The MOU should be signed by the CSD Director and an authorized employee at the customer laboratory before any work is conducted.

III. Attachments

None

I. Scope (top ↑)

The OSBI CSD will routinely solicit customers for positive and negative feedback to identify any potential areas for improvement of the CSD management system and testing services.

II. Procedure

A. Feedback Regarding Testimony

In order to solicit feedback regarding courtroom testimony provided by CSD personnel, the witness critique form will be distributed as indicated in **QP 32**.

B. General Feedback

The following methods will be used to solicit feedback regarding services provided by the OSBI CSD.

1. The OSBI Forensic Laboratory Survey may be sent to customers, made available on the OSBI website, or in hard copy form at OSBI facilities.

2. CSD employees may also complete applicable portions of the survey (such as additional comments – ideas for improvement or complaints) based on feedback received during a consultation or conversation with a customer. The employee receiving the feedback should ask the customer for his/her permission to document the comments and for permission to include the customer's contact information.

3. The CSD Administrative Staff, or a designee, may contact customers for additional input as needed.

4. An OSBI Forensic Laboratory or Customer Service Survey will be distributed at least once per calendar year to OSBI customers, including law enforcement agencies and District Attorney's Offices.

5. Additional surveys may be designed and distributed as needed to collect feedback for specific projects (e.g. development of training courses, updating evidence submission policies, etc.).

C. Analysis of Feedback

Feedback received from customers will be used and analyzed in the following manner.

1. Feedback from surveys developed and distributed with the assistance of the Office of Criminal Justice Statistics (OCJS) will be recorded and after collecting responses for an

appropriate amount of time, the data will be forwarded to OCJS for analysis using SPSS (Statistical Package for the Social Sciences) software.

2. Suggestions for improvement will be forwarded for consideration as preventive measures according to **QP 15**.

3. Critique forms and survey results will further be analyzed during the management system review to identify trends which indicate further opportunity for improvement. See **QP 18**.

III. Attachments

None

I. Scope (top ↑)

This policy is applicable to internal and external customer complaints of a technical or administrative nature where the customer expresses dissatisfaction and expects a response. It does not apply to personnel or human resources issues which should be forwarded to the appropriate Supervisor who will be guided by **OSBI Policy 133**. Complaints may identify opportunities for improvement within the quality system. Valid complaints will be dealt with in a responsible and appropriate manner. This procedure is available to any interested party as a part of the OSBI CSD Quality Manual via the OSBI website.

When the OSBI CSD receives information about a customer from a source other than the customer, the OSBI CSD shall keep this information confidential between the OSBI and the customer. In addition, the OSBI CSD shall not divulge the source of the information to the customer, unless agreed to by the source in writing.

If a customer expresses dissatisfaction, but indicates he/she does not want or expect a response, then this procedure does not apply. However, such concerns should be evaluated following **QP 15** (Preventive Action) as a potential opportunity for improvement.

II. Procedure

A. Filing a Complaint

1. CSD employees wishing to file a complaint will route a memo that thoroughly describes the issue to the Quality Manager (QM).

2. In the event that a customer indicates dissatisfaction with the OSBI CSD, the employee speaking with the customer should take any appropriate action to remedy the situation or to connect the customer with an individual with the authority and/or capability to resolve the situation. After taking appropriate steps to resolve the situation, the employee should offer the name and phone number of the QM to the customer. The employee receiving the complaint should also offer to document and route the complaint according to this policy.

3. If appropriate, individuals filing complaints against the quality system may submit their complaint to the CSD Director, who may personally handle the complaint or assign the complaint to a Criminalistics Administrator (CA) for verification, investigation, and resolution.

4. In the event of a conflict of interest, the QM may also forward a complaint to the CSD Director for handling.

B. Verifying and Acknowledging Complaints

1. Upon receiving a written complaint, the QM or designee, will begin a Complaint Tracking Form (OSBI CSD **QPA 12.1**) and assign a tracking number.

2. The QM, or designee, is responsible for investigating the condition(s) stated in the complaint. If the condition(s) can be verified, the complaint will be reviewed to determine its validity. Validity will be determined based on the significance and impact of the condition. The purpose of validity screening is to eliminate complaints that do not deal with substantive or appropriate issues. The verification and validity status will be identified on the Complaint Tracking Form.

3. Following the verification and validity screening, the QM, or designee, will notify the complainant of the status of the complaint. This notification may be oral, written, or by e-mail. The notification will be documented on the Complaint Tracking Form.

C. Investigating and Resolving Complaints

1. The QM, or designee, may forward the complaint package to the appropriate CA, TM, or Supervisor for investigation and determination of appropriate action(s). When forwarding complaint packages, the QM, or designee, should include an appropriate timeline. The selected manager's name and date will be entered on the Complaint Tracking Form.

2. The CA, TM, or Supervisor selected is responsible for investigating the situation, condition, or action that caused the complaint and after consultation with the CSD Director, recommending any necessary course of action.

3. The selected CA, TM, or Supervisor will report the cause and recommended actions to the QM and CSD Director. The QM, or designee, will enter the date the report was received on the Complaint Tracking Form and forward the report to the appropriate manager for approval of any proposed actions. When approval is obtained, the selected manager will implement the approved actions.

4. The QM, or designee, will track the progress of the complaint process to ensure timeliness, including notification progress reports to the complainant. The QM, or designee will periodically analyze complaints to determine if there are systemic or underlying problems that require attention.

D. Final Notification

Upon completion of actions dealing with a complaint, the QM, or designee, will notify the complainant that the complaint has been resolved. The completion date and notification date will be documented on the Complaint Tracking Form.

III. Attachments

OSBI CSD QPA 12.1 Rev01 Complaint Tracking Form
(Available in QMS Forms Folder)

I. Scope (top ↑)

This procedure establishes the process to identify, categorize, track, investigate, correct, and prevent nonconforming work within the OSBI CSD system, including all disciplines and personnel. This procedure identifies the proper methods for addressing and documenting laboratory activities that do not comply with OSBI CSD policies and procedures or meet the agreed needs of the customer.

II. Procedure

A. Overview

1. Nonconforming work is defined as testing work that does not meet the standards set forth in policy, procedure, protocol, or does not meet the needs of the customer. This may occur due to protocol drift or due to a quality or technical problem with a reagent, supply, or instrument.

2. Technical or administrative case-related nonconforming work shall be categorized into one of the four classes as determined by the risk and impact on the OSBI CSD.

3. Class I nonconforming work shall be documented and corrected on the spot, while Class II, Class III, and Class IV nonconforming work require management involvement.

   As included in the NOTE in CSD QM 7.5.2, contemporaneous revisions are not considered amendments and therefore, do not need to be tracked or documented in accordance with this procedure.

B. Responsibilities and Authority

1. Every CSD employee is responsible for knowing the procedures to recognize and to report nonconforming work.

2. Individuals who identify any Class I nonconforming work shall correct the issue on the spot and document the correction in the case record appropriately.

3. Individuals who identify any Class II nonconforming work shall inform the Supervisor and/or Technical Manager (TM) as soon as possible. The TM shall keep a file of all Class II nonconforming work on the Nonconforming Work Record spreadsheet.

   If the Supervisor or TM feel the nonconforming work rises to the level of Corrective Action (Class III or Class IV), the CSD Director, Quality Manager (QM), and appropriate Criminalistics Administrator (CA) will be notified as described in the following paragraph.

4. Individuals who identify a potential Class III or Class IV nonconforming work shall inform the Supervisor and TM as soon as possible. The Supervisor or TM shall document the nonconforming work and method of identification by completing a corrective action record

(Class III or Class IV) and submitting the record to the QM (copies to CSD Director and appropriate CA) within two business days of the identification of the nonconformity.

5. The QM, in consultation with the CSD Director and CA, shall determine the appropriate class of the nonconforming work. The QM shall assign a tracking number and individuals to evaluate the nonconforming work. The individual/team shall confer with the QM to develop an approach to the inquiry and shall determine whether the employee shall be permitted to conduct casework. The team shall usually include the Supervisor and TM.

6. Every Supervisor, TM, and CSD administrative staff, in consultation with the QM and CSD Director, is responsible for and has the authority to immediately suspend any observed nonconforming work activity that could result in erroneous reports or unreliable testing data. In addition, for any work suspended in the Forensic Biology Discipline, the Forensic Biology Discipline Technical Manager must also be informed.

7. Authority to resume work that has been suspended lies with the appropriate TM or CA. The authority to resume suspended DNA work belongs to the Forensic Biology TM. Individuals authorizing work to resume, shall notify the QM and CSD Director prior to issuing the authorization to resume if the work suspension applied to an entire discipline or type of testing. The QM shall notify ANAB of the intent to resume work before the authorization is issued.

C. Levels of Nonconformance

There are four levels of nonconforming work based on risk to and impact on the OSBI CSD. In order to determine the appropriate mechanism for addressing the nonconforming work, the scope and significance of the issue must be considered. A description of each class is provided below, along with a graphical representation of levels Class II through Class IV. It is important to note that it may be challenging to decide which is the most appropriate class at which to address and document the nonconforming work. Regardless of which class is selected, care should be taken during the risk assessment to ensure that the steps adequately address correcting the problem, minimizing potential for recurrence, and recalling reports and notifying customers if necessary. Records related to these evaluations shall be retained as a part of the documentation of the nonconformance.

If there is a question regarding the class of nonconforming work, the QM and CSD Director will be consulted. They, in conjunction with the appropriate CA, shall determine if the nonconforming work is Class I, Class II or rises to the level of Corrective Action (Class III or Class IV).

1. **Class I Nonconforming Work**

a. **Class I Nonconforming Work** generally:

i. Are discovered prior to case completion
ii. Are foreseeable
iii. Have a clear-cut, immediate cause
iv. Have a defined remedial action, which shall be adequately documented in the case record or noted in the BEAST review routing.
v. Shall be corrected on the spot by the individual who discovers them or by the original analyst
vi. Do not compromise the overall quality of work if properly addressed
vii. Are not required to be documented on the Nonconforming Work Record spreadsheet
1. Examples: administrative or transcription error, failure to attach a quality control scan that was properly completed, failure to scan in administrative case documentation. NOTE: Some class I nonconforming work may be section specific and defined by the discipline TM.

Class I nonconforming work occurs as a part of casework. Remediation for such Class I nonconforming work shall be made on the spot by the individual. Remedial actions (corrections) shall be documented in the case record.

2. **Class II Nonconforming Work Raised by OSBI CSD Employee**

a. **Class II Nonconforming Work** generally:
i. Are discovered prior to case completion
ii. Are unexpected
iii. Have a clear-cut, immediate cause
iv. Do not compromise the overall quality of work if properly addressed
v. Are required to be documented on the nonconforming work record spreadsheet
1. Examples: contamination issues, non-systematic identification of a CSD employee by DNA / fingerprint, expired reagent used with controls functioning properly.

The individual who identifies any Class II nonconforming work shall inform the Supervisor and/or TM. Remedial actions (corrections) shall be documented in the case record, as applicable.

3. **Corrective Actions – Class III and IV Nonconforming Work**

a. **Class III Nonconforming Work** generally:
i. Are unexpected

ii. Require an inquiry to determine the cause(s)
iii. Require comprehensive action with documentation
iv. Require management involvement
v. May affect the quality of work, but are not serious enough to cause immediate concern for the overall quality of the OSBI CSD work product.
vi. Are required to be documented on the Nonconforming Work Record spreadsheet
3. Examples: missed identifications (failing to identify something present), false negatives, inconsistencies in proficiency test results.

b. **Class IV Nonconforming Work** generally:
i. Are unexpected
ii. Require an inquiry to determine their cause(s)
iii. Require comprehensive action with documentation
iv. Require management involvement
v. Raise immediate concern and may compromise the quality of the OSBI CSD work product
vi. Are required to be documented on the Nonconforming Work Record spreadsheet
1. Examples: erroneous identifications (identifying something not present) or systemic quality issues

4. The goals of this corrective action policy are to identify the cause(s) of a problem, correct nonconforming work, implement a solution to avoid recurrence, and to maintain the highest level of quality.

D. Response to Nonconforming Work

Once the level of nonconforming work has been identified, it will be handled as indicated below.

1. Class I nonconforming work are corrected on the spot and documented in the case record.
2. Class II nonconforming work will be addressed by following **QP 14.1**.
3. Class III nonconforming work will be addressed by following **QP 14.2**.
4. Class IV nonconforming work will be addressed by following **QP 14.3**.

Potential RISK (Significance)				
	HIGH	**Class IV**	**Class IV**	**Class IV**
	MEDIUM	**Class III**	**Class III**	**Class III or IV**
	LOW	**Class II**	**Class II or III**	**Class II or III**
		LOW	MEDIUM	HIGH
	FREQUENCY of Occurrence (Scope)			

III. Attachments

None

I. Scope (top ↑)

The following procedure will be used to address and document Class II nonconforming work - that is limited in scope and significance. This procedure will also be used to monitor Class II nonconforming work for any developing patterns which would require an elevated response.

II. Procedure

A. Evaluation of Acceptability

When notified of Class II nonconforming work that is believed to be limited in scope and significance, the Technical Manager (TM), or designee, will evaluate whether or not the work can be accepted with or without correction. Determining whether the nonconforming work is acceptable shall be based on whether or not results associated or impacted by the nonconforming work are reliable. The TM, or designee, will make one of three determinations:

1. The nonconforming work is **acceptable without correction**. For example, it was noted after analysis that expired reagents were used. However, based on an evaluation of controls, it is clear that the results are reliable and were not impacted by the use of expired reagents. In such an example, the TM, or designee, could accept the nonconforming work without any correction, so long as this approval is clearly documented in the case record.

2. The nonconforming work is **acceptable following correction**. For example, a required control is inadvertently not included with a batch of samples. However, there is more than enough sample remaining to repeat the test for all samples in the batch. The test is repeated and results are reported after verifying that all controls were included and performed as expected. This additional work shall be included in the case record.

3. The nonconforming work is **not acceptable and cannot be corrected**. For example, a required control is inadvertently omitted when testing a batch of samples. The batch included samples which were consumed during the initial test. In this case, the results are not reportable and for the consumption samples, there is no way to correct the nonconformance. In these circumstances, the TM will notify the Quality Manager (QM). The QM, in conjunction with CSD Director, will determine the level of the non-conforming work (Class III or Class IV).

B. Document Approval

The following steps will be taken to document approval of Class II nonconforming work and ensure that corrections are completed before work is accepted or reported.

1. The TM, or designee, shall document his/her evaluation and approval of the nonconforming work, including any correction taken, in an appropriate location. For example, if the

nonconforming work occurs in a case, the documentation of the evaluation and approval of the nonconforming work and correction should be in the case notes or in a narrative in the BEAST file. If the Class II nonconforming work occurs for the maintenance of equipment, recording the evaluation and approval in the applicable section of the equipment maintenance log would be appropriate.

2. If the Class II nonconforming work occurs in casework and is identified prior to a report being issued (i.e. during technical review), the TM, or designee, shall evaluate the nonconforming work and any proposed correction and **document his/her approval PRIOR to the technical review being approved and the report being issued**.

3. Each TM shall enter each Class II nonconforming work entry onto the appropriate tab of the Nonconforming Work Record spreadsheet that is maintained by the QM.

C. Tracking and Monitoring

1. Each TM shall review the appropriate tab of the nonconforming work record spreadsheet for his/her discipline periodically to determine if there is any indication of a pattern or trend that would warrant corrective action.

2. When Class II nonconforming work is routinely required under the same circumstances or for the same individual, the TM will be responsible for notifying the QM according to **QP 14.2**.

D. Delegation

1. TM's may delegate the authority for evaluating and approving Class II nonconforming work to unit Supervisors or other designees. However, each TM must ensure that each Class II nonconforming work is entered onto the Nonconforming Work Record spreadsheet and that a periodic evaluation of the Nonconforming Work Record spreadsheet is conducted to monitor for patterns or repetition that is spread among different units.

2. If a unit Supervisor or other designee is evaluating and approving nonconforming work on behalf of the TM, he/she shall notify the TM of the Class II nonconforming work concurrently with the evaluation and approval, so the instance can be documented as described above.

3. The TM may also use technical reviewers as designees. When technical reviewers serve as designees, approval of the technical review may be used to indicate approval of the Class II nonconforming work. TM's using technical reviewers as designees shall establish a mechanism for relevant corrections to be recorded as described above (such as a review of the routing history in the LIMS). The approval of the Class II nonconforming work by the

technical reviewer during the review should be clearly documented in the BEAST routing information.

E. Class II Nonconforming Work for TM's

In the event nonconforming work is encountered in work performed by a TM, the TM will notify the QM as specified in **QP 13**. The QM, or designee, will evaluate and approve the Class II nonconforming work in accordance with this policy and ensure that the approval is documented and documented/tracked appropriately.

III. Attachments

None

I. Scope (top ↑)

This procedure will be followed when nonconforming work or a departure from management system or technical procedures or policies has occurred, the quality of work is affected but is not serious enough to cause immediate concern for the overall quality of the OSBI CSD work product, and there is potential for recurrence if no corrective action is taken.

II. Procedure

A. Tracking Class III Nonconforming Work

The following procedure will be used to initiate and track Class III nonconforming work.

1. Upon notification of nonconforming work which may require corrective action, the Quality Manager (QM), in consultation with the CSD Director, will review the circumstances to ensure that the issue does require corrective action according to this procedure. The QM and CSD Director may determine upon review that the issue should be addressed as a Class II nonconforming work or as a Class IV nonconforming work. If the issue needs to be addressed as a Class II nonconforming work, the QM will ensure that the issue is handled in accordance with **QP 14.1**.

2. After completing the review, the QM, or designee, will initiate a Class III Nonconforming Work Record Form by completing Section I including assignment of a Class III nonconforming work tracking number, and document the Class III nonconforming work onto the Nonconforming Work Record tracking spreadsheet located at \\pm-fsc13000s\qa\Spreadsheets.

3. In the event that a CSD employee disagrees with the determination made by the QM and CSD Director regarding the class of corrective action required he/she shall notify the QM and CSD Director regarding his/her concern. The QM and CSD Director will discuss the specifics of the instance with the employee. The CSD Director has the final authority for deciding what class of corrective action is required.

4. The QM, or designee, will designate individuals to complete section II through Section V of the Class III and Class IV Nonconforming Work Record Form (OSBI CSD **QPA 14**)

   Upon completion of the assigned tasks in the sections of the Class III Nonconforming Work Record Form (OSBI CSD **QPA 14**), the individual(s) shall forward the form to the QM and CSD Director.

B. Cause Assessment

The process for developing a corrective action will start with a cause assessment. In addition, consideration should be taken to the amount of time that will be needed to conduct a cause assessment and complete the necessary corrective action plan(s). An evaluation should be made to determine whether work should be suspended, based on the time needed to resolve the issue, and the risk for additional nonconforming work. If suspension of work is necessary, the QM and CSD Director will communicate the suspension to the appropriate individual(s), including appropriate Supervisor(s), TM, and Criminalistics Administrator (CA) of the impacted area.

1. The individual assigned to complete Section II be responsible for an investigation to determine the cause(s) of the issue. Section II will include a description of the event(s) and description of area(s) impacted.

2. If the cause is not obvious, a systematic analysis of all potential causes will be conducted. The author of Section II will list actions taken to evaluate potential causes. In addition, any suggested suspension of work, need for customer notification, and need for amended reports will be included in Section II.

3. If necessary, the author may create a committee or conduct a unit/discipline meeting to gather additional input regarding potential causes.

C. Developing Corrective Actions for Class III Nonconforming Work

Once potential causes have been identified in Section II, potential corrective actions will be listed and evaluated to determine the corrective action(s) most likely to prevent a future occurrence of the same type of problem.

1. Section III will contain possible corrective actions identified by the author. If it is not clear how the corrective action would correct the cause, an explanation should be included.

2. After considering possible corrective actions, the author will select the corrective action(s) most likely to prevent a recurrence. The corrective action(s) must also be appropriate to the magnitude of the problem. The author will also designate individual(s) responsible for the corrective action(s) selected and set a timeframe for completion.

3. The author will also list or describe the mechanism(s) that will be used to monitor the implementation of the corrective action(s) to include timeframes for monitoring period(s).

D. Selecting and Implementing Corrective Actions for Class III Nonconforming Work

1. The cause analysis, proposed corrective action plan, including designees and timeframes, and monitoring mechanism will be reviewed and approved by the QM and CSD Director.

2. Once Section III is approved by the QM and CSD Director, the author shall implement the changes required as part of the corrective action. The author shall also be responsible for ensuring the completion of corrective action(s) occur within the timeframe provided in the corrective action plan. In the event circumstances arise which delay the completion of a corrective action, the author shall document the circumstances and adjust timeframes accordingly. For corrective action plans that require an extended period of time, a report on the progress shall be submitted to the QM and CSD Director every 15 days.

E. Monitoring Corrective Actions for Class III Nonconforming Work

The TM will monitor activities according to the method approved as part of the corrective action plan.

1. If the monitoring of the corrective action indicates that it is not/was not effective, the matter will be re-evaluated for a subsequent cause-analysis and/or selection of an alternate corrective action. The TM will document the additional cause analysis and/or selection of an alternate corrective action on an attachment to the original corrective action request form. If necessary, the QM may assign a different author to conduct a second cause analysis.

2. If the nature of the nonconforming work indicates a failure to comply with laboratory policies/procedures or applicable accreditation standards, the appropriate areas of activity will be audited as soon as possible. The audit may be conducted following the implementation of corrective action to further assess the effectiveness of the corrective action. The TM, or designee, of the impacted area will be responsible for coordinating and documenting this audit. He or she may request assistance from other audit trained Supervisors and analysts, TM's, CA's, or the QM.

F. Authorization to Resume Work

If work was suspended in conjunction with the corrective action request, the QM or CSD Director will be responsible for requesting authorization for work to resume. The TM or Supervisor will verify the corrective action plan has been completed and will indicate in the appropriate section of the form whether or not the resumption of work is approved.

G. Notification of Administration

CSD Administration shall be notified as indicated below.

1. The author of Section II-IV will place a copy of the corrective action request form in the appropriate folder on the QA server (\\pm-fsc13000s\qa\Lab-System_Records) at the steps in the process described below. In addition, it is recommended that the author send an e-mail to notify the appropriate individuals when an updated copy is available on the server.

   a) Once cause analysis, corrective action plan, and monitoring plan has been developed and approved.

   b) Once the corrective action plan has been completed and verified and authorization has been given to resume work, if applicable.

2. The QM, CA's, and CSD Director retain the authority to direct CSD employees to conduct and document additional cause analysis, monitoring, and corrective action, if necessary.

III. Attachments

OSBI CSD QPA 14, Rev00 Class III or Class IV Nonconforming Work Record Form
(Available in QMS Forms Folder)

I. Scope (top ↑)

The following procedure will be used to investigate and respond to nonconforming work that indicates that erroneous results may have been reported or issues that cause immediate concern and may compromise the quality of the OSBI CSD work product.

II. Procedure

When Class IV nonconforming work is identified, the following actions will be taken. It is imperative that the actions described happen as quickly as possible and that the documentation be forwarded as soon as is practical.

A. Completing and Routing Class IV Nonconforming Work Records

1. Any CSD employee who believes he/she has identified Class IV nonconforming work shall notify the Quality Manager (QM) and CSD Director. The QM will initiate a Class IV Nonconforming Work Record (OSBI CSD **QPA 14**) and instruct the appropriate individuals to complete the necessary sections of the Class III and Class IV Nonconforming Work Record Form (OSBI CSD **QPA 14**).

2. The following shall be considered when evaluating Class IV nonconforming work.

   a) Evaluate the **scope** of the nonconforming work.

      i. Determine and document whether the nonconforming work is limited to the case/event reported or if the nonconforming work may extend to other cases/work.

      ii. If the full scope of the nonconforming work is not immediately apparent, document what steps must be taken to identify all work potentially impacted, including who will be responsible for all steps and when the review will be completed.

   b) Evaluate the **significance** of the nonconforming work.

      i. Document how the nonconforming work impacted results, caused immediate concern or compromised the quality of the OSBI CSD. For example, were incorrect results reported or were results invalid due to the nonconforming work?

      ii. If the significance of the nonconforming work is not readily apparent, determine what steps must be taken to further investigate the matter and document the plan. Include in the plan who will be responsible and when the investigation should be completed.

c) Based on the scope and significance of the nonconforming work, take appropriate action and **document the actions taken** on the Class IV Nonconforming Work Record (OSBI CSD **QPA 14**). Appropriate actions may include, but are not limited to halting casework/finalization of reports, review of and correction to any relevant casework, issuing amended reports, remedial training, revision of policies, procedures, forms, and/or inclusion of additional quality measures.

i. Have erroneous or invalid results been reported? If so, recall work or issue amended reports and contact the customer to explain the nonconforming work, as appropriate.

