Laboratory Quality Assurance Manual

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1 Scope

This Laboratory Quality Assurance Manual (QAM) contains or references the policies, practices and methods of the Ohio Bureau of Criminal Investigation (BCI) laboratory quality management system that ensure technical competence and reliable forensic examination results. The Laboratory Quality Assurance Manual and associated laboratory practices facilitate meeting the ANSI National Accreditation Board (ANAB) accreditation program requirements.

ANAB is an accrediting body for forensic science testing laboratories. The program requirements include the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) International Standard ISO/IEC 17025 (ISO 17025) and the ANAB ISO/IEC 17025:2017 Forensic Science Testing Laboratories Accreditation Requirements. The combined requirements of ISO/IEC 17025 and ANAB Accreditation Requirements are hereafter referred to as ANAB Accreditation. The Laboratory Quality Assurance Manual and associated laboratory practices also facilitate internal audit and external assessment of the quality management system to evaluate the BCI laboratory's compliance with ANAB accreditation standards.

2 Normative References

The following referenced documents are indispensable for the application of this document. Unless otherwise stated, the most recent versions of the listed documents should be referenced.

- ANAB ISO/IEC 17025:2017 Forensic Science Testing Laboratories Accreditation Requirements, AR 3125, Effective 2023/02/01.
- ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland,2017.
- Ohio Attorney General's Office (AGO) Policy and Procedures ~~Manual,~~ Columbus, OH.
- Ohio Revised Code
- Ohio Bureau of Criminal Investigation (BCI) Bureau Directives, BCI, London, OH.
- Quality Assurance Standards for DNA Databasing Laboratories, US Department of Justice (DOJ), Federal Bureau of Investigation (FBI).
- Quality Assurance Standards for Forensic DNA Testing Laboratories, US DOJ, FBI.
- National DNA Index System (NDIS) Procedures, US DOJ, FBI.
- Minimum Requirements for Operating Standards ~~Procedure~~, Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)

3 Terms and Definitions

Accreditation - A process by which an authoritative body, such as ANAB, gives formal recognition that an entity is competent to carry out specific tasks.

Accreditation cycle – The period of time between the date that accreditation is granted and the date accreditation expires.

Administrative documentation - Records that do not constitute data or information resulting from testing, including but not limited to: testing related conversations, evidence submission receipts, and item tracking (chain of custody) records.

Administrative error - An error such as a typographical or a transcription error.

Administrative personnel - Staff who provide administrative/clerical support.

Administrative review - A method used to check that case documentation is complete and that the laboratory report complies with BCI laboratory policy.

Administrative reviewer - A laboratory staff member authorized to conduct an administrative review.

Analytical or interpretative error - An error in the examination process that produces an incorrect result or conclusion.

Approved test provider - A proficiency test provider that is accredited to ISO/IEC 17043.

Assessment– An external review conducted to compare the various aspects of the laboratory's quality management system with criteria for that performance.

Assessor - An appropriately trained person who conducts a portion of an assessment.

Association- A relationship which is concluded to exist between individuals and/or objects based upon testing.

Audit – Process for obtaining relevant information about the management system and evaluating it objectively to determine the extent to which specified requirements are fulfilled.

Auditor - An appropriately trained person who conducts a portion of an audit.

Calibration - The adjusting or standardizing of any instrument and/or equipment to ensure agreement with a reference standard or working standard of known value.

Case record – All administrative and technical records, whether electronic or hard copy, generated or received by the laboratory pertaining to a particular case and stored in one or more locations.

Casework - BCI laboratory activities concerning the examination/analysis of submitted test items.

Certified reference material - Reference material, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Chain of custody - A record used to document all transfers/locations of case items while in laboratory control.

Competency test - The evaluation of a person's knowledge, skills, or ability prior to performing testing on test item(s) or performing specific tasks that create items that could be used for testing.

Competent - Possessing the requisite knowledge, skills and abilities to perform a job or task.

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

Contract - A binding agreement between two or more persons or parties.

Contractor - An individual employed on a contractual basis by the BCI laboratory. Contractors are required to meet the provisions of the BCI laboratory quality management system.

Control - A sample analyzed in parallel with test samples that is designed to demonstrate that a method worked correctly.

Controlled document - A document issued and distributed in a traceable manner.

Corrective action – An action designed to eliminate the cause of nonconformity or other undesirable quality related situation.

Crime scene - An area, object or person, from which evidence is identified, documented, collected, and/or interpreted.

Critical finding – A decision about an association between items based on observable class and individual characteristics of the items.

Critical reagent - Any reagent that has a significant effect on the quality of a test performed as part of an examination. Critical reagents require regular quality control through initial and intermediate checks. Reagents such as commercial supplies and kits, which have an expiration date, are included in this group.

Critical task – Any task that has a significant effect on the quality of a test performed as part of an examination.

Complaint- 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.

Custody - The care and control of an item implying responsibility for its protection and preservation.

Customer - Any agency, group or individual at whose request or on whose behalf the laboratory provides services, information or advice. For the purpose of BCI laboratory quality documents the customer generally denotes the test item submitting agency.

Derived evidence – Evidence resulting from another evidentiary item submitted for testing.

Deviation - An authorized variance from a documented policy, practice, or method.

Deficiency - An inadequacy; is lacking in some necessary quality element, including missing data, incomplete data, or incomplete reports.

Digital evidence - Information of probative value stored or transmitted in binary form.

Director- The highest ranking manager within BCI laboratory.

Discipline - A major area of casework testing in forensic science, as specified by the Organization of Scientific Area Committees (OSAC).

Document - Information in any medium including, but not limited to, paper copy, computer disk or tape, audio or video tape, electronic file, compact or digital video disc, photograph, overhead, or photographic slide.

Document control - The process of ensuring that controlled documents describing quality affecting activities or specifying quality requirements are reviewed for adequacy,

approved for release by authorized personnel, and distributed for use to the personnel performing the applicable activities.

Drug evidence - Illegal substances, drug paraphernalia, prescription and nonprescription drugs.

Environmental conditions - Any facility characteristic that could reasonably be expected to impact the quality of the laboratory's work product.

Evidence - An item submitted for examination(s), equivalent to "test item" as described in ANAB accreditation references.

Examination - An analysis of an item or comparison of items.

Examiner or forensic scientist – Personnel who are recognized by the BCI laboratory as having successfully completed a documented training program, including competency testing, in a particular forensic discipline(s) or test category. They conduct, or are responsible for, examinations within their discipline(s) or test category, write laboratory reports conveying their examination results and testify to those results in court.

Examination documentation or 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.

External proficiency test - A test provided by a source external to the BCI laboratory.

Finding - Nonconformity identified during an audit with documented requirements.

Forensic Science - A field of science dedicated to the methodical gathering and analysis of evidence to establish facts that can be presented in a legal proceeding.

Good laboratory practice - Operating practices and methods for promoting quality and ensuring the integrity of the work product.

Impartiality- presence of objectivity

Individual characteristic database - A computerized, searchable collection of features associated from individual characteristic database samples of known origin.

Individual characteristic database sample - A specimen of known origin from which individual characteristic information originates (e.g., reference biological specimens, fingerprints of known individuals including electronic fingerprint records, test fired ammunition).

Interested Party- Person or group having an interest in the performance or success of an organization.

Interlaboratory Comparison- Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. To be considered an interlaboratory comparison, there must be participants from two or more laboratories operating under separate management systems.

Intralaboratory Comparison- Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.

Internal proficiency test - A proficiency test prepared by BCI laboratory personnel.

Instructions- Detailed documentation of how to perform a specific task.

Item identifier - A numeric designator assigned to an item submitted to the BCI laboratory.

Key managerial personnel- Personnel designated as top management and additional personnel who do not have laboratory-wide authority but are “key” to the laboratory providing testing services. BCI laboratory key management includes the Laboratory Supervisors.

Known sample - A specimen of an identified source acquired for the purpose of comparison with an evidence sample.

Laboratory - In this manual, this term refers to all units of the BCI laboratory system that are responsible for test item receiving, inventorying and testing.

Laboratory discipline - Designated sections within the laboratory system assigned to perform a collection of related examinations. BCI laboratory disciplines include Chemistry(CHEM), Combined DNA Index System (CODIS), Firearms (FA), Forensic Biology (FB)/DNA, Latent Prints (LP), Trace Evidence (TE) and Questioned Documents (QD).

Laboratory management – Those persons with the responsibility for directing and controlling organizational units or programs within the laboratory.

Laboratory number - BCI laboratory’s unique identifier assigned to each case. This number indicates the original receiving year, original receiving location and sequential submission within the year at each receiving location.

Laboratory report - The official document that presents case related information, including test results, to a customer regarding BCI laboratory activity.

Laboratory unit – Personnel groupings within each laboratory or the laboratory system assigned to perform a collection of related examinations or tasks.

Management system- The quality, administrative and technical systems that govern the operations of a laboratory

May - A word used when an element of the quality management system is optional or discretionary.

Measurand – Quantity intended to be measured.

Measurement uncertainty - A parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

Media - Objects on which electronic data can be stored.

Method - The course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.

Must - A word used when an element of the quality management system is required.

National measurement standards - May be primary standards, which are primary realizations of the International System of Units (SI) units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute such as the National Institute of Standards and Technology (NIST).

Natural science – Chemistry, biology and physics.

Nonconformity – A situation or condition that fails to meet a requirement of the quality management system.

Notes - The documentation of methods, standards, controls, instruments used, observations made, results of tests performed, charts, graphs, photos, and other documents generated which are used to support the examiner's conclusions.

Objective- A measurable, definable accomplishment which furthers the goals of the organization.

Open proficiency test - A proficiency test, known to the participant as such, prepared to evaluate the participant's competence related to casework.

Performance check - Verification that the equipment, instrument, or process is working as expected.

Policy - A guiding principle, operating practice, or plan of action governing decisions made on behalf of BCI laboratory.

Practices – Groups of approved quality affecting policies and processes customarily employed by the BCI laboratory.

Preventive action – An action designed to eliminate the cause of a potential nonconformity or other undesirable situation.

Primary standard - A standard designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

Procedure- A specific way to carry out an activity or a process.

Proficiency test - A test used to evaluate the continuing capability of forensic scientists and the performance of the BCI laboratory. The expected results of the test are unknown to those individuals taking the test.

Proper seal - A seal that prevents evidence loss, cross-transfer, contamination or deleterious change while ensuring that accessing the evidence will result in obvious damage or alteration to the seal.

Qualified - A term used to identify personnel who successfully complete a discipline's training program, pass required competency testing and participate in the BCI laboratory proficiency testing program.

Qualitative analysis - Methods that use visual, microscopic, or instrumental methods to determine the characteristics or constituents of a sample or specimen without regard to quantity.

Quantitative analysis - Analysis of a substance that determines the amount or proportion of its constituents.

Quality assurance - Those planned or systematic actions necessary to provide sufficient confidence that the laboratory's product or service will satisfy given requirements for quality.

Quality control - Internal activities or activities conducted according to externally established standards, used to monitor the quality of analytical data and to ensure that it satisfies specified criteria.

Quality documentation - Documents or records pertaining to the quality management system such as audit reports, corrective action documents, and testimony evaluations.

Quality management system - The organizational structure, responsibilities, methods, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly. This term is equivalent to "management system" as used in ISO/IEC 17025:2017.

Questioned or unknown sample – An evidence sample examined for the purpose of comparison or identification.

Reagent - A substance used because of its chemical or biological activity.

Record - A document that provides evidence of a condition, work performed, activities conducted, and/or quality for archival purposes.

Reference collection- Data or materials of known origin or property, which are retained for identification, comparison, or interpretation purposes (e.g. mass spectra, motor vehicle paints, firearms, ammunition).

Reference material - Material, sufficiently homogeneous and stable with respect to one or more specified properties which has been established to be fit for its intended use in a measurement process. These materials may be used for the identification of unknown substances, calibration of instruments, assessments of a measurement method, or assigning value to materials.

Reference standard - A sample acquired or prepared that has known properties for the purpose of calibrating equipment and/or for use as a control in examinations.

Request - The act or an instance of a customer asking for testing services by the BCI laboratory.

Root cause - The fundamental reason for a condition adverse to quality, that if corrected or precluded, would minimize or prevent that condition, and/or similar conditions, from occurring.

Routine process or method - A process or method that is performed on an on-going basis.

Sample selection - A practice of selecting a sample(s) of the whole based upon training, experience and competence. There is no assumption of homogeneity of the whole.

Sampling - Selection and/or collection of material or data.

Sampling plan- A statistically valid approach to determine the number of samples that must be tested in order to make an inference about the whole population.

Sampling procedure- A defined procedure used to collect a sample or samples from the larger whole, to ensure that the value obtained in the analysis is representative of the whole.

Secondary evidence - Material derived from an item of evidence.

Secured area - Locked or otherwise limited access space under laboratory control that has access restricted to personnel authorized by the Laboratory Director (LD) or designee.

Shall - A word used when an element of the quality management system is required.

Should - A word used when an element of the quality management system is recommended, but not required.

SI Units - The International System of Units consisting of seven base units that have been adopted by the General Conference on Weights and Measures.

Standard method - A method that specifies the steps necessary to perform a test, contains documented performance characteristics, and is published by a standards producing organization such as OSAC.

Subcontractor - An entity that conducts examinations on behalf of laboratory that are within the scope of the BCI laboratory's accreditation.

Subcontracting - Engaging the services of a subcontractor.

Sub-item - Multiple items that were originally inventoried as a single item, or derivatives of the primary item, that have subsequently been assigned a unique identifier.

Technical management- The person(s) who has technical responsibility for a discipline that may or may not supervise any persons and that may or may not have "manager" in a job title or job description.

Technical records- Accumulations of data and information which result from carrying out test(s) and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, workbooks, check sheets, work notes, control graphs, external and internal test reports, customers' notes, papers and feedback.

Technical review - The assessment of technical records, test reports, and testimony to ensure the validity of test results, opinions and interpretations.

Technical reviewer - A person who is qualified in a specific discipline or sub-discipline that conducts a technical review in that discipline or test category.

Test category - A specific type of examination/analysis within an accredited discipline of forensic science.

Top management- Person or group of people who directs and control an organization at the highest level (ISO 9000:2015). BCI laboratory top management includes the following positions: Laboratory Director, Quality Assurance Manager, DNA Technical Leader, CODIS Technical Leader, ~~Director of Research/Development and Training~~, Laboratory Manager of Comparative Sciences, Laboratory Manager of Chemistry, and Laboratory Manager of DNA.

Traceability - Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

Testimony review - The courtroom testimony of ~~all~~ forensic scientists is reviewed to ensure quality presentation and technical accuracy.

Uncontrolled copy - A copy of a controlled document that is not distributed in a trackable manner.

Validation – The confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Valuable evidence - Money (irrespective of country of origin), jewelry (irrespective of composition), medals, rare coins, works of art, antiques, furs, and other items of intrinsic value.

Verification- The procedure used to evaluate the validity of a test results/opinion reached by re-performing the comparison between the unknown and the known.

Will - A word used when an element of the quality management system is required.