NOTE: In some circumstances, notification and recall of work may be performed on a case by case basis. However, in other circumstances, it may be necessary to ensure information regarding nonconforming work is communicated more broadly to the entire criminal justice system. When it is necessary to conduct broad notifications, communication may be assisted by contacting various professional organizations, such as the District Attorney's Council (DAC), the Oklahoma Indigent Defense System (OIDS), the Oklahoma Criminal Defense Lawyers Association (OCDLA), or the Oklahoma Bar Association.

ii. Is there a need to suspend work activities? Suspension of work may pertain to an individual analyst, a particular method, etc. Any suspension of work must be clearly communicated to the employees affected and should be limited to the work activities impacted.

iii. What corrective action is required? Corrective action will be required for nonconforming work which meets one or more of the following criteria:

a. The scope of the nonconforming work is broad and impacts work conducted by multiple analysts and/or over a range of time.

b. The significance of the nonconforming work is serious. Incorrect or invalid results were reported.

c. The problem is likely to recur without corrective action.

d. There is doubt regarding whether OSBI CSD operations comply with agency and/or CSD policies and procedures.

e. The nonconforming work has been previously reported, regardless of scope or significance.

d) Determine the most appropriate method for remediation of the nonconforming work.

i. Document the method for remediation in the appropriate location on the nonconforming work report.

e) Conduct a cause assessment and develop a corrective action plan as described in **QP 14.2**.

B. Review of Class IV Nonconforming Work Records

Once the Class IV Nonconforming Work Record has been completed through section IV (or V, if applicable), the report will be forwarded to the QM and CSD Director. The QM or CSD Director will take the steps indicated to review and approve the report.

1. Evaluation and documentation whether the steps taken and the proposed remediation are acceptable. The QM in consultation with the CSD Director, shall also determine whether the nonconformance must be reported to ANAB immediately in accordance with the current ANAB Accreditation Manual.

2. If further action is needed, the QM or CSD Director will provide instruction for what additional steps must be taken and return the report back to the appropriate individual.

3. Once the Class IV Nonconforming Work Record has been approved, it will be routed to the appropriate Technical Manager (TM), or designee, for implementation of the remediation, if applicable. The TM, or designee, will be responsible for documenting the completion of the remediation, and maintaining a record of the Class IV Nonconforming Work Record.

C. Resuming Work

If work was suspended during the evaluation of the nonconforming results, the decision to resume work will be made by the QM or CSD Director in consultation with the appropriate Criminalistics Administrator (CA), Supervisor(s) and TM. Authorization to resume work will be documented at the bottom of the Class IV Nonconforming Work Record.

NOTE: For the Forensic Biology discipline, the decision to resume work will be made by the Technical Manager.

D. Notification of Administration

CSD Administration shall be notified as indicated below.

1. A copy of the Class IV Nonconforming Work Record will be placed in the appropriate folder on the QA server (\\pm-fsc13000s\qa\Lab-System_Records) at steps in the process described below. An e-mail should also be sent notifying the appropriate CA, QM, and CSD Director that an updated copy of the report has been placed on the server.

   a) Once sections I through III have been completed.

   b) Once sections IV and V (if applicable) have been completed.

2. The CA's, QM, and CSD Director retain the authority to direct CSD employees to take additional action and/or document additional information, if necessary.

III. Attachments

OSBI CSD QPA 14, Rev00 Class III or Class IV Nonconforming Work Record Form
(Available in QMS Forms Folder)

I. Scope (top ↑)

All CSD employees are responsible for monitoring work flow, technical procedures, and management system practices for potential improvements and/or potential sources of nonconformities. CSD employees will follow this procedure for documenting, routing, implementing, and monitoring preventive actions **which are not already covered under another procedure**. Preventive actions which can be adequately addressed by a change to policy or procedure will be requested and documented in accordance with **QP 3**.

II. Procedure

A. Recommending Preventive Actions

1. Any CSD employee who identifies a potential source for nonconforming work or improvement to the CSD technical operations or management system must submit a suggestion in writing through his/her supervisory chain. The written suggestion (which may be in memo or e-mail format) must include the following elements:

   a) A description of the problem or opportunity for improvement,

   b) An explanation of any potential for nonconforming work,

   c) A proposed action plan or description of the steps necessary to implement the suggestion, and

   d) A proposed control mechanism for monitoring the effectiveness of the suggested change.

2. Any CSD employee who receives a suggestion for improvement or preventive action from a customer shall forward the information according to section II.A.1 above.

B. Review and Approval of Preventive Actions

1. Preventive actions will be reviewed and approved at the lowest management level appropriate to the suggested change. For example:

   a) Proposed changes to work flow processes impacting a single unit should be reviewed and approved or disapproved by the Unit Supervisor.

   b) Proposed changes to technical procedures should be reviewed by any impacted Supervisors and the appropriate Technical Manager, but approved or disapproved by the Technical Manager.

c) Proposed changes to case acceptance policies or other changes which may impact customer service or satisfaction should be routed to and approved or disapproved by the CSD Director.

2. Individuals reviewing and/or approving suggested preventive actions should research further or make modifications to the suggestion as necessary to ensure that it complies with section II.A.1 above.

C. Implementation and Documentation of Preventive Actions

1. The individual approving a preventive action will be responsible for directing the implementation of the plan and monitoring the implementation and effectiveness of the plan. Alternately, the approving individual can designate one or more individuals to implement and monitor the plan.

2. Supervisors will be responsible for maintaining documentation of preventive actions that are proposed. Supervisors will also be responsible for reporting on the status of preventive actions in accordance with **QP 18**.

3. Individuals who review and/or approve preventive actions should ensure that the status of the review, approval, and implementation is communicated to affected employees in a timely fashion.

III. Attachments

None

I. Scope (top ↑)

This procedure will be used for quality and technical records to ensure that they are readily identifiable and retrievable, protected from damage, and kept confidential.

II. Procedure

A. Identification of Records

Quality and technical records, whether hard copy or electronic, will be identified in the following manner:

1. Case files are identified by the laboratory case number. The case file may be further identified by the unit or discipline, when necessary.

2. Technical records which are not stored in the case file, such as quality control records associated with batched cases, will be identified in a manner that facilitates associating the data with the proper case(s). For example, quality control results could be identified by an instrument name or number and date/time of the run.

3. Quality records should be identified with sufficient detail to facilitate proper filing and storage.

B. Indexing/Filing Records

Technical and quality records will be indexed and filed according to the record identification.

1. Case files will be stored numerically according to the case number.

2. Quality records will be indexed according to subject, location, and/or date.

C. Collection and Storage of Records

Hard copy technical and quality records will be stored in designated areas with appropriately controlled access.

1. Unassigned case files pending analysis will be stored in a secure location designated by the Supervisor.

2. Case files and technical records for cases in the process of examination will be stored in the analyst's work area or other appropriate and designated location.

3. Completed case files will be stored in a file room or other designated secure area of the appropriate CSD facility until they are archived.
4. Technical records such as quality control results, reagent logs, etc., will be stored in an orderly fashion in (a) location(s) determined by the Technical Manager, or designee.

5. Quality records will be stored as directed by the Quality Manager (QM).

D. Access of Records

1. Access to quality and technical records will be limited to those CSD employees that require access to conduct analysis and assist customers. This includes management, analysts, and physical evidence and analytical technicians.

2. Other CSD employees, practicum students, contractors, and visitors will be restricted from accessing technical and quality records according to **QP 20**.

3. Access will be limited by restricting access to the physical storage location (e.g. file room).

4. Access to electronic records will be further restricted by issuing user names and passwords and setting appropriate permissions.

E. Maintenance of Records

1. Technical and quality records may be maintained in hard copy or electronic format.

2. When case files are maintained in an electronic format and no hard copy file is created, the BEAST barcode which is automatically generated to track the hard copy file will be scanned to the location code "electronic case file."

3. Technical records will be maintained in accordance with current administrative rules which can be found at www.oar.state.ok.us. Administrative rules governing the OSBI are located in Title 375 and section 8 of that title covers record retention.

4. Quality records will be maintained for a minimum of one accreditation cycle or five years, whichever is longer.

5. Management system documents will be maintained indefinitely.

   Original records will not be removed from OSBI CSD facilities, with the following exceptions.

   a) Case files may be removed for the purpose of referencing during courtroom testimony or meetings with attorneys or officers.

b) Case files or other technical records will only be removed from OSBI laboratory facilities for regular business purposes such as transfer of cases, court, conferences with court officials or investigators, or with permission of the Unit Supervisor or Criminalistics Administrator over the unit.

c) Quality records may be removed from OSBI CSD facilities only at the permission of the QM.

6. Removal of completed hard copy case files will be documented by scanning the case file barcode or by inserting a piece of card or paper, labeled with the case number, examiner's initials and date of removal, in the specific location from which the file was removed.

F. Disposal of Records

1. Hard copy records may be disposed of once converted to an electronic format for archiving and the electronic copy has been verified as complete.

2. With the exception of drug and toxicology records, technical records will be retained in either hard copy or electronic format, indefinitely. Drug and toxicology technical records will be maintained in hard copy or electronic format for a minimum of six years. After six years, the documents listed below may be disposed of and not retained in either hard copy or electronic format.

   a) any subpoenas that have been placed in the file

   b) officer reports and information, with the exception of the officer affidavit and consent to test blood for toxicology cases

   c) any duplicate documents

3. When disposing of quality and/or technical records, the documents will be shredded or otherwise disposed of in a manner that ensures the confidentiality of the information within the documents is protected.

G. Electronic Storage of Records

Electronic records will be stored utilizing the BEAST Laboratory Information Management System (LIMS), the LaserFische system, or on a network server.

1. Documents stored in the BEAST will be protected in the following manner:

   a) Access to the documents will be limited through the use of a user name and password with appropriate permissions specified.

b) Alterations to completed documents will be tracked through the system's audit log.

c) Information in the system will be replicated between servers at different OSBI facilities and backed up on a regular basis.

2. Documents stored on a network server will be protected in the following manner:

a) Access to the folder(s) will be limited to the appropriate individuals through permission settings.

b) Files will be backed up on a regular schedule.

c) Records stored in this fashion will be saved as pdf files or another file format which prevents unintended and/or unauthorized alteration.

III. Attachments

None

I. Scope (top ↑)

This procedure details the administrative and technical documentation which must be maintained for all forensic analyses performed.

II. Procedure

A. Documentation Required for Case Records

The following documentation is considered a record of analysis performed and shall be maintained in the case record. If a discipline does not maintain all related technical and administrative documentation in the test record, the discipline quality manual or protocols shall specify what technical and administrative records will be maintained in the test record.

1. Administrative Records

   a) submission information

   b) evidence inventory

   c) all case related conversations and communications (see below)

   d) copies of reports

   e) documentation of administrative and technical review

2. Technical Records

   a) Technical records include notes concerning the analysis of evidence, scans, chromatographs, and all other documents produced and used to derive conclusions in the analysis of the case. The following details must be included in the examination documentation or another appropriately specified location in the case record:

      i. The method used for analysis;

      ii. The condition of the item, as it was received;

      iii. If applicable, a reference to the sampling plan used for analysis and date and location of sampling;

      iv. The date(s) that analysis was conducted or the start and end dates of analysis, at a minimum. The discipline quality manual or protocols must define how this

requirement is met (e.g. where start and stop dates of analysis are documented in the technical records).

b) Technical records must be sufficient to establish an audit trail and identify relevant documentation (calibration records, staff records, etc.).

c) At a minimum, the technical records maintained in the test record must be sufficient to support the reported results, conclusions, interpretations, or opinions. However, each discipline should define in the discipline quality manual or protocols what documentation is required to support conclusions and what happens to any additional documentation or data. The procedure should clearly define the following factors:

i. Whether raw instrument data is retained in addition to analyzed or derived data

ii. If documentation is retained for data not used for interpretation such as an initial scan that was rejected (e.g. sample required further concentration or dilution, controls were not acceptable, etc.)

iii. Location of any additional retained data or documentation

iv. Procedure for protecting any additional retained data or documentation that is not kept in the case record (e.g. method for limiting access, method for back up, retention time, etc.)

d) When test results, data, or observations are rejected, the reason, the identity of the individual, and the date shall be recorded in the test record.

e) Technical records will include information identifying factors affecting uncertainty of measurement, where possible. This includes the identity of instruments used, personnel conducting each step of analysis, software used, etc.

f) Observations, data, and calculations will be recorded and appropriately identified at the time they are made.

3. Supporting Technical Documentation

a) Quality control results, including standards, ladders, calibrators, and positive and negative controls are considered technical documentation/records.

b) Supporting technical documentation may be stored in the case file or in an appropriate alternate location.

4. Case Related Communications

   a) All case related communications for existing CSD cases, including in person meetings, phone calls, and e-mails shall be recorded in the Narrative section of the BEAST case file. Communications which are recorded in the case notes or routing comments in accordance with another policy or procedure do not need to be duplicated in the Narrative section.

   b) A statement may be placed at the bottom of out-going case related e-mails to notify the recipient that the e-mail and any response will be saved as part of the case record.

   c) A link to the customer service survey may also be placed at the bottom of outgoing e-mails. (https://osbi.ok.gov/sites/g/files/gmc476/f/documents/survey_-_customer_service_02-20-19_1.pd_.pdf)

B. Guidelines for BEAST Case Files

1. All administrative documentation should be maintained in the BEAST case file.

2. Any technical record which can be readily documented electronically should be maintained within the BEAST.

3. When mistakes occur in technical records, they shall be corrected in a manner that ensures the original data or information is not lost and the identity of the individual making the correction is recorded. This may be accomplished using the equivalent of a single line strike-through and initials of the person making the correction, the routing function (for mistakes caught during administrative or technical review in accordance with **QP 31**), case narratives/events, or an alternate method described in a discipline-specific policy or procedure. Regardless of the method used, analysts must ensure that the correction is made in a manner that preserves the original data and identifies who made the change.

4. Similarly, all changes made to technical records as a result of technical review or verification shall be recorded in the test record.

5. Technical records which are generated in an electronic format and stored in the BEAST do not require page numbers. When multiple pages of technical records are prepared in hard copy format and then scanned into the BEAST, the pages shall be numbered prior to scanning.

6. When **manually** saving electronic documents to the image vault in the BEAST, each file shall be given a unique description which includes the case number. In the event that documentation from one CSD file needs to be added to a separate CSD file, both case numbers should be included in the description.

C. Guidelines for Hard Copy Case Files

1. Any administrative or technical records which are required to be retained but are not readily incorporated into the BEAST case file should be maintained in the hard copy case file. For example, documentation received in hard copy format (faxes, instrument printouts) must be maintained in the hard copy file if they are not imaged into the BEAST case file.

2. No evidence items should be stored in the Criminalistics case file, with the exception of latent lifts, photos, and/or negatives. Latent lifts will be placed into a sealed manila envelope that is clearly marked with case number, examiner's initials, barcode, and date. The items may then be placed into the case file, providing the case files are located in a secure evidence storage location.

3. All notes, forms, and documents generated by OSBI personnel (with the exception of latent evidence) shall be utilized on one side only. No two-sided forms or yellow sticky notes will be used.

D. Maintenance of Hard Copy Case File Documentation

1. All paperwork in the case file will be clearly identified with the Criminalistics' case number and handwritten initials.

2. Additionally, all Criminalist generated paperwork will be clearly identified with the examiner's initials, date, and item numbers if applicable. In some circumstances it may be acceptable for the date not to be printed on each page, provided the date the work was generated can be determined through other documentation in the file.

3. Notes generated by analysts shall be sequentially numbered for each assignment completed. When analysts conduct analysis at a later time on a separate assignment, the subsequent notes may be sequentially numbered (starting with page 1) or added to the sequence of notes already in the file. The first page of notes will be labeled to indicate the total number of pages in the set. (e.g. 1 of 5)

4. The case file will be orderly, complete, and concise, thus facilitating administrative and technical review. Notes will be neat, readable, and written in ink. Notes may be typed.

5. Any corrections to notes will be made by an initialed single strikeout. Nothing in the handwritten information should be obliterated or erased and additions to notes (interlineations) must be initialed by the person making the entry.

6. It will be the responsibility of the examining Criminalist to ensure the contents of the case file are in compliance with the above sections.

7. It will be the responsibility of the Unit Supervisor to oversee case work and case files completed by their unit to ensure they are in compliance with all existing policies and analytical protocols.

E. Documenting Limited Samples

All evidence received of insufficient quantity to allow a representative sample after testing should be documented in the following manner. This section does not apply to reference samples, such as DNA buccal swabs, which can be recollected if necessary.

1. The District Attorney involved in the case will be advised by the examining Criminalist prior to limited quantity samples being analyzed and consumed. A letter from the appropriate prosecuting attorney authorizing the consumption of those samples will be placed into the case record. This requirement shall not apply to property crime cases without a suspect listed on the RFLE.

2. The evidence will be photographed. A ruler or size standard will be included in the photograph, if possible.

3. Photographic documentation will be made as necessary according to the appropriate discipline protocol.

4. Every reasonable attempt will be made to comply with any special request regarding the analysis of limited quantity evidence. Any special requests should be documented in an appropriate fashion (memo, e-mail, narrative, etc.) in the case record. The CSD Director should be notified of any special requests.

III. Attachments

None

I. Scope (top ↑)

Internal audits of the OSBI CSD facilities and functions will be conducted according to this procedure.

II. Procedure

A. Scheduling Audits

1. The OSBI CSD will conduct internal audits annually for each of the following facilities:

   a) Forensic Science Center (FSC)

   b) Northeast Regional Laboratory

   c) Northwest Regional Laboratory

   d) Eastern Regional Laboratory

   e) Southwest Regional Facility

   f) ATTDFL (DEU)

2. If necessary, audits of facilities may be further sub-divided into specific units/functions, provided all units of each facility are audited annually.

3. A schedule of audits including the Unit/Program and audit dates for the following calendar year will be issued by the Quality Manager (QM) during the fourth quarter of each calendar year.

4. Audit schedules may be adjusted depending on conflicts with auditors or lab staff. All changes must be requested through the appropriate Criminalistics Administrator (CA) and approved by the QM.

B. Conducting Audits

1. Prior to the audit, the QM, or designee, will assemble an audit team.

   a) The audit team at a minimum will consist of a lead auditor (normally the QM or designee) and other auditors responsible for specific areas or disciplines as assigned by the lead auditor.

   b) Each auditor shall have training in the audit process. Training may be provided by an

approved external source or conducted by the QM or designee.

c) Additional interagency or outside personnel may be requested to help in the audit process. These individuals will be included on the audit team at the approval of the CSD Director.

2. Once the audit team has been identified, the QM, or designee, will prepare a checklist of assignments indicating which criteria each individual will assess based on the defined scope of the audit. The defined scope of the audit (Audit Plan) will be retained on the Quality Server. Each audit shall include direct observation of a sampling of the testing performed within each discipline of the lab/unit audited.

3. At the scheduled time of the audit, the audit team will assemble at the designated location. An opening meeting may be conducted if appropriate. Each auditor will review the appropriate documentation and/or conduct interviews in order to determine whether the work/operations conform(s) to the standard and applicable policies and procedures. During the review, the auditors will be clear on the documents/activities they wish to see and will write clear and concise descriptions/non-conformances/positive findings, as applicable.

4. After completing the review and/or interviews, each auditor will report to the lead auditor and provide a summary of what was reviewed. In addition, each auditor will list or describe the objective evidence observed for any findings or non-conformances.

5. An exit meeting will be conducted to inform the Supervisor(s), TM(s), appropriate Criminalistics Administrator, and/or laboratory director of the results of the audit.

6. The QM, or designee, will compile the information provided by auditors into an audit report. The audit report will be in the appropriate format as indicated below.

a) All OSBI CSD audits will be reported referencing the most current accreditation standards. Findings will be reported in the following manner:

i. Issues which are on the level of a Class I or Class II nonconforming work, recommendations, and observations will be summarized in memo format.

ii. Findings which require corrective action will be reported on the nonconforming work record (Class III or Class IV) forms (OSBI CSD **QPA 14**).

iii. Findings which bring into question the reliability of reported results and require a consideration of work suspension and recall of reports will be addressed through the Class IV nonconforming work procedure (**QP 14.3**).

b) For OSBI CSD facilities conducting DNA analysis, an audit report will also be completed

using the most current applicable version of the Quality Assurance Standards audit document. At the discretion of the QM and DNA Technical Manager, the QAS audit document does not need to be completed if an external QAS audit has been or will be conducted in the same year.

7. The audit report(s) should be completed and provided to the appropriate Supervisor(s), TM(s), appropriate Criminalistics Administrator, and/or CSD Director within 2 weeks of the audit.

8. Within 30 days of receipt of the audit report, the appropriate Supervisor(s), TM(s), and/or CSD Director will send a response to the QM. Responses to any Class III corrective action will be documented according to **QP 14.2**. A response will also be required to address any minor issues or recommendations as indicated in the audit memo. This response should address what corrections and/or preventive measures have been taken and why.

9. If the cause and corrective action cannot be completed within 30 days, the response will include a plan for completing these steps and (a) projected completion date(s).

10. The QM, or designee, will monitor the progress of corrective action plans submitted until all corrections and corrective actions are completed.

11. When necessary, the customer will be informed of nonconforming work and work will be recalled. The QM and each discipline Technical Manager, or designee, will monitor nonconformances and effectiveness of corrective actions arising from audits to ensure that customer notifications and work recalls are conducted in an appropriate and timely fashion.

C. Notifying NDIS

Each year, the Biology Technical Manager, CODIS Administrator, or designee, will prepare appropriate documentation of internal audits and external assessments as required by the current NDIS Procedures. Biology and CODIS Supervisors will prepare responses to internal and external DNA audit findings and forward them through the Biology Technical Manager to the Quality Manager. The Technical Manager, with assistance from the CODIS Administrator if needed, will forward a copy of external assessment/audit reports to the NDIS Custodian in the manner and timeframe required by NDIS Procedures.

III. Attachments

None

I. Scope (top ↑)

The following procedure will be used to conduct management reviews. A list of topics covered by management reviews is included in section 8.9 of the Quality Manual.

II. Procedure

A. Committee Structure

The following committees are established for the purpose of conducting management reviews:

1. The primary committee for conducting management review is the Quality Improvement Committee (QIC).

   a) All CSD Supervisors, Technical Managers, and the administrative staff will serve as members of QIC.

   b) The Quality Manager (QM), or designee, will chair QIC.

2. The following subcommittees may also be established for the purpose of assisting the management review process as needed. The QM may assign tasks to sub-committees to facilitate the management review process.

   a) Chemistry Subcommittee

      i. CSD Supervisors and Technical Managers (TM's) that have been or will be trained in controlled substances, trace, or toxicology analysis will serve as members of the Chemistry subcommittee.

      ii. The Controlled Substances and Toxicology TM's, or designees, will co-chair the Chemistry Subcommittee.

   b) Biology Subcommittee

      i. The Forensic Biology TM and any CSD Supervisor that has been or will be trained in forensic biology casework or database analysis will serve as members of the Biology subcommittee.

      ii. The Forensic Biology TM, or designee, will chair the Biology Subcommittee.

   c) Identification Subcommittee

i. The Latent Evidence TM and any CSD Supervisors and Criminalistics Administrators that have been or will be trained in the disciplines of Firearms, Digital Evidence, and Latent Evidence will serve as members of the Identification Subcommittee.

ii. The TM of the Latent Evidence Discipline, or designee, will chair the subcommittee.

d) Evidence Subcommittee

i. The Evidence APO, FSC Forensic Biology Unit Supervisor, Specialized Forensic Biology Unit Supervisor, FSC Forensic Chemistry Unit Supervisor, and Latent Evidence Supervisor will be regular members of the Evidence Subcommittee.

ii. The Evidence APO, or designee, will chair the subcommittee.

iii. The Evidence APO can select additional members for the Evidence Subcommittee (e.g. Toxicology, Firearms, and Regional Lab representatives) as needed.

iv. The Evidence Subcommittee will routinely review the suitability of the Evidence Collection Manual and applicable evidence acceptance and tracking policies and provide feedback for revision of these documents as needed.

3. Subcommittees may solicit assistance from other qualified analysts as necessary to complete tasks assigned to them. Subcommittee chairs are responsible for avoiding conflicts of interest when completing tasks assigned to the subcommittee. For example, chairs should ensure that subcommittee members do not review their own proficiency tests.

B. Meeting Schedules and Agendas

1. QIC will meet at least quarterly.

2. QIC schedules and agendas will be coordinated by the QM.

3. Subcommittees will meet as needed.

4. Subcommittee meeting times and agendas will be coordinated by the subcommittee chairperson(s).

5. The QM will be notified of subcommittee meeting times and may attend at his/her discretion.

C. Documenting Management Reviews

All aspects of the OSBI CSD Management System will be reviewed at least annually according to the schedule and procedure listed below.

1. Lab management will initiate the management review process through the completion of quarterly, calendar year (CY), and fiscal year (FY) reports. Supervisors, Technical Managers, Lab Administrators, Grant Program Managers, the Research Committee Chair, and designees will complete the applicable sections of the applicable quarterly report template (OSBI CSD **QPA 18.1, QPA 18.2, QPA 18.3, and QPA 18.4**).

2. During the first quarter of each calendar year, Supervisors will ensure that each analyst or technician reviews his/her most current authorization to work (ATW). During the review, employees shall verify that there is no discrepancy between the types of work authorized, the types of proficiency tests assigned and completed, and the types of work the employee has performed or testified about over the past year. In the event potential discrepancies are identified, the employee shall inform his/her Supervisor. The Supervisor shall:

   a) Notify the Technical Manager if the analyst may have performed work which is not included on the ATW or which the analyst may not have completed a proficiency test for within the last year. These types of discrepancies will be further evaluated in accordance with **QP 13**.

   b) Make any appropriate recommendations to the Technical Manager for updating the ATW. For example, if an employee has not conducted a specific type of testing for an extended period of time, it may be appropriate to rescind that particular authorization. Similarly, if an analyst has transferred from one discipline or unit to another and no longer completes proficiency tests for the original discipline/unit then the ATW for that discipline should be rescinded or updated as appropriate.

   c) Provide a summary of the review of ATW's in the management review report. The summary should clearly document that all analysts/technicians have completed the review and list any discrepancies noted and the actions taken (or being taken) to address them.

3. The following topics will be reviewed according to the schedule indicated. The quarters listed correspond to the calendar year quarter when the activity will be conducted. Discussion and documentation of the review of the activity will be conducted and reported in the following quarter. For example, all Supervisors will review the Guiding Principles with their staff during the first quarter of the calendar year (January to March). Supervisors will report the status of this activity in the first quarterly report that is conducted shortly after the end of the quarter.

   a. Review of **Guiding Principles** - first quarter;

b. Review of **Authorizations to Work** – first quarter;

c. An evaluation of **laboratory objective(s)**, indicating whether they are still appropriate for the unit and/or lab, whether the objective(s) was/were met during the last fiscal year and an explanation of any circumstances which contributed to the lab/unit's ability or inability to meet the stated objective(s)– second quarter;

d. The status of **annual policy/procedure/training manual review**, including whether or not the policies and procedures are deemed suitable – third quarter;

e. A review of any **reports** made by the Supervisor or managerial staff during the year, which might include changes in **internal and external issues** relevant to the laboratory such as legislative changes that have impacted the unit/lab, staffing levels, etc. – fourth quarter;

f. Update on **status of any actions arising from previous management reviews** – each quarter;

g. A review of the outcome of **internal audits, property room inventories, and safety audits**, including the status of any corrective action that was required – each quarter;

h. A review of **corrective and preventive actions** submitted or performed by the unit/lab during the reporting period and the current status of those actions – each quarter;

i. A review of any **external assessments** conducted during the reporting period, including the status of any necessary corrective actions – fourth quarter;

j. A review of the results of any inter-laboratory comparisons or **proficiency tests** completed during the reporting period – each quarter;

k. An evaluation of the volume and type of **work submitted and performed** by the unit/lab that highlights any changes during the reporting period – each quarter;

l. A review of any **customer feedback** received during the reporting period – each quarter;

m. A review of any **complaints** received during the reporting period including the status of any improvements implemented as a result of the complaint(s) – each quarter;

n. A review of the status of the **effectiveness of any previously implemented improvements** – each quarter;

o. Any recommendations for **improvement** – each quarter;

p. A review of the **adequacy of resources** - each quarter;

q. Results of any **risk identification** – each quarter;

r. Any other **relevant factors** (which might include **outcomes of the assurance of the validity of results**, quality control activities, resources, and staff training) – each quarter.

4. All sections of the report will be completed by the deadline specified by the CSD Director.

5. Following the completion of the quarterly reports, a full QIC meeting will be held.

6. Each QIC agenda will consist of the following items, at a minimum:

   a. Reports on past action items;

   b. Discussion points selected by the QM based on the quarterly, CY or FY reports, if needed;

   c. Summary of new action items identified;

   d. Ethics presentation/discussion.

7. During QIC discussion, items which require action will be noted. Whenever practical, each action item should be assigned to an individual who is responsible for ensuring the item is completed by a documented deadline.

III. Attachments

OSBI CSD QPA 18.1, Rev01 1st Quarter Management System Review
OSBI CSD QPA 18.2, Rev01 2nd Quarter Management System Review
OSBI CSD QPA 18.3, Rev01 3rd Quarter Management System Review
OSBI CSD QPA 18.4, Rev01 4th Quarter Management System Review
(Available in QMS Forms Folder)

I. Scope (top ↑)

OSBI CSD employees will be properly trained and qualified prior to performing independent or unsupervised testing, evidence collection or handling, or testing support activities. This policy shall be used to develop and maintain written training programs which ensure all technical staff (analysts, evidence technicians, and technical support staff) have the appropriate training and skills to competently perform their assigned tasks.

II. Procedure

A. Training Program Structure

1. New Employee Training Manual
   a) New employees will undergo training from the New Employee Training Manual in addition to discipline-specific training outlined below. The New Employee Training Manual is designed to give introductory information including general knowledge of forensic science, the application of ethical practices in forensic science, introduction to criminal and civil law procedures, an overview of the quality system (to include a meeting with the CSD Director and Quality Manager), and general safety topics to each new employee.

2. Each discipline will have a written training program as outlined below.

   a) Each discipline's training manual/program to the extent necessary based on the job function, for each function influencing the results of testing activities, must include the following discipline-specific sections:

      i. Application of ethical practices in forensic sciences/discipline;

      ii. Applicable criminal and civil law and procedures to the discipline;

      iii. Aspects of quality system specific to the discipline;

      iv. Applicable Safety Topics (bloodborne pathogens, chemical hygiene, etc.);

      v. Discipline-specific topics;

      vi. presentation of evidence in court (testimony), when applicable;

      vii. Provisions for re-training;

      viii. Provisions for maintenance of skills and expertise specific to the discipline; and

ix. Criteria for acceptable performance for qualification/authorization

3. Training manuals shall define the knowledge, skills, and abilities needed to perform work.

4. Each section of the training manual/program will include a list of goals which must be met for the trainee to have the skills necessary to complete the duties listed in the trainee's job description.

5. Each section of the training program will also establish the tasks or activities that will be completed by the trainee in order to meet the stated goal.

6. Successful completion of training programs for testing or for evidence collection will be assessed through the use of competency tests as indicated below. Evidence collection includes any tasks which create items for testing (test firing ammunition, photographing prints, collection of trace evidence, swabbing stains for serology/DNA testing, etc.). Training programs for evidence receiving personnel and laboratory support personnel who do not perform testing or evidence collection tasks should define the method for assessment and criteria for acceptable performance.

7. The training program should be reviewed annually. The Quality Manager (for new employee training manual), discipline Technical Manager (TM) (for discipline-specific training manuals) and the CSD Director must approve any changes.

B. Conducting Training

1. The TM will be responsible for the assignment of training for any new employee assigned to that discipline.

2. Prior to training any individual, an assessment should be done to identify his/her specific training needs. This assessment may include a review of his/her education, experience, and/or a quiz or other competency evaluation to assess his/her knowledge/skill level.

3. Based on the results of the assessment, the training program can be modified according to the knowledge, skills, and abilities of the trainee.

4. OSBI Criminalists competent in the assigned discipline may act as trainers, at the request of the TM.

5. New training goals will not be assigned until both the trainer and trainee are satisfied that current goals are understood.

C. Documenting Training

1. Training Records

The CSD administration will maintain training records for each CSD employee. This includes information concerning the job description, education, training, and continuing education of the employee. Individual training records will be stored in the appropriate folder located at \\Pm-fsc13000s\qa\Individual_Records. Each CSD employee is responsible for placing a copy of the following documents in his/her folder:

a) all transcripts indicating any degrees conferred

b) certificates or agendas for continuing education/professional development classes attended

c) updated transcripts when additional courses are completed

d) all memos approving individuals to perform work

2. Supervisory Training File

The Supervisor or appropriate TM will be responsible for maintaining a file for each trainee which includes:

a) A copy of a completed checklist of the knowledge and skills for each trainee. Alternately, the Supervisor or TM can instruct the trainee to maintain the checklist in his/her training notebook or records.

b) Copies of all evaluation tools used (written tests, sample lists, etc.).

c) The expected and reported results for any/all competency test(s).

3. Monthly Training Updates/Memos

The progress of each trainee will be documented in the form of a monthly update stating what training was completed during the previous month. The trainer will provide the monthly update to the Technical Manager.

a) The Technical Manager will provide a copy of the monthly training update to the trainee, Supervisor, and appropriate CA.

b) The monthly update is in addition to any documentation or evaluation required by OSBI Human Resources.

c) The update should be submitted to the appropriate individuals by the 5th working day of the month.

D. Competency Tests

1. Regardless of education, qualifications, or past experience, all personnel shall successfully complete a competency test(s) prior to performing testing or tasks that create items that could be used for testing.

2. In order to successfully complete a competency test, the analyst must achieve the intended results. Any discrepancies must be reviewed and re-training conducted as necessary to achieve the expected results, prior to the test being accepted as satisfactory.
3. The minimum components and objectives of a competency test are as follows:

a) Analysis of an adequate number of unknown samples:

Unknown samples should be prepared and assigned under the direction of the TM. The samples should encompass the range of samples which the employee will be expected to test upon successful completion of the test. The number of samples should be sufficient to evaluate an employee's ability to select and perform proper testing methods in accordance with laboratory policy.

b) Written report (if applicable):

Results of competency tests should be reported in the same fashion as casework or database analysis. The report should then be reviewed to evaluate the employee's ability to accurately and clearly convey testing results and the significance of the results.

c) Providing Testimony (if applicable):

Each employee must also demonstrate an adequate knowledge of the area being tested through the completion of a written and/or oral examination. This portion of the competency test should include a mock trial, when appropriate. Prior to the assignment of a written and/or oral examination, the TM, or designee, should identify the knowledge necessary to perform testing (e.g. specific technical knowledge necessary to perform testing, conduct trouble-shooting, etc. and/or specific knowledge and ability to convey the knowledge clearly to lay-people), develop questions to assess the knowledge level of the individual, prepare a scoring mechanism and/or key, and set the minimum score that will be accepted as passing.

4. The trainee must successfully complete all applicable phases of the competency test before being released to perform independent testing.

5. Upon the successful completion of a competency test, an Authorization to Work (ATW) memo shall be issued or updated by the TM to reflect the release to begin work.

E. Competency Evaluations

On some occasions, additional evaluations of competency are needed after a competency test has been given. This may be due to the training of qualified analysts in a new method, instrument, or other significant modification to protocol, or after re-training of analysts as described in section II.F. Competency evaluations must be tailored to ensure that the training was effective in providing the necessary skills and knowledge base to the analyst.

1. The TM, or designee, shall document the procedure and criteria for successful completion of the competency evaluation prior to assignment.

2. Upon successful completion of a competency evaluation, the TM shall update the analyst's ATW to reflect the release to begin work. Successful completion of a competency evaluation requires obtaining the expected results. If expected results are not obtained, additional training and competency evaluation will be performed until the individual obtains the expected results.

F. Re-training

Re-training is occasionally needed for various reasons including transfer of employees into a section or discipline where they have previously been authorized to work or where there has been an indication that training was not effective (e.g. nonconforming work or unsuccessful completion of competency test).

1. Re-training should begin with an assessment of the training needs of the individual. This may include completing a cause analysis related to nonconforming work or evaluating contributing factors for incorrect responses on competency tests. For employees re-training in an area of prior competence, this should also include an evaluation of changes to the methodology since the analyst last conducted work in the discipline.

2. Re-training may be conducted using specific portions of the discipline training manual, or may be developed and tailored to the needs of the individual being re-trained. Modified or newly created training programs used for re-training must be documented and approved by the TM before use. When modifying an existing training program for use in re-training, the TM shall document justification for eliminating or significantly reducing specific training requirements.

3. Any re-training conducted should be documented in the same fashion as initial training.

4. All re-training must be followed by an evaluation to determine the effectiveness of the re-

training. This evaluation may or may not include a full competency. The decision of the method used to determine the effectiveness of the re-training shall be made and documented by the TM.

G. Authorizations to Work

Upon successful completion of training, the TM shall authorize the individual to conduct work (e.g. casework, database analysis, access to and operation of individual characteristic databases, etc.) in an Authorization to Work (ATW) memo. ATW memos will be maintained as a single document per individual per discipline (or unit) and will be updated as needed to reflect additional authorizations to work. ATW memos shall include the following information:

1. The date the authorization and/or competency is confirmed. Whenever possible reflect the date the authorization is made (e.g. when the individual is released for casework). Otherwise, specify the date that their authorization/competency was verified/confirmed.

2. List types of work (include any sampling procedures, if applicable) the individual is authorized to perform. Work can be listed as specific tasks, specific protocols, or categories of protocols. For example, TX-4 ELISA, TX-5 Ethanol Analysis by headspace GC or all approved Toxicology methods related to ELISA, blood alcohol analysis, and qualitative identification of drugs in whole blood.

3. For testing authorizations, list types of equipment/instrumentation the individual is authorized to operate: List specific instruments or reference instruments through protocols. For example, "Tecan Freedom EVO75 (ELISA), Headspace GC, GC/MS, GC/FID, LC/MS/MS" or "all equipment referenced in the currently approved toxicology protocols governing ELISA presumptive screening for drugs, blood alcohol analysis, and qualitative identification of drugs in whole blood."

4. Describe what the individual is authorized to report and testify about. Be sure to specify results, interpretations and/or opinions as appropriate.

5. Each ATW shall include a statement reminding the analyst that he/she must limit his/her work and testimony to the types of work described in his/her **current** ATW.

6. It is recommended that an ATW be issued or updated any time an employee is approved to perform any tasks related to testing or evidence handling, including support functions. At a minimum, ATW's must be issued or updated when the following authorizations are provided:
    a) Release to perform sampling, testing, give opinions and interpretations through a report or testimony, or operate equipment;

    b) Release to conduct technical reviews of test reports and test records;

c) Release to perform tasks that create items that could be used for testing.

7. Analysts may be authorized to participate in the development, modification, verification, or validation of methods outside the Authorization to Work memo. This authorization should be in a written format (e-mail, memo, etc.) from the discipline Technical Manager, but may be less formal than the Authorization to Work memo. The authorization should clearly state the intent and scope of the authorization for the development, modification, verification, and/or validation and include all aspects of testing activities such as the use of equipment.

H. Continuing Education

Employee development is critical to the quality program of the laboratory. Laboratory employees must keep current on the latest techniques and technologies. The OSBI CSD supports the continuing development of its employees through various methods, including the following.

1. Attendance at professional meetings is encouraged. Employees should refer to OSBI Agency Policy 202.1 for more information on regulations concerning attendance at professional meetings. Required materials concerning the course must also be turned in to the training office.

2. OSBI CSD employees are also encouraged to recommend training classes which can be hosted in the FSC training rooms. Recommendations for training classes should be forwarded through the supervisory chain to the CSD Director.

3. The OSBI encourages attendance at local colleges and universities in areas related to the job description of the employee by offering tuition assistance when funding is available as outlined in OSBI Agency Policy 202.2. A copy of a completed transcript for any course related to professional development should be saved by the employee in the appropriate folder located at \\Pm-fsc13000s\qa\Individual_Records.

4. An employee development plan is a part of each annual evaluation as required by Oklahoma law and OSBI Agency Policy 214.

5. Other sources of training and development include:

   a) Courses offered by the Council on Law Enforcement Education and Training (CLEET)

   b) Courses offered by the Office of Personnel Management

   c) In-house seminars, employee conferences, training and technical meetings

   d) FBI, DEA, or other outside training

6. An evaluation of any Coverdell grant funded training or meeting will be documented on form OSBI CSD **QPA 19.1** and submitted to the CA responsible for overseeing grants.

7. Current literature review is important to the development of employees. The TM (or his/her designee) of each discipline will assign and/or circulate articles of interest for their discipline. The TM will make sure each analyst has had an opportunity to read each article.

Literature Resources
The OSBI CSD provides access to current literature sources by ordering journals and by providing internet access and on-line subscriptions to employees. OSBI CSD employees also have access to the Oklahoma Department of Libraries catalog of books and periodicals free of charge at http://libraries.ok.gov/welcome/.

III. Attachments

OSBI CSD QPA 19.1, Rev02 Coverdell Grant Training Report
(Available in QMS Forms Folder)

I. Scope (top ↑)

The OSBI CSD maintains the integrity and prevents contamination of evidence and ensures the confidentiality of records by limiting access to restricted areas to authorized personnel.

II. Procedure

A. Facilities

1. Access to laboratories, file rooms, and evidence rooms/lockers will be limited to employees assigned to the laboratory unit, evidence technicians assigned to the physical facility, Criminalistics Administrative personnel, and other personnel as authorized by the CSD Director on a limited or permanent basis. All other personnel, including service/maintenance personnel, will only have access to the laboratory and evidence room areas when accompanied by employees authorized to have access.

2. In regional facilities which include laboratory and OSBI investigative operations, the OSBI CSD Director has approved the placement of file rooms in a central location, even if it allows investigative personnel access to the files.

3. Laboratories and evidence rooms will remain locked. Any exception must be authorized by the laboratory administration. At the end of each workday, the last person leaving is to ensure the unit and building are secured and alarmed.

4. No exterior or lab access door shall be propped open under normal circumstances. If an exterior or lab access door is propped open (e.g. while moving equipment), the employee propping the door open will ensure that appropriate OSBI personnel are present to monitor who enters and exits, until the door is closed. It will be the responsibility of any employee opening an outside door during normal work hours to ensure that door is locked at the end of that activity.

5. Access to quality and technical records will also be restricted. Access may be limited by maintaining these records in a location that is in a secure space. In addition, keys, proximity devices, and access cards which provide access to quality and technical record storage areas will only be issued to individuals who are authorized by the CSD Director to access these records.

B. Lock Security

Keys, proximity devices, and access cards which provide access to laboratory spaces or evidence storage areas will be tracked as indicated below. In addition, building keys for OSBI CSD owned facilities which contain a laboratory shall be tracked as indicated below. Each key, proximity device, and access card, should be engraved or stamped with unique identification if not already provided. Excess keys which are not issued for use may not require unique identification. However, these keys should be maintained in a secure location and be labeled in a manner that they can be associated with the coordinating lock.

1. Tracking Keys

a) Key control logs (OSBI CSD **QPA 20.2**) will account for the number of assigned keys to a laboratory unit and a sign out log will document who has keys to each door, locking refrigerator, freezer, work area drawer, or evidence locker. A master key log will be maintained (OSBI CSD **QPA 20.4** or OSBI CSD **QPA 20.4b**) for all keys within a unit or regional laboratory. The total number of keys will be verified annually and recorded on the Master Key Log.

b) Laboratory units having proximity access devices (key fobs, etc.) will use OSBI CSD **QPA 20.2** to document the issue and receipt of proximity access devices, excluding identification badge proximity access devices which are handled according to section II.B.2.a, below. Cipher lock codes will be maintained on OSBI CSD **QPA 20.3**.

c) Assigned keys will not be copied or loaned. Proximity access devices will not be loaned. Cipher lock combinations, access codes, and alarm codes will not be further disseminated by the individuals receiving the combination or code.

i. Loss of assigned keys and proximity access devices will be handled as per OSBI Directive 211. The employee shall immediately report the loss to their Supervisor.

ii. Previous key control log forms must be archived by the responsible person(s) designated in II.B.2. When key control log forms are revised, the older revision may be used until a change in key assignment occurs.

d) Occasionally, a common key is issued to a Supervisor or a key is needed for only a short period of time. In those instances, the person checking out the key must sign and date when the key is removed and when it is returned using OSBI CSD **QPA 20.1**.

e) The drying stall key control log (OSBI CSD **QPA 20.5**) may be used when temporarily issuing drying stall keys to individuals outside the OSBI CSD.

2. Issuing Keys, Proximity Access Devices, and Lock Codes

The following individuals are responsible for issuing keys, proximity access devices, and lock codes and maintaining their corresponding logs:

a) Forensic Science Center (FSC) –

i. Identification Badge Proximity Access Devices: Human resources personnel, or a designee, will issue an identification badge/proximity access device to each CSD employee and assign the employee a personal identification number (PIN). New or modified FSC access privileges should be requested through the supervisory chain to the CSD Director for approval. The CSD Director, or designee, will then forward approved requests to the FSC Facility Manager, who will be responsible for programming the identification badge proximity access device with the authorized level of access to FSC.

ii. The FSC Facility Manager will issue FSC building entry keys and maintain records documenting the issuance of those keys.

iii. Unit Supervisors are responsible for unit keys used for temporary evidence storage areas within their assigned sections.

b) Regional Laboratories – With the exceptions of the Lawton Facility and Northwest Regional Laboratory, the Laboratory Supervisor is responsible for tracking keys and access codes. For Lawton, tracking keys and access codes will be the responsibility of the Evidence APO, or designee. For the Northwest and Eastern Regional Laboratories, the Criminalistics Administrator is responsible for tracking keys and access codes.

3. Changing Access Codes/Privileges

At a minimum, cipher lock combinations, access codes or privileges, and alarm system codes will be changed or deleted under the following conditions:

a) When necessary to prevent unauthorized access to a laboratory or unit by a former employee.

b) When a situation or circumstance involving a potential security breach occurs as determined by the Unit Supervisor or Criminalistics Administrator over the unit.

c) Employee PIN's should also be changed when necessary due to technical difficulties, such as repeatedly and inadvertently entering duress code.

4. Responsibilities for Updating Codes

Updating access codes for cipher locks and alarm systems will be the responsibility of the following individuals:

a) Forensic Science Center – The FSC Facility Manager will be responsible for controlling the levels of access granted to employees for FSC. Modifications to access privileges should be requested, approved, and routed as indicated in section II.B.2.a above.

b) Regional Laboratories – With the exceptions of the Lawton Facility and the Northwest and Eastern Regional Laboratories, the Laboratory Supervisor will be responsible for updating access codes at Regional Laboratories.

C. Evidence Storage and Security

1. Each laboratory site shall establish a secure and organized evidence storage room(s) and/or building.

2. Evidence rooms/lockers will be kept neat and clean and will have limited and controlled access. Evidence rooms will have security alarm systems.

3. Each laboratory evidence room or building shall at a minimum meet the following standards:

a) An inside room or building with no windows, or, if windowed, the windows must be covered with secure steel bars or grate; or the room must be on an upper floor not easily accessible; or monitored by suitable motion detectors or other devices.

b) Doors must have secure locks.

c) Sufficient shelving or floor space must be available so that all evidence can be stored in a safe and orderly manner.

4. Prior to being logged in and labeled, evidence may be held in a secure, approved designated temporary evidence holding area, evidence locker, or in an Evidence Room. The evidence or the holding area should be labeled to identify it as pending log in. All other evidence placed in an evidence room shall be marked for identification with a Criminalistics case number, the submitting agency, and barcode.

5. No CSD personnel may store evidence at home, in their vehicle, in their office/work area, or at any other such place. This does not apply to latent lifts, impressions, or images of latent prints/impressions or digital evidence which may be maintained by analysts and examiners in their desk areas. CSD personnel may also temporarily maintain custody of evidence while working with the evidence, transporting the evidence, traveling to and from court, or for any other short-term investigative or prosecutorial purpose.

D. Alarm Systems

1. All buildings in which laboratories and evidence rooms are located will have security alarm systems. The security alarm will monitor the facility when it is not occupied. Changing and redistribution of access codes/levels will be done as described above.

2. Each laboratory facility will maintain a call list for the alarm system. The list is maintained by the person responsible for maintaining keys, magnetic cards, and keypad lock codes as described above. Copies of the call list shall be forwarded to the alarm monitoring company in the event the alarm company does not provide the list. The call list will be kept on file with the Regional Laboratory Supervisor in regional laboratories or Administrative Office at the FSC. These same individuals are responsible for archived lists when changes are made.

E. Enforcement

It will be the responsibility of the immediate unit Supervisor to ensure and monitor compliance with this policy.

III. Attachments

OSBI CSD QPA 20.1, Rev02 Temporary Key Control Log
OSBI CSD QPA 20.2, Rev01 Key Control Log
OSBI CSD QPA 20.3, Rev01 Keypad Control Log
OSBI CSD QPA 20.4, Rev01 Master Key Log
OSBI CSD QPA 20.4b, Rev01 Excel Master Key Log
OSBI CSD QPA 20.5, Rev01 Drying Stall Key Control Log
(Available in QMS Forms Folder)

I. Scope (top ↑)

This procedure will outline the process for recommending and evaluating research projects. Research projects may be more informal evaluations of potential new or modified methods and/or instruments. Research may be proposed and conducted by OSBI CSD employees or by volunteers such as students completing a practicum study, internship, or student research project.