Working standard - Used routinely to calibrate or check material measures, measuring instruments or reference materials.

3.1 General Examination Abbreviations

The following abbreviations may be used in case file notes. Additional approved abbreviations are included in Discipline Specific Methods Manuals.

bpb	brown paper bag
brn	brown
ct	clear tape
cts	clear tape sealed
cont	containing
dh_2o	deionized/filtered water
dk	dark
env	envelope
et	evidence tape
exp	expires
hs	heat-sealed
lab	labeled
lg	large
lt	light
mk'd	marked
me	manila envelope
med	medium
npv	not preserved
ne	not examined
nr	not reported
nt	not tested
obs	observed
orig	original
pb	paper bag
pg	page
pkg	package
plb	plastic bag
rec'd	received
SEB	stain extraction buffer
sld	sealed
sm	small
sme	small manila envelope
std	standard
sw	swab
s/w	sealed with
un-sld	unsealed
w/	with
we	white envelope
wpb	white paper bag
zlb	zip loc bag

4 General Requirements

4.1 Impartiality

4.1.1

BCI laboratory has policies specified in this manual and supporting laboratory practices; the BCI Bureau Directives; and AGO Policies and Procedures that provide guidance concerning any situations that could lessen confidence in the competence, impartiality, judgment or operational integrity of the BCI laboratory.

4.1.2

The laboratory management is committed to impartiality.

4.1.3

BCI laboratory has policies to ensure that all personnel are free from any undue pressures and influences that may negatively impact the quality of their work including the prohibition of strict quota implementation; mandatory ethics training; and AGO Policies and Procedures which address secondary employment, nepotism, and other personnel regulations. All laboratory personnel are responsible for assuring the integrity of the testing process.

4.1.3.1

BCI laboratory management recognizes the “Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists” as the foundation of its commitment to good professional practice.

- The code of ethics is controlled in PowerDMS to facilitate laboratory staff access.

- The BCI Laboratory Ethics Committee ensures the “Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists” is reviewed annually by all laboratory personnel and a record of that review is retained by the Quality Assurance Manager.

- The BCI Laboratory Ethics Committee is comprised of staff representative of a variety of laboratory disciplines and functions throughout the lab system. New members will be considered for participation in the committee every two years.

- The BCI Laboratory Ethics Committee shall meet annually to review feedback from the previous annual ethics review, schedule and plan subsequent ethics review sessions and develop suggestions for improvement to lab management. The Quality Assurance Manager, *or designee,* serves as the chair of the committee and presents their feedback to lab management during the Annual Management Review.

- Should a BCI employee be aware of a significant ethics violation, the employee must act to notify lab management or the AGO Human Resources Manager or the EEO Compliance Officer (as appropriate) so that actions can be taken.

4.1.4

The BCI Superintendent is responsible for the overall administration of the organization. The Laboratory Director (LD) administers the laboratory system. The LD reports directly to the BCI Superintendent or designee. This organizational structure separates the laboratory from the rest of the organization.

The laboratory identifies risks to its impartiality on an on-going basis. This includes risks that rise from its activities, or from its relationships, or from the relationships of its personnel.

4.1.5

Identified risks to impartiality will be evaluated and appropriate actions taken to eliminate or minimize such risks. Such actions include, but are not limited to, excluding examiners from working on cases where the individual(s) are known to them; retaining separation of duties for employees who are in a relationship; and the fair application of evidence submission policies. Actions taken will be documented appropriately in order to demonstrate how the risk to impartiality was eliminated or minimized.

4.2 Confidentiality

4.2.1

The laboratory is responsible, through ORC 149.43 (g), (h) and (j), for the management of all information obtained or created during the performance of laboratory activities.

Information contained in laboratory reports is considered confidential and the property of the customer. Authorization for a typical report or information release is documented in the case record.

Following administrative review and approval, laboratory reports and preparer statements of qualifications are made available to the evidence submitting agency and the affected prosecutor’s office electronically through the Ohio Law Enforcement

Gateway (OHLEG). Access to OHLEG and other restrictions are documented in Bureau of Criminal Investigations Ohio Law Enforcement Gateway Data Security Use Policy; and OHLEG Rules and Regulations. If a laboratory report is unavailable to the submitting agency or affected prosecutor's office through OHLEG, it may be provided via US mail or e-mail, if in accordance to established AGO policies for distribution of confidential records. Statements of qualifications (or notarized statements for chemistry assignments) are provided with the laboratory report in either electronic or hard copy form, as necessary to meet specific legal requirements. Laboratory reports are designated "mailed" in the LIMS to document report release. The approved report as it resides in LIMS is considered an official BCI report relative to the applicable testing. Any reproduction of those reports is considered a copy.

Bureau Directive 6.2 - Facility Security; and specific AGO Policies and Procedures regarding confidentiality include guidance for protecting the electronic storage and transmission of BCI laboratory examination reports.

4.2.2

The prosecutor (customer representative) is included when release of information is required for discovery requests.

4.2.3

Information about the customer obtained from sources other than the customer shall be confidential between the customer and the laboratory. The source of the information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source, except as required by law.

4.2.4

Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5 Structural Requirements

5.1

The Ohio Bureau of Criminal Investigation (BCI) is a section within the office of the Ohio Attorney General (AGO). BCI is authorized by the Ohio Revised Code to provide technical support, such as forensic laboratory services, and to otherwise cooperate with those with criminal investigative authority in Ohio in the investigation of criminal matters. Services may also be provided to law enforcement agencies outside Ohio and to federal agencies. The laboratory does not routinely accept evidence in cases for which no criminal prosecution is intended; however, various entities of government may have cases arise that require the assistance of the laboratories.

The BCI laboratory system is comprised of laboratories in London, Richfield~~, Springfield~~ and Bowling Green, Ohio. In addition to the *three* ~~four~~ laboratories, test items are also regularly received and returned by laboratory personnel at other designated locations so as to facilitate customer access to laboratory services.

5.2

The Laboratory Director has the authority to make and enforce decisions affecting the BCI laboratory.

The BCI laboratory:

a) Provides its personnel the authority and resources needed to carry out their duties including the implementation, maintenance and improvement of the quality management system. All laboratory employees are responsible for identifying departures from the quality management system and initiating actions to prevent or minimize any conditions adversely affecting the quality management system.
   - The Laboratory Director's duties include but are not limited to oversight and administration of activities required to implement and maintain scientific quality in all procedures and operations of the BCI laboratory system; retaining accreditation standards; BCI laboratory purchasing approvals; and strategic planning for staffing needs.
   - The BCI laboratory defines the organizational structure and the relationships between laboratory management, forensic scientists, laboratory technicians, and support services as demonstrated by the Laboratory Organization Chart. The BCI laboratory's position in the AGO is shown in the AGO Organization Chart.
   - Laboratory management is responsible for technical operations and provision of the resources necessary to ensure the reliability and integrity of laboratory operations. In addition, laboratory management has designated experienced forensic scientists as Forensic Science Coordinators (FSC) in each laboratory discipline. These individuals, as well as the casework DNA, CODIS and Massively Parallel Sequencing (MPS) Technical Leaders have technical responsibility within their respective disciplines and are designated in the laboratory organizational chart.
   - The BCI laboratory appoints a *member of lab management* ~~Lab Supervisor~~ to serve as Safety Coordinator. That individual is identified on the laboratory organizational chart. The Safety Coordinator serves under the general direction of the *Lab Director, or designee,* ~~Quality Assurance Manager~~. That individual has responsibility and authority for ensuring the health and safety program, as defined in the Laboratory Safety Manual, is implemented and followed at all times.

- The BCI laboratory appoints a Lab Supervisor to serve as Training and Equipment Coordinator. That individual is identified on the laboratory organizational chart. The Training and Equipment Coordinator serves under the general direction of the Quality Assurance Manager. That individual has responsibility and authority for ensuring the ongoing competency of staff and monitors compliance to equipment and training program objectives.

To be successful, the BCI laboratory quality management system must have the complete support and commitment of all personnel. It is the responsibility of every member of the laboratory to identify and bring to the attention of laboratory management recognized possible quality affecting situations.

Laboratory Position	Responsibilities
Laboratory Director (LD)	• Support and promote the quality management system. • Ensure conformance with the ANAB accreditation program, FBI Quality Assurance Standards NDIS, and ATF Minimum Requirements for Operating Standards • Ensure that BCI laboratory personnel understand and apply current policies and practices to appropriate situations. • Review and approve all quality management system manual and practice revisions prior to their implementation. • Is the issuing authority for all BCI laboratory quality management system manuals.
Laboratory Manager	• Support and promote the quality management system. • Ensure that the current policies and practices are implemented within their supervised units. • Ensure conformance with the ANAB accreditation program, FBI Quality Assurance Standards, NDIS and ATF Minimum Requirements for Operating Standards (as applicable). • Assist units, as needed, in the development of specific quality management system policies, practices, and methods. • Coordinate the development and revision of the quality management system. • Identify and coordinate training for laboratory staff • Ensure that appropriate corrective actions are taken and documented to resolve deficiencies when they are found.
The Quality Assurance Manager and Technical Leaders	• Ensure conformance with the ANAB accreditation program, FBI Quality Assurance Standards, NDIS, and ATF Minimum Requirements for Operating Standards. • Ensure all quality assurance programs function in accordance with BCI laboratory goals and objectives. • Review and approve all quality management system manual and practice revisions prior to their implementation, and all quality forms in their respective areas. • Ensure the policies, practices and methods within

	the quality management system are documented. • Oversee the Proficiency Test program. • Advise top management regarding the development, implementation, and maintenance of the quality management system. • Advise management on issues relating to BCI laboratory quality and good laboratory practice. • Coordinate the development and revision of the quality management system. • Assist units, as needed, in the development of specific quality management system policies, practices, and methods. • Coordinate and conduct periodic quality audits to provide management with the necessary verification that established quality policies, practices, methods, and objectives are being met. • Provide guidance and direction to BCI laboratory personnel regarding conformance with accreditation standards. • Ensure quality inquiry and corrective action is taken and documented to resolve deficiencies when they are suspected or found. • Coordinate and conduct periodic training for laboratory staff
State CODIS Administrator	• Ensures the state and local CODIS programs comply with the terms and conditions of the NDIS MOU, State and Federal Laws. • Ensures the state has documented procedures for the expungement of DNA records, confirmation of intrastate matches, definitions for DNA records eligible for state, state specific DNA searches and access to DNA records at the state level. • Communicates with the FBI all state and local laboratory information and changes. • Uploads DNA records to national level and review generate reports. • Distributes investigative information to law enforcement agencies.
~~Director of Research, Development and Training~~	~~• Support and promote the quality management system.~~ ~~• Advise management on issues relating to BCI laboratory quality and good laboratory practice.~~
Quality Assurance Laboratory Supervisor	• Support and promote the quality management system. • Ensure conformance with the ANAB accreditation program, FBI Quality Assurance Standards, NDIS and ATF Minimum Requirements for Operating Standards. • Communicate the quality management system and related policies, practices, and methods to all employees within the laboratory. • Ensure that all laboratory personnel receive necessary training and are qualified for their assigned work. • Ensure that appropriate corrective action follow-up measures are taken and documented. • Conduct quality audits, as directed by the Quality Assurance Manager, to provide management with the necessary verification that established quality policies, practices, methods, and objectives are being met. • Provide guidance and direction to BCI laboratory personnel regarding conformance with accreditation

	standards.
Laboratory Supervisors	• Support and promote the quality management system. • Ensure conformance with the ANAB accreditation program, FBI Quality Assurance Standards, NDIS and ATF Minimum Requirements for Operating Standards. • Communicate the quality management system and related policies, practices, and methods to all employees within the unit. • Appropriately delegate authority within the unit to implement the quality management system. • Ensure that all unit personnel receive necessary training and are qualified for their assigned work. • Ensure the completeness of laboratory reports and supporting case documentation. • Ensure that appropriate corrective actions are taken and documented to resolve deficiencies when they are found.
Training and Equipment Coordinator	• Provide/coordinate training for laboratory staff ranging from technical skills to soft skills • Coordinate/conduct lab observations and evaluations of ongoing competency of staff • Monitors reference material and training sample inventory records • Ensure conformance to equipment program objectives including, but not limited to, performance check compliance, method validation plan development, supply/vendor selections and evaluations, chemical storage inventory, calibration program schedule, and quality check compliance • Identify and recommend improvements to the equipment program.
Safety Coordinator	• Ensure conformance with the safety program. • Identify and recommend improvements to safe handling of laboratory equipment and chemicals.
Forensic Science Coordinators (FSC)	• Support and promote the quality management system. • Identify and recommend improvements to discipline-specific technical methods. • Assist in the interpretation of applicable Proficiency Test results, as necessary. • Assist in the completion of quality inquiry and corrective action steps within their discipline, as necessary. • Assist in the design and implementation of training programs and evaluation of training needs within their discipline. • Review and approve quality management system documents and revisions specific to their discipline prior to their implementation. • Participate in internal quality audits. • Coordinate scientific discussion or meetings concerning scientific accuracy, accreditation standards, etc.
Safety Officers	• Monitor compliance with the safety program.
Forensic Scientists	• Ensure compliance with current policies, practices, and methods. • Ensure that discipline methods are performed in a careful and responsible manner in accordance with

	current policies and practices. • Make recommendations and suggestions for improving the BCI laboratory quality management system, as appropriate. • Participate in internal quality audits
Local CODIS Administrator	• Ensures compliance with the terms and conditions of the NDIS MOU, State and Federal Laws. • Ensures only authorized CODIS users are permitted access. • Uploads DNA records to the state and reviews generated reports. • Distributes investigative information to law enforcement agencies.
NIBIN Program Administrator	• Ensures local compliance to National Integrated Ballistic Information Network (NIBIN) Program
NIBIN Technical Administrator	• Ensures local technical compliance to NIBIN program
~~Forensic~~ Lab Technician 1	• Maintain laboratory supplies and inventories. • Prepare and retain quality related records. • Assists in laboratory quality control measures. • Make recommendations and suggestions for improving the BCI laboratory quality management system, as appropriate.
Lab Technician 2	• Ensure compliance with current policies, practices, and methods. • Ensure that discipline methods are performed in a careful and responsible manner in accordance with current policies and practices. • Make recommendations and suggestions for improving the BCI laboratory quality management system, as appropriate.
Evidence Intake Technician (EIT) ~~Administrative Personnel~~	• Perform administrative/clerical duties in a careful and responsible manner. • Ensure compliance with applicable policies, practices, and procedures. • Make recommendations and suggestions for improving the BCI laboratory quality management system, as appropriate.

5.2.1

Laboratory Director responsibilities and authorities are defined in Section 5.2 of this manual and the LD job description is retained by the AGO Human Resources Section.

5.3

The range of laboratory activities where the BCI laboratory conforms to ISO/IEC 17025 requirements is included in each Lab Section Methods manual.