II. Procedure

A. Research Committee

CSD employees may volunteer to serve on the Research Committee. Individuals interested in serving on the committee must notify the CSD Director. The CSD Director will select individuals to serve on the committee based on the needs of the CSD. The CSD Director will assign a committee member to chair the committee. The Research Committee can solicit input from other individuals as needed.

B. CSD Employee Research Proposals

OSBI CSD employees will use the following steps to propose and obtain approval to conduct research.

1. Obtain approval and guidance for purchasing, storing, and using any new reagents. Refer to **OSBI Policy 121.1** concerning proper procedures for procuring new reagents.

2. Prepare a written research plan including the following information:

   a) goal(s), objective(s), and relevance of the research;

   b) description of research project(s) to be performed;

   c) list of employees that will participate, including their roles;

   d) description of sample types to be used (use of evidence for research must be evaluated and conducted in accordance with **QP 6.2**);

   e) financial impact, including:

      i. a list of additional equipment, reagents, and supplies necessary to complete the validation and projected cost;

      ii. a projected cost per sample, including a comparison to any existing method used.

f) project timeline, which must include start and end dates and deadlines for major milestones.

3. Route the research plan to the CSD Director.

4. The CSD Director will solicit feedback from the Research Committee and the administrative staff as necessary.

5. The CSD Director will notify the Research Committee chairperson if the plan was approved or denied.

C. Student Research Proposals

Students or other individuals who would like to conduct research in collaboration with OSBI CSD employees or utilizing OSBI CSD resources should contact the Research Committee Chair. Student and any other non-OSBI CSD research projects should be evaluated, approved, conducted, and documented in accordance with procedures established by the Research Committee.

If student research is performed on CSD equipment used for casework analysis, the equipment may need to be checked for proper function and calibration prior to resuming casework analysis. Refer to section **6.4.2** of the Quality Manual.

D. Reporting Research Results

Following the completion of an OSBI CSD research project, a summary should be prepared and routed in the same fashion as the research proposal.

1. The summary should indicate whether the research was successful and what further action, if any, is recommended.

2. When enough data from research has been obtained to determine that it is desirable to introduce a method for use in casework, the research should be summarized with a recommendation to proceed to validation. A more thorough and detailed validation plan should then be submitted according to section **QP 21.2**.

III. Attachments

None

I. Scope (top ↑)

All new methods, instruments, equipment, and software used for testing must be evaluated by the OSBI CSD prior to use to ensure they are fit for the intended use. This procedure explains the process for proposing the implementation of methods, instruments, equipment, or software and evaluating their suitability for casework or database analysis.

II. Procedure

A. Implementation of New Methods, Instruments, Equipment, or Software

Periodically, it is necessary to change the methods, instruments, equipment, or software used for analysis so that the OSBI CSD has the resources to provide quality services which meet the needs of customers. Most of the time, this process will require an investment of resources, such as purchase of new reagents, consumable supplies, equipment, or software as well as an investment of time as CSD staff evaluate the suitability of the method, instrument, equipment, or software, conduct training, and perform competency evaluations of staff as necessary.

1. Prior to implementing a change to an existing OSBI CSD method or implementing a new method, instrument, equipment, or software for analysis, a change proposal will be submitted to the CSD Director, through the appropriate Criminalist Supervisor(s), Technical Manager (TM), and Criminalistics Administrator (CA) for review. This does not apply to changes which are approved as minor deviations or which have been approved through the annual budget request process.

2. The proposal must contain the following elements:

   a) A full description of the proposed change.

   b) Goals/objectives of the change. This section should address why the change is being proposed. For example, the proposed change may be necessary to increase sensitivity, improve throughput, decrease analysis time, or to provide a new service.

   c) A description of the financial impact, including:

      i. a list of additional equipment, reagents, software, and supplies necessary to complete the evaluation and projected cost of the implementation and evaluation process;

      ii. recommended mechanism for funding the necessary purchases (e.g. identification of any relevant grant funds or indication that agency funds will be required); and

iii. a projected continued cost (total cost or per sample cost when practical), including a comparison to any existing method used.

d) A description of the evaluation process that will be used to determine the new/modified method, equipment, or software is suitable for use. The description of the evaluation process must contain sufficient detail to determine the impact on current operations (e.g. how many staff will be involved, how long the evaluation will take, etc.).

i. If desired, a written copy of the evaluation process can be attached to the change proposal.

ii. If an evaluation plan is not attached, the proposal should at least summarize the steps necessary (full validation including sensitivity, precision, reproducibility studies, etc. or a performance verification comparing old vs. new) to evaluate the change and an approximate amount of time required.

B. Review and Approval of Evaluation Process

The process used to evaluate the suitability of a new method, instrument, equipment, or software must be as extensive as necessary to verify that it is suitable for the intended purpose. Depending on the scope of the change and available guidance documents from relevant working groups such as NIST OSAC, SWGDAM, SWGDE, etc., the evaluation process may be referred to as a validation, performance verification, performance check, or other name. Regardless of how the evaluation process is named, the following aspects of the evaluation process shall be documented prior to the start of the evaluation process.

1. Obtain approval and guidance for purchasing, storing, and using any new reagents. Refer to **OSBI Policy 121.1** concerning proper procedures for procuring new reagents.

2. A written plan outlining the steps that will be used to evaluate the suitability of the new method, instrument, equipment, or software shall be prepared by or provided to the TM. Once a draft evaluation plan has been completed, the TM may, at his or her discretion, route the evaluation plan to the appropriate QIC subcommittee for review. Upon receipt of an evaluation plan, the subcommittee shall review the merit and completeness of the plan and provide feedback to the TM regarding any necessary modifications. Once any subcommittee feedback has been addressed if applicable, the TM will review the plan, make or direct any necessary changes, and then document his/her approval of the completed plan. Once the plan has been approved, the TM shall provide a copy of the approved plan to the appropriate personnel (e.g. individual(s) who will perform or oversee the evaluation), as necessary.

3. The evaluation plan must evaluate the suitability of the test process, including data analysis and interpretation, and should include the following sections and/or attachments, as applicable:

   a) study descriptions, including:

      i. purpose and type of study;

      ii. parameters for testing;

      iii. types of samples (pristine, simulated forensic, non-probative) and approximate number of samples;

      iv. controls and any standard reference materials;

      v. method for evaluating data and acceptance criteria to determine if the method is fit for the intended use.

   b) data required for reporting a result, opinion and/or interpretations;

   c) any identified limitations of the method, results, opinions, and/or interpretations;

   d) Evaluation plans for methods which are already validated, but new to the laboratory (e.g. standard methods) shall contain sufficient studies to demonstrate the method works reliably and achieves the documented performance characteristics when performed in-house;

   e) references, including:

      i. any applicable recommendations/requirements from a relevant working group ;

      ii. any applicable peer reviewed literature;

      iii. draft protocol or procedure that will be used for testing during the evaluation process;

   f) plan for training analysts once the evaluation is complete or an explanation why training is not deemed necessary;

   g) plan for competency testing or competency evaluation of analysts or an explanation why competency testing or evaluation is not deemed necessary.

4. The evaluation plan and all related documentation are to be archived with the Technical Manager of the discipline.

C. Review of Evaluation Reports

Once the evaluation process has been completed, a report detailing the results of the evaluation will be prepared and routed for approval by the TM, as described below.

1. Following the completion of the evaluation process, the TM, or designee, will prepare a summary report of the evaluation results. Evaluation reports should include the following sections/attachments and shall be retained:

   a) A brief summary of the testing procedures conducted, including the conclusions made. For example, if an evaluation included a study to determine the sensitivity of an instrument, the relevant section of the report should describe the sample set(s) analyzed (e.g. double serial dilution set from neat to 1:512) and then identify the most dilute sample that yielded acceptable results.

   b) A summary of any observation or result that diverges from the overall pattern (e.g. an outlier) or that otherwise does not fit within expected results. An explanation should be provided detailing what the presumed or possible cause(s) of the outlier was and any action taken to correct or confirm the outlier.

   c) A summary stating the overall outcome of the evaluation process. For example, based on the evaluation is the method, instrument, equipment, or software suitable for the intended use or not?

   d) A description of any limitations of the method, instrument, equipment, or software, etc. and any limitation of the reported test results, opinions or interpretations. For example, some techniques or equipment should only be used on certain sample types or substrates. Any limitations should also be clearly defined in the scope of the associated protocol.

   e) A description of circumstances or changes which will require the method, including the data analysis and interpretation process, to be re-evaluated.

   f) A final draft of the technical protocol including any required controls and/or standards and any quality control/calibration protocols required. The protocol shall specify what data is required to report a test result, opinion, or interpretation.

2. Once the draft report of the evaluation has been completed, the TM may, at his or her discretion, route the evaluation report and the associated draft protocol for review by the

appropriate QIC subcommittee. Upon receipt of the evaluation report and protocol, the QIC subcommittee shall provide feedback to the TM regarding any necessary modifications. During the review, the subcommittee should also determine if each of the applicable aspects outlined in **QP 2** section II.G.5 have been clearly addressed by the draft protocol and are properly supported by the evaluation results. The subcommittee should document any aspect which it deems not applicable and the reasons supporting that determination.

3. Once any subcommittee feedback has been addressed, the completed validation report/summary should be forwarded to the appropriate Criminalistics Administrator (CA), the QM, and the CSD Director. A summary of the subcommittee recommendation, including any dissenting opinion(s), should be included.

4. If the CA, QM, and CSD Director unanimously agree with the subcommittee, the validation report will be approved.

5. If the CA, QM, and CSD Director do not unanimously agree, they may return the validation for additional action or the QM may forward the validation report to all QIC members including all comments and recommendations for feedback.

6. The CSD Director can then approve the technique or remand the validation for additional study.

7. Typically, formal approval of a completed evaluation will be documented through the approval of an associated protocol. If necessary, the approval may also be documented via e-mail or by making a notation on the evaluation report. The approved evaluation report will be retained in hard-copy or electronic format as a record of the validation work completed.

D. Exceptions

Under some circumstances, an evaluation may not be necessary. The sections below describe how to request and/or document an exception.

1. If significant modifications are needed to existing methods, instruments, or equipment, the modification shall be proposed and evaluated in accordance with this policy. Other modifications, which are determined by the TM not to be significant are outside the scope of this policy.

2. Software used for casework or database analysis will typically be routinely updated by the vendor. A routine software update does not require an evaluation if it can be determined that the update does not impact the core functionality of the software. This may be determined based on a review of the software release notes or other available information.

If a software update will be installed for use in casework without an evaluation, the TM, or designee, should retain a record of the information reviewed to determine the update did not impact the core functionality of the software.

3. If an item, such as equipment or software, will be used for casework and it is believed that the item does not require evaluation due to the item's widespread acceptance in the relevant forensic community, an exception to this policy may be requested by the TM. The TM shall e-mail the appropriate CA and CSD Director and provide the following information in the request for exemption:

   a) Identification of the item;

   b) Description of how the item will be used in casework including any controls or quality checks that will be required;

   c) Summary of available documentation supporting the item's reliability; and

   d) A description of the potential impact if, for some reason, the item didn't function as expected.

If the exception is approved, the TM shall retain a record of the approval.

III. Attachments

OSBI CSD QPA 21.2.1, Rev01 Change Proposal
(Available in QMS Forms Folder)

I. Scope (top ↑)

This procedure will be used for the estimation and documentation of uncertainty of measurement for quantitative test results which are reported or provided in testimony.

II. Procedure

A. Tests Which Require Estimation of Uncertainty of Measurement

The OSBI CSD shall have and shall apply a procedure to estimate the uncertainty of measurement when quantitative test results are reported or provided in testimony. This includes:

1. Weight of controlled substance evidence;

2. Concentration of drugs in toxicology samples;

3. Barrel length and/or overall firearm length;

4. Distance determination;

5. Trigger pull measurements.

The OSBI CSD does not currently report the following types of test results: volumes of controlled substance evidence, quantitation (purity) of controlled substance evidence, or calibration of breath alcohol instruments or reference materials. In the event that OSBI CSD policy is modified to provide these services, a procedure for estimating uncertainty of measurement will be developed and applied to these areas as well.

B. Procedure Requirements

The Toxicology, Chemistry, and Firearms Units will each issue a discipline-specific procedure detailing the process to use for estimating and reporting the uncertainty of measurement. The procedure must require the specific measuring device or instrument used for a reported test result to be included in or evaluated against the estimation of measurement uncertainty for the test method. These procedures must also include a process for rounding the expanded uncertainty and must require a minimum coverage probability of 95.45%. In addition, the policy must ensure the following information is recorded:

1. The measurand;

2. Description of how traceability is established for the measurement;

3. The method for measurement, including the equipment or instrument used to take the measurement;

4. List of all uncertainty components considered;

5. List of all uncertainty components of significance and how they were evaluated;

6. Data used to estimate repeatability, intermediate precision, and/or reproducibility;

7. All calculations performed;

8. The combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty;

9. The schedule to review and/or recalculate the measurement uncertainty.

C. Documenting Uncertainty Calculations

1. The Technical Manager (TM), or designee, will be responsible for maintaining documentation of any uncertainty of measurement calculations conducted. Documentation must include the data elements listed in section II.B above.

2. Analysts must document in the case record those factors which impact the uncertainty of measurement. This may include the identification of the instrument or measuring device used or an indication of the size or capacity of the measuring device.

D. Reporting Uncertainty of Measurement

1. Reporting uncertainty of measurement will be conducted as indicated in the discipline-specific procedure. At a minimum, uncertainty of measurement must be reported in the following circumstances:

   a) The uncertainty of measurement will be reported upon request by the customer;

   b) The uncertainty of measurement will also be reported when the measurement and applicable uncertainty of measurement overlap an established and applicable legal threshold. For example, if the legal threshold for trafficking methamphetamine is 20 grams, the reported measurement is 20.02 grams and the uncertainty of measurement is +/- 0.03 grams, then the uncertainty of measurement should be reported;

   c) When necessary for interpretation of test results.

2. When the uncertainty of measurement is reported, it must be reported using the same units

of measurement and the same number of significant figures (i.e. same number of decimal places or digits) as the reported measurement. The rounded expanded uncertainty should be reported using up to two significant digits. In the event it is necessary to report using more than two significant figures, the discipline-specific procedure must document the reason(s) for using more significant figures. The associated confidence level of the estimated uncertainty of measurement must also be reported.

3. If the uncertainty of measurement is reported without a customer requesting it, the reporting analyst should ensure that the customer understands what the uncertainty of measurement is. This can be accomplished by calling the customer and explaining the new reporting language prior to or shortly after releasing the report. Alternately, the TM, or designee, may prepare and have approved by CSD Administration a written explanation of uncertainty of measurement that can be attached as an appendix to reports or e-mailed to customers as necessary.

III. Attachments

None

I. Scope (top ↑)

The OSBI CSD will use the following procedure to ensure adequate traceability of measurements where measurement uncertainty is estimated or when the measurement result has a significant impact on the final test result.

II. Procedure

Any OSBI CSD discipline which conducts measurements requiring an estimation of uncertainty of measurement or which significantly impact results must have a written procedure for calibration which complies with the current accreditation requirements.

A. Internal Calibrations

The OSBI CSD shall not perform calibrations of equipment or reference standards without first obtaining accreditation in the necessary field of calibration from an accrediting body with an appropriate scope of recognition from IAAC or ILAC.

Any instruments operated by the OSBI CSD which are capable of performing an internal self-calibration shall be addressed through discipline protocol/policy. The discipline policy shall identify whether the instrument internal calibration will be utilized or not. If instrument internal calibrations are permitted, the discipline policy shall identify any performance checks which may be required.

B. External Calibrations

In order to ensure that external calibrations of measuring equipment/instruments and reference standards provide adequate traceability, the following steps will be used to select an appropriate vendor and maintain adequate documentation of the calibration. When used for establishing or maintaining traceability, calibrations (of equipment, reference materials, or reference standards), reference standards, and reference materials are considered critical supplies and services as referenced in ISO/IEC 17025:2017 standard 6.5.1 and AR 3125 6.5.1.1. As a result, the evaluation of the vendors used to provide these calibrations and/or supplies must be conducted and documented in accordance with **QP 9**.

1. The vendor conducting the calibration must demonstrate and provide documentation of **competence** and adequate **measurement capability** and **traceability**.

   a) **Competence** and **capability** will be demonstrated by selecting a calibration vendor which is:

      i. A laboratory that is ISO/IEC 17025 accredited by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement (MRA), with a scope of

accreditation that includes a measurement range applicable to the instrument, measuring equipment, or reference standard being calibrated. Listings of current ILAC MRA signatories may be found on the internet at http://ilac.org/ilac-mra-and-signatories/; or

ii. A National Metrology Institute that is a signatory to the BIPM (refer to AR3125 6.5.1.1.a))

b) **Measurement traceability** should be verified by obtaining documentation from the calibration laboratory which documents traceability to NIST standards.

2. In the event that a vendor meeting the requirements above is not available, the Technical Manager (TM) shall be responsible for confirming competence, measurement capability, and measurement traceability for the supplier and service being purchased and maintaining objective evidence of the confirmation.

3. The calibration certificates received from outside calibration laboratories should include:

a) the measurement results and the associated uncertainty of measurement, and/or

b) a statement of compliance with a metrological specification.

4. Instruments, equipment, reference standards, and reference materials which have been externally calibrated to obtain appropriate traceability will not be adjusted by OSBI CSD personnel. If intermediate checks are performed and results indicate that the item is no longer within the calibrated range, the item will be taken out of service until an appropriate external calibration can be performed.

5. If the only supplier available for calibration used for measurement traceability is accredited to ISO/IEC 17025 by a non-IAAC MLA or non-ILAC MRA signatory accrediting body, then the discipline TM shall **verify and document** the competence (accreditation), measurement capability, and traceability.

C. Intermediate Checks

Each discipline shall determine if intermediate checks are necessary to maintain confidence in the calibration (and associated traceability) status of equipment, reference standards and reference materials. If intermediate checks are needed, they shall be conducted according to discipline-specific protocols or policy and schedule. Once a calibration schedule has been established, calibrations and/or intermediate checks shall not be conducted less frequently without documented empirical data supporting the change in frequency.

D. Calibrations to Alternate Reference Standards or Materials

If calibrations cannot be made in SI units, the OSBI CSD will provide confidence in reported measurements by:

1. Establishing traceability to a certified reference material (see **QP 26**), or

2. Using a specified method or consensus standard agreed on by OSBI CSD management and the customer.

III. Attachments

None

I. Scope (top ↑)

The OSBI CSD will furnish CSD facilities with equipment and instrumentation which will provide the correct performance for the analysis conducted. This procedure will be used to track, maintain, and verify calibration of equipment and instruments. This may include computers or automated equipment used to process, record, report, or store test data. This procedure will also be used to ensure proper functioning, prevent contamination or deterioration, safe handling, transport, storage, use, and maintenance of measuring equipment.

II. Procedure

A. Inventory

1. The Supervisor of each unit and of each regional laboratory must have access to an inventory of their instruments/equipment and analysis software.

2. The inventory for instruments/equipment should include the following information:

   a) Name

   b) Manufacturer, model number, and serial number

   c) OSBI asset number (not required for equipment which is the asset of an ATTDFL participating agency)

3. As each unit or laboratory receives new instruments/equipment, the Supervisor, or designee, will send information concerning the new instruments/equipment to the FSC Administrative Office.

4. A file containing original paperwork (manufacturer's information, etc.) for instruments/equipment should be readily accessible by the Supervisor.

B. Calibration and Maintenance Procedures

1. Equipment procedures (protocols) will be established as necessary to ensure the following criteria are met:

   a) Each discipline shall have a written procedure or program for the calibration of equipment. The procedure shall identify:

      i. a list of equipment which requires calibration

      ii. specifications for the calibration laboratory (must comply with **QP 23** if applicable)

iii. specified requirements for the calibration

iv. required frequency of calibration (Once established, any decrease in the frequency of calibration must be based on empirical data and an evaluation of the risk.)

b) Equipment will be checked (e.g. function verification) or calibrated before being placed into service to ensure it meets the necessary specifications established in OSBI CSD protocols.

c) Equipment used for tests which has a significant impact on accuracy or validity of tests results shall be calibrated before being put into use.

d) For measuring equipment (or test equipment with measuring functions) that has a significant impact on the accuracy or validity of a test result or the total uncertainty of the test result, the calibration procedure must ensure that any calibrations and measurements made are traceable according to **QP 23**.

e) For equipment where the calibration does not have a significant effect on the test result or the total uncertainty of the test result, the discipline TM shall determine whether a calibration will be performed and establish requirements for a reliable calibration laboratory, if calibration is performed.

2. Equipment procedures will require and specify the maintenance of the following records for equipment and software which has a significant effect on the accuracy or validity of test results. Each TM shall maintain a list clearly identifying which equipment and software within their discipline significantly impacts the accuracy or validity of test results.

a) **user's manuals** or manufacturer's instructions or a reference to the location of the manuals/instructions (if they are not in located at or near the equipment);

b) **calibration records** which include the dates, results, and copies of calibration reports/certificates, as well as records of any adjustments, acceptance criteria, and the due date for the next calibration;

c) **results of function verifications** (at a minimum the record should include the date of the verification, initials of the person conducting the verification, a description of the verification activity, and identification of any reference standards or materials used);

d) **maintenance plan and records** of maintenance (at a minimum maintenance records should include the date of the maintenance, initials of the person conducting the maintenance, and a description of the maintenance activity)

e) **records of any damage, malfunction, modification, or repair**.

3. Maintenance procedures should include a maintenance plan, maintenance contract information, and routine preventive maintenance.

4. Whenever an applicable laboratory instrument/equipment is taken out of service, an entry will be made in the logbook including the "out of service" date and again the "in service" date. Additionally, the instrument/equipment must have an "out of service" sign placed on it or be otherwise isolated and/or identified to prevent use until it is placed back into service.

C. Measuring Equipment

1. At a minimum, measuring equipment, such as pipettors, balances, pH meters, etc., will be handled, transported, stored, used and maintained according to manufacturer's or calibration vendor's recommendations in order to prevent deterioration and/or contamination. If additional procedures are necessary to adequately prevent deterioration and/or contamination, the discipline Technical Manager will issue a protocol detailing the appropriate additional steps.

2. The manufacturer's user's manual should be maintained for all measuring equipment. In the event that the manufacturer's user's manual is not available, the discipline Technical Manager will be responsible for issuing a protocol detailing proper handling, transportation, storage, use, and maintenance of the equipment.

A. Attachments

None

I. Scope (top ↑)

This procedure will be followed to ensure traceability of reported measurements, when applicable, and to ensure proper calibration and handling of reference standards.

II. Procedure

A. Calibration of Reference Standards

1. Disciplines which use reference standards shall have a written procedure which identifies the following factors:

   a) A list of reference standards which require calibration;

   b) Specifications for the calibration laboratory (must comply with **QP 23**);

   c) Specifications for the calibration;

   d) How frequently the reference standard(s) must be calibrated.

2. Calibration Requirements

   a) Reference standards shall be calibrated in a manner that ensures compliance with **QP 23**.

   b) Calibration certificates will be maintained at the CSD unit using the reference standard. The original calibration certificates for reference standards used by multiple units will be maintained with the standards. Units using the standards should maintain a copy of the calibration certificate for easy reference. Expired certificates will be maintained by the appropriate unit Supervisor or Technical Manager.

B. Transport and Storage

1. Calibrated reference standards will be stored separate from evidence in a secure location that does not invalidate their performance as reference standards.

2. The current location of calibrated reference standards used by multiple units will be tracked through the use of a sign out sheet or equivalent tracking mechanism.

3. Calibrated reference standards will be used for their intended purpose only, unless it can be demonstrated that alternate uses do not invalidate their performance as reference standards.

4. Manufacturers' recommendations will be followed for the handling, storage, transport, and use of reference standards to ensure that they are protected from damage.

III. Attachments

None

I. Scope (top ↑)

This procedure outlines the legal, safety, transportation, storage, handling, and use requirements for reference materials, such as drug standards and certified reference materials (CRM's). These requirements will be followed to prevent contamination or deterioration of reference materials and in order to protect their integrity.

II. Procedure

A. General Requirements

When it is not possible or appropriate to trace reported results to SI units, the OSBI CSD will ensure the reliability of reported results, wherever practicable, through the use of certified reference materials.

1. In order to ensure appropriate traceability, certified reference materials (CRM's) must only be ordered from suppliers which meet the requirements outlined in AR 3125 requirement 6.5.1.1, if available.

2. If a CRM is used to establish measurement traceability but can only be obtained from a provider that does not meet the criteria listed above, then the TM shall be responsible for confirming and documenting the competence and measurement capability and traceability.

3. Certificates of analysis from manufacturers will be maintained in a location designated by the Supervisor and/or Technical Manager.

4. Reference materials will be labeled with the date of receipt and receiving analyst's initials, date opened, initials of the individual opening the reference material, and expiration date, if applicable.