5.4

The BCI laboratories provide forensic services to address customer requests for the examination of evidence and databasing. These testing activities are conducted in such a way as to conform to the current requirements of ISO/IEC 17025:2017, ANAB Requirements, Quality Assurance Standards for Forensic DNA Testing Laboratories, Quality Assurance Standards for DNA databasing Laboratories, Minimum Requirements

for Operating Standards for NIBIN Network sites (MROS) and the BCI laboratory quality management system.

BCI laboratory conforms to the established requirements in the National DNA Index System (NDIS) Operational Procedures Manual and when applicable FBI Quality Assurance Standards.

Forensic scientists performing DNA analysis comply with the proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for Convicted Offender DNA Databasing Laboratories.

BCI laboratory management employs the laboratory quality management system in its oversight of work conducted at each of the permanent laboratory sites (in Bowling Green, London, and Richfield) and at any other location where laboratory employees might be required to perform forensic services.

Whenever ANAB is referenced in any communication (report, webpage, documents, etc.) by use of the accreditation symbol, business name, or business acronym, BCI will take the following actions:

- Restrict its use to the applicable laboratory accreditation as named on the certificate of accreditation;
- Ensure the accreditation symbol used is specific to the ANAB Forensic Testing Program;
- Any non-accredited testing is clearly identified as such by use of a disclaimer or reference to the scope of accreditation document(s).
- Ensure that the representation of accreditation status is accurate and not misleading;
- Ensure that there is no implication that the accreditation body accepts responsibility for BCI test results; and
- Ensure that there is no implication that a product, process, system or person is approved by the accreditation body.

BCI laboratory reports shall not refer to accreditation when the testing included in the report is not within the scope of accreditation.

If the accreditation is referenced in a BCI laboratory report, opinions or interpretations outside the scope of accreditation are clearly identified by use of a disclaimer.

If the International Laboratory Accreditation Cooperation (ILAC) mark is displayed on a BCI laboratory report, BCI ensures that a signed sub-licensing agreement is on file with

ANAB and the ILAC mark must be used in conjunction with the ANAB accreditation symbol.

5.4.1

BCI Laboratory conforms to requirements in PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status.

5.4.2

Any event or nonconformity that could substantially affect the integrity of BCI laboratory activities and is related to an accreditation requirement or the requirements of regulatory authorities shall be disclosed to ANAB with 30 calendar days of the occurrence. If the event or nonconformity is identified more than 30 days after the occurrence, it shall be disclosed to ANAB immediately.

5.5

The BCI laboratory defines the organizational structure and the relationships between laboratory management, forensic scientists, laboratory technicians, and support services as demonstrated by the Laboratory Organization Chart. The BCI laboratory's position in the AGO is shown in the AGO Organization Chart.

The responsibility and authority of all BCI laboratory personnel is defined in this manual. Each BCI laboratory employee is accountable to only one immediate supervisor per function.

The BCI laboratory is committed to its quality management system as outlined in this manual, supporting laboratory practices, NIBIN, DNA and CODIS Quality Manuals, the Laboratory Safety Manual and all unit method and training manuals. These documents are readily available electronically to all BCI laboratory personnel via the agency intranet and the electronic records management system. Additional quality management system documents such as worksheets, log forms, technical review forms, instrumentation manuals, etc. are available electronically or in hard copy form.

- Notifications of updates to management system documents are communicated to staff by the Quality Assurance (QA) manager or Technical Leader, as appropriate.
- The laboratory staff documents their review and understanding of the document(s) via electronic signature in the electronic record management system.

5.6

All BCI Laboratory personnel have resources and authority to carry out duties. BCI laboratory has personnel designated to serve as the Quality Assurance Manager (QA

Manager), casework DNA Technical Leader, MPS casework DNA Technical Leader and CODIS Technical Leader. Those individuals have defined responsibility and sufficient authority to ensure the quality management system is implemented and followed at all times. They have direct access to the LD, who has full authority to implement laboratory policy and direct resources, including:

- Implementation, maintenance and improvement of the management system;
- Identification of deviations from the management system or from the procedures for performing laboratory activities;
- Initiation of actions to prevent or minimize such deviations;
- Reporting to laboratory management on the performance of the management system and any need for improvement;
- Ensuring the effectiveness of laboratory activities;

5.7

The Ohio Attorney General's Office provides e-mail, telephones and video conferencing capability to ensure adequate communication processes are available to all BCI laboratory personnel. Laboratory personnel utilize these technologies, meetings and other mechanisms to share information regarding the effectiveness of the quality management system. Laboratory management encourages all personnel to improve the effectiveness of the quality system by initiating improvements or otherwise notifying affected management whenever quality concerns are identified. Laboratory management ensures BCI laboratory personnel are aware of the relevance and importance of their activities and how they relate to the objectives of the quality management system.

Laboratory management emphasizes the importance of addressing customer requests and complying with any relevant statutory and regulatory requirements through the quality management system policies, the BCI Mission Statement and specific required actions as directed by this manual, laboratory practices, policies and methods that comprise the quality management system.

The LD, QA Manager and Technical Leaders are responsible for ensuring that the integrity of the laboratory quality management system is retained when changes to that system are necessary.

Quality management system changes are accomplished and documented using the mechanisms provided within the quality management system.

6 Resource Requirements

6.1 General

The laboratory has available personnel, facilities, equipment, systems, and support services necessary to manage and perform its activities.

6.2 Personnel

6.2.1

The BCI laboratory may employ contracted or technical personnel. The laboratory ensures that all personnel are adequately supervised, competent and work in accordance with the laboratory's quality management system.

Any laboratory work that could influence the laboratory activities is conducted by staff who have demonstrated competency in the task.

6.2.1.1

Periodically, BCI Laboratory employs collegiate student externs. The externs are selected in collaboration with Lab Management and AGO Human Resources staff. All externs undergo established pre-employment checks prior to beginning their externship at the BCI Laboratory. The externs are supervised by Lab Management. The 10-week Externship Program is composed of a series of modules designed to prepare students for careers in a forensic laboratory and to further evaluate BCI's established training program.

Module	Duration	Details	Assignments
All about BCI	1 week	Students will attend a presentation of the "BCI orientation". They will learn who BCI's customers are, where BCI offices are located, and the goals and objectives of the agency overall.	-Job Shadowing -Interview staff about job duties
Evidence Reception and Handling	1 week	Students will shadow Evidence Receiving. They will learn how law enforcement agencies utilize the laboratory services from BCI, how evidence must be packaged and sealed, and chain of custody tracking mechanisms.	-Property Room article -General Evidence Receiving (ER) Training video
Laboratory Testing	3 weeks	Students will complete a selected module(s) from the assigned section's training manual, under the guidance of the section's trainer. Module(s) will be selected depending on available resources. This training will include use of mock evidence samples and the LIMS training environment (whenever applicable).	-Exercises will be selected by designated Lab mentor

		The student(s) will learn how to perform the testing method(s), interpret the findings and draft a mock report of their results.	
Quality Assurance	2 weeks	Student(s) will attend a presentation of the "QA Overview" and learn about BCI's Quality Management program and how it relates to the accreditation program objectives.	-QA Project related to assigned lab section (may include corrective action follow up or soliciting customer feedback) -Written Summary or PowerPoint presentation
Testimony	2 weeks	Student(s) will attend a presentation of the "Courtroom Testimony". Student(s) will review published documents related to courtroom testimony, archived transcripts, etc. Whenever available, the student(s) will observe BCI Forensic Scientist testimony in court.	-Testimony monitoring activities (videos, transcripts, observations) -Compose Testimony Monitoring forms -Mock Trial
Final Externship Evaluation	1 week	--	-Written externship program feedback project

6.2.2

BCI laboratory management ensures that only qualified personnel conduct forensic examinations, confirm conclusions, review results, and issue reports.

Those personnel are qualified on the basis of appropriate education, training, experience, technical knowledge and/or demonstrated skills, as required by their position. Discipline training manuals specify the evaluation of successful completion of assessment activities.

Current job descriptions for all BCI laboratory personnel are retained by the laboratory in association with the Ohio Department of Administrative Services (DAS). Job descriptions are readily available to all personnel.

Designation	Requirements
Laboratory Director	Master's degree (or equivalent) in physical or biological science (e.g., chemistry; biology, or physics); 3 yrs. experience. in analytical testing & evaluation of evidence in criminal matters. -Or Undergraduate degree (e.g., B.S., B.A., or equivalent) in physical or biological science; 4 yrs. analytical testing & evaluation of evidence in criminal matters. -Or 6 yrs. training or 6 yrs. experience in physical or biological science that included 3 yrs. experience in analytical testing & evaluation of evidence in criminal matters.
Laboratory Manager	Completion of graduate core program in physical or

	biological science (e.g., chemistry, biology); 3 years' experience in analytical testing and evaluation of crime-related evidence; 1 year of training or 1 year of experience in supervisory principles/techniques. -Or completion of undergraduate major core program in physical or biological science; 4 years' experience in analytical testing and evaluation of crime-related evidence; 1 year of training or 1 year of experience in supervisory principles/techniques. -Or equivalent of Minimum Class Qualifications for Employment
DNA Technical Management	Master's degree (or equivalent) in physical science and: -3 yrs. experience in forensic human DNA laboratory as an analyst on forensic samples. -Completion of a combination of undergraduate and graduate core coursework in biochemistry, genetics, molecular biology, and statistics or population genetics
Non-DNA Technical Management (i.e. Forensic Scientist Coordinator, FSC)	5 yrs experience in casework for applicable discipline
Forensic Scientist (includes those performing tests and personnel creating items such as test fires, DNA cuttings or swabs, etc.)	A baccalaureate or an advanced degree in a chemical, physical, biological or forensic science.
Forensic Science Laboratory Technician	Undergraduate core program in physical or biological sciences (e.g. biology, chemistry, physics, forensics) which includes coursework that required scientific laboratory testing

6.2.2.1

Laboratory personnel who issue reports that include testing results, opinions, or interpretations must meet the minimum education requirements below:

Discipline	Minimum Education Requirements
Biology Gunshot Residue ~~Materials (Trace)~~ Seized Drugs	A baccalaureate or an advanced degree in a chemical, physical, biological or forensic science.
Firearms/Toolmarks Footwear and Tire Document Examination Friction Ridge	Meet the educational requirement(s) specified in the job description

6.2.2.2

Basic Training

Each discipline within the BCI laboratory has a documented basic training program that is used to develop employee knowledge, skills, and abilities required to perform forensic examinations. The trainee's supervisor is responsible for ensuring trainers are provided, the appropriate training program/outcome expectation is identified, and trainees are adequately supervised throughout the training process. The trainee's Laboratory Supervisor is responsible for determining successful completion of the scientist's training program and recommendation for independent casework release or retraining.

The Laboratory Trainer must be qualified in the testing methods and have successfully completed a "Train the Trainer" course.

Scientists with prior forensic experience may be subject to abbreviated training, at the discretion of the responsible QA Manager or Technical Leader. These scientists should successfully complete an initial assessment that may include, but is not limited to, a review of previous employment records, a written or oral test, or a laboratory practical. A Modified training plan must be documented in accordance with the results of the initial assessment of the scientist's experience when exclusions to the established training program are made. Demonstrated prior applicable training may substitute for completion of elements of the training program, however, at minimum, the employee must successfully complete a competency test prior to conducting independent casework.

The training program (as it related to job function) includes:

- The knowledge, skills and abilities needed to perform work;
- General knowledge of forensic science;
- Application of ethical practices in forensic sciences;
- Any applicable criminal and civil law procedures;
- Court testimony training;

The BCI laboratory system retains and provides access to forensic science resources such as relevant books, journals and other literature dealing with each discipline. The AGO retains a comprehensive library; facilitates access to a broader literary resource network; and provides regular notification of forensic and other related resources available to all laboratory staff.

All personnel must successfully complete competency testing prior to performing testing or tasks that create items that could be used for testing regardless of prior experience. A moot court exercise must be completed that mimics actual courtroom experience. Trainee performance should be evaluated in regards to technical knowledge, composure, communication objectivity, and understanding of BCI policies and procedures. Documentation of successful moot court completion will be reviewed

by the Laboratory Supervisor and retained with the trainee training record. Demonstrated prior applicable court testimony experience or formal testimony training may be substituted for in-house moot court. Successful completion of the training program is achieved by obtaining passing scores on written exams, demonstration of scientific knowledge through established oral exam content, and demonstration of skills related to sample handling and testing methods in accordance to established approved methods.

Remedial Training

Identified quality concerns may indicate a level of retraining as a practical corrective or preventive measure. Retraining will be done in accordance with Practices for Quality Inquiry and Corrective Action or Practices for *Improvements* ~~Preventive Action~~.

Ensuring ongoing competency

Laboratory supervisors are responsible for ensuring individuals previously authorized to perform independent casework are prepared to resume those activities. The laboratory supervisor may require a competency exam when an individual has not performed a particular test for an extended period of time.

Prior to resumption of independent casework, the returning individual must:

- Review and acknowledge receipt of any pending controlled quality document or revision
- Complete any pending proficiency test
- Successfully complete a laboratory management identified test designed to verify continued casework capability and provide on-going training of staff.

6.2.3

BCI laboratory management further ensures any personnel who are undergoing training are appropriately supervised and are competent to perform laboratory activities and evaluates the significance of any deviations.

6.2.3.1

Laboratory personnel must complete competency test(s) and achieve the intended result(s) prior to performing laboratory testing or creating items that could be used for testing. The competency test(s) associated with their initial authorization for independent casework activities must include, at a minimum:

- Examination of sufficient unknown samples to cover the anticipated range of assigned duties and evaluate the individual's ability to perform proper testing methods/tasks.
- A written test report demonstrating the individual's ability to properly convey test findings and the significance of those findings, when applicable.
- An oral examination to assess the personnel's ability to provide testimony.

Written or oral examinations assess the individual's knowledge of the discipline. Any incorrect responses/answers will be reviewed to ensure full comprehension.

Discipline training programs may specify elements of closely monitored laboratory casework, also known as supervised casework. Whenever possible, supervised casework should include the following details:

- Laboratory shadowing of qualified scientist to observe casework workflow and case record documentation practices
- Performance of initial technical reviews, where the final technical review is completed by a qualified scientist

6.2.3.2

Personnel who perform technical review of results or testimony, shall meet the competency requirements specified for those performing the testing tasks being reviewed.

6.2.4

The duties, responsibilities and authorities of the laboratory is communicated to personnel.

6.2.5

The laboratory manual for Lab Management (LM-Lab Management) describes the procedure for determining competency; selecting personnel; training of personnel; supervision of personnel; authorization of personnel; and monitoring competence of personnel.

6.2.6

The Quality Assurance Manager or responsible Technical Leader authorizes qualified personnel to perform independent work, including:

- Development, modification, verification and validation of methods;
- Analysis of results, including statements of conformity, or opinions and interpretation;
- Report, review and authorization of results

6.3 Facilities and Environmental Conditions

6.3.1

All examinations require normal laboratory environmental conditions unless noted in the standard operating method. Extreme care is taken if sampling or examination is required at a location other than a BCI laboratory space. If a BCI laboratory moves to a new permanent facility or the testing is performed in a space outside of the laboratory additional actions may be taken to ensure compliance with the quality system; see the Laboratory Practice for Laboratory Relocation.