5. Reference materials should not be stored with evidence samples.

6. Whenever possible, only one lot number of standards will be open and in use at a time.

7. The safe handling, transport, and use of reference materials will be conducted according to the manufacturer's instructions or an approved discipline protocol to prevent contamination, deterioration and to protect the integrity of the reference material.

8. Reference materials shall be stored in accordance with **QP 8.1**.

9. If a CRM is changed in a way that alters the traceable measurement value, then the equipment used to alter the CRM shall be evaluated according to **QP 24**. Specifically, if the equipment used to alter the CRM has a significant impact on the accuracy or the validity of

the test result or on the total uncertainty of the test result, then the equipment shall be calibrated by a vendor that is accredited to ISO/IEC 17025 with a scope of accreditation covering the calibration.

B. Drug Standards

Drug standards are considered reference materials and will be received, handled, and logged according to applicable discipline Quality Manuals. Requirements for the suppliers of drug standards **which are not used to establish traceability** shall be determined and documented as necessary in applicable discipline Quality Manuals.

III. Attachments

None

I. Scope (top ↑)

This procedure provides for assistance by criminalists at crime scenes. This procedure will be followed to ensure proper notification of crime scene requests and responses and documentation of activities conducted at a crime scene. This procedure will apply to crime scene response/activities at remote locations and crime scene response/activities at CSD facilities (e.g. processing a vehicle in the FSC vehicle bay).

II. Procedure

A. Requests for Crime Scene Assistance

The OSBI CSD provides crime scene assistance through the Latent Evidence Unit (LEU). Requests for response by any other criminalists must be evaluated and approved by the CSD Director. Requests for assistance by a Criminalist in the LEU will be routed as indicated below:

1. Latent Evidence Unit

   a) The Supervisor, or designee, will be notified of the request and determine if the scene warrants the use of a criminalist.

   b) In the event that the Supervisor, or designee, is unavailable, the Criminalistics Administrator (CA) responsible for LEU will be contacted and make assignments as needed.

   c) The CSD Director should be notified (via phone, e-mail, etc.) when criminalists attend a crime scene.

2. Miscellaneous Requests for Assistance

   Any CSD employee who receives a request for assistance that is not covered by the LEU must notify his/her Supervisor. The Supervisor will verify that the employee has received appropriate training, successfully completed a competency test, and received written authorization to conduct the type of crime scene work that was requested. The Supervisor must also notify the CSD Director prior to authorizing the employee to respond to a scene.

3. Requests for Digital Evidence Crime Scene Assistance

   The OSBI CSD does not provide digital evidence crime scene assistance. An example of digital evidence crime scene assistance is the preview of computers or electronic devices during the execution of a search warrant to identify which items should be collected. While the OSBI CSD does not perform this analysis, some ATTDFL participating examiners may perform this service on behalf of their parent agency or a task force.

In the event a participating examiner assists with a crime scene, the reporting requirements in this policy do not apply. The examiner shall ensure that any report or testimony regarding his or her observations from the crime scene are reported separately from any subsequent analysis of the evidence. The examiner shall also ensure that reports or testimony regarding crime scene response does not infer or imply that these activities are accredited, as these activities are outside the scope of the OSBI CSD Quality System.

B. Crime Scene Memorandum

1. Crime scene responses require a Crime Scene Memorandum (OSBI CSD **QPA 27.1**) if the work is performed outside of the OSBI Laboratory facilities.

2. Copies of the crime scene memorandum will be distributed as follows:
   a) One copy each will be forwarded to the CSD Director and the LIMS Administrator. At the latest, this copy should be turned in by 10:00 A.M. on the following Monday.

   b) The original will be placed in the criminalistics case record, if applicable.

   c) A copy <u>may</u> be retained by the responding criminalist(s) and/or Supervisor.

3. If the responding OSBI Criminalistics personnel did not leave together, travel together in the same unit and return together, separate crime scene memos must be completed.

4. Separate crime scene memos will be filled out when a Criminalist responds to different locations (scenes) on the same case.

C. Crime Scene Narrative Report

1. Any criminalist collecting, preserving, diagramming, photographing, or analyzing evidence at a crime scene or at the morgue will complete a Crime Scene Narrative Report. A Crime Scene Narrative Report is not required if a criminalist provides assistance in an advisory capacity or if no evidence will be submitted to the OSBI CSD.

2. The narrative report will include a general description of the Criminalist's activities at the crime scene, an itemized list of what was inventoried or collected, and if testing was performed at the scene. Work conducted outside of OSBI CSD facilities shall be reported in a Crime Scene Narrative Report which does not include the accreditation symbol. This can be done by completing the narrative from a “CS” assignment. A copy of a Crime Scene Narrative Report can be distributed to district attorneys, investigating officers, and other appropriate parties. The original Crime Scene Narrative will be retained in the case file.

III. Attachments

OSBI CSD QPA 27.1, Rev03 Crime Scene Memorandum
(Available in QMS Forms Folder)

I. Scope (top ↑)

This procedure establishes consistency in the format, content, style, and distribution of analytical reports.

II. Procedure

A. Generating Analytical Reports

OSBI CSD analytical reports will be generated in the BEAST Laboratory Information Management System (LIMS). Although the procedure may vary some from discipline to discipline, this is typically done in the following manner:

1. The analyst will click on the "Analysis" button from the "Assignments" tab in the BEAST.

2. This should open exam log and/or matrix panels that the analyst can use to document the analysis.

3. Once the necessary data has been entered, clicking on the "Send to Word" button should open a draft report. Analysts should verify that the information in the report is complete and properly formatted.

4. Analysts will not modify the laboratory name or address on the report in the Word document/draft report. If the lab name or address is incorrect in the report, the analyst will need to correct the lab code for the assignment found on the "Assignments" tab.

B. Use of Accreditation Symbol in Reports

The use of the accreditation symbol in OSBI CSD reports is governed by accreditation requirements. The requirements set forth in the ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status (**PR 1018**) shall be followed.

While the appropriate symbol for Forensic Testing Accreditation has been placed into report templates, it is the responsibility of the reporting analyst to ensure that use of the symbol does not inadvertently infer accreditation in an area where the OSBI CSD is not accredited. This could include a new discipline or type of testing which has not yet been accredited or a type of testing which the OSBI CSD has elected not to accredit, such as Crime Scene.

In order to avoid inferring accreditation in an area where the OSBI CSD is not accredited, the reporting analyst shall remove the accreditation symbol from the report (if none of the reported work is covered by the OSBI CSD scope of accreditation) or include a clear disclaimer to identify any area where the OSBI CSD is not accredited (if the report contains work that is covered by the scope of accreditation and work that is not). If there is any confusion regarding what types of

work are included under the OSBI CSD scope of accreditation, the Quality Manager (QM) shall be consulted to ensure the OSBI CSD maintains compliance with accreditation requirements.

In addition, in the event any work is sub-contracted to another laboratory, results of the subcontracted work shall not be reported in an OSBI CSD report without prior approval of the QM.

It is the responsibility of each qualified analyst to ensure the opinions and interpretations included in conversations and testimony are based on results for which accreditation is held. Any opinions and interpretations offered that are outside the scope of accreditation but are based on results for which accreditation is held, shall be clearly identified by the analyst.

C. Correcting Reports

On occasion, mistakes are noted in reports after a report has been approved. If the mistake impacts the findings or results of the report, a corrected report will be issued using the applicable procedure listed below. If the mistake does not impact the findings or results, then the need to issue a corrected report will be evaluated on a case by case basis and corrected reports will be issued at the discretion of the Unit Supervisor.

Any analyst requesting a report be reset, shall include reason for the need for the report reset in the request. The LIMS Administrator, the discipline Technical Manager, as well as the Supervisor shall be included in the request.

1. When a report has been approved, **but not distributed (hard copy or pdf via website)**, it may be corrected with assistance from a LIMS administrator using the following **reset** process:

   a) Reset the report – this creates a new assignment and the matrix data is still in place.

   b) Delete the reset report – this deletes the current report number along with the report.

   c) From the matrix, regenerate the report. The analyst can then proceed to sign, route for review, and approve the report.

2. When a report has been distributed and needs to be corrected, the following process will be used to issue an **amended report**:

   a) Open a Word copy of the original report. This can be done as follows:

      i. Selecting the desired report by clicking on the correct report in the list of reports shown on the “Reports” tab in the BEAST.

ii. With the correct report selected, press and hold the shift key while clicking on the "Print" button at the bottom of the "Reports" tab.
iii. In the window that opens, document the editable version of the report is being printed to prepare an amended report. Select OK. This will generate an unsigned report in Word with "uncontrolled copy" labeled on the report which can be used for copy and paste.

b) Create an assignment with the same items selected for the assignment that were included in the report being corrected.

c) In the lower right corner of the "Assignments" tab, indicate the report number that is being corrected in the "Amended From" field. Select Save.

d) Create a draft amended report by clicking on the "Analysis" button and then navigating to and selecting the "Send to Word" button or "print report" button. All of the exam log and matrix panels from the amended report assignment should be blank, so the report generated should not include any results.

e) Copy and paste the necessary content from the report being amended into the new report document. Do not copy the signature block.

f) Make the necessary corrections to the content of the report and identify the changes made. Changes can be identified by putting the changed text in bold or italics, underlining the change, or inserting a footnote to explain the change if the change removed text from the report. If appropriate, add a statement to the report indicating how the changes are identified.

g) Identify the report as an amended report by adding "Amended From Report X" below the new report number. "X" should identify the report number that the amended report replaces. When appropriate, the reason for the change shall be included in the report.

h) Conduct review and approval of the report according to applicable procedures.

D. No-Analysis or Partial Reports

1. Occasionally, case circumstances will change and requested analysis will no longer be necessary. When this happens and notification is received before the analysis begins, the following procedure will be used to issue a **"no-analysis" report**.

a) First, enter a narrative in the BEAST case file.
i. From the "Case Info" tab, click on the "Narrative" button.
ii. Click on the "Add" button in the lower left corner. Then enter details of the

conversation, including the first and last name of person, the agency, and what analysis is no longer needed.

iii. Select "NA" for no analysis communication in the "Type" field.

iv. When all information has been entered, click "save."

b) Next, generate the no analysis report.

i. From the "Assignments" tab, highlight the appropriate assignment, and click the "Edit" button at the bottom of the screen.

ii. In the "Lab/Format" field in the lower left corner of the screen, select "NOAN" and, if necessary, select the appropriate analyst in the "Analyst" field. Click "Save."

iii. Click on the "Notes" button and enter the amount of time spent on the "no analysis."

iv. Click on the "Analysis" button and navigate through the exam log/matrix panels and click on the appropriate "Send to Word" button. Verify the information is correct, and then save the report.

c) Finally, close the assignment.

i. Back on the "Assignments" tab, click on the "No Analysis" button.

ii. Click on "Yes" in the next window.

d) The analyst closing the assignment is responsible for ensuring that the evidence is moved or routed appropriately so that it can be returned to the proper agency in a timely fashion.

2. In the event that a request for analysis is canceled after analysis has started but before it has been completed, a **partial analytical report** will be issued. At a minimum the report should address the partial results in one of the following two ways:

a) The report can be issued indicating that analysis was started but then canceled at the request of the customer or due to case circumstances (suspect pled guilty, DA declined to file charges, etc.). The report should include the name (first and last) of the customer who canceled the service request or confirmed that analysis was no longer necessary. The report may then indicate that results of testing are not reported since the analysis was not completed. This type of report must be administratively reviewed, but no technical review is required.

b) Alternately, the report may include results from any testing/items which were completed and a statement similar to that described above to address any testing which was not completed.

E. Sub-contracting Reports

When evidence is sent to a contract laboratory for analysis, an OSBI report is not required. However, the requesting agency shall be notified in writing (e.g. report, letter, or memo) that the evidence was sent to a private lab for analysis. At a minimum, this written notification should include the requesting agency case number, OSBI Lab case number, a description of the evidence and/or packages sent, and the name of the laboratory the evidence was submitted to.

F. Numbering Reports

1. Reports and notifications generated in the BEAST will be assigned a sequential number by the BEAST. This number will not be modified by analysts.

2. On amended reports, the analyst will indicate below the report number, "Amended From Report X" where X is the number of the report that was amended.

3. When issuing an amended report for a report that was generated prior to the implementation of the BEAST, the analyst will indicate in the report what report was amended. If the report does not have a number, the issuing analyst and date of issue will be referenced for identification purposes.

4. Similarly, if a case has been worked both before and after the implementation of the BEAST and a duplicate report number is assigned by the BEAST, it is recommended that the analyst place a statement of explanation in the report.

G. Report Content

The format of analytical reports will include the following information. The following requirements do not apply to reports or notifications which do not contain results of analysis. This includes no-analysis reports and CODIS Notification Letters.

1. All OSBI CSD analytical reports will have the title, "Criminalistics Examination Report" or "Digital Evidence Examination Report."

2. All OSBI CSD analytical reports will include the date the report is issued.

3. The name and address of the OSBI Laboratory issuing the report (where the testing was performed) will be reflected in the header of the report. If part or all of the analysis is conducted at another location, this shall be documented in the case record.

4. All OSBI CSD analytical reports will contain and be uniquely identified by the case number and a report number.

5. The name and agency and/or address of the requesting officer will be located in the report header.

6. All OSBI CSD reports will reflect the date evidence was first received by the CSD. For evidence that has left the custody of the OSBI CSD and then been resubmitted, the first date that the evidence was received back into CSD custody will be reflected in the report.

7. Where practical, all OSBI CSD reports should include a description (unambiguous identification) of all items received by a submitting agency which are associated with the assignment completed.

8. OSBI CSD reports will also describe any evidence created or collected by the reporting analyst which could be used for testing. However, items which are created for testing purposes and are tested and reported do not need to be specifically listed. Examples include GC/MS sample vials, GSR stubs from clothing, etc. Discipline-specific quality and/or policy manuals will address the requirements for reporting for each discipline.

9. When available and practical, department item numbers (from the requesting agency) should be included in the report as part of the item description. This may not be required if the department item number cannot be clearly associated with an item. In addition, department item numbers are not required if a more unique and unambiguous descriptor is used (e.g. kit number, etc.).

10. All current OSBI CSD reports, with the exception of no-analysis reports, shall include a signature block showing the type-written name and title of the analyst authorizing the report and an electronic signature.

11. Requesting agency case numbers should be listed on the first page of the report immediately below the header. Be sure to indicate the agency number by using the initials or title of the agency with the agency case number. Agency case numbers will be reported as they have been entered into the BEAST. If the case number appears to include additional information (e.g. property receipt number), it will be reported as entered.

12. Identification of the method(s) used may be included in the OSBI CSD report. See OSBI CSD **QMA 1.1**.

13. The date(s) of testing may be included in the report. See OSBI CSD **QMA 1.1**.

    NOTE: The date(s) may be reflected as a range of dates or the date of each test. Each discipline quality and/or policy manual will reflect the requirements for the discipline.

14. The date of issue of the OSBI CSD reports will be included in each report as the date the case was completed (approved).

15. If a sampling plan is used during testing, reference to the sampling plan will be included in the OSBI CSD report.

16. Any additions to, deviations or exclusions from the method may be included in the OSBI CSD case record. See OSBI CSD **QMA 1.1**.

17. If an external provider is used, the OSBI CSD report shall clearly reflect this information to the customer.

18. All DNA reports will include qualitative or quantitative interpretive statements; the method of analysis and amplification system or loci used for analysis; and a disposition of the evidence, as applicable.

19. When evidence has been transferred to another unit or will be/has been retained by the OSBI CSD, the disposition of items transferred or retained shall be reflected in the report. In addition, if an evidence disposition will differ from the standard practice outlined in OSBI CSD **QMA 1.1**, the disposition of the evidence shall be included in the report.

H. Reporting Results

Care must be taken when reporting results to ensure that the results are clear and not confusing to any lay person (attorney, DA, juror) who will ultimately read the report. The following criteria are provided as guidance to provide clear and unambiguous report language. However, the reporting Criminalist bears the ultimate responsibility for ensuring the report language accurately reflects the analysis performed in the case.

1. All results must be reflected in the report in an accurate, clear, unambiguous, and objective manner.
    a. For the purposes of this procedure, initial database entry and a confirmed association resulting from a database search are considered "tests." However, in some cases, reporting of confirmed associations (such as CODIS hits) may be reported in a simplified format, such as a "hit letter." (See OSBI CSD **QMA 1.1** – Notice to Customers regarding Simplified Reporting and discipline-specific quality manuals for additional required content.)

2. Analysis of evidence or results sections will include identification of the item tested and test results including (where appropriate) units of measurement.
    a. In some circumstances, test results may encompass a series of tests performed, provided that results are consistent. For example, if presumptive and confirmatory tests are performed on the same item and both are positive, then

one statement could be used to communicate the results (e.g. blood was detected). Discipline-specific quality and/or policy manuals shall address test results that are not consistent (e.g. one was positive, and one negative or inconclusive).

3. In some cases, it may be necessary to collect and/or create items for future testing for which no further testing may be performed.
   a. In such instances, the collection and/or creation of these items shall be clearly reflected in the report. For example, if seven soda cans are received and each are swabbed for DNA testing, but only two are analyzed for DNA, the report should reflect:

      Item 1: Seven soda cans
      Result: Each can was swabbed for DNA. Two of the seven swabs (1A1 and 1B1) were analyzed…

4. In some cases, it may be necessary to report results of evidence searching or examination, even though no testing has been performed. In such cases, the report shall clearly identify the item(s) searched and the outcome of the search, including a description of any material identified for further examination or testing.

5. Where relevant, OSBI CSD reports should include a statement indicating that the reported results apply only to the items tested and that yielded the reported result. For example, if 10 tablets are received, three are tested with no controlled dangerous substance (CDS) detected in two tablets and hydrocodone confirmed in a third tablet, report wording should be:

   Item 1: 10 white oval tablets, marked M365

   Result: Three tablets were tested. Hydrocodone was confirmed in one tablet. Two other tablets were negative for controlled substances.

6. When associations are made, the significance of association shall be communicated clearly and properly qualified in the report. Language regarding how to qualify associations should be located in discipline-specific policy manuals.

7. When comparisons are made and result in an elimination, the elimination shall be clearly stated in the report.

8. When results are inconclusive, the report shall clearly communicate why no definitive result can be made. Language regarding how to communicate inconclusive results should be located in discipline-specific policy manuals.

I. Analytical Report Format

1. All OSBI CSD reports will be numbered to indicate the page number and total number of pages in the report.

2. OSBI CSD reports will follow proper rules of grammar and correct spelling in the Criminalistics Examination Report.

3. All Criminalistics Examination Reports will be in Times New Roman font. The preferable font is size 10 or 12. Only the certification block, Digital Evidence Unit Technical Summaries, and any report footer should have a font size of less than 10 (with a minimum font size of 7).

4. The signature block will be located on the right side at the bottom of the report. This serves as identification of the person(s) authorizing the report.
5. Analysts may choose to include any individual certifications held in the report signature block once documented approval is received from the discipline technical manager and the LIMS Administrator. Analysts are responsible for ensuring any individual certifications included in the signature block are relevant to the analysis task type reported, accurate, and kept up-to-date.
    a. Example: Analysts certified in drug analysis through ABC but performing Ignitable Liquid (IL) analysis should not include certification in IL reports.

6. The report certification block will be placed next to or above the signature block.

7. Opinions and interpretations reported will be appropriately identified in the report.

8. Multiple submittals should be listed in a paragraph format immediately preceding the description of those items of evidence.

9. With the exception of the Drug and Toxicology reports, the "Analysis of Evidence" / “Opinions and Interpretations” section should be written in semi-narrative style. Item numbers and analytical results are included under this section.

10. Reports of evidence searches should be written in a narrative style and may use an alternate heading, such as “Search Narrative,” instead of “Analysis of Evidence” or “Results and Interpretations,” etc.

III. Attachments

None

I. Scope (top ↑)

Criminalists will accurately document the number of items submitted, the number of examinations performed, and the time expended analyzing items of physical evidence in each sub-case worked.

II. Procedure

A. Criminalistics statistics will be recorded by clicking the "Notes" button on the "Assignments" tab in the BEAST. Criminalists may, at their discretion, maintain a personal log book.

B. Each Criminalist who inventories and/or analyzes items in a sub-case will record the appropriate numbers in the BEAST.

C. It is the responsibility of each Criminalist to accurately record their statistics at the conclusion of the analysis.

D. Worksheets can be utilized to document the kinds and numbers of examinations made on all items of a sub-case analyzed. Worksheets will be retained in accordance with **QP 16.1** and **QP 16.2**.

E. It is acknowledged that some analytical procedures utilize reference standards, controls, or both and these shall be counted as examinations as well.

F. It is not the intent of this policy to mandate standard analytical procedures for Criminalists to follow for the analysis of specific kinds of items. However, each Criminalist shall perform sufficient analytical procedures to support the opinion rendered by the report. The following procedures are not all-inclusive. Any additional procedures to be used for statistical purposes must be approved by the appropriate Criminalistics Administrator.

G. **ANALYTICAL PROCEDURES**

Any of the following listed analytical procedures performed on an item will be counted as ONE examination. Items inventoried for report purposes only (no analysis cases) will not be counted as items analyzed or counted as examinations.

1. Seized Drugs

a) Any measurement to determine quantity of an item (i.e., weight, volume, count)

b) Macroscopic or microscopic examination for a specific purpose

c) Reference/literature search

d) Spot/color test (includes Duquenois-Levine test)

e) pH determination

f) Thin layer chromatography examination

g) Wet chemistry extraction

h) Individual instrument analysis

2. Toxicology

a) Alcohol (Volatile) Analysis

b) Immunoassays – Immunoassays for each individual drug assay will each be considered one examination

c) Blood Drug Screen – Each screen for different classifications of drugs (bases, acid – neutral) will be considered one examination

d) Quantitations for Blood Drug Concentrations – Quantitations which require separate extractions due to drug classifications will each be considered one examination

e) Reference/literature search

3. Forensic Biology

Forensic biology examinations will be counted using the spreadsheet "Biology_Number_of_Exams_Stats_Calculator_v1.0" which can be found on the DNA server (\\pm-fsc13000s\biology)

4. Firearms & Toolmarks

a) Visual examination

b) Determination of class characteristics

c) Determination of individual characteristics

d) Comparison of individual known samples to individual unknown sample

e) Firearm function examination

f) Reference/literature search

g) Any distance determination procedure

h) Chemical procedure to identify obliterated serial number

i) Shot cup or wad examination

j) Comparison of cutting or pry tool to individual cut or pry mark

5. Latent Print

a) Macroscopic examination

b) Light source examination

c) Image enhancement

d) Use of any development or processing technique

e) Electrostatic dust lifter

f) Comparison of unknown latent impression to any known impression

g) Casts and Photographs

i. Visual examination for comparison suitability

ii. Comparison to physical items for class characteristics

iii. Comparison to physical items for individual characteristics

6. Trace Evidence

a) Sample preparation

b) Macroscopic or microscopic examinations for a specific purpose

c) Specialized light examination (either macroscopic or microscopic)

d) Spot/color test

e) Microcrystal examination

f) Thin layer chromatography examination

g) Melting point determination

h) Solubility determination

i) Density determination or comparison

j) Refractive index determination or comparison

k) Individual instrument analysis

l) Reference/literature search or comparison

m) Any physical measurement or comparison

n) Arson

i. Macroscopic or microscopic examination for a specific purpose

ii. Sample preparation or isolation

iii. Burn tests

iv. Individual instrument analysis

v. Reference/Literature Search

7. Digital Evidence

a) Extraction

b) Analysis

III. Attachments

None

I. Scope (top ↑)

Proficiency tests will be used to monitor the quality of results provided by OSBI CSD analysts. This procedure will be used to conduct external and internal proficiency testing, and any re-analysis of casework samples.

II. Procedure

A. Proficiency Review Program Overview

1. The OSBI CSD shall implement a proficiency testing program which complies with current ANAB accreditation requirements and policies. ANAB requirements and policies may require, but not be limited to, the following:

   a. Promptly notify ANAB of any false positive or erroneous identification encountered in a proficiency test and provide updates regarding the investigation of the discrepancy and actions taken to correct the issue;

   b. Provide timely responses to communications from ANAB Proficiency Review Committees (PRC);

   c. Notify ANAB of any failure to comply with external proficiency testing requirements;

   d. Notify the test provider and ANAB in a timely manner regarding any concerns related to an external proficiency test and request a replacement test as soon as possible, if there is a problem that impacts the quality of the original test samples, and;

   e. Notify ANAB prior to resuming analysis in a discipline or category of testing that has been suspended as part of a corrective action.

2. In order to ensure compliance with ANAB policies, OSBI CSD employees shall communicate promptly with the Quality Manager (QM) regarding any concerns related to external proficiency tests.

3. In order to ensure compliance with the FBI's Quality Assurance Standards for DNA Databasing and Testing Laboratories, the QM shall solicit a review of the proficiency testing plan by the Biology Technical Manager (TM) prior to submitting an IPR for and, when necessary, prior to assigning DNA proficiency tests. This review can be documented by retaining a copy of e-mail correspondence in an appropriate folder within \\pm-fsc13000s\qa\Lab-System_Records\Proficiency_Tests, if desired.

4. The OSBI CSD proficiency testing program will utilize external proficiency tests or internal proficiency tests prepared in a manner such that the expected tests results are not known or

readily available to the analyst(s) assigned the test.

5. For the purpose of this policy, annual is once per calendar year.

B. Scheduling Proficiency Tests

Each year, the QM, or designee, will coordinate with Technical Managers to prepare a draft proficiency test schedule that meets the following guidelines:

1. Each OSBI CSD laboratory shall complete at least one external proficiency test in each discipline listed on the scope of accreditation annually.

2. Every employee authorized to perform testing shall complete at least one internal or external proficiency test in each accredited discipline in which he/she performs testing, annually.

3. Where practical, the proficiency testing schedule shall include a representative sample of all tests within each discipline on the scope of accreditation, annually. However, at a minimum, proficiency testing will be conducted for all test methods within each discipline, at least once per accreditation cycle.

4. Each Forensic Biologist conducting DNA analysis must complete two external proficiency tests per year. One proficiency test must be completed in the first six months of the calendar year and the second in the last six months of the calendar year. The time between tests must be at least four months, but not longer than 8 months. For calculating time periods between tests, the vendor due date will be used.

5. Forensic Biologists who are qualified for multiple DNA methods or technologies must complete proficiency tests as follows:

   a) Forensic Biologists must complete a test on each method at least once per year. Examples of different methods are GlobalFiler for casework, Fusion for database samples, manual extraction or setup, automated extraction or setup, etc.

   b) Forensic Biologists must complete at least two tests approximately 6 months apart for each technology they are qualified to use for casework or database samples. Examples of different technologies are STR analysis, Y-STR analysis, and mitochondrial DNA analysis.

   c) Results from different technologies, but not different methods, may be reported on the same test. For example, STR analysis and Y-STR analysis results may be reported on the same test.

C. Ordering External Proficiency Tests

1. The QM, or designee, will then prepare an internal purchase request to order a sufficient number of external tests as indicated by the schedule.

2. External proficiency tests will be obtained from vendors who are accredited to ISO/IEC 17043 by an accrediting body that is a signatory to the APLAC MRA or IAAC MLA and has a scope of accreditation which includes the tests being ordered, where available. If tests are needed and such a vendor is not available, the QM will obtain approval from ANAB for an alternate method or provider.

D. Assigning External Proficiency Tests

The following steps should be used to assign external proficiency tests.

1. Upon receipt of test samples from an external provider, the QM, or designee, will determine which employee each test will be assigned to and what analysis the analyst will need to conduct.

2. The QM, or designee, will then log the proficiency tests into the BEAST as described below. Some steps may be skipped or modified for proficiency tests where the test samples are received digitally or without hard-copy documentation.

   a) Open the BEAST receive.exe program.

   b) From the main screen click on the “New Lab Case” button.

   c) Click on the manual submission button on the screen that comes up. This icon looks like a hand on top of a piece of paper.

   d) Click OK on the screen that opens next.

   e) Enter PT as the case type, 00 as the county and 3 as the priority.

   f) Enter the appropriate test provider in the “Department” field.

   g) Enter “Quality Manager” in the case officer field.

   h) Enter “UPS” or the most appropriate submission type in the “Submission Type” field.

   i) If applicable, enter the UPS or other tracking number from the box or package that the proficiency tests were received in. This can also be done by scanning the barcode on the shipping label.

j) Enter the proficiency test number, including an abbreviation for the provider and the letter designator for the participant code, in the "Department Case" field.

k) Enter a name in the "Submitted By" field. For example, C.T. Services can be used as the "Submitted By" name for a CTS proficiency test.

l) Enter the date that the proficiency tests were received as the "offense date."

m) On the "Names" tab in the Quick Create screen, enter names based on the proficiency test scenario.

n) On the "Containers" tab, enter the appropriate container designator, package type, item number(s) and service request(s). Refer to **QP 5** if necessary.

o) On the "Items" tab, enter a description of what was submitted in the "Description" column.

p) Complete the case creation process by clicking the "Quick Create" button at the bottom of the screen.

3. After the case has been logged in, the QM, or designee, will attach the evidence barcode generated to the sample packet or container, if applicable, and the file folder barcode may be attached to the proficiency test data sheets.

4. Next, the QM or designees will assign the proficiency test "case" to the appropriate analyst.

a) From the main BEAST screen, click on the "Assignments" button at the top of the screen.

b) Use the search tab to bring up the list of recently created proficiency test cases. This can be done by searching on a Case Type of "PT" or a Priority of "3."

c) From the list of cases that comes up, highlight the appropriate case and click on the "Assign" button in the lower left corner.

d) Select the appropriate analyst, priority, and status.

e) Enter in the "Comments" field when the test must be returned to the QM and, if necessary, any specific analysis instructions and click "OK."

f) Repeat this process until all proficiency tests are assigned.

5. Once all proficiency tests have been logged in and labeled with barcodes, the QM, or

designee, will scan the barcodes for the case files to the FSC File Room or other appropriate location. The data sheets will be provided to the appropriate analyst (hard copy or electronically) and no further custody transactions will be tracked for the data sheets.

6. The sample packs will be transferred to the custody of the appropriate analyst or transferred to/routed to the appropriate property room location, if applicable.

E. Preparing Internal Proficiency Tests

Internal proficiency tests may consist of re-usable, expired external proficiency tests, external proficiency tests which can be analyzed multiple times, internally prepared samples, or re-analysis casework. When internal proficiency tests (including any observation-based monitoring) are prepared, the Technical Manager of the discipline will ensure the expected results are not known to the participant or readily available to the participant. For internal proficiency tests, a key or similar grading rubric, will be prepared prior to administering the test to the participant that establishes criteria for determining successful completion of the test.

1. When internal proficiency tests are used, the individual preparing the test shall utilize an appropriate mechanism to ensure the quality of the test prior to assignment. Examples of such a mechanism may include one or more of the following methods:

   a) Inspecting the items to verify there has been no degradation since last testing;

   b) Inspecting samples to verify sufficient quantity remains for further testing;

   c) Inspecting samples to verify they are not labeled in a manner which would preclude their use;

   d) Ensuring proper documentation of the correlation between original case and item numbers and the case and item numbers used for the internal proficiency test;

   e) Testing a portion of a sample or a replicate sample prepared at the same time and in the same manner;

   f) Where permissible by policy, using items previously and recently tested in casework.

2. Internal proficiency tests may be prepared from re-used external proficiency tests by following these steps:

   a) The samples will first be packaged in a fashion which precludes associating the samples with the original manufacturer test number.

   b) The samples will be assigned a proficiency test number in the following format IPT-QM-

YY-NNN, where YY is a two-digit representation of the year the proficiency test will be assigned, and NNN is a chronological number assigned to the test. Alternately, "QM" may be replaced with a designator for the discipline of the test (e.g. LP for latent prints).

c) The test number and the expected results associated with the test must be recorded.

3. An external proficiency test may be assigned to one or more analyst(s) as an internal proficiency test when the test samples lend themselves to multiple examinations (e.g. comparison of latent print images ordered on a DVD). In these situations, the test will be assigned in the same fashion as an external proficiency test and must be completed prior to the release of the manufacturer's results. The department case number for an external test that will not be submitted to the manufacturer will include a suffix with "IPT" and a letter to designate the participant. (e.g. CTS11-518-IPT-A)

4. Internal proficiency tests prepared "from scratch" in-house will be prepared by the appropriate Technical Manager, or designee, using the following guidelines:

a) The composition of the proficiency test will be determined based on the type of procedure and samples tested.

b) All proficiency tests should be prepared using samples, materials, and methods that ensure the uniformity, integrity, and identity of the proficiency testing samples.

c) Duplicate testing samples should be prepared and retained when possible. Alternately, test samples should be prepared in a fashion that will facilitate re-testing, in the event of a potential discrepancy.

d) Proficiency test samples that use comparisons or produce qualitative results should be prepared in such a way that they contain sufficient class/individual characteristics for meaningful analysis and comparison.

e) For those proficiency tests that evaluate procedures which produce quantitative results, samples should contain an amount of testing material sufficient to enable a conclusion to be drawn from the results of the analysis.

f) Proficiency tests should include appropriate controls among the samples submitted, where appropriate or necessary. Standard reference materials may be used as part of the control system if available for a particular examination.

g) Each set of proficiency samples must be labeled with a test set identifier using the format IPT-TMD-YY-NNN, where TMD is a designator for the discipline or the individual preparing the test (e.g. CDS, TM's initials, etc.), YY is a two-digit abbreviation of the year the test will be assigned/created, and NNN is a chronological number assigned to the

test.

h) Preparation documentation, including expected results, for internally prepared proficiency tests will be stored on the Quality server in the Lab-System_Records folder, Proficiency_Tests, Year, Internal folder.

i) After analysis, any remaining portion of each proficiency test sample will be returned to the QM, or designee, for possible reassignment and/or re-analysis and comparison if circumstances dictate.

5. Cases may be selected for re-analysis at the discretion of the Technical Manager, following the guidelines set forth below.

F. Assigning Internal Proficiency Tests

1. Re-used external proficiency tests will be assigned by the QM or designee, using the procedure outlined in section II.D, with the following exceptions:

   a) II.D.2.f - In the department field, enter IPT to indicate the case is an internal proficiency test.

   b) II.D.2.h and i – For the submission method, choose hand delivered no signature.

   c) II.D.2.j – Enter the internal proficiency test case number.

   d) II.D.3 – The barcode for the case file may be placed on a hard copy of the RFLE and routed to the appropriate analyst.

2. Internal proficiency tests created in-house will be assigned by the appropriate TM or designee, using the procedure outlined in section II.D, with the same exceptions listed above. TM's, or a designee, must provide the QM a record of the test number, method of preparation, and the expected results at the time the test is assigned to an analyst.

G. Analysis of Proficiency Tests

1. Proficiency tests will be analyzed using the same approved analytical protocols as casework. This includes all verifications and administrative and technical reviews required by current OSBI policy. Similarly, any work on a proficiency test that would constitute nonconforming work in casework or database analysis shall be evaluated and addressed following **QP 13** and **QP 14.1** through **QP 14.3**.

2. All proficiency tests will be handled in compliance with the OSBI CSD Quality Manual and Quality Procedures. This includes policies regarding itemization and evidence handling.

3. Proficiency tests will be analyzed to the full capability of the analyst assigned. Each analyst will conduct all appropriate examinations for which he/she is qualified based on the case information provided with the test. If the test provider's instructions conflict with this practice, the test will be analyzed per the test provider's instructions. For example, for a toxicology proficiency test, if the test instructions indicate the sample(s) should not be analyzed for ethanol, then ethanol testing will not be performed.

4. The same examination documentation generated during testing will be generated and retained in the case records or according to discipline-specific requirements during the analysis of proficiency tests.

5. Results of proficiency tests will be reported to the QM in an OSBI report or according to the normal protocol documentation for any discipline which does not issue a standard OSBI report (e.g. database units).

6. External proficiency test data sheets will be completed by the analyst in their entirety. This includes any section which requires the analyst to list a narrative statement of how their conclusions would be reported. It is not acceptable to put "See Attached Report," since only the data sheets are submitted to the vendor.

7. Remaining samples will also be returned to the QM, or they may be archived according to the unit's standard procedures for database proficiency samples. When multiple analysts in the same lab or unit have participated in the same proficiency test, all sample packets from the unit/lab should be returned at one time to the QM.

H. Submitting External Proficiency Test Results

All assigned external proficiency test results must be submitted to the vendor prior to the assigned deadline and submitted for release to ANAB, unless the QM approves an exception.

1. **Collaborative Testing Services (CTS)**

CTS tests which are assigned as an external proficiency test shall be submitted through the CTS on-line portal. The following steps may be used to enter results:

NOTE: QM may assign proficiency tests when received; therefore, some steps below may not be necessary for tests already assigned in the portal.

a) Login to the portal at http://www.cts-portal.com/. (New users will need to contact the Quality Manager to be registered as a user. The login requires an analyst's OSBI e-mail address and a password established by the analyst during the registration process.)

b) Click on "Claim New Data Entry" from the menu on the left side of the webpage.

c) Select the appropriate test and enter the participant code and web-code. Once the participant code has been entered, the web code field should self-populate. Verify the web code is also correct, and then click on "Find Test." Once the test appears, click on "Claim this test."

d) Once the test is claimed, open the test and enter results in the form. DNA analysts should ensure that the proper analysis kit has been selected in order to put the loci in kit order.

e) When the form is complete and the case file is routed for review, clicking on "Forward to a Group," selecting the group that represents the discipline (e.g. Analysts_Biology), and clicking "Send" will allow a reviewer to conduct an administrative review of the data sheets prior to submission.

f) Once the test is completed and ready for submission to CTS, submit the test to "QM_Review." The test will be reviewed by the QM and submitted to CTS upon completion of the review.

The follow steps may be used as a guide to review another analyst's results during the administrative or technical review process:

a) Locate the analyst's test assigned for review.

b) Click "Claim" in the "Action" column.

c) A new window will pop up and in the "Tests I'm Reviewing" section, click the "Open" link for the test you are reviewing.

d) Review the data sheets to ensure the reported results are consistent with the OSBI report and examiner's notes. Use the "next" button in the bottom corner to advance through all pages of the data sheets as necessary.

e) After the review is complete, click the "Back" link in the top left corner of the screen, which will return to the "Tests I'm Reviewing" section.

f) Click the link for "Post Review Actions" and select the appropriate option (e.g. "Return to User as Complete").

2. **Pre-Submission Review**

Tests which are completed by multiple analysts may be reviewed by the QM prior to submission of results to the proficiency test vendor. In the event that the QM identifies a discrepancy, the QM will evaluate whether the discrepancy is due to a transcriptional error

or not. If the discrepancy is clearly a transcriptional error (e.g. results on the data entry sheet does not match the results reported by the analyst in the OSBI report or documented in the analyst's notes), then the QM may notify the analyst and request the data sheets be corrected.

In the event that the discrepancy is not due to a transcriptional error, no changes will be made and the source of the discrepancy will be researched further in accordance with **QP 13**.

I. Review of Proficiency Tests

Proficiency tests will be reviewed to determine if they have been successfully completed. Proficiency tests are considered successfully completed under two sets of circumstances. First, tests are successful when the results obtained are consistent with the expected, manufacturer's, and/or consensus results. However, in some circumstances, results do not match the expected results. This can indicate that improvements may need to be made to the quality system, such as improved procedures/instrumentation, clarified protocols, or more thorough training programs. After laboratory policies are followed and any necessary corrective action is successfully completed, then the proficiency test that may have yielded discrepant results may be considered successfully completed. The following steps will be used as a guide for reviewing proficiency tests and routing for corrective action when necessary.

1. Upon receipt of a completed test, the QM or TM will review the following documentation to determine if the expected results were obtained.

   a) External tests – manufacturer's results and consensus results (once received)

   b) Re-used external tests – manufacturer's results and consensus results

   c) Internal tests created in-house – expected results provided by TM

   d) Re-analysis cases – memo from TM indicating whether second results were consistent with original analysis.

   e) Observation-based tests – memo from TM indicating the expected steps/results for the procedure/test

2. The QM will forward any external proficiency test results received to the discipline TM for grading. The TM is responsible for grading proficiency tests. The TM will notify the analyst/participant of the grading either by forwarding the hard copy results page to the participant(s) or by an e-mail notification to the analyst and any other participants. Each individual will acknowledge the grading by either initialing or signing and dating the hard-copy page to document his/her notification or will respond to the e-mailed proficiency test

grading notification from the TM. This acknowledgment will be returned to the TM for archival.

3. The TM will ensure any test with discrepant results is routed for corrective action as needed. This may include forwarding the test to a designee for a more detailed review. Potentially nonconforming work will be evaluated according to **QP 13**.

J. Review of Toxicology Proficiency Tests

Toxicology proficiency tests will be reviewed using the following criteria to evaluate whether the reported results are or are not consistent with manufacturer and consensus results.

1. Alcohol and drug quantitative results shall be evaluated by comparing the reported result to the grand mean of responses. Results which fall within two standard deviations or which fall within +/- 10% for alcohol or +/- 20% for drug quantitations will be considered acceptable.

2. Measurement uncertainty shall also be taken into consideration when comparing the reported result to consensus results.

3. Qualitative results shall be evaluated by determining whether all expected compounds were identified. Any discrepancies indicating a potential false negative or false positive shall be referred for further review.

K. Review of DNA Proficiency Tests

It is the responsibility of the Biology TM to evaluate DNA proficiency tests in accordance with the current revision of the Quality Assurance Standards (QAS) for Forensic DNA Testing or Databasing Laboratories. This includes grading the analyst's performance on the test as satisfactory or unsatisfactory based on a review of the electropherograms and the analyst's compliance with current OSBI interpretation guidelines. The procedure below provides a guide for facilitating this review.

1. For DNA proficiency tests, the QM will route the results page(s) to the Biology TM and the following information will be noted by the TM:

   a) Are results satisfactory or unsatisfactory?

   b) Are all reported inclusions correct (if applicable)?

   c) Are all reported exclusions correct (if applicable)?

   d) Are all reported genotypes and/or phenotypes correct or incorrect according to consensus results or within the laboratory's interpretation guidelines?

e) Are results reported as inconclusive or not interpretable consistent with written laboratory guidelines?

2. For any DNA proficiency test identified with non-administrative discrepancies that affect the typing results and/or conclusions, the TM will inform the appropriate CODIS Administrator at the time of discovery. The CODIS Administrator will sign/initial and date the pages to indicate he/she has been notified.

3. The TM will sign/initial and date the page(s) and then forward them to the appropriate analyst and any other participant for him/her to sign/initial and date to indicate he/she received notification of test results.

4. The Biology TM and QM will work together to ensure any DNA test with discrepant results is routed for corrective action as needed. This may include forwarding the test to the Biology sub-committee, or a designee, for a more detailed review. Potentially nonconforming work will be evaluated according to **QP 13**.

5. When necessary or practical, notifications of analysts, other participants, TM's, or the CODIS Administrator may be done via e-mail or an alternate method, provided that adequate documentation is maintained to demonstrate that the notification has been received.

L. Documentation of Proficiency Tests

The following documentation shall be maintained for each test completed:

1. Test set identifier

2. Disciplines tested

3. Expected results

4. How the samples were obtained (test provider for external) or created

5. Identity of analyst and other participant(s), if applicable and location where the test was taken (e.g. FSC, NERL, etc.)

6. Date of analysis

7. Date of completion

8. All data sheets, notes, and technical records (scans, electropherograms, etc.)

9. Report of results

10. Documentation of results submitted to external proficiency test providers

11. Provider's proficiency test evaluation, for external tests

12. Review of any discrepancies noted, if applicable

13. Notice to the analyst/participant of the proficiency test results and review

14. Notification to TM of results and review, for DNA proficiency tests

15. Notice of any deficiencies and corrective action (if needed)

M. Re-examination

Re-examination casework may be assigned as an additional quality control measure, at the discretion of the TM. The guide for re-examination cases is as follows:

1. Re-examination cases will be selected and issued by the TM of each discipline. Re-examination cases may be selected from evidence already authorized for destruction, if appropriate.

2. If possible and practical, the original analytical results will be unknown to the second analyst.

3. Re-examination results will be reported in the same fashion as original analysis with the following exceptions:

   a) A statement or footer will be placed on the report indicating that the results reported were generated from a re-examination of the evidence conducted as part of a routine OSBI quality control process.

4. Upon completion of the re-examination, the re-examining analyst will provide his/her results to the TM for review **prior to approving his/her report of analysis**.

5. Once completed, all documentation of the re-analysis will be placed in the original case file.

6. The Technical Manager will issue a memo stating the case number, analysts involved in retesting, whether the test was assigned as an internal proficiency test or additional QC, and a summary of results indicating whether results were concordant or discrepant to the QM.

7. Inconsistent results will be evaluated as nonconforming work according to **QP 13**.

8. The QM will retain re-examination documentation memos.

III. Attachments

None

I. Scope (top ↑)

All case record documentation is subject to review. Review assists in ensuring the quality of the products of work in the CSD. Two types of review will be used: administrative review and technical review.

II. Procedure

A. General

1. The review process does not shift responsibility for an analyst's findings to the reviewer. Each Criminalist has the ultimate responsibility for their casework.

2. Prior to submitting case files for administrative or technical review, each criminalist will thoroughly review his/her own reports and case records. Upon completion of this review the analyst will click on the "Sign" button on the right side of the assignments window. This will lock the report and documentation in the BEAST and prevent unintentional changes.

3. Administrative and technical reviews may be done consecutively in either order (AR-TR or TR-AR) or concurrently (at the same time).

4. Additional administrative or technical reviews (above the minimum required by policy) may be done as necessary or desired by CSD management.

5. Cases requiring correction will be routed in the BEAST to the appropriate analyst for correction. When routing cases for correction, it is recommended the reviewer include an explanation in the comments field or in an e-mail to the analyst describing what must be corrected. However, in some cases it may be more productive to discuss the expected corrections via phone or an in person discussion. Regardless of how the reviewer's observations are communicated, **any changes made to technical/examination records during or after the review process must be recorded.**

B. Technical Review

Technical reviews will be performed according to the procedure below to ensure that reported conclusions are correct and reasonable, in accordance with validated scientific knowledge, and supported by the examination documentation in the case record.

1. Qualifications of Technical Reviewers:

   An individual performing technical reviews must meet the following requirements:

   a) He/she must be a qualified individual who is not the author or co-author of the report **or examination records** being reviewed.

b) He/she must have received authorization from the discipline Technical Manager (TM) to conduct the technical review based on successfully completing a competency test(s) in the task(s) being reviewed.

c) He/she must have knowledge of the discipline protocols/quality manual applicable to the case he/she is reviewing.

2. Scope of Technical Reviews:

A technical review is a thorough review of the entire case file/record including the Examination Report. Verifications of latent evidence identifications and firearms/toolmarks identifications do not constitute a technical review.

Technical reviews are not required for reports which do not contain the components described below (e.g. analytical results, conclusions, associations, etc.). Some examples of reports which may not contain these elements include amended reports, if the correction made does not impact the results, conclusions, or associations of the original report. Additionally, CODIS Hit Letters may also not contain these elements.

For technical reviews, a legible photocopy or fax of the entire file, including the signed report, are to be sent for review only when the original case file cannot be examined on site. **ORIGINAL CASE FILES WILL NOT BE MAILED.**

3. Parameters for Technical Review Process:

Discipline protocols and/or quality manuals may describe more specific portions of technical records which must be checked to complete a technical review. However, any discipline-specific review procedures must include a verification of the following, at a minimum:

a) compliance with all applicable sections of the discipline quality manual and protocols and CSD policies and procedures;

b) all reported results, opinions, and interpretations are accurate and supported by the data in the case record;

c) any associations are properly qualified in the report;

d) report contains all information required by discipline quality manual and protocols.

4. Documenting Technical Reviews:

Technical reviews will be documented using one of the following methods:

a) Using the BEAST to complete the following steps:

i. click on the "Tech Rev" button from the assignments tab

ii. complete the checklist in the window that opens (if applicable)

iii. click the "Tech Rev" button in the lower right corner

iv. enter your password and click "yes"

b) Completing a hard copy version of the checklist and signing and dating the hard copy. Hard copy technical review forms will be obtained by accessing the "Reports" button from the main BEAST screen. Run the "TECH_REVIEW: Hardcopy Tech Review form" report and print the discipline appropriate form. The hard copy must then be placed in the case file or scanned and saved to the image vault in the BEAST. This method should only be used for documenting additional technical reviews or if technical difficulties with the BEAST necessitate an alternate method.

5. Handling Technical Review Discrepancies

If an analyst and technical reviewer disagree whether a report and case file meets the criteria listed above, the following steps will be taken to resolve the discrepancy or disagreement.

a) The analyst and the technical reviewer will discuss the issue and attempt to resolve the issue together.

b) If the criminalists cannot resolve the issue together, they will seek input from the appropriate TM.

c) Any disagreements which cannot be resolved by the TM will be brought to the attention of the Criminalist Administrator assigned to that discipline and the Quality Manager for further evaluation.

Any nonconforming work identified during review will be handled according to **QP 13**.

6. Frequency of Technical Reviews:

a) All case files of Criminalist I's will be technically reviewed until the TM of the discipline feels that the Criminalist is fully competent and no longer requires 100 percent technical review. The TM of the discipline determines the level (within policy) of technical review for employees within their discipline.

b) The minimum level of technical review for all Criminalists will be at least six cases per month or 20 percent of the cases worked per month, whichever is less.

c) The TM of each discipline will determine the number or percentage of cases and the types of cases which must be technically reviewed.

d) The TM of the discipline is responsible for designing a system to monitor the number of cases technically reviewed ensuring that the minimum number specified are reviewed.