6.3.2

All BCI laboratory facilities are configured to permit the correct performance of forensic examinations. Discipline units ensure that the environmental conditions do not adversely affect the quality of any critical measurement. Any environmental conditions that can affect the results of examinations are documented in the appropriate standard operating method.

6.3.3

If environmental conditions may affect the quality of an examination, affected units monitor, control and record those conditions as required by method. Examinations are terminated if environmental conditions risk the reliability of the results.

6.3.4

Laboratory units are responsible for retaining effective separation between incompatible activities to prevent cross-contamination. BCI has measures to control facilities which are monitored and periodically reviewed, including designated work areas, cleaning and layout of the lab space.

6.3.4.1

All laboratory personnel are responsible for maintaining security. General BCI facility and laboratory security policies are found in Bureau Directive 6.2 (Facility Security) and the AGO Policy and Procedures ~~Manual~~ (Employee Security Responsibilities). All BCI laboratories meet the minimum security policy requirements listed below. Enhanced site-specific policies may be maintained at each location.

- Access to the operational areas of each laboratory are controlled and limited. No unauthorized individual may have unrestricted access to an operational area of the laboratory.
- Laboratory exterior entrance/exit points and outer perimeters are secured through combinations of locks, motion detectors, intrusion alarms, exterior lighting, video cameras and recording devices.
- All internal areas requiring limited/controlled access have a lock system.
- All laboratory access keys, codes and magnetic cards are managed by AGO facilities staff and are restricted to those individuals designated by laboratory management to have access.
- A key log is maintained by a designated Laboratory Supervisor(s), which is used to track keys associated with secured evidence and confidential records stored in the laboratory areas.
    - For example, keys associated with office furniture stored in a community space are tracked only if case records or other confidential records are routinely stored inside. If case records or confidential records are stored within a locked office, the key associated with the office door is tracked.

- Instances of lost keys/access magnetic cards or malfunctioned lock mechanisms/magnetic card readers are reported to laboratory management promptly, and appropriate action(s) are taken to ensure the integrity of the security access.
- Each BCI laboratory is monitored during vacant hours by intrusion alarm system or personnel.
- Long-term evidence storage areas in each laboratory are secured and access is controlled and recorded to prevent theft or interference. Evidence storage conditions are designed so as to prevent loss, deterioration, or contamination and to maintain the integrity and identity of the evidence. These storage, security and access control measures apply both before and after examinations have been performed.
- Each BCI laboratory facility has a fire detection and suppression system.
- Access to individual characteristic database samples under control of the laboratory is restricted in a manner consistent with that of evidence samples.

6.3.5

When BCI laboratory performs laboratory activities at sites or facilities outside its permanent control, the requirements related to facilities and environmental conditions of this document are met.

6.4 Equipment

6.4.1

Each BCI laboratory is furnished with all the equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) required for the correct performance of forensic examinations identified within its scope. All instruments and equipment having a significant effect on the accuracy or validity of forensic testing results are properly calibrated and maintained. Requirements for instrument calibration and maintenance are described in the applicable discipline methods manual and/or instrument calibration/maintenance record.

6.4.2

If a laboratory discipline needs to use equipment outside its permanent control, it is responsible for ensuring applicable equipment performance requirements are met. If for any reason equipment leaves the direct control of the BCI laboratory, equipment function and calibration status is verified to be satisfactory before the equipment is returned to service.

6.4.3

Guidelines for handling, transporting and storing *equipment* ~~instruments~~ is typically defined by the manufacturer. *Manufacturer's recommendations or guidelines are followed, as applicable, in order to prevent contamination and/or deterioration unless other approved criteria are specified and documented in lab section procedures.* Exceptions or additions to the manufacturer's instructions are specified in the appropriate ~~methods~~ *laboratory* manual or ~~instrument~~ *equipment* maintenance record.

The following procedures are identified for the safe handling, transport, storage and use of reference standards.
Balance calibration weights:

- Balance calibration weights are used solely for that purpose.
- Weights are manipulated with included tweezers or cloth gloves.
- When not in use weights are stored in manufacturer; certifier supplied; or other suitable containers and locations so as to prevent damage, contamination and inadvertent use.
- Each laboratory is equipped with certified balance calibration weight sets. Any intra-laboratory transport must be management approved and by hand.
- Transport to and from the recertification vendor will be sufficient to ensure the integrity of the items.
- Any damaged or otherwise compromised weight must be removed from service immediately. Accuracy must be confirmed prior to placing the weight back in service.

Firearms measuring reference standards:

- Firearms measuring reference standards are used solely for the purpose of checking the calibration of measuring devices utilized in casework.
- Measuring reference standards are handled with extreme care so as to prevent damage.
- Any damaged measuring reference standard is removed from service immediately. Accuracy must be confirmed prior to placing the measuring standard back in service.
- When not in use, measuring reference standards are stored in suitable containers and locations so as to prevent damage and inadvertent use.
- Each laboratory is equipped with measuring reference standards. Any intra-laboratory transport must be management approved and by hand.
- Transport to and from the recertification vendor will be sufficient to ensure the protection and integrity of the standard.

The following procedures are identified for the safe handling, transport, storage and use of reference materials:

- Reference materials will be handled and stored in such a way as to prevent their loss, damage, contamination or deleterious change.

- Reference materials must be identified and/or separated so as not to become inadvertently comingled with case evidence.
- Drug reference materials must be stored to prevent unauthorized access and as necessary to prevent degradation.
- Reference weapons must be stored to prevent unauthorized access.
- Reference materials may be used for comparative reference, Quality Control (QC) procedures or to facilitate testing.
- Intra-laboratory transport is permitted. Reference materials will be transported in such a way as to adequately protect them from loss, damage, contamination or deleterious change.
- Laboratory Safety Manual precautions apply, as necessary.

Maintenance procedures document the frequency and type of maintenance to be performed.

The performance of any moved equipment is verified and documented prior to casework analysis.

6.4.3.1

All equipment that influences the results of testing is stored within the control of the laboratory's restricted access areas.

Commercial reagents and chemicals will retain their original manufacturer's labels and will also be marked with the following information:

- Date of receipt
- Date of opening
- Opener's written initials

Reagents prepared in the BCI laboratory are labeled with the following information, at minimum:

- Name of the reagent
- Date of preparation or lot number (if applicable)
- Preparer's written initials
- Storage Requirements, when conditions required are other than room temperature
- Expiration Date (if applicable)

Reagents are prepared according to the guidelines established in the unit methods manual and reagent preparation logs. The preparer is responsible for ensuring the following information is included in the reagent preparation log:

- The name of the reagent

- The date of preparation
- The initials of the preparer
- The name and manufacturer of the individual chemical components
- Expiration dates (if applicable) of individual chemical components
- Lot number of individual chemical components (if applicable)
- The actual weight/volume of individual chemical components used
- Storage condition requirements of the reagent
- Expiration date of the reagent (if applicable)
- pH of the reagent (if applicable)
- Location (i.e. Laboratory Section Name)
- Documentation of reliability testing performed (it is recognized the reliability of some prepared reagents can only be assessed concurrent with the test)

Note: If the reagent being prepared uses previously prepared reagents as constituents, the date of preparation of the reagent is used as the lot number.

6.4.3.2

Laboratory disciplines may establish reference collections of data or test materials encountered in casework for future identification, comparison or interpretation purposes. Those collections are fully documented, uniquely identified and properly controlled. Examples of these reference collections may include, but are not limited to mass spectra, drug samples, weapons, ammunition, or exclusion DNA profiles.

The laboratory maintains a list of reference materials which includes information describing documentation; item identification; and control practices.

6.4.4

Equipment performance is verified and records are retained according to documented procedures. All equipment is performance checked or calibrated, at a minimum, before being placed into service or returned to service, with the exception of raw chemicals/solvents purchased.

6.4.5

Equipment and its software used for testing must meet the requirements of the relevant testing method, including the measurement accuracy and/or measurement uncertainty, where applicable.

6.4.6

BCI laboratory disciplines exhibit measurement traceability on measurements that have a significant effect on the accuracy or validity of the result of the test, including all measurements explicitly requiring a measurement uncertainty calculation and/or when

the calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7

Procedures and intervals for calibration activities having significant effect on the results of testing are defined by the laboratory discipline.

Whenever the calibration of equipment contributes little to the total uncertainty of the test result, the equipment does not require calibration.

BCI laboratory reference standards include drug chemistry balance calibration weights, *temperature kits for moisture analyzers,* and measuring devices used in the determination of critical firearm related measurements.

Reference standards must be recertified as calibrated every three (3) years, at minimum by a qualified service provider. Laboratory disciplines may describe additional requirements for the calibration of their reference standards. Reference standards are calibrated by organizations that can provide traceability as described in 6.5.1.1 and 6.5.1.2 of this manual.

A reference standard may only be used for calibration purposes unless it can be shown that any additional use will not invalidate it.

6.4.7.1

The following table lists examples of equipment used for testing that can be calibrated by an external laboratory using traceable reference standards.

Type of Calibration Reference Standard	**Type of Equipment**
Mass	Balance
Mass-derived	Pipette (volume)
Length	~~Ruler,~~ gauge block
Temperature	Thermal cyclers
Temperature and Mass	Moisture Analyzer

External calibration laboratories must be accredited to the ISO 17025 standard and the calibrated reference standard will be within its scope.

Calibration of equipment used in the BCI laboratory requires that measurements made are traceable to the International System (SI) units by means of an unbroken chain of calibrations or comparisons linking them to the relevant primary standards of the SI units of measurement when such measurements are significant to the test results.

- International Bureau of Weights and Measurements (BIPM) SI- maintains the international prototype kilogram (IPK)
- National Metrology Institute (NIST)- maintains the national prototype reference standard (K20), calibrated against the IPK
- Primary Calibration Laboratory (PCL)- reference standard calibrated by NIST
- Accredited Calibration Service Provider- reference standard(s) calibrated by the PCL and calibrates BCI equipment

Regardless of established interval defined by the laboratory discipline, BCI laboratory equipment is calibrated or performance checked before being placed into service and following scheduled preventive maintenance, following repair, or any unusual equipment shut down.

These actions are recorded in the appropriate maintenance or calibration check record and, if necessary, any affected examination documentation.

6.4.8

The current calibration status, including the date of the last calibration and information identifying the recalibration requirement, is documented and readily available for all BCI laboratory equipment requiring calibration.

Balances used for the determination of critical weights are calibrated annually. Calibration is performed by a laboratory approved provider capable of demonstrating ISO 17025 certification for the balances calibrated. Calibration documentation is retained in the associated balance log. Service tags affixed to each balance identify last date of vendor calibration.

Moisture Analyzers and pipettes used for quantitative analytical scheme in Drug Chemistry are calibrated annually by an approved provider capable of demonstrating ISO 17025 certification for analyzers calibrated. The temperature check kits are calibrated every 2 years. Calibration documentation is retained in the associated equipment log. Service tags affixed to each moisture analyzer identify the last date of vendor calibration.

Laboratory microscopes used for examinations critical to the conclusions drawn are serviced every other year by an approved provider. Documentation is retained in the associated equipment log. Service tags affixed to each microscope identify last date of vendor service. All other laboratory microscopes used for preliminary examinations are serviced as needed. The following microscopes have been identified as critical to the conclusion drawn with the intended use listed:

Microscope Type	**Intended Use**
Stereoscope	Drug Chemistry-Quantitative Analysis

	Questioned Documents-VSC, original document
Compound Microscope	DNA-Body Fluid Identification, Hair Root/Tissue Examination
Comparison Scope	Firearms- Microscopic Comparisons

The DNA unit(s) identifies minimum annual preventive maintenance requirements for genetic analyzers, Real Time PCR, robotic systems, thermometers, and thermal cyclers and calibration requirements for pipettes. Additional information is provided in the DNA Quality Assurance and the CODIS Quality Assurance Manuals.

Laboratory approved vendors for these services are identified on the critical service and supply list(s).

6.4.9

Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, is taken out of service and clearly labeled or is isolated from use as such to prevent use until repairs are completed. Only when it is shown by calibration or standard intermediate check to operate correctly will the equipment be returned to service.

Date of removal from service, reason for removal, and date of return to service is documented in the equipment maintenance log.

Laboratory personnel determine the effect of the malfunction, if any, on previous tests. Practices for nonconforming work detailed in this manual shall be initiated.

6.4.10

Intermediate checks are performed to maintain confidence in the calibration status of the equipment. Intermediate checks are performed on reference, primary, or working standards as well as reference materials to maintain confidence in their calibration status as described by the discipline method or the reference material list.

The Quality Assurance Manager will initiate review of reference materials annually to ensure their continued full documentation, unique identification and proper control. Drug reference materials are inventoried *in accordance with DEA licensing requirements*. ~~annually~~, or as otherwise directed by the LD to ensure their safekeeping.

When intermediate checks of the calibration status are needed, the procedure and frequency is described in the test methods and/or calibration record by the testing unit.

Any extension of the interval of intermediate checks will be based on empirical data and an evaluation of risks associated with:

- Calibration interval;
- Use of the equipment;
- Stability of the equipment;
- Test method specifications; and
- Risks associated with a failed check

6.4.11

Where calibrations give rise to a set of correction factors, these factors are updated, communicated to affected personnel and documented in the calibration record and examination documentation, as appropriate.

6.4.12

Testing equipment, including both hardware and software, are safeguarded from adjustments that would invalidate the results through access control to the laboratories.

6.4.13

All laboratory equipment, reagents and consumables used for testing and significant to the result has a unique identifier. Identifiers may include serial number, AGO asset number, lot number or uniquely assigned name.

Records are retained for each item of equipment and its software critical to the test results. The records include the following, where applicable:

a) Identity of the equipment and its software and firmware version
b) Manufacturer's name, model, and serial number or another unique identifier
c) Checks that equipment complies with specifications
d) Current location, where appropriate
e) Manufacturer's instructions (or reference to their location) when they describe an essential element of the testing, calibration, or maintenance process not otherwise addressed in a controlled quality system document
f) Dates, results and copies of calibration certificates, adjustments, acceptance criteria and calibration schedule
g) Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity
h) Maintenance plan, where appropriate, and maintenance history including any damage, significant malfunction, modification or repair

6.5 Metrological Traceability

6.5.1

The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. If the quantitative value of a reference material is changed (e.g. diluted), then the calibration of the equipment used to alter the reference material impacts the traceability chain.

6.5.1.1

Suppliers of external calibration services for reference standards requiring calibration and equipment where the calibration of the equipment has a significant effect on the accuracy or validity of the sampling or test result or the total uncertainty of the test result must be either:

- A National Metrology Institute (i.e. NIST) that is a signatory to the BIPM; or
- A service supplier accredited to ISO 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration to be performed listed in the scope of accreditation.

If available, suppliers of certified reference material used to establish or maintain measurement traceability shall be either:

- A National Metrology Institute (i.e. NIST) that is a signatory to the BIPM; or
- An accredited reference material producer that is accredited to ISO 17034:2016 by an accrediting body that is a signatory to a Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material.