C. Administrative Review

1. All OSBI case files, with the exception of BEAST generated no analysis reports, will be administratively reviewed by an individual other than the reporting analyst in accordance with the following procedure, prior to being released to an outside agency.

   a) Administrative reviews may be performed by any casework qualified analyst or Supervisor. A casework qualified analyst or Supervisor may conduct administrative reviews for any discipline, not just the discipline for which he/she is qualified to perform casework.

   b) Administrative reviews may also be performed by a properly trained laboratory analyst or laboratory technician. Administrative review training for these employees must include a review of **QP 31** and the discipline-specific case documentation which they will be responsible for reviewing. The appropriate Supervisor and/or TM will be responsible for documenting the training completed and the date that the individual has been approved to conduct administrative reviews.

2. Administrative reviews will include the following:

   a) a review of the report(s) for spelling and grammatical accuracy;

   b) a review of all administrative and examination records to ensure they are labeled with the case number and initials of the appropriate individual(s) and/or any alternate or additional identification required by discipline or laboratory policy/procedure;

   c) a review of the report to ensure that all key information required by **QP 28** is included;

   d) a review of the evidence described in the report compared to the evidence described on the original RFLE and/or submission paperwork;

   e) a review of the report (for DNA reports) to ensure that it includes a description of the technology and loci or amplification system used and a disposition of the evidence.

3. Documentation of administrative review will be done by one of the following methods:

   a) Completion of the technical review documentation process for an AR/TR conducted concurrently. It must be documented in the discipline procedure or checklist that the review includes both administrative and technical review.

   b) Completion of a similar BEAST method developed for a specific discipline with the LIMS Administrator's assistance/guidance which has been written into the discipline quality

manual or protocol.

c) Completion of a hard copy or electronic version of OSBI CSD **QPA 31.1**. A hard copy should be signed and dated by the reviewer and placed in the case file or scanned and saved to the image vault in the BEAST. Alternately, if the form will be placed in the image vault in the BEAST by the reviewer, it may be completed electronically with the analyst's typed name and date.

III. Attachments

OSBI CSD QPA 31.1, Rev01 Case File Administrative Review Form
(Available in QMS Forms Folder)

I. Scope (top ↑)

Each OSBI CSD employee will use this procedure to actively solicit feedback regarding testimony he/she provides. In addition, the OSBI CSD will ensure testimony in each discipline is reviewed by a qualified technical reviewer in the discipline annually.

II. Procedure

A. Procedures for Using the Witness Critique Form

1. Whenever possible, testifying employees shall give a Witness Critique Form (OSBI CSD **QPA 32.1**) to judges, prosecutors, defense attorneys, and other persons in a position to evaluate their testimony. Alternately, examiners assigned to the ATTDFL may provide OSBI CSD **QPA 32.2** in order to solicit feedback. Employees will actively encourage them to objectively complete the form and provide the form (via mail, fax, or e-mail) to the OSBI CSD Quality Manager (QM). Employees may directly accept a completed form to return to the QM.

2. Supervisors and peers not qualified in the type of testimony provided will use the Witness Critique Form OSBI **QPA 32.1** or **QPA 32.2** when observing and evaluating the testimony of laboratory employees.

3. Supervisors and peers qualified in the type of testimony provided will use the Testimony Review Qualified Reviewer Form (OSBI CSD **QPA 32.4**) when observing and **technically reviewing the testimony of employees.** The qualified reviewer should review the case record, including the report, as well as the analyst's Authorization to Work when technically reviewing testimony.

4. The QM, or designee, will document all witness critique forms received and forward them to the immediate Supervisor of the evaluated employee.

5. The Supervisor shall review each evaluation with the employee. Strengths and deficiencies will be noted and discussed, and recommendations for improvements may be made. Both the Supervisor and employee will sign the form after the review and discussion. The Supervisor shall then ensure that an imaged copy of the signed review form is placed in the employee's training file located on the quality server in the following directory: \\pm-fsc13000s\qa\Individual_Records.

6. The QM, or designee, will maintain a spreadsheet summarizing all completed Witness Critique Forms. The spreadsheet will track who has been evaluated. The QM may provide access to the spreadsheet to Supervisors and Criminalistics Administrators as necessary and appropriate.

7. It is recommended all testifying employees are evaluated by a qualified reviewer at least once per calendar year. However, at a minimum, Supervisors shall ensure that all their testifying employees are evaluated by a qualified reviewer at least once per accreditation cycle. Ideally,

a qualified reviewer should be an individual who is also currently qualified in (authorized to perform) the type of work the employee is testifying about. However, at a minimum, a qualified reviewer must have been previously competency tested in the task(s) which the review encompasses. The review may be conducted by witnessing the employee's testimony or by a review of a transcript or recording of the employee's testimony.

8. Supervisors and TM's are strongly encouraged to personally observe the testimony of each of their testifying employees. Once a year is recommended. More frequent intervals are encouraged for less experienced personnel. It is desirable that employees testifying for the first time be observed by their Supervisor or Technical Manager.

B. Other Methods of Monitoring and Evaluating Employee Testimony

1. It is recommended that Supervisors periodically read the transcripts of testimony given by their employees when such transcripts are readily available, and discuss the testimony with the employee.

2. It is recommended that Supervisors periodically telephone or personally contact one or more officers of the court to solicit feedback on the testimony of their employees. The information obtained should be recorded on the Witness Critique Form (OSBI CSD **QPA 32.1** or **QPA 32.2**), discussed with the employee, and forwarded to the QM.

C. Corrective Action

When the rating received on a witness critique form is less than satisfactory (response of disagree or strongly disagree), the Supervisor will coordinate with the Technical Manager to review the circumstances of the testimony to determine whether the analyst needs additional training. The Supervisor will document the review in the appropriate section of OSBI CSD **QPA 32.1, QPA 32.2** and **QPA 32.4**.

In the event that it is determined that erroneous or misleading testimony was provided, the Supervisor of the testifying employee will follow **QP 13** to evaluate the nonconforming work.

D. Reporting Testimony Appearance

1. Each individual in the CSD who testifies or makes an appearance at a court or DPS hearing is required to complete a Testimony Report Form (OSBI CSD **QPA 32.3**).

2. Copies of the Testimony Report Form will be distributed as follows:
   a. A copy will be uploaded into the BEAST for the case for which the appearance was made. The file name will include the word "Testimony".

   b. A copy will be forwarded to the LIMS Administrator. At the latest this copy should be provided to the LIMS Administrator by the end of the month in which the appearance took place.

c. A copy may be retained by the testifying individual.

3. Any CSD personnel who attend court or a hearing as an observer of testimony do not need to complete a Testimony Report Form (OSBI CSD **QPA 32.3**).

III. Attachments

OSBI CSD QPA 32.1, Rev03 Witness Critique Form
OSBI CSD QPA 32.2, Rev01 ATTDFL Witness Critique Form
OSBI CSD QPA 32.3, Rev01 Testimony Report Form
OSBI CSD QPA 32.4, Rev00 Testimony Review - Qualified Reviewer Form
(Available in QMS Forms Folder)

I. Scope (top ↑)

Laboratory analysis case records and reports and other information concerning products of work from the OSBI CSD are made confidential by State Statutes. Case information may only be provided as allowed by law.

II. Procedure

A. Persons or Agencies Authorized to Receive OSBI Analytical Reports

1. Title 74 O.S., § 150.2, paragraph 1 states the OSBI shall "maintain a nationally accredited scientific laboratory to assist all law enforcement agencies in the discovery and detection of criminal activity."

2. Title 74, O.S., § 150.5(D) states: "all records relating to any investigation being conducted by the Bureau, including any records of laboratory services provided to law enforcement agencies pursuant to paragraph 1 Section 150.2 of this title, shall be confidential and shall not be open to the public….." and "the person or entity authorized to initiate investigations (laboratory services) in this section shall receive a report of the results of the requested investigation." Therefore, a copy of an OSBI laboratory analysis case record, including the report, can be provided to the following requestors of forensic laboratory services:

   a) Governor

   b) Attorney General

   c) Council on Judicial Complaints

   d) A Legislative Committee with Subpoena Powers

   e) Chief Medical Examiner

   f) Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control

   g) Law Enforcement Agency or Officer

   h) District Attorney

3. Title 74, O.S., § 150.5(D) further states: "The person or entity requesting the investigation (forensic laboratory services) may give that information only to the appropriate prosecutorial officer or agency having statutory authority in the matter..." therefore, the requestor of forensic laboratory services may provide, or authorize the OSBI Laboratory to provide, a copy of a laboratory analysis report to a prosecutor or prosecutorial agency with jurisdiction in the case.

4. Title 74, O.S., § 150.5(D) also states "officers and agents of the Bureau may disclose, at the discretion of the Director, such investigative information (laboratory analysis case record information and reports) to officers and agents of federal, state, county, or municipal law enforcement agencies and to district attorneys, in the furtherance of criminal investigations within their respective jurisdictions." The OSBI Director has given authority over laboratory report dissemination to the CSD Director. Unless specifically requested not to by the submitting agency, the CSD Director has authorized that prosecuting attorney offices with jurisdiction may always receive copies of laboratory analysis reports.

5. Title 47, O.S. § 47-752(J) states "Any agency or laboratory certified by the Board…which analyses breath, blood, or urine shall make available a written report of the results of the test administered by or at the direction of the law enforcement officer to:

   a) The tested person, or his/her attorney

   b) The Commissioner of Public Safety

   c) The Fatality Analysis Reporting System (FARS) analyst of the state, upon request."

6. Regarding the provision of laboratory reports and information to OSBI Investigative Division personnel, authority is provided in two areas. First, intra-agency sharing of forensic laboratory and criminal investigative information in furtherance of criminal investigations or prosecutions is not prohibited by the confidentiality statute, and is desirable and beneficial. Second, the state statute provides for, at the discretion of the Director, the disclosure of records of laboratory services to officers and agents of state law enforcement agencies in the furtherance of criminal investigations within their respective jurisdictions. The person granting the information will document all requests and disseminations in the respective laboratory case file as to the information provided.

B. Criminalistics Analysis Report Dissemination

1. The appropriate number of reports will be made and distributed as follows:

   a) A minimum of one signed report should be issued to the prosecuting authority having jurisdiction and/or the requesting agency. In some circumstances it may be appropriate to send a report to the requesting agency only. For example, some case types such as property crimes where no suspect has been identified do not need to be distributed to the prosecuting authority.

   b) No hard copy report needs to be distributed if the receiving agencies have already been issued access to the reports on-line. The list of agencies which don't require hard copy reports will be issued at the discretion of the LIMS administrator.

   c) An electronic copy of each report prepared using the BEAST Laboratory Information Management System (LIMS) will be maintained in the BEAST.

d) Reports will not be distributed via e-mail without the express permission of the CSD Director.

e) When reports or other case related information containing confidential information are disseminated by fax, they shall be sent using OSBI CSD **QPA 33.1** as a fax cover sheet so that a notice of confidentiality is included with the fax transmission.

2. One copy of the report can be retained with the evidence.

3. The only exception to the above is in a situation noted on the RFLE limiting report distribution at the request of the submitting officer, or with the permission of the appropriate Criminalistics Administrator or CSD Director.

C. Inquiries Concerning Case Related Information

1. Occasionally, calls are received requesting information on laboratory cases, including requests for reports and case records, from the news media, family members, attorneys and others. These requests should be handled as indicated below.

a) All calls from the news media will be routed through the Oklahoma State Bureau of Investigation Public Information Office.

b) Other calls from families, friends or others interested in information concerning a CSD case should be directed to the original submitting agency in the case.

c) Information may be provided to prosecutors, investigators, and, for toxicology cases, defendants as outlined above. However, the statutes referenced above do not permit direct release of case information to defense attorneys. When requests for case information are received directly from the defense, OSBI CSD employees will contact the prosecuting attorney and request permission to share case information with the defense. The prosecuting attorney's approval shall be obtained prior to providing case information. The approval shall be documented in a narrative in the case record. In the event the prosecuting attorney does not approve, CSD employees should notify their Supervisor to see what other steps can be taken to accommodate the defense request for information.

d) Care should be taken prior to releasing case information to ensure the identity of the individual requesting the information. CSD employees can use the following methods to verify the identity of requestors:

i. Use of caller ID.

ii. Returning calls to attorneys and investigators after looking up an office number for the appropriate agency.

iii. Verifying attorneys of record through searching OSCN.net records.

iv. Requiring a copy of a driver's license when providing toxicology results directly to defendants.

e) The CSD Director must approve any exceptions to the release of case information.

2. Discovery orders will be handled as per **OSBI Policy 226**.

III. Attachments

OSBI CSD QPA 33.1, Rev01 OSBI CSD Fax Cover Sheet
(Available in the QMS Forms Folder)

APPROVAL

Per OSBI CSD QP 2 – Document Control

OSBI CSD Quality Manager: Digitally signed by J. Janice Joslin DN: cn=J. Janice Joslin, o=Oklahoma State Bureau of Investigation, ou=CSD Administration, email=janice.joslin@osbi.ok.gov, c=US Date: 2020.08.16 11:25:11 -05'00' 08/16/2020

J. Janice Joslin Date

OSBI CSD Director: 8/16/2020

Andrea R. Fielding Date

HISTORY

Rev00 (effective date July 15, 2019)
Reformat entire Manual in order to align with ISO/IEC 17025:2017 Standards and AR 3125 order. Additionally, reformatted to include a table of contents and font type/size. Updates throughout in order to move to ISO/IEC 17025:2017 and AR 3125.

Grammatical changes throughout.

Table of Contents
Added hyperlinks to QMA 1.1, QMA 2, QMA 3, QMA 4.1, QMA 4.2, QMA 5, and QPA 6.2.1.

QM_2 REFERENCES
Updated references to reflect ISO/IEC 17025:2017 and AR 3125.

QM_3 TERMS and DEFINITIONS
Updated 17025:2005 versions of definitions for Complaint, Customer, and Sampling to 17025:2017 version. Also deleted 17025:2005 reference in Preventive Action definition. Changed Sample Selection definition to reflect definition provided in AR 3125 (effective date 11-2018) – the 04-2019 revision removed this definition, but this definition remains in the OSBI CSD Quality Manual. Added 17025:2017 reference to Verification.

QM_4.1.3
Added “conflicts of interest” and “The OSBI CSD will not allow commercial, financial, or other pressures to compromise impartiality.”

QM_4.1.5
Added “the examiner shall make the Supervisor aware of this potential risk.” And changed “may” to “should” regarding documenting the circumstance in a case narrative.

QM_4.2.1
Added “All case related information is considered proprietary information and shall be regarded as confidential with the exception of information the customer makes publicly available, or when agreed between the OSBI CSD and the customer (e.g. for the purposes of responding to complaints).”

QM_4.2.3
Added “in writing”.

QM_4.2.4
Added “/assessors”.

QM_5.1
Added “(ATTDFL)”.

QM_5.2.1
Added “of as well as the education and experience requirements for”.

QM_5.4
Added “and regulating authorities”, “within the OSBI CSD Scope of Accreditation”, and “and at sites away from its permanent facility or at a customer’s facility”.

QM_5.4.1
Added “FBI Quality Assurance Standards for Forensic DNA Testing Laboratories and the FBI Quality Assurance Standards for DNA Databasing Laboratories”.

QM_5.5
Added “the Quality Management System…program” to define the QMS acronym, added “(including analysis and data interpretation to arrive at a result, opinion, or interpretation)”, “documents”, and “policy/”. Updated link to job descriptions.

QM_5.6
Added “/departures” in two places.

QM_5.7
Added “OSBI CSD management” and “Changes to the management system will be monitored through regular discussion (meetings, etc.) to ensure changes to the management system are achieving intended goals.”

QM_6.1
Added “The OSBI CSD shall make available the necessary personnel, facilities, equipment, systems, and support services necessary to manage and perform laboratory activities.”

QM_6.2.2
Added list of laboratory activities which influence the resutls of testing (a-j).

QM_6.2.2.1
Added AR 3125 6.2.2.1 reference.

QM_6.2.2.2
Added “and/” and “general”.

QM_6.2.3
Added “/departures from policy and protocols.” Removed “if applicable” to align with QP 19 procedures.

QM_6.2.3.1
Added “testing (including those that”, “review reports or testimony – see section 6.2.2 above)”, added examples of activities that influence the results of testing activities. Added “The competency test shall

include a practical examination for the spectrum of tasks related to the testing. The competency test intended results shall be achieved prior to authorization to perform the tasks on test items." and "NOTE: No supervised casework on evidentiary samples will occur prior to authorization for testing. Trainees will only perform work on training samples."
QM_6.2.3.2
Added "for the testing tasks being reviewed."

QM_6.2.4
Added "Current job descriptions are located at https://omes.ok.gov/careers/job-family/criminalist.

QM_6.2.5
Added "In accordance with accreditation requirements, the OSBI CSD has procedures and retains record for the following as required:

g) Determining competence requirements (**QP 19**);
h) Selection of personnel (see **OSBI Policies 215.1** OSBI Recruitment Plan, **215.2** Interview and Selection Procedures, **215.3** Promotional Postings and the State of Oklahoma Human Capital Management regulations(https://www.ok.gov/opm/State_Jobs/index.html));
i) Training (**QP 19** and discipline quality/training manuals);
j) Supervision of personnel (see **OSBI Policies 214** Performance Evaluation (PMP), **115** Attendance and Leave, Human Resources Department);
k) Authorization of personnel (**QP 19** and discipline quality/training manuals)
l) Monitoring competence of personnel (**QP 30** Proficiency Tests, **OSBI Policy 214** Performance Evaluations, **QP 31** (and discipline quality manuals) Technical and Administrative Review, and **QP 32** Testimony Reviews)

QM_6.2.6
Added "Individuals will be authorized to perform specific laboratory activities as listed in **QP 19** – Training, including but not limited to:

d) development, modification, verification, and validation of methods;
e) analysis of results, including statements of conformity or opinions and interpretations;
f) reporting, review, and authorization of results.

The authorization should include all aspects of testing, including the use of equipment – see **QP 19**."

QM_6.3
Added "for which each laboratory in the OSBI CSD system".

QM_6.3.2
Added "for each discipline."

QM_6.3.4.a)
Added "CSD".

QM_6.3.4
Removed "health and" from "health and safety coordinator" to leave as "safety coordinator".

QM_6.3.4.1
Added reference to QP 20 for laboratory security procedures and alarm systems used during non-operational hours and OSBI Policy 104 for identification badges and access by visitors.
Added "individual characteristic databases" to define ICD's, (CODIS).
Added "ICD's are computerized, searchable collections of features, generated from samples of known origin from which individual characteristic information originates (*e.g.,* DNA profiles, friction ridge data, or firearm bullet/cartridge case images)."
Added "The Latent Evidence Technical Manager and the Firearms Technical Manager shall authorize individuals in the OSBI CSD to access and operate ICD's in the analysts' Authorization to Work memo (see **QP 19**). The Forensic Biology Technical Manager, in consultation with the CODIS Administrator, shall authorize individuals to access and operate the CODIS ICD in the analysts' Authorization to Work memos (see **QP 19**)."

QM_6.3.5
Added "When CSD personnel perform laboratory activities in the Scope of Accreditation at sites or facilities outside its permanent control, the CSD personnel shall ensure that the accreditation requirements in section 6.3 related to facilities and environmental conditions are met."

QM_6.4.1
Added "(instruments, software, measurement standards, reference materials, reference data, reagents, consumables, or auxiliary apparatus)" and "and that can influence results."

QM_6.4.2
Added "requirements" and "NOTE: Applies to equipment sent out or used externally by someone not trained in applicable procedures. Does not apply to equipment that has service performed in-house (for example: annual service by a vendor). It is recommended that any required and/or necessary performance checks successfully completed prior to use on casework."

QM_6.4.3
Added "planned".

QM_6.4.3.1
Added title of "Reliability of Reagents"

QM_6.4.3.2
Added "Reference collections (data or materials) maintained by the OSBI CSD for identification, comparison, or interpretation purposes will have each entry documented, uniquely identified, and handled properly to protect the characteristic(s) of interest.

Example: Biology discipline employee DNA profiles for comparison for contamination evaluation purposes may be documented in a controlled spreadsheet, uniquely identified, and verified for accuracy."

QM_6.4.4 through QM_6.4.6
Added "6.4.4 Instruments and equipment will be verified for conformance to specified requirements prior to be placed into or returned to service. 6.4.5 Measuring equipment shall be capable of achieving measurement accuracy and/or measurement uncertainty required to provide a valid result. 6.4.6 Measuring equipment shall be calibrated when the accuracy or uncertainty affect the validity of the reported results, and/or when the calibration is required to establish traceability (for measurement uncertainty) of reported results."

QM_6.4.7
Added "The calibration procedures will be reviewed and adjusted, as needed, in order to maintain confidence in the status of calibration".

QM_6.4.7.1
Added "Each discipline quality/procedure manual will include a list of equipment requiring calibration which will include the specification for the calibration laboratory (as applicable), the requirements for calibration, and the interval of calibration. The list shall include specifications of the calibration laboratory, specified requirements for calibration, and the interval of the calibration."

QM_6.4.8
Added "Depending on the equipment size and/or function, the labeling may need to be abbreviated and supplemented by providing the full information elsewhere (i.e. maintenance log)."

QM_6.4.9
Added "Any associated maintenance log will reflect the date the instrument/equipment was taken out of service and will include the description of the issue and the steps taken to resolve the issue."

QM_6.4.10
Added "performance checks" and "NOTE: Evaluation of a need for an intermediate check will include consideration of factors such as calibration interval, use of equipment, stability, method specifications, and risks associated with a failure."

QM_6.4.11
Added "and implemented."

QM_6.4.12
Added "Each discipline in the CSD will use practicable measures to safeguard against any unintended adjustments of equipment (including software) that could invalidate results."

QM_6.4.13
Added "equipment" and "(measuring instruments, measurement standards reference materials, reference data, consumables, or auxiliary equipment)".
Added in a) "(including software and firmware version, as applicable)", in section b) "type identification", section f) "documentation of reference materials, results, acceptance criteria, relevant dates, and the period of validity".

QM_6.5.1
Added section. Also added sections 6.5.1.1, 6.5.1.2, 6.5.1.3, and 6.5.1.4.

QM_6.6.1
Added "The OSBI CSD shall ensure that only suitable externally provided products and services affecting laboratory services are used when such products and services:

a) are intended for incorporation into the laboratory's own activities;
b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
d) are used to support the operation of the laboratory.

NOTE: Products may include measurement standards and equipment and consumable materials. Service may include calibration services, testing services, facility and equipment maintenance, proficiency testing services, or assessment/auditing services. See also Evaluation of Suppliers in section 6.4.3.1 above." and "Similarly, when the laboratory does not have the resources of areas of competence to perform the requested testing, this is not considered subcontracting."

QM_6.6.2
Added "The OSBI CSD will have procedures in each discipline quality/procedure manual and <u>retain records</u> for the following:

e) defining, reviewing, and approving requirements for externally provided products and services;
f) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
g) ensuring that externally provided products and services conform to the CSD's established requirements, or when applicable, to the relevant requirements of ISO 17025, before they are used or directly provided to the customer;
h) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers."

QM_6.6.2.1
Removed "When appropriate" to align with 7.1.c and QP 4.

QM_6.6.3
Added "**Laboratory Communication with External Providers**
The OSBI CSD will communicate the following requirements to external providers:

e) products and services to be provided (using the procedures for submitting Internal Purchase Request (IPR) and other purchasing procedures outlined in OSBI Policy 208 and in QP 8.1);
f) acceptance criteria (including reagent or equipment specifications);
g) competence, including qualification of personnel, as applicable (for example: for subcontractors or critical services);
h) activities that the CSD and/or customer intend to perform at external provider's premise (example: annual onsite visit for outsourcing cases)."

QM_7.1.1
Added in section c) "Where external providers are used, the requirements outlined in section 6.6 above are applied and the CSD advises the customer of the specific laboratory activities to be performed by the external provider and gains customer approval" and in section d) "and procedures are selected and are capable of meeting the customers' requirements." Added "narrative".

QM_7.1.2
Added "CSD personnel shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date. This will be recorded in a conversation log, e-mail, or equivalent document and maintained in the case record if the case is accepted."

QM_7.1.3
Added section.

QM_7.1.4
Added title "Differences in Request or Tender and Contract" and "Any deviations requested by the customer that could impact the integrity of the OSBI CSD laboratory or the validity of the results will not be approved."

QM_7.1.5
Added "Refer to OSBI CSD QMA 1.1 – Notice to Customers."

QM_7.1.6
Added "ensure the contract review is repeated and will".

QM_7.1.7
Added "This may be accomplished through a variety of methods including discovery requests, reports, tours, etc." and "In addition, the OSBI CSD will ensure that the cooperation with a customer's request doesn't compromise the OSBI CSD integrity and is in line with the Guiding Principles for Forensic Testing Laboratories."