6.5.1.2

If a supplier of external calibration services meeting the specifications stated above is not available, the Quality Assurance Manager or Technical Leader must confirm competence, measurement capability, and measurement traceability for the supplier and the service being purchased. The record of this assessment will be retained. If a producer of reference material meeting the specifications stated above is not available, Quality Assurance Manager or Technical Leader must confirm competence, measurement capability, and measurement traceability for the producer and the material being purchased. The record of this assessment will be retained.

6.5.1.3

The BCI laboratory is not a calibration laboratory and will utilize external calibration services whenever available.

6.5.2

The BCI laboratory ensures that measurement results are traceable to the International System of Units (SI) through:

a) Calibration provided by a competent laboratory;
b) Competent producers and traceability. Instances where SI traceable reference materials are not available is addressed below in QA 6.5.3; or
c) Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards

6.5.3

a) Calibration checks that cannot provide strict measurement traceability to SI units are conducted such that the calibration check results can provide confidence in the test measurements.

b) Inter-laboratory comparisons or proficiency test materials may be considered as an alternative to demonstrate traceability when the preferred methods of traceability to SI units cannot be established.

6.6 Externally Provided Products and Services

6.6.1

The BCI laboratory ensures that only suitable externally provided products and services are used when they affect laboratory activities.

Services and supplies must be purchased from laboratory approved vendors. Wherever possible, vendors of critical laboratory services such as balance calibration; standard weight calibration/recertification; pipette calibration; and other measuring device calibration/recertification will be accredited to the ISO/IEC 17025 Standard. The laboratory will document evidence of vendor accreditation status and scope.

Critical equipment will be serviced by the manufacturer or a service vendor demonstrably capable of providing the service (e.g. as certified by the manufacture, demonstrated through past performance, etc.).

Service and supply vendors will be evaluated annually to ensure their continued compliance with the applicable standard or quality requirement. Record of that evaluation will be retained.

6.6.2

The BCI Laboratory procures services and supplies that affect the quality of examination from approved providers. Authorization and spending guidelines are established by the Ohio Attorney General's Office.

- The purchaser must select services, supplies and vendors capable of meeting or exceeding minimum requirements for the intended application. The purchaser will utilize the *Ohio Buys* ~~Request to Purchase (RTP)~~ process found on *MyOhio.gov* ~~the AGO intranet~~ to order all services, supplies, reagents, and consumable materials totaling $5000 and over. ~~All services must be submitted via RTP, to ensure that AGO Business Counsel reviews the terms and conditions~~.
- Orders of supplies totaling less than $5000 may be acquired via state issued credit card or purchase order with the Laboratory Director review and authorization. Documentation of the approval for the use of funds must be retained in accordance to the established AGO retention schedules. The purchaser must identify the selected approved vendor and provide detailed description to ensure the item purchased meets the technical specifications required. Wherever possible, supplies will be obtained from vendors certified to the applicable ISO Standard or otherwise capable of providing demonstrable proof of consistently reliable product, such as laboratory assessed past performance.
- Vendors must meet applicable AGO Finance rules, which may include provision of tax information, approved contractual agreements, etc.
- The initial purchase request approver ensures the items selected meet or exceed the minimum technical requirements for the intended application prior to purchase. ~~RTPs will be routed for approvals by the Laboratory Director. The Laboratory Director may need to seek additional approvals from other AGO departments as needed. For example, IT related purchases have a specific routing plan in the RTP system. Additional directions are listed on the AGnet/Finance SharePoint location~~.
- Following AGO Purchase Order creation, the purchaser is notified and directs the Purchase Order to the vendor. Service contracts may be established in conjunction with the Ohio Department of Administrative Services. Service required relative to a service contract will follow that agreement.
- Upon receipt, the recipient must:
    - Verify the service or supply received was that ordered. If supplies received were not in compliance with technical specifications the receiver shall take measures to ensure the supplies do not enter general circulation, and laboratory management is immediately notified.
    - Vendor receipt or packing slip is directed as per operational policy.
    - Any prescribed marking; inventory entry; log entry; equipment label: notification; or storage requirement is completed.
    - The recipient will verify the service performed and associated documentation against the Purchase Order request (as applicable).

The BCI laboratory selects competent subcontractors to conduct forensic tests and databasing when necessary. A subcontractor's competence can be demonstrated by

their compliance with the applicable International Standard with a scope of accreditation that covers the work in question, by satisfactory results of an audit conducted by BCI laboratory personnel or qualified independent audit, or by being a regulated government agency.

Laboratory staff evaluates quality affecting supplies, reagents and consumables purchased to ensure they comply with specifications as required in their applications. These materials are not used until their compliance is verified, as follows:

- Critical supplies are QC checked as per discipline method prior to use in casework, and during on-going QC checks in association with testing (e.g. blanks, etc.).
- For methods where reagents are QC checked concurrent with testing, efforts are made to ensure that the critical supplies are appropriate for use prior to use in casework. Examples include Serial Number Restoration in the Firearms section.
- Results of QC checks will be recorded in the appropriate log and/or case documentation.
- Any critical supply failing QC check will be immediately removed from service and any associated stock quarantined to prevent use. Laboratory management will be notified. Additional evaluation may allow the supply to be used depending on the reason for failing the QC check.

6.6.3

The BCI laboratory communicates its requirements to external providers through the use of purchase orders, legal contracts, and memorandums of understanding. These detail the products and services to be provided, acceptance criteria, competence, and location of activities, as applicable.

The BCI laboratory submission receipt provides written notification to the customer that the laboratory may subcontract work to meet operational needs. When appropriate, the customer's approval is gained before subcontractor work is initiated.

The BCI laboratory is responsible for the subcontractor's work and ensures the results are within the standards of the BCI laboratory quality management system requirements, unless the customer or another controlling authority specifies the subcontractor to be used.

The BCI laboratory retains a register of all subcontractors that it uses and a record of the evidence of the subcontractor's compliance with the requirements of ISO/IEC 17025 regarding the scope of accreditation that covers the work in question. Register amendment is the responsibility of the Quality Assurance Manager or applicable Technical Leader.

7 Process Requirements

7.1 Review of Requests, Tenders and Contracts

7.1.1

Review leading to agreement for testing is done in a practical and efficient manner prior to the commencement of work. Review procedures include the following:

- The submission receipt is verified complete and accurate, and the test methods to be used are adequately defined, documented and understood.
- The laboratory has the capability and resources to meet the customer requests.
- The tests selected are capable of meeting the customer requirements.
- Reviews of requests are also performed on any work that is to be subcontracted by the BCI laboratory. The BCI laboratory submission receipt provides written notification to the customer that the laboratory may subcontract work to meet operational needs. When appropriate, the customer's approval is gained before subcontractor work is initiated.

7.1.2

The laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

The BCI laboratory may develop a test method for its own use. This will be a planned activity, under laboratory management authority, performed by qualified personnel with adequate resources. Plans may be updated as development proceeds, any significant changes will be effectively communicated to all personnel involved in the development process. The method must be reviewed and approved prior to implementation according to the procedure for Document Control.

7.1.3

When the customer requests a statement of conformity to a specification (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification and the decision rule are clearly defined in applicable Lab Methods Manuals and are communicated via issued lab reports.

7.1.4

Any differences between the request and the testing to be provided are resolved before work commences.

Each agreement must be acceptable to both the customer and the BCI laboratory.

7.1.5

Any substantive laboratory deviation from the original request is communicated to the customer and documented in the case record.

7.1.6

If a request requires amendment after work has commenced, the same review process is repeated and amendments are communicated to all affected laboratory personnel and the customer.

7.1.7

Laboratory employees communicate with customers, as needed, to clarify their requests and to answer any questions concerning the status of their requests. The BCI laboratory facilitates active customer interaction through the Ohio Law Enforcement Gateway (OHLEG) and the inclusion of relevant direct contact information on laboratory reports and receipts created on behalf of the customer.

Procedure for recording the review is defined in Laboratory Practices for Evidence Handling.

7.1.8

Any special circumstances or deviations from standard test requests, as directed by the customer, are documented in the case record. These might include original request amendment, priority requests, cross reference with other case submissions, unique confidentiality requests, etc.

7.1.9

The extent of database searches routinely conducted at BCI laboratories is communicated on the AGO Laboratory Division webpage. Investigative leads identified from searches conducted on BCI laboratory assignments are communicated to customers via laboratory reports, memos or verbal communication documented in the case record.

7.2 Selection, Verification and Validation of Methods

7.2.1 Selection and Verification of Methods

7.2.1.1

The BCI laboratories use scientifically valid methods accepted by the forensic community in the performance of casework. These methods are documented in discipline specific method manuals for all tests performed within its scope. These methods include applicable instructions for evidence sampling, handling, transfer, storage and preparation. Where necessary, methods also describe estimation of the measurement uncertainty; calculation information, including any statistical techniques for the analysis of examination data; and any limitations of the method, including any quality affecting environmental conditions.

All methods used in the laboratory are reviewed and approved prior to implementation according to the procedure for Document Control. New methods are subject to job hazard evaluation by the Safety Coordinator, in accordance to the Lab Safety Manual.

7.2.1.1.1

BCI laboratory forensic scientists are responsible for selecting the test method(s) and methods for sampling that most effectively meet the analytical needs of the customer while taking into account the nature of the evidence and the facts of the case. Test methods are selected from the following:

- International, national, or regional standards of analysis
- Technical organizations
- Scientific texts or journals
- Equipment manufacturers
- Laboratory-developed methods

The approved method used is:

- The latest valid edition
- Supplemented with additional details, when necessary, to ensure consistent application
- Quality control verified, as described by method, to ensure testing reliability
- Quality control verified, as described by method, following any significant change

All methods, except for Standard Methods published by a Standards Document Organization (SDO) such as ASTM, AAFS/ASB, etc., require a validation. The reliability of a test method that is new to the BCI laboratory is confirmed in-house against any documented performance characteristics of that method prior to first use. Records of *validations and* performance checks conducted are retained for future reference.

7.2.1.1.2

All test methods that involve the comparison of an unknown to a known for the purpose of source association shall require the evaluation of the unknown item(s) to identify characteristics suitable for comparison and, if applicable, characteristics suitable for statistical rarity calculations, prior to comparison to one or more known item(s).

7.2.1.1.3

BCI is not a calibration laboratory.

7.2.1.2

Methods for operating associated laboratory equipment and for handling and preparing evidence for examination to ensure the quality of the results may be described in the methods manuals or in other readily available controlled quality system documents. The methods are kept up to date and are available to authorized personnel.

7.2.1.3

BCI laboratory ensures that the latest valid version of a method is used, unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

Laboratory personnel use approved test methods as described in their discipline method manuals whenever possible. It is recognized; however, method deviation may be required to accommodate the nature of the evidence, or another atypical situation.

7.2.1.4

When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. ~~Methods published either in international, regional or national standards, or by reputable technical organization, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. Laboratory-developed or modified methods can also be used.~~

7.2.1.5

Prior to implementation of a validated test method, its reliability is demonstrated in-house against any documented performance characteristics. Records of performance verification are retained.

7.2.1.6

Method development is a planned activity, which is assigned to competent personnel authorized to perform the validation tasks. A method validation plan is approved by technical management for the discipline and the Quality Assurance Manager (*or designee*) to ensure that the personnel are equipped with adequate resources, appropriate for the needs of the customer. Any modifications to the development plan shall be approved and authorized.

7.2.1.7

Any test method proposed by the customer, but later deemed inappropriate or out of date by the responsible forensic scientist, may be changed. The customer will be notified of substantive test method changes and that notification recorded in the case record.

Method deviations must be within the bounds of good laboratory practice. Method deviation must be reviewed, justified and approved by laboratory management and documented in the case record. Substantive test method deviation must also be

performed with the agreement of the customer, and that agreement recorded in the case record.

The deviated method developed must be validated prior to use on casework.

7.2.2 **Validation of Methods**

Validation is defined as confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the BCI laboratory (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

Records of the validation including, but not limited to, the validation method used, the results, and a statement as to whether the testing method is fit for its intended use are retained in accordance to established AGO retention schedules.

Only one complete validation study is required for all like applications throughout the BCI lab system.

7.2.2.1

The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.1.1 Validation Procedure

A validation plan must be established that provides parameter evaluation and parameter acceptance criteria to determine whether the method is fit-for-purpose prior to starting the method validation. The validation plan must be approved by the discipline's technical management and the Quality Assurance Manager (or designee).

The validation must:

- Be conducted according to a validation plan;
- Include the associated data analysis and interpretation;
- Establish the data and acceptance criteria required to report a result, opinion, interpretation, or statement of nonconformity; and
- Identify limitations of the method

7.2.2.2

When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.

7.2.2.3

The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements. This includes, but is not limited to, measurement range, accuracy, measurement uncertainty, limit of detection, selectivity of the method, repeatability or reproducibility, or robustness against external influences.

7.2.2.4

Records of the validation including, but not limited to, the validation method used, specification requirements, determination of the performance characteristics of the method, the results, and a statement as to whether the testing method is fit for its intended use are retained in accordance to established AGO record retention schedules.

7.3 Sampling

7.3.1

BCI laboratory sampling plans and procedures are unique for each discipline. They are described in the applicable discipline methods manual readily available to affected laboratory personnel. Sampling plans are based on appropriate statistical methods. A sampling plan provides a statistically valid approach to determining the number of units that must be tested in order to make an inference about the whole population. Sampling processes address the factors to be controlled to ensure the validity of the test results.

7.3.2

The sampling method describes:

a) The selection of samples or sites;
b) The sampling plan;
c) The preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration

7.3.2.1

In general, the sampling plans shall:

- Evaluate the selected population for homogeneity;
- Ensure that the population has a reasonable expectation of homogeneity;
    - Statistical sampling at a stated level of confidence shall be used if an inference will be made to report on the whole population
- Make use of probability and provide an opinion or interpretation with a minimum confidence level of approximately 95 %. Unless otherwise identified, Hypergeometric Probability Distribution is the recognized sampling plan of the laboratory.

- Require each item selected meets the sampling plan level of confidence to be tested completely;

If one or more selected items demonstrate a lack of homogeneity, then they must be considered a separate population.

7.3.3

All relevant data and operations pertaining to the sampling that form part of the testing are recorded in the case record, this includes:

a) The statistical method on which the sampling procedure is based;
b) Date and time (where relevant) of sampling;
c) Data to identify and describe the sample (e.g. number, amount, name);
d) Personnel performing sampling;
e) Equipment used;
f) Environmental or transport conditions
g) Photographic documentation or diagramming necessary to demonstrate sample source;
h) Customer requested deviations, additions or exclusions from the accepted sampling procedure are documented in the case record.

7.4 Handling of Test or Calibration Items

7.4.1

The BCI laboratory describes procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items in the Laboratory Practices for Evidence Handling.

7.4.1.1

The Laboratory Practices for Evidence Handling, the Latent Print Methods Manual, Drug Chemistry Methods Manual and the DNA QA Manual address laboratory activities conducted to control and protect the integrity of all evidence received and handled by the laboratory, including:

a) Requirements for storage, packaging and sealing items to protect evidence integrity;
b) Measures to be taken to secure unattended items which are in the process of being tested;
c) Requirements for tracking the internal chain of custody for all items received, items created and used or those that could be used for testing, and all internal transfers;
d) Requirements for tracking the chain-of-custody record securely and accurately;

e) Requirements for communicating to the customer the disposition of all items received
f) Address communication to the customer regarding items collected or created and preserved for future testing

In order to reduce the risk of laboratory staff contamination of test items and encourage a safer work environment, laboratory coats and gloves are provided and must be worn when handling test items at risk of contamination or presenting an exposure hazard. The Laboratory Safety Manual provides additional information on the safe handling of test items.

Outside observers are defined as individuals who are not employed by the laboratory or its laboratory equipment contractors, or are not representing the accrediting body during an external assessment. The presence of outside observers in the laboratory is specifically prohibited for reasons of safety, evidence integrity and timeliness.

- Outside observers are not aware of the specific chemical hygiene and blood borne pathogen risks and pose safety and liability risks.

- The presence of an outside observer poses a contamination risk. Forensic scientists in the lab have their DNA profiles in a database to search for inadvertent contamination. Scientific staff rather than maintenance staff perform most of the cleaning procedures in the sensitive laboratory areas. A considerable amount of effort is expended decontaminating the laboratory after visits by repairmen and others.

- The presence of an outside observer poses a risk to the integrity of the evidence. BCI forensic scientists are trained to work in such a way as to minimize the potential for evidence handling errors. This includes specific work area set-ups and the elimination of distractions such as conversation, visitors and telephones. Furthermore, BCI forensic scientists are instructed not to handle evidence when they cannot give their full concentration to the work. The presence of an observer has the potential to be distracting and to increase the chance of an error.

- The presence of an outside observer would significantly impact the output of the laboratory. Rather than subject evidence from multiple cases to the same distraction, all testing in the laboratory work area would have to stop when the outside observer was present. In the case of DNA, ~~two to three~~ *several* days are required to complete the testing process. During that time, no other casework would be possible, delaying many other cases, some with trial deadlines.

Requests for observations of re-weighing of evidence in the Drug Chemistry section may be accommodated by offering a live video capture of an analytical balance.

In order to demonstrate compliance with accreditation standards, staff/technical assessors will be escorted throughout the laboratory work space during external laboratory audits. Staff/technical assessors are current or previously trained forensic scientists from accredited laboratories and are well versed in laboratory safety, evidence integrity, and timeliness requirements. Prior to accessing the lab environment, the assessor(s) must be dressed with appropriate laboratory Personal Protective Equipment (PPE) and may be requested to submit a DNA reference sample for inclusion in the Employee Elimination DNA database.

7.4.2

The BCI laboratory describes a system for unique identification of test items in Laboratory Practices for Evidence Handling. The system is designed and operated to ensure items cannot be confused physically or when referred to in case records or other documents. These practices include requirements for marking items that do not lend themselves to direct marking.

Unique identifiers remain in place so long as the items remain in the control of the laboratory.

When test items are subdivided and separated in the laboratory, sub-items are created and tracked through a documented chain of custody record to the same extent as the parent item.

Individual characteristic database samples may be assigned unique identifiers under the policies of the controlling BCI division or the laboratory may assign its own unique identifier. Any characteristic database sample under the control of the laboratory is uniquely identified.

7.4.2.1

The system used to identify items includes all items received.

7.4.3

Upon receipt of any item for testing, its condition is evaluated and any conditions adverse to quality are documented in the case record.

When test items do not meet established acceptance criteria, there is a substantive discrepancy between the item and the description provided, or the testing request is unclear, the customer is consulted before proceeding and that communication is documented in the case record.

7.4.4

Laboratory Practices for Evidence Handling provide details for protecting test items from deterioration, loss or damage during storage, handling and processing.

Where appropriate, ~10% Bleach is used to prevent contamination of evidence from surfaces. The diluted bleach is made fresh weekly.

When multiple laboratory sections are assigned to examine an evidentiary item, forensic scientists will refer to the workflow specified in this manual when applicable. Otherwise, they will discuss the description of the evidence, case approach and determine appropriate actions to prevent the potential loss or contamination of evidence. Correspondence and case approach considerations must be documented in the case record. Additionally, if one scientist scans the evidence to their custody in LIMS, the other scientist(s) must document and initial the lab notes that they co-examined the evidence.

Any unique handling instructions provided with an item are followed. When evidentiary items have to be stored or handled under specified environmental conditions, those conditions are retained, monitored and recorded.

Laboratory Practices for Evidence Handling, the Laboratory Safety Manual and individual discipline method manuals describe additional handling and storage requirements for drugs, weapons, valuables and other special items.

7.5 Technical Records

7.5.1

The testing method contains adequate information to identify factors affecting the uncertainty. Examination documentation is detailed such that another qualified examiner could repeat the examination under conditions as close as possible to the original.

- When instrumental analyses are conducted, operating parameters or test methods including the parameters used are recorded.
- The individual responsible for examination of the evidence, the administrative reviewer, technical reviewer, and verifier (if applicable) are identified in the BCI laboratory case record.
- When examination documentation is prepared by a forensic scientist other than the forensic scientist responsible for the case, the handwritten initials (or secure electronic equivalent of initials or signature) of the preparer also appears on each page of the case documentation representing his/her work.

Each BCI case record must:

- Be traceable to a unique BCI Case number and the forensic scientist's handwritten initials (or secure electronic equivalent of initials or signature) appear on each page of the examination documentation. Electronic entries in a single file may be treated as a single page. Any hard copy subsequently created from an electronic record will be subject to hard copy requirements.

- Reflect the date(s) that the testing was performed; individual evidence item open and seal dates are recorded in the examination documentation, as applicable. These dates signify the starting and ending dates of individual evidence item testing; and

- Observations, data and calculations are recorded at the time they are made and are identifiable to the specific test performed.

7.5.1.1

The BCI laboratory retains examination and administrative documentation as part of the BCI laboratory case record for a defined period in accordance with established record retention requirements.

7.5.1.2

Approved abbreviations and symbols specific to the laboratory are permitted for use in the preparation of examination documentation. General examination abbreviations may be used universally during co-assignment examination for purposes of evidence preservation (see the "General Examination Abbreviation" section of the Terms and Definitions of this manual). Each laboratory discipline maintains a list of abbreviations and symbols approved for use in the discipline methods manual. Universally recognized abbreviations, symbols or acronyms (such as: etc., %, USA) are permissible without expressed approval.

7.5.1.3

Technical records to support test results, opinions, and interpretations must be such that another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data.

7.5.1.4

Records are of a permanent nature. Handwritten case documentation is prepared in ink. Electronic case documentation stored in the case record is secured by the forensic scientist.

7.5.1.5

If observations, data or a test result is rejected, the reason, the identity of the forensic scientist taking action, and the date must be recorded in the BCI case record.

7.5.1.6

BCI is not a calibration laboratory.

7.5.2

When mistakes occur in technical records, errors are corrected with a single strike-out and the correction entered alongside. All such corrections are initialed by the person making the correction. No part of the case record may be erased or otherwise made illegible. In the case of electronically stored records, equivalent measures are taken to signify the individual responsible for the correction and to avoid loss or change of original data.

Any changes made to BCI case technical records as a result of verification or technical review must be tracked in the case record. Any additions made to technical records are initialed and dated by the person making the addition.

7.6 Evaluation of Measurement Uncertainty

7.6.1

Measurement uncertainty is reported when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law or other legal requirement. The laboratory identifies the following as the only current standard report conditions for which measurement uncertainty will be included:

- when values are reported for the weight of controlled substance evidence
- when values are reported for the % THC in controlled substance evidence

7.6.1.1

The ~~Laboratory Practices for~~ Measurement Uncertainty procedures:

- Require the specific measuring devices or instruments used for a reported test result to have been included in or evaluated against the estimation of measurement uncertainty for that test method;
- Include the process of rounding the expanded uncertainty;
- Require the coverage probability of the expanded uncertainty to be a minimum of 95.45% and
- Specify the schedule to review and/or recalculate the measurement uncertainty

7.6.2

The BCI laboratory does not perform calibration services and thus does not have a method for estimating measurement uncertainty (MU) for calibrations.

7.6.3

Estimation of measurement uncertainty is based on knowledge of the performance of the test method, previous experience and validation data as well as any significant parameters that affect the measurement result.

Estimated qualitative and quantitative MU values are recalculated in accordance with the applicable procedure upon changes in the affected equipment/personnel/measuring process; following significant changes in a laboratory environment; and following recalibration/certification of the measuring equipment.

7.6.3.1

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

7.6.4

The following records are retained by the Quality Assurance Manager:

~~a)~~ The measurand is defined in the *Chemistry Methods Manual* ~~Appendix- Laboratory Practices for Measurement Uncertainty~~

~~b)~~ The methods used to establish traceability are detailed in the *Chemistry Methods Manual* ~~Laboratory Practices for Measurement Uncertainty Appendix- Laboratory Practices for Measurement Uncertainty~~

c) Equipment used

d) Uncertainty components considered

e) Uncertainty components of significance and how they were evaluated

f) Data used to estimate repeatability, intermediate precision, and reproducibility

g) All calculations performed

h) Combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty

7.7 Ensuring the Validity of Results

7.7.1

Individual laboratory discipline methods describe quality control procedures for monitoring the reliability of test results and testimony. Monitoring data is recorded in such a way that trends may be detectable.

Quality control measures are selected as appropriate for the type and volume of testing performed. They may include, but are not limited to use of the following:

a) Certified and internally generated reference materials and reference collections

b) Use of alternative instrumentation

c) Intermediate functional check(s) of measuring and testing equipment
d) Spiked samples, standard additions and internal standards
e) Participation in proficiency testing programs
f) Replicate tests using the same or different methods
g) Retesting
h) Independent checks by authorized personnel
i) Technical review and verifications
j) Intralaboratory comparisons
k) Blind sample(s) and positive and negative controls

Appropriate controls and standards are specified in discipline methods and their results are recorded in the case record.

Verification Procedure

- Each laboratory section manual details the examination findings that require verifications. All verifications should be performed prior to completion of technical review.

- Verification of test results are carried out by an individual who is currently authorized to perform the testing, or an external service provider qualified to perform the testing.

- Verifications must be documented in the case record with the initials of the verifying scientist, the date on which the verification was completed and the results of the verification. The resolution of any discrepancy shall be recorded. Cases submitted to the laboratory for routine quality re-examinations do not require verification if the analyst performing the re-examination agrees with the original findings. If findings differ from what was previously reported, then verification is required.

Technical Review Procedure

The BCI laboratory has established a procedure for technical review of examination documentation, reports and testimony.

- Following completion of all casework (with the exception of NIBIN database and Lottery QA), including CODIS data, a technical reviewer is assigned. To the extent possible, technical review will be randomly distributed amongst all qualified personnel, and may include inter-laboratory distribution.

- Technical reviews must be conducted by individuals that have been competency tested in the task being reviewed. The technical reviewer need not be an active examiner and only DNA ~~and Forensic Biology~~ technical reviewers require current proficiency testing in the reviewed test category. All technical reviewers must

have sufficient knowledge of the testing to verify compliance with BCI laboratory quality management system requirements and that conclusions reached are supported by the examination documentation.

- Laboratory personnel cannot technically review their own work.

- At a minimum, each technical review shall include a review of all examination documentation and the laboratory examination report to ensure:
  - Conformance with proper technical methods and applicable laboratory policies and procedures.
  - Accuracy of laboratory examination reports and that the examination documentation supports the results and/or conclusions in the laboratory examination report.
  - Associations are properly qualified in the laboratory examination report and supported by the technical record; and the laboratory examination report contains all required information.

- BCI laboratory personnel who provide court testimony as part of their job duties are subject to review at least once per calendar year to monitor performance. At a minimum, one individual in every discipline in the laboratory system must undergo a technical review of testimony offered each year.
  - The individual performing the technical review must have been competency tested in the tasks related to the testimony subject to review.
  - Technical review of testimony may be accomplished by any of the following methods: direct observation, transcript review, video or audio review.
  - If qualified personnel does not have an opportunity to testify during a calendar year, or testifies and it is not monitored as described, the scientist's supervisor must document the occurrence and reason(s) on the Testimony Exception form and provide it to both the affected personnel and the QA Manager. The affected personnel will be monitored at the first subsequent opportunity.

Additional technical review criteria may be assigned by the QA Manager or Technical Leader pursuant to corrective or preventive action.

In the event of a disagreement in the conclusion discovered during the technical review or verification process, the Laboratory Supervisor will be notified. An attempt to resolve the disagreement will be made prior to the release of the laboratory report.

- Resolution will be sought via consultation between the original forensic scientist, verifier, a third qualified individual, Laboratory Supervisor, and Quality Assurance Manager or Technical Leader. If a resolution is reached, the verification process is complete. If resolution is not reached,

the conclusion will be reported as inconclusive, along with supporting documentation of why there is insufficient support for another conclusion (as applicable). The case record includes documentation of the outcome of the disagreement resolution.

7.7.2

The BCI laboratory will monitor its performance by comparison with results of other laboratories where available and appropriate. This will be a planned activity, which includes:

a) Participation in proficiency testing
b) Participation in interlaboratory comparisons other than proficiency testing

7.7.2.1

a) Successful performance in at least one proficiency test (or an alternative means of interlaboratory comparison) for each discipline included in the scope of accreditation each year.
b) Each laboratory location on the scope of accreditation successfully completes at least one proficiency test (or an alternative means of interlaboratory comparison) for each discipline included in the scope of accreditation.

7.7.3

The BCI laboratory has defined criteria for quality control data in its practices and methods. When data is found to be outside the established acceptance criteria, action is taken in accordance with that described in the practice or method.

7.7.4

The performance of all personnel who perform laboratory activities is monitored. The monitoring demonstrates successful performance in at least one proficiency test, other interlaboratory comparison, or intralaboratory comparison per calendar year in each accredited discipline in which the individual is authorized to conduct work. Qualified DNA and CODIS forensic scientists must undergo two external proficiency tests each year, in accordance with FBI Quality Assurance Standards.

In the event that intralaboratory comparison, interlaboratory comparison or proficiency testing cannot be completed for any personnel in each discipline listed on the scope of accreditation, observation-based performance monitoring will be conducted.

If an individual misses a required proficiency test due to extended leave, temporary reassignment, or other management approved circumstance, that individual must successfully complete a proficiency test or another approved qualifying test to

demonstrate competency prior to resuming independent casework. The length of leave considered to be "extended leave" will be at the discretion of laboratory management.

7.7.5

Proficiency testing is an integral part of the BCI laboratory quality system. It is one of many quality control measures used to monitor performance, verify procedures and identify areas where improvement may be needed.