QM_7.1.8
Added title "Records of Contract Reviews" and "Records of reviews, including any significant changes, shall be retained in the case record. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the CSD laboratory activities."

QM_7.1.9
Added title "Extent of Database Searches".

QM_7.2.1.1.1, 7.2.1.1.2
Added sections.

QM_7.2.1.2
Added "All methods, procedures, and supporting documentation relevant to testing activities, shall be kept up to date through review by the Quality Manager and/or discipline Technical Managers. Current versions are made available to personnel in QMS."

QM_7.2.1.3
Added "The OSBI CSD uses the latest valid versions of standard methods when appropriate and possible".

QM_7.2.1.4
Added "The", "CSD", and "analysis and".

QM_7.2.1.5, 7.2.1.6, and 7.2.1.7
Added sections.

QM_7.2.2
Added "authorized per QP 19."

QM_7.2.2.1
Added "(laboratory-developed methods and standard methods used outside their intended scope or otherwise modified)", "and given application".

QM_7.2.2.1.1
Added "QP 21.2 covers the procedure for the Evaluation of Methods, Instruments, Equipment, and Software."

QM_7.2.2.2, 7.2.2.3
Added section.

QM_7.2.2.4
Added "The OSBI CSD will retain the following records of validation obtained per **QP 21.2**:

c) any specific sample and/or analysis requirements
d) the range and accuracy of the values obtainable by the method (e.g. limit of detection, selectivity, repeatability, reproducibility)",

"using the procedures outlined in **QP 21.2**.", "which may be incorporated into the validation work", and "per **QP 21.2** and any applicable discipline quality or protocol manuals."

QM_7.4.1
Added “contamination”.

QM_7.4.1.1
Added “all test items (evidence)”, “item”, “items are”, “Items that are collected or created and preserved as evidence for future testing (e.g. Test fired ammunition, latent print lifts, trace evidence, DNA extracts, retained sample vials in seized drug unit) shall require the same chain of custody documentation. These items shall be reported to the customer as described in **QP 28**.

> NOTE: Not all items created during testing are considered evidence – some may be considered work products. This delineation will be included in each disciplines’ quality manual.”

Added “All evidence items will be re-sealed as soon as practicable.”
Added “as practicable” and examples of items that may not be able to be “properly packaged”.

QM_7.4.2
Added “all” and “received”.

QM_7.4.3
Added examples of abnormalities.

QM_7.4.4
Added “When items need to be stored or conditioned under specific environmental conditions (i.e. refrigerated), these conditions shall be maintained, monitored, and recorded.”

QM_7.5.1
Added “date and” will also be included along with the identity of the individual(s) “responsible for each laboratory activity and for checking data and results.” Added “ Dates may be reflected as a range or the date of each test.” Added “Original” before observations and “/task”.
QM 7.5.1.3
Added “possessing the relevant knowledge, skills, and abilities”.

QM 7.5.1.4
Added Examination documentation will be permanent in nature.

QM_7.5.1.6
Added “If an adjustment or repair is performed to testing equipment due to a calibration that does not meet specifications, pre and post adjustment/repair data shall be retained.

> Example: As found / as left for scale calibration certificates.

QM 7.5.2
Added first paragraph in this section speaking about sufficiency of tracking amendments to previous version / original observation. Added “and dated” after initialed and “alteration/”.

QM 7.6.1.1
Added this section with the exception of "when specific environmental conditions are required by the technical procedure or could impact the quality of results, the OSBI CSD shall monitor, control, and record the appropriate environmental conditions. Testing shall be stopped if the environmental conditions would negatively impact test results."

QM 7.6.2, QM 7.6.3.1, and 7.6.4
Added these sections.

QM 7.7.1
Added "currently", "in the case record", "the qualifications of a technical reviewer", and the last sentence referring to the use of the Qualified Testimony Review Form.
QM_7.7.2
Added "The OSBI CSD shall monitor its performance by comparison with results of other laboratories and intra-laboratory results through involvement in external and internal proficiency testing."

QM_7.7.2.1
Added section.

QM_7.7.3
Added "shall" and "The Quality Manager or discipline Technical Managers may monitor for any variances between analysts and/or facilities by reviewing proficiency testing results."

QM_7.7.4
Added section.

QM_7.7.6 – 7.7.8
Added sections.

QM_7.8.1.1 and 7.8.1.1.1
Added sections.

QM_7.8.1.2
Added "and", "of evidence items", and "written".
Added "The procedure for reporting of results in each discipline quality or policy manual shall identify what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for partial work performed.
All initial database entries (e.g. CODIS, AFIS, NIBIN) will be included in the report.
Any associations made from database searches (e.g. CODIS, AFIS, NIBIN) will be reported to the customer.
The reporting of results does not include testing of known origin samples for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database."

QM_7.8.1.3
Added section.

QM_7.8.2.2
Added section.

QM_7.8.3.c)
Added "(or in an annex to the test report) when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement" and "The measurement uncertainty shall include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability, and be in the format of y+/- U. The measurement uncertainty shall be limited to two significant digits, unless there is a documented rationale for reporting additional significant digits and be reported to the same level of significance (i.e. same number of decimal places or digits) as the measurement result. **QP 22** and discipline-specific quality and policy manuals further address uncertainty of measurement."

QM_7.8.5
Added "in addition to the requirements in section 7.8.2 above", "unique", "(including any diagrams, sketches, photographs)", "If statistical sampling is used, the report shall contain the confidence level and corresponding inference regarding the population", and "information required to evaluate measurement uncertainty for subsequent testing".

QM_7.8.6
Added section.

QM_7.8.7
Added "to ensure release of this information by authorized personnel only.", "based on the results obtained from the tested item and shall be", and "When opinions and interpretations are directly communicated by dialogue to the customer, a record of the dialogue shall be maintained in the case record. Examples: pre-trial conferences, phone conversations."

QM_7.10
Added "discipline quality manuals or", "Actions taken shall be based upon the risk levels established by the OSBI CSD.", and "The OSBI CSD shall retain records of nonconforming work and actions taken as a result of the evaluation of risk as specified in QP 13."
QM_7.11.1
Added section.

QM_7.11.2.1
Added There shall be a plan for validation of computer software developed by the OSBI CSD and records of the successful validation shall be maintained.", "protection from unauthorized users", and "system failures will be recorded along with the appropriate immediate and corrective actions."

QM_7.11.4 and 7.11.5
Added sections

QM_7.11.6
Added "When possible, this check shall not be performed by the person who performed the calculation(s) or data transfers. This check may be part of the technical review.

NOTE: This requirement does not apply if the calculation or data transfer is secure and not subject to human error."

QM_8.1.1 through 8.1.3
Added sections.

QM_8.2.1 and 8.2.2
Added sections.
QM_8.2.3
Added "assigning".

QM_8.2.5
Added "All OSBI CSD personnel involved in laboratory activities shall have access to the parts of the management system documentation and related documentation that are applicable to their responsibilities."

QM_8.2.3.1
Added "CSD" in two places.

QM_8.4.1
Added "NOTE: Contractual obligations for records retention include legal requirements and customer expectations."

QM_8.5.1
Added section.
QM_8.5.2
Added "Any OSBI CSD member that recognizes a potential risk or opportunity shall notify his/her immediate Supervisor. Depending on the level of the risk and/or opportunity, the Supervisor shall notify the discipline Technical Manager, the CSD Administrator, and/or the Quality Manager." and "Additionally, expanding the scope of the laboratory activities, addressing new customer needs, using new technologies and/or methods, can also be addressed using the appropriate procedures outlined in **QP 21.1** Research and **QP 21.2** Evaluation of Methods, Equipment, Instrumentation, and Software."

QM_8.5.3
Added section.

QM_8.6.1
Added section.

QM_8.7.1
Added "During the monitoring period defined in the plan, the effectiveness of the executed corrective action plan will be assessed. If the desired results are not being achieved, the risks and opportunities will be updated and adjusted, as needed.
TIMEFRAMES for CORRECTIVE ACTION
The timeframes set forth in the Corrective Action Plan shall establish reasonable timeframes for completion of the associated tasks and for the period of monitoring (as applicable)."

QM_8.7.2
Added "The corrective actions shall be appropriate to the effects of the nonconformities identified during the process."

QM_8.7.3
Added section.
QM_8.8
Added "in order to assess the conformance to the laboratory's own requirements as well as accreditation standards and requirements, competence, and effectiveness of the laboratory's activities.", "and will include direct observation of accredited services within each laboratory discipline. The scope of each internal audit will be determined by the Quality Manager, or designee, as listed in **QP 17**." and "The audit report information addresses whether the OSBI CSD management system conforms to the ISO/IEC 17025 requirements. The audit of the management system will be performed in conjunction with each internal audit."

QM_8.9.2
Added a), b), "(Status of actions from previous mgmt.. reviews)" to d), "assessments" to g), k), and m) through p).

QM_8.9.3
Added section.

QP 1
Added "DNA databasing" to CSD Director section.
Updated duties of Criminalistics Administrators.
Added NIBIN Program Administrator, Sexual Assault Tracking System Program Administrator, and Construction / Maintenance Technician.
Added duties to Criminalistics Supervisors section.
Added clarification to QM and TM responsibilities to "ensure compliance with accreditation standards and requirements" based on internal audit suggestion.

QP 2
II.C. Added "(e.g. moved to an archived/rescinded folder in QMS)" based on an internal audit comment to clarify the document doesn't need to be removed from QMS entirely, just away from the point of issue.
II.H. Added back the requirement for management system documents to be reviewed annually.

II.C Added the naming scheme for QMS documents will mirror the guidelines detailed for the QA server folder.

QP 4
Added "If external providers are used, the requirements outlined in section 6.6 of the Quality Manual above must be applied. The OSBI CSD shall advise the customer of the specific laboratory activities to be performed by the external provider and document customer approval." to section II.A.3.
Added "This agreement regarding the modification will be documented in the case record" to section II.B.3.

QP 5
Updated MSDS to SDS.
Added information to section II.D.12, 13 and 14.
II.H. Added "barcode" after "folder" and "/folder" after package.
II.J.10. Added the primary linked case number to the secondary case items tab for easier tracking to the primary case based on 2018 internal audit suggestion.
Added clarification that the RFLE signature for mailed submissions needs to be checked. If not signed, the RFLE can be faxed for signature or a phone call can be documented indicating the officer agrees to the information outlined in QMA 1.1.
Deleted the requirement to click DA Case Restriction in section II.I.4.

QP 6.2
II.C.2. Added OSBI CSD".

QP 6.3
II.C. Deleted Janam procedure and adjusted BEAST procedure to match the Evidence Training Manual language.

QPA 7.2
Updated Evidence Release Form to include a field for time.

QP 9
Changed from "will" to "may" for approved supplier list. This is referenced in QM_6.4.3.1 and 6.6. Some disciplines may choose to require this in the discipline-specific quality manuals after evaluating any risks associated with the removal of the requirement.

QP 12
Added "external" and "This procedure is available to any interested party as a part of the OSBI CSD Quality Manual via the OSBI website."

QP 13
Added "In addition, for any work suspended in the Forensic Biology Discipline, the Forensic Biology Discipline Technical Manager must also be informed.", "during the risk assessment", and "Records related to these evaluations shall be retained as a part of the documentation of the nonconformance."

Added “RISK” to evaluation chart.

QP 14.3
Added “NOTE: For the Forensic Biology discipline, the decision to resume work will be made by the Technical Manager.” And “”Report” in the attachment section.

QP 16.1
II.C.5. Changed “specified” to “directed”.

QP 16.2
Added “CSD”.

QP 17
Changed “Laboratory” to “Facility” for Southwest Regional Facility”, added “based on the defined scope of the audit. The defined scope of the audit (Audit Plan) will be retained on the Quality Server”, “TM(s), appropriate Criminalistics Administrator” to the list of those included in the exit meeting, “applicable” to II.B.6.b), “TM(s) , appropriate Criminalistics Administrator” and “CSD” to II.B.7 and “CSD” to II.B.8, “and each discipline Technical Manager”, “and effectiveness of corrective actions” to II.B.11. and “Biology Technical Manager”, “Administrator, or designee”, and “CODIS Administrator” to II.C.
Changed “CODIS Supervisor” to “CODIS Administrator” regarding the notification of the FBI of completed QAS internal and external audits/assessments.

QP 18
Updated reference in Scope to “8.9”.
Added “changes in internal and external issues relevant to the laboratory such as” to II.C.3.e) and added sections f), n), p), q), and “outcomes of the assurance of the validity of results” to section r).
Added “documented” to II.C.7., “QP 19 Added “for each function influencing the results of testing activities”, “Provisions for re-training, Provisions for maintenance of skills and expertise specific to the discipline and Criteria for acceptable performance for qualification/authorization”, “CSD” to section II.C.1, “Analysts may be authorized to participate in the development, modification, verification, or validation of methods outside the Authorization to Work memo. This authorization should be in a written format (e-mail, memo, etc.) from the discipline Technical Manager, but may be less formal than the Authorization to Work memo. The authorization should clearly state the intent and scope of the authorization for the development, modification, verification, and/or validation and include all aspects of testing activities such as the use of equipment.” to section II.G. and moved the Literature Resources section here to the end of II.H.
Removed the following sentence from II.G. *“The CODIS Administrator shall be responsible for issuing the ATW for access to and operation of the CODIS database.”*

QP 20
Changed to reflect Lawton Facility v. Laboratory.

QP 21.1
Added “assign” to II.A.

QP 21.2
Added “analysis” to II.B.3.
Added sections II.B.3.b) and c).
Added “and shall be retained” to II.C.1.
Added “procedures” to II.C.1.a) and “analysis” to II.C.1.e).
Added “the completed validation report/summary should be forwarded to the appropriate Criminalistics Administrator (CA), the QM, and the CSD Director. A summary of the subcommittee recommendation, including any dissenting opinion(s), should be included.” back to II.C.3.
Added sections II.C.4-6 and added “The approved evaluation report will be retained in hard-copy or electronic format as a record of the validation work completed.” To II.C.7.

QP 22
Added “(i.e. same number of decimal places or digits)” based on AR 3125 language.

QP 23
Added “ISO/IEC 17025:2017 standard 6.5.1 and AR 3125 6.5.1.1” reference.

QP 24
Added “proper functioning, prevent contamination or deterioration”.

QP 26
Added AR 3125 6.5.1.1 reference.
Changed “RMP” to “provider” since RMP wasn’t defined.

QP 27
In the attachment section, changed “Memo” to “Memorandum”.

QP 28
Added “The requirements set forth in the ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status (PR 1018) shall be followed.” and “for Forensic Testing Accreditation”.
Added “It is the responsibility of each qualified analyst to ensure the opinions and interpretations included in conversations and testimony are based on results for which accreditation is held. Any opinions and interpretations offered that are outside the scope of accreditation but are based on results for which accreditation is held, shall be clearly identified by the analyst.”
Added “Any analyst requesting a report be reset, shall include reason for the need for the report reset in the request. The LIMS Administrator, the discipline Technical Manager as well as the Supervisor shall be included in the request.” to section II.C.1.
Added “When appropriate, the reason for the change shall be included in the report.” to section II.C.2.g).
Added “and CODIS Notification Letters” to II.G.
Added “(where the testing was performed)” to II.G.3.
Added (unambiguous identification) to and deleted “At a minimum, all OSBI CSD reports will include an unambiguous identification of the items searched or tested in conjunction with the assignment” from II.G.7.

Added "Discipline-specific quality and/or policy manuals will address the requirements for reporting for each discipline" to II.G.8.
Added II.G.13 through II.G.18.
Added "in an accurate, clear, unambiguous, and objective manner" to II.H.1.
Added "(See OSBI CSD QMA 1.1 – Notice to Customers regarding Simplified Reporting)" to II.H.1.a.
Added "including (where appropriate) units of measurement" to II.H.2 and "Discipline-specific quality and/or policy manuals shall address test results that are not consistent (e.g. one was positive, and one negative or inconclusive)." To II.H.2.a.
Added section II.H.3.
Added "This serves as the identification of the person(s) authorizing the report" to II.I.4.
Removed II.D.1.b.v. regarding printing a sufficient number of reports for mailing if the agency doesn't receive reports online since all agencies received reports online.
II.H.1.a. Added language to refer to discipline-specific manuals for any additional requirements for simplified reporting.
II.H.6 and 8. Added reference that language to address qualifications of associations and inconclusive results should be located in discipline-specific manuals.

QP 30
Added "When internal proficiency tests (including any observation-based monitoring) are prepared, the Technical Manager of the discipline will ensure the expected results are not known to the participant or readily available to the participant. For internal proficiency tests, a key or similar grading rubric, will be prepared prior to administering the test to the participant that establishes criteria for determining successful completion of the test." To II.E.
Added "Quality Manual and Quality Procedures" to II.G.2.
Added "and retained in the case records or according to discipline-specific requirements" to II.G.4.
Added "or designee", "reviewed", "to the discipline TM for grading. The TM will grade the test as satisfactory and forward to the analyst" and "TM" to II.I.2.
Changed to "TM" in II.I.3.

QP 31
Added "CODIS Hit Letters may also not contain these elements." To II.B.2.
Added "technical" to II.B.3.
Added "Case File" to title of document in Attachments section to match title of document.

QP 32
Added "In addition, the OSBI CSD will ensure the testimony in each discipline is reviewed by a qualified technical reviewer in the discipline annually.".
Added "provide the form (via mail, fax, or e-mail)" to II.A.1.
Added language to differentiate between Witness Critique and Testimony Review - Qualified Technical Review of testimony – added QPA 32.4 for qualified reviewers.
Added Testimony Report Forms in II.D.

QP 33

Added “case records and” to Scope.
Added “case record, including the” to II.A.2.
Added “case record information and” to II.A.4.

QMA 1.1 – updated references from 17025:2005 to 17025:2017. Updated to Rev03.

QMA 4.1 – changed “5 facilities” to “6 facilities”, changed “Laboratory” to “Facility” for Lawton facility, changed “Y-STR analysis is only available at FSC and NERL…” to “DNA analysis is only available at FSC and NERL…”. Updated to Rev03.

QMA 5 – changed spelling of Glenpool. Updated to Rev06.

QPA 32.3 Testimony Report Form – added “Attn: LIMS Administrator” to header, added “Qualified Testimony Review Form Distributed – Yes, No”.

QPA 32.4 Qualified Testimony Review Form – added this form for qualified analysts technically reviewing testimony of analysts.

QPA 33.1 – OSBI CSD Fax Cover Sheet updated to reflect Fielding and to add other Administrators to header.

Rev01 (effective date June 1, 2020)
General formatting and grammatical corrections.

QP 8.2 section II.A – removed “Firearm” since the Firearms Unit is using this class for their reference collections.

QP 10 – add sections regarding requirements for external verifications and reviews and added “These consultations will be included in the case record in accordance with QM section 7.1.1” to II.A.1.

QP 13, QP 14.1 through QP 14.3 – rewritten.

QP 32 – change “senior peer” to “Technical Manager” in section II.A.8.

QM 7.4.3 – incorporate deviation adding guidance and timeframe for customer consultations.

QP 1 – correct “prepare” to “proper” in NIBIN Administrator duties, b).iv.

QP 28 – added “and Digital Evidence Unit Technical Summaries,” to section II.I.3.

QP 17 – re-worded II.C to be consistent with requirements and practices.

QMA 2 – added language that Digital Evidence Unit evidence must be submitted in-person and that forensic biology sexual assault kits and known buccal swabs may be mailed in.

QP 28 – deleted II.G.9. regarding work product being transferred.

QP 30 – updated section II.E.4.h. regarding storage location for expected results for internally prepared PTs and section II.I.2 regarding PT notification (updated to reflect current procedure).

QP 27 – Clarified that Crime Scene Memos are not required if the work is performed at an OSBI Laboratory.

QP 2 Added clarification that archived or obsolete documents are stored in an appropriate folder on the Quality Server. This will allow for entire folders that may need to be removed from use (an abundant amount of time required to move an entire folder in QMS v. deleting and storing on Quality Server) and will limit the potential for inadvertent use of an obsolete version.

QP 6.1 II.B.2.e – added "Analyst discretion may be used on sub-itemizing packages and containers if it is an evidence kit (e.g. sexual assault kit, GSR kit)."

QP 6.4 II.A – added "compartment" to clarify the ranges are for refrigerator and freezer compartments monitored separately.

QP 18 – Added quarterly management review template forms.

QP 1 – Added sentence from QM 5.1 to QP 1 regarding authority of CSD Director, updated CA assignments, changed LIMS Admin section to reflect online reports v. OkLEX, II.A.2 – removed "Each" since QM doesn't oversee an entire unit/lab, II.B.2.a) – changed Quality Assurance Program to Quality System.

QP 28, II.I – Added allowance for individual certification to be included in signature block of reports.

QP 30 – removed reference to modifying report header for re-analysis cases.

QM 7.8.1.2 and QP 28 – Changed "Results of all tests of series of tests" to "Results".

Quality Policy (p. 2) – changed "attain" to "maintain"; also added "and now ANSI National Accreditation Board (ANAB)" at the top of page 2.

Section 3 – DEFINITIONS: Corrective Action – updated QAS reference from 14.1.b.5 to 14.2.c; Remediation – updated QAS reference from 14.1.b.4 to 14.2.b; Criminalist Supervisor – added "/technicians".

QM 6.2.4– changed from link to Criminalist job description to "available from and maintained by OSBI Human Resources section" to include all job descriptions.

QM 6.4.7 and 6.4.12 – removed terms referring to performing calibration.

QM 6.5.1.4 and 6.5.2 – added "International System of Units" to define SI in 6.5.1.4 (first mention) and removed from 6.5.2.

QM 6.6.2 – added "/IEC".

QM 7.1.7 – corrected title of GD 3150 Guiding Principles document.

QM 7.5.1 – removed "(initialed and case numbered)".

QM 7.8.1.2 – added "Criminalistics".

QM 7.8.6 – added "routinely" and reference to section 7.1.3.

QM 7.10 – added "or QP 14.3".

QM 7.11.2 and 7.11.3 – rearranged and edited language to better align with standards.

QM 8.2.1.1 – added section referencing key words from AR 3125.

QM 8.6.1 – added "/assessment".

QM 8.7.1 – updated language to align with revisions made to QP 13, QP 14.1 through QP 14.3.

QP 8.1 II.E.2.d) – changed 1 to 0, II.G.8 – added "and CODIS".

QP 1 – added responsibility for biology-related grants to the CA responsible for the management of the FBUs and Cold Case Unit, removed numbers 7 (Facility Manager) and 8 (Construction) from CSD personnel, added wording that TMs will work in consultation with QM and CSD Director for any issues that may result in work stoppage, added "after consultation with CSD Director" to section B.2.a regarding QM's authority to suspend testing, modified wording for Supervisors to match wording for TMs regarding consulting with QM and CSD Director prior to suspending work.

QP 12 – added reference to OSBI Policy 133.

QMA 4.1, QMA 4.2 – modified documents to remove Tire Impression analysis. QMA 4.2 also changed contacting SFBU to CCU for cold case submittals.

QP 19 - Added New Employee Training Manual (section II.A.) and "(or unit)" to section II.G.

QM 6.3.4 – Added "Employees entering the walk-in freezer at the FSC facility shall wear proper personal protective equipment (PPE). This includes, but is not limited to, freezer gloves and a freezer jacket. All employees accessing the walk-in freezer shall notify a Physical Evidence Technician or other individual with direct access to the freezer prior to entering. Once the employee has finished accessing the freezer, they will report to the notified individual once again to ensure safety of the employee accessing the freezer."

Rev02 (effective date August 17, 2020)
QMA 2 – Added evidence locker submissions and updated link to Evidence Collection Manual.

QPA 5.1 – Added evidence locker as submission type.

QM 6.3.4 – Added "/lockers".

QP 5 – Added evidence locker to II.D.10, added steps for entering SA kit tracking number in II.D.16.c, added II.E.4 to discuss mail, courier, and evidence locker submittal receipts being available on the law enforcement portal.

QP 6.3 – Added evidence lockers to Scope, added that evidence lockers should be cleaned after each use to II.A.3.

QP 20 – Added evidence lockers to II.A.1, II.B.1.a), II.C.2, and II.C.4. Added Eastern Regional Laboratory to II.B.2.b) and II.B.4.b).

QM 7.5.2 Clarified expectations for documentation of non-contemporaneous amendments to technical records.

QP 6.4 – modified freezer temperature to be at or below $0^{o}C$ in II.A.4.

QP 30 – II.D.2, II.D.3, II.D.5 each updated to allow for proficiency tests that may not arrive with hard-copy documentation (provided electronically or via manufacturer portal). II.H.1 added a note regarding the QM assigning proficiency tests in the CTS portal, so some steps (i.e. claiming test) may not be necessary.

QP 18 – Modified attachment forms for management review reports to reflect Safety section for each quarter.