Responsibilities of Lab Staff:

QA Manager/Technical Leader (TL)	Lab Supervisor	Proficiency Test Participant
Implementing and monitoring the BCI laboratory proficiency testing program.	Ensuring proficiency tests are created as regular laboratory cases, and are appropriately designated as proficiency tests, assigned to the designated laboratory personnel and distributed.	Addressing each external proficiency test as much like regular casework as practicable, using current approved discipline methods and following established laboratory practices.
Ensuring ISO 17043 accredited test providers are used, where available.	Ensuring proficiency test results are not known or readily available to the test taker.	Completion of examiner applicable sections of the provider test result form (however named).
Ensuring annual proficiency test purchase orders are prepared and approved in accordance with Ohio Attorney General purchasing guidelines and as necessary to meet provider deadlines.	Ensuring local completion deadlines are established and met.	Endeavoring not to seek or share active proficiency test information with other test participants, except as necessary to meet regular casework and quality system requirements.
Ensuring external proficiency tests are appropriately received, distributed, evaluated, and recorded.	Ensuring all necessary test documentation is provided to the appropriate QA Manager or Technical Leader prior to the test provider submission deadline.	Ensuring each proficiency test is conducted using approved test methods.
Ensuring external proficiency tests are released to ANAB from the test provider.		Meeting established submission deadlines.
Identification of the laboratory personnel assigned each test and apportioning test samples,		

as necessary, to accommodate those assignments.		
Overseeing the resolution of proficiency test result discrepancies.		
Ensuring participating examiners are notified of proficiency test results.		
Ensuring all proficiency test records are retained in accordance with these practices.		
Notifying ANAB within 30 days when the expected result is not attained during any monitoring activity[1]		

[1]For a consensus-based proficiency test, the consensus result is the expected result. When an identification or exclusion is the expected result, an outcome of inconclusive is considered an unexpected result.

For External Proficiency Tests:

- *External* Proficiency tests will be distributed to the appropriate facility by the QA Manager, QA Supervisor or Technical Leader and will be assigned in cooperation with the *Laboratory Supervisor* to individual forensic scientists in a timely manner. For record keeping purposes, proficiency tests will be created in the LIMS, assigned to the appropriate personnel and designated in the LIMS record as a proficiency test.
- Individual deadlines will be established by Laboratory Management for the completion of the test and return of required documentation and test sample materials. The QA Manager or Technical Leader must be notified of any assigned proficiency test that cannot be completed prior to the provider designated due date.
- Laboratory management ensures proficiency test results are not known or readily available to the test taker by utilizing double blind test designs within the performance monitoring schedule, when possible.
- Proficiency tests will employ the currently approved methods and established laboratory practices in use at the time of the test. Marking, sealing, storage, and other administrative actions should be handled as much like regular casework as possible. Completed proficiency test case files follow regular technical and administrative case review practices, as described in this document. The forensic scientist is responsible to return by individual assigned deadline the following materials in electronic or hard copy format, as assigned:
    - Completed test report form (however named)
    - BCI laboratory report

  - Examination documentation and technical review records
  - Proficiency test samples
- Proficiency tests are evaluated by the QA Manager or applicable Technical Leader to determine successful completion of the test.
  - Verification that the results for each completed external proficiency test are consistent with the test provider's manufacture information.
  - Confirmation that results submitted to the test provider were accurately transcribed in the provider's summary report.
  - Review of the provider's summary report to determine if the participant's results are consistent with the majority of other test respondents, whenever the results are not consistent with the manufacturer's test design expected results.
  - DNA proficiency tests include additional specific evaluation criteria as described in the Quality Assurance Standards for Forensic DNA Testing Laboratories and Quality Assurance Standards for DNA Databasing Laboratories.
  - Completion of any directed corrective actions pursuant to laboratory quality inquiry and/or directive from ANAB.

For internal (BCI-prepared) tests:

- *Internal tests will be distributed to the appropriate facility by the QA Manager, QA Supervisor or Technical Leader and will be assigned in cooperation with the Laboratory Supervisor to individual forensic scientists in a timely manner. For record keeping purposes, internal tests will be created in the LIMS, assigned to the appropriate personnel and designated in the LIMS record as a proficiency test, unless distributed as a blind test.*

- *Internal test materials may be prepared by the QA Laboratory Supervisor (however named), the FSC of the discipline, or other qualified individual as selected by the QA Manager or Technical Leader. Internal tests must be examined by qualified staff prior to distribution of the test to participants, to ensure the quality of the test design. Records of the materials used, preparation instructions, and pre-distribution testing will be retained in accordance with the AGO retention schedule BCI-LAB-24. A representative portion of the test material must be retained and available in the event re-examination of the material becomes necessary. Re-examination confirmation of the original case findings shall be considered successful completion of an internal test by the original examining laboratory personnel.*

- *Individual deadlines may be established by Laboratory Management for the completion of the test and return of required documentation and test sample materials. The QA Manager or Technical Leader must be notified of any assigned internal test that cannot be completed prior to the provider designated due date.*

- *Laboratory management ensures internal test results are not known or readily available to the test taker.*

- *Internal tests will employ the currently approved methods and established laboratory practices in use at the time of the test. Marking, sealing, storage, and other administrative actions should be handled as much like regular casework as possible. Completed internal test case files follow regular technical and administrative case review practices, as described in this document. The Forensic Scientist is responsible to return by individual assigned deadline the following materials in electronic or hard copy format, as assigned:*
    - *BCI laboratory report*
    - *Examination documentation and technical review records*
    - *Internal test samples*

Internal tests are evaluated by the QA Manager or applicable Technical Leader to determine successful completion of the test:

- Verification that the result for any internally prepared test is consistent with the expectation of the preparer.
- Verification that the method and laboratory practices observed are consistent with the expectation of the established approved laboratory method.
- Completion of any directed corrective actions pursuant to laboratory quality inquiry.

For internal re-work tests:

- *Internal re-work tests will be identified and assigned in cooperation with the Laboratory Supervisor to individual forensic scientists in a timely manner. For record keeping purposes, internal re-work test assignments will be created in the LIMS and assigned to the appropriate personnel as follows:*

    - *Drug Chemistry: QA supervisor (or designee) will notify Drug Chemistry Lab Supervisors of the scheduled re-work scenario, so that a case can be identified within the criteria (see below). A case will be assigned to each Forensic Scientist in LIMS by the QA Supervisor, with the course of normal casework activities for completion, not to exceed 90 days. Once both assignments are approved, the supervisor will notify QA Supervisor.*

    - *Firearms: QA supervisor (or designee) will notify staff of the scheduled re-work, so that a case can be identified within the criteria (see below). Forensic Scientists will identify an active case based upon pre-determined criteria (see below) and once the report has been drafted, will assign the case to another FA scientist in LIMS. Once the rework is complete, for efficiency purposes,*

another qualified person can verify and technically review the case and then will have the rework scientist route it to the Firearms Lab Supervisor for approval of both assignments. Once both assignments are approved, the supervisor will notify QA Supervisor.

- *Latent prints: QA supervisor (or designee) will notify staff of the scheduled re-work. Forensic Scientists will identify an active case within the full range of examinations. A copy of the original images and any exemplars will have the case identifiers removed by the scientist. The latent image(s) will then be placed into a network folder. The QA and LP supervisors will be notified via e-mail of the original case number, the original image numbers and what they were renamed as well as the conclusions reached by the original LP scientist. The original LP scientist can draft the report. Once all the images have been received by QA, another LP scientist will then be notified which case is assigned by the QA Supervisor in the network drive (i.e. Case 1, 2, etc.). The scientist will complete the rework examination and e-mail the blind verification worksheet, documentation, and notes to the QA Supervisor. The QA Supervisor will then take the following actions:*

    - *Complete the blind verification worksheet*
    - *Review/confirm results for consistency*
    - *Add the documents to the image vault*
    - *Notify the original LP scientist that the assignment can be routed for technical review*

Once the assignment is technically and administratively approved by the supervisor, they will notify QA Supervisor.

- *Questioned Documents: QA supervisor (or designee) will notify staff of the scheduled re-work. Forensic Scientists will identify an active case based upon pre-determined criteria (see below) and once the report has been drafted, will assign it to another QD scientist in LIMS. Once the rework is complete, for efficiency purposes, another qualified person can verify and technically review the case and then will have the rework scientist route it to the Lab Supervisor for approval of both assignments. Once both assignments are approved, the supervisor will notify QA Supervisor.*

- *Trace Evidence: QA supervisor (or designee) will notify staff of the scheduled re-work. Forensic Scientists will identify an active case based upon pre-determined criteria (see below) and once ~~completed~~ the report has been*

drafted, will assign it to another scientist in LIMS. Once the rework is complete, for efficiency purposes, another qualified person can verify and technically review the case and then will have the rework scientist route it to the Lab Supervisor for approval of both assignments. Once both assignments are approved, the supervisor will notify QA Supervisor.

- *DNA: QA supervisor (or designee) will notify staff of the scheduled re-work. Forensic Scientists will identify an active case based upon pre-determined criteria (see below) and once completed, will assign it to another scientist in LIMS, designating the assignment status to "rework/additional". Once the rework is complete, another qualified person will verify and technically review the case for efficiency purposes and then will have the rework scientist route it to the DNA Lab Supervisor for approval of both cases. Once both assignments are approved, the supervisor will notify QA Supervisor.*

- *Other re-work scenarios may be assigned as necessary.*

	Case Scenarios to Avoid	***Routine Re-examination Scenarios***
Drug Chemistry	• *Avoid significant safety hazards (e.g. carfentanil)* • *Avoid cases with co-assignments to other lab sections* • *Original weight recorded less than 0.10 grams*	• *Tablet Count verification* • *Statistical Sampling Verification* • *Non-controlled substances* • *General controlled substance verification*
DNA	*N/A*	• *Forensic biology screening*
Firearms	• *Avoid significant safety hazards (e.g. broken firearms)* • *Serial restoration*	• *Firearm and 1-2 cartridge cases comparison*
Latent Prints	• *Borderline sufficiency*	*N/A*
Questioned Documents	• *Avoid cases that have multiple checks for examination*	• *1-2 items comparison*

	• *Avoid cases with a large number of unknown evidence items*	
Trace Evidence	• *Avoid clothing evidence to reduce the SEM run time*	• *GSR stubs*

Internal re-work tests are evaluated by the QA Manager (or designee) or applicable Technical Leader (or designee) to determine successful completion of the test:

- *Verification that the method and laboratory practices observed are consistent with the expectation of the established approved laboratory method.*
- *Completion of any directed corrective actions pursuant to laboratory quality inquiry.*

For Observational Tests:

- *Internal observational tests will be identified and assigned in cooperation with the supervising laboratory manager to individual forensic scientists in a timely manner. For record keeping purposes, internal re-work test assignments will be documented in the LIMS and assigned to the appropriate personnel as follows:*
  - *Drug Chemistry: Case workflows will be observed during the calendar year by another qualified Forensic Scientist. Observations can include but are not limited to the pulling of evidence, mass determination, count, and testing procedures. The observing Forensic Scientist will document all observations on the appropriate form and will be uploaded into LIMS. Once the observations are complete, the assigned Forensic Scientist will notify the QA supervisor. The QA supervisor, in conjunction with Chemistry Management, will review the documentation. Any deviations from the current workflow will be documented and addressed accordingly.*
  - *DNA/NIBIN: The Laboratory Technicians who perform blind swabbing procedures will be observed by a qualified Forensic Scientist or Laboratory Technician. Observations can include but are not limited to the pulling of evidence, preparation of workspace, notes, and testing procedures. The observing Forensic Scientist will document all observations on the appropriate form and will be uploaded into LIMS. Once the observations are complete, the Forensic Scientist will notify the QA supervisor. The QA supervisor, in conjunction with DNA/Firearms Management, will review the documentation. Any deviations from the current workflow will be documented and addressed accordingly.*
  - *NIBIN: Laboratory Technicians have the requirement of entering cases into NIBIN. Observations can include but are not limited to pulling the evidence, case documentation, and entry into the NIBIN database. The observing*

Forensic Scientist will document all observations on the appropriate form and will be uploaded into LIMS. Once the observations are complete, the Forensic Scientist will notify the QA supervisor. The QA supervisor, in conjunction with Firearms Management, will review the documentation. Any deviations from the current workflow will be documented and addressed accordingly.

- *Latent prints: One Latent Print Forensic Scientist will observe the casework workflow for another Forensic Scientist during the calendar year. Observations can include but are not limited to pulling evidence case documentation and latent print processing. The observing Forensic Scientist will document all observations on the appropriate form and will be uploaded into LIMS. Once the observations are complete, the Forensic Scientist will notify the QA supervisor. The QA supervisor, in conjunction with Latent Print Management, will review the documentation. Any deviations from the current workflow will be documented and addressed accordingly.*

	Type of Observational Test	***Type of evidence***
Drug Chemistry	• *Casework workflow (including Mass Determination)*	• *Controlled/Non-controlled substance*
DNA/NIBIN	• *Blind swabbing*	• *Cartridge case* • *DNA evidence*
Firearms	*N/A*	*N/A*
NIBIN	• *Cartridge case entry*	• *Cartridge case*
Latent Prints	• *Casework workflow*	• *Evidence to be processed*
Questioned Documents	*N/A*	*N/A*
Trace Evidence	*N/A*	*N/A*

Internal observational tests are evaluated by the QA Manager (or designee) or applicable Technical Leader (or designee) to determine successful completion of the test:

- *Verification that the method and laboratory practices observed are consistent with the expectation of the established approved laboratory method.*
- *Completion of any directed corrective actions pursuant to laboratory quality inquiry.*

Performance Monitoring Test Notifications

- The affected laboratory personnel will be notified by the QA Manager (*or designee*) *or applicable Technical Leader of successful completion of the test or fulfillment of related corrective action directive necessary to satisfy successful completion criteria.
- External and internal testing is used for self-evaluation, to monitor performance, and to identify any needs for training and other improvements. Should the QA Manager or Technical Leader identify an unexplained response discrepancy, or other substantive performance issue, Practices for Quality Inquiry and Corrective Action are initiated. Flagrant proficiency test errors, or problems identified as part of a broader individual pattern, may result in administrative action.
- The QA Manager will notify ANAB within 30 days when the expected result is not attained during any monitoring activity.

7.7.6

The QA Manager maintains a plan for proficiency testing within the current accreditation cycle to ensure that the minimum tests assigned to personnel represent the types of tests routinely encountered in each discipline listed on the scope of accreditation.

7.7.7

a) External proficiency test providers must be accredited to ISO 17043 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA) and has applicable proficiency test(s) on its scope of accreditation
b) External proficiency test results must be submitted to the proficiency test provider, if applicable, on or before the agreed upon due date.
c) The external proficiency test provider will be authorized to release the test results to ANAB.
d) BCI will gain approval from ANAB for an alternative means of interlaboratory comparison. This requires demonstration that the proposed alternative means of monitoring performance is substantially similar to proficiency testing (see ANAB form, FM 3041 Alternative Proficiency Test Request Form).

7.7.8

Records of all proficiency tests conducted will be retained, which include the following details:

a) Discipline tested
b) How the test was created
c) Expected proficiency test results
d) BCI lab where the test was taken

e) Records submitted to external proficiency test providers
f) Appropriate technical records
g) Evaluation of results and action taken for unexpected results
h) Feedback provided to participants

7.8 Reporting of Results

7.8.1 General

7.8.1.1

Laboratory results must be reviewed and authorized prior to release.

7.8.1.1.1

Forensic scientists who issue findings, including writing reports and providing testimony, based on examination documentation generated by another person are required to document the review of examination documentation by initialing (or identifying with a secure electronic equivalent) the relevant pages or otherwise documenting the review in the case record.

7.8.1.2

BCI laboratory forensic scientists report the results of their testing accurately, clearly, unambiguously and objectively. When comparative examinations result in the elimination of an individual or object, the BCI laboratory report clearly communicates the elimination. All laboratory disciplines, with the exception of CODIS, issue their test results by means of a BCI laboratory report. Unique CODIS reporting requirements are described in the CODIS Methods manual.

Test results include all information requested by the customer and necessary for the proper interpretation of the test, as well as all information required by the test method. All issued reports are retained as technical records.

7.8.1.2.1

The results are provided in a written report, via electronic access.

7.8.1.2.2

BCI laboratory reports test results as follows:

a) All items received in the laboratory, items not tested, and items created that were or could be tested will be addressed in the laboratory report regarding the laboratory assignment. Additional procedures are detailed in the section methods manuals.

   a. This does not apply to the receipt of known individual characteristic database samples.
   b. No laboratory report is required if assigned testing is cancelled by the customer or responsible prosecutor's office prior to examination.

b) When associations are made, the significance of the association is clearly communicated and properly qualified in the BCI laboratory report. Suggested language can be found in the section methods manuals, as applicable.
c) When no definitive conclusion can be reached, the reason(s) for the decision is clearly communicated in the BCI laboratory report. Suggested language can be found in the section methods manuals, as applicable.
d) Initial database entries must be reported.

7.8.1.2.3

The BCI laboratory is not a calibration lab.

7.8.1.3

If a BCI laboratory section has established a simplified report format, the section methods manual(s) will detail procedures.

All required reporting information must be retained in the case record and available upon request.

7.8.1.3.1

When results are reported in a simplified way, the agreement with the customer must specify which of the required report information (see 7.8.2-7.8.7) will not be included in a written report.

7.8.2 **Common Requirements for Reports**

7.8.2.1

BCI laboratory reports are designed to contain all information necessary to meet ISO/IEC 17025 requirements for test reports. Report templates are generated from the Laboratory Information Management System (LIMS). Reports include the following required details:

a) A title
b) Name and address of the testing laboratory
c) Location of performance of the laboratory activities
d) Unique report identifiers on each page and clear indication of end of report
e) Name and address of the customer
f) Identification of the test method used
g) Identification and description of the item(s) tested and when necessary, the condition of the item

h) Identification, description and date of test item(s) receipt and date of sampling, where this is critical to the validity and application of the results.
i) The date(s) of performance of the laboratory activity
j) The date of issue of the report
k) Sampling plan (where applicable)
l) A statement to the effect that the results relate only to the items tested
m) Test results, e.g. “Conclusions” (including units of measurement, whenever appropriate)
n) Additions to, deviations, or exclusions from the method
o) Name, title and signature (or equivalent identification) of the scientist authorizing the test report
p) Clear identification when results are from external providers
q) Description of the items not tested (where applicable)
r) Disposition of all items received

7.8.2.2

BCI laboratory reports are created in a general standardized format as defined by the Ohio Attorney General and BCI laboratory management. They are further formatted by discipline to accommodate the type of test conducted and to minimize the possibility of misunderstanding or misuse. Any data provided by a customer is clearly identified in the report. In addition, a disclaimer is included in the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage, it shall state in the report that the results apply to the sample as received.

7.8.3 **Specific Requirements for Test Reports**

7.8.3.1

The following information is included in laboratory reports when it is necessary for the interpretation of the test results:

a) Information on specific test conditions, such as environmental conditions;
b) A statement of conformance or non-conformance with specifications (where relevant)
c) Where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in the test reports when it is relevant to the validity of application of the test results, when a customer’s instruction so requires, or when the uncertainty affects compliance to a specification limit.
    - *The Chemistry Methods Manual* ~~Laboratory Practices for Measurement Uncertainty~~ describe a detailed procedure for the on-going collection of data, performance of subsequent calculations, evaluation of the results and reporting.

d) Where appropriate, opinions and interpretations
e) Additional information which may be required by specific methods or customers

7.8.3.1.1

If a regulatory body, statute, case law, or other legal requirements specify the format for the reporting of a test result or prohibits including measurement uncertainty in a test report, the following actions will be taken:

- BCI laboratory will retain~~ed~~ objective evidence of the regulation, statute, case law, or other legal requirement.
- The established policy and procedure for measurement uncertainty will be applied prior to reporting the test result.

7.8.3.2

BCI laboratory reports include information regarding sampling when it is necessary for the interpretation of the test results.

7.8.4 Specific Requirements for Calibration Certificates

The BCI Laboratory is not a calibration lab.

7.8.5 Reporting Sampling- specific requirements

When sampling activity is performed, the laboratory report shall include the following information, where necessary for the interpretation of the results:

a) The date of sampling;
b) Unique identification of the item or material sampled
c) The location of sampling, including any diagrams, sketches or photographs;
d) A reference to the sampling plan and sampling method
    a. When sampling plans are used, the report must contain the confidence levels and corresponding inferences regarding the population.
e) Details of any environmental conditions during sampling that affect the interpretation of the results;
f) Information required to evaluate measurement uncertainty for subsequent testing or calibration

7.8.6 Reporting Statements of Conformity

~~BCI Quantitative Chemistry reports include a statement of conformity when applying statutory requirements to THC concentrations in the reporting of marihuana and hashish. The coverage probability in such instances is 95.45% (k=2). Guidelines for the reporting of quantitative results are outlined in the Chemistry Methods Manual.~~

BCI does not report statements of conformity.

7.8.7 **Reporting Opinions and Interpretation**

7.8.7.1

Laboratory testing resulting in material identifications and comparative assessments require authorized personnel opinion and interpretation.

7.8.7.2

The basis upon which opinions and interpretations are made are included in the case examination documentation. BCI laboratory reports include a statement informing the reader that the reported findings include the opinions and interpretations of the responsible forensic scientist and are based on results of examination.

7.8.7.3

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

7.8.8 **Amendments to Reports**

7.8.8.1

The preparer is permitted to amend his/her laboratory report as needed prior to its release to the customer. No change tracking, added report designation, or specific notification is required.

When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

Material amendment to a BCI laboratory report after report release must be brought to the attention of laboratory management. Initiation of quality inquiry and possible corrective action is at the discretion of the responsible lab management.

7.8.8.2

Amendment (i.e. a change ~~or addition~~) to a BCI laboratory report after report release is done in the form of an "Amended" report. *The original issued report is not available to customers in OHLEG/Prelog.net* ~~Copy of the original report (later amended) is retained in the case record~~. Situations where amended reports are issued include, but are not limited to:

- ~~those that offer additional testing findings on evidence items that have been previously reported (Note: this does not apply to additional comparisons performed to additional standards or exemplars); and~~

- those that correct errors identified in a released report. While the original issued report exists and has been released, the amended report is intended to replace the original report;

To issue an Amended Report in LIMS.Net:

1. *From the Reports tab, click "Reset".*
2. *Enter the reason for the Amended Report.*
3. *From the Assignments tab, update the matrix accordingly.*

In addition, the preparer will display corrected~~/new~~ text in bold font. If the correction involves the removal of content from the original report or an amendment to text already existing in bold font, the change will be indicated with strike-out and bold font.

7.8.8.3

When an Amended report is issued, it is uniquely identified by date and when applicable, includes a statement explaining that the Amended report replaces the original report, *such as "This report replaces the original report issued by (insert name here) dated (insert date here) in its entirety."*

See *Amended Report scenario* examples below (other scenarios may exist):

- Incorrect information on original report (case info, item description, report findings)
- QICA-related Reexamination (original conclusions incorrect)

~~**Situation**~~	~~**Report Designation**~~	~~**Additional verbiage**~~
~~Incorrect information on original report (case info, item description, report findings)~~	~~Amended~~	~~"This report replaces the original report issued by (insert name here) dated (insert date here) in its entirety."~~
~~Additional testing on items previously tested in the case (new type of testing, different technology)~~	~~Amended~~	~~"This report replaces the original report issued by (insert name here) dated (insert date here) in its entirety." or "This report supplements the original testing performed on Item(s) X issued in the report dated (insert date here)."~~

~~Situation~~	~~Report Designation~~	~~Additional verbiage~~
~~Original testing conducted at BCI; Additional testing requested of items not previously tested in the case~~	~~Normal Report (not Amended)~~	~~N/A~~
~~New testing on known standards/exemplars for comparison to findings that were previously issued (i.e. submission of new standards for comparison or cross-linked cases)~~	~~Normal Report (not Amended)~~	~~N/A~~
~~New testing on known standards/exemplars for comparison to findings that were previously issued under different interpretation guidelines (i.e. new sufficiency criteria in use currently)~~	~~Normal Report (not Amended)~~	~~"Based on current interpretation guidelines, (insert new conclusion here)" as applicable~~
~~Standard submitted to compare to previous reported data but would interpret differently with current guidelines. The conclusion will change from suitable to not suitable.~~	~~Amended~~	~~Strike through original conclusion. Report new conclusion in bold with footnote "Based on current interpretation guidelines"~~
~~Routine Quality Assurance Reexamination (additional testing performed to evaluate original issued findings)~~	~~Amended~~	~~"The above listed item(s) was re-examined for quality assurance purposes and the findings concur with those listed on the report issued by (insert name here) dated (insert date here)."~~
~~Evidence Reexamination performed due to original examiner unavailable (e.g. no longer employed by BCI or on extended leave)~~	~~Amended~~	~~"The above listed item(s) was re-examined due to the lack of availability for testimony purposes of the original reporting Forensic Scientist (insert name here) originally dated (insert date here)."~~

~~Situation~~	~~Report Designation~~	~~Additional verbiage~~
~~Original examiner not available for testimony (no additional testing performed/review of original analyst documentation; no interpretative discrepancies from original report; updated report wording/layout used)~~	~~Normal Report (not Amended)~~	~~"The above listed item was re-examined as the original reporting Forensic Scientist, (original scientist), was unavailable to testify to the report dated (insert date here)."~~
~~Original testing performed at vendor laboratory; Original examiner not available for testimony– Rework can include testing of additional item(s) originally untested.~~	~~Normal Report (not Amended)~~	~~"The above listed item was re-examined as the original reporting laboratory was unavailable to testify to the report dated (insert date here)."~~
~~Original testing performed at vendor laboratory; however additional testing is required at BCI due to insufficient testing. Re-examination can include any and all pieces of evidence in case.~~	~~Normal Report (not Amended)~~	~~"The above listed item(s) was re-examined for quality assurance purposes. This report supplements the original issued by the original reporting laboratory (insert name here) dated (insert date here)."~~
~~QICA-related Reexamination (additional testing performed, found to differ from original issued findings)~~	~~Amended~~	~~"The above listed item(s) was re-examined for quality assurance purposes. This report replaces the original report issued by (insert name here) dated (insert date here) in its entirety."~~

The following scenarios will be issued using the "Supplemental" feature in LIMS.net. These scenarios need to include the statement "This report supplements the original report issued by the laboratory (insert name here) dated (insert date here)." These are not noted as "Amended Reports". Examples include:

- *Standard submitted to compare to previous reported data but would interpret differently with current guidelines. The conclusion will change from suitable to not suitable.*
- *Additional testing findings on evidence items that have been previously reported*

The following scenarios will be issued as a "normal report" in LIMS.net. These are not noted as "Amended Reports":

- *Original testing conducted at BCI; Additional testing requested of items not previously tested in the case*
- *New testing on known standards/exemplars for comparison to findings that were previously issued (i.e. submission of new standards for comparison or cross-linked cases)*
- *New testing on known standards/exemplars for comparison to findings that were previously issued under different interpretation guidelines (i.e. new sufficiency criteria in use currently)*
- *Routine Quality Assurance Reexamination*
- *Evidence Reexamination performed due to original examiner unavailable (e.g. no longer employed by BCI or on extended leave)*
- *Original examiner not available for testimony (no additional testing performed/review of original analyst documentation; no interpretative discrepancies from original report; updated report wording/layout used)*
- *Original testing performed at vendor laboratory; Original examiner not available for testimony– Rework can include testing of additional item(s) originally untested.*
- *Original testing performed at vendor laboratory; however additional testing is required at BCI due to insufficient testing. Re-examination can include any and all pieces of evidence in case.*

7.9 Complaints

7.9.1

A complaint is an allegation of conduct or omission that is contrary to Ohio Revised Code, AGO Policies, BCI Bureau Directives, or BCI Laboratory Policies and Procedures.

Internal and external complaints are submitted in writing. In lieu of written submission, a verbal complaint may be documented by the recipient and directed for evaluation, as specified below. Any complaint received or generated by laboratory personnel is promptly conveyed to the immediate supervisor who is responsible for evaluating the complaint and the nature of the appropriate response. Any external complaint received by the laboratory requires prompt notification to the BCI Superintendent.

External or internal complaints concerning the quality management system are directed to the appropriate QA Manager or Technical Leader. The QA Manager or Technical Leader is responsible for reviewing the complaint and if warranted, initiating Practices for Quality Inquiry and Corrective Action or Improvements.

Other operational complaints are handled at the lowest management level consistent with the authority to take action on the matter in question. That manager is responsible for ensuring actions taken are in accordance with applicable established policy.

Complaints regarding very serious issues involving activity that may be illegal, immoral or unethical are addressed according to Bureau Directive (Internal Affairs).

7.9.2

Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, must document actions taken to address the original complaint.

Personnel that become aware of a complaint either from an internal or external source have the responsibility to communicate the complaint through their chain of command. Lab Management has the responsibility to ensure that complaints are resolved appropriately and is responsible for all decisions at all levels of the handling process for complaints.

Complaints regarding any aspect of the Laboratory testing, and results of testing, that do not conform to established policies and/or procedures shall be directed to the QA Manager or DNA Technical Leader for a Quality Inquiry.

If Lab Management determines that the complaint originated due to a misunderstanding of laboratory policy, the manager may respond directly to the complainant and attempt to resolve the issue by discussing existing policies. Corrective or preventive actions may be initiated as a response as necessary.

7.9.3

a) Whenever possible, the complaint should be submitted in writing to ensure an accurate description of the concern is documented by the complainant. The Lab Management responsible for investigating the complaint should attempt to interview all affected parties in an effort to validate the complaint. If the investigation finds that the conduct or omission is unacceptable, then actions must be taken.
b) A Laboratory Complaint Form must be completed by ~~the~~ Lab Management. The action plan must be reviewed and approved by the Laboratory Director.
c) Once all actions are completed, the form must be submitted to the Laboratory Director for approval for closure.

7.9.4

The BCI laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5

Whenever possible, Laboratory Management shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.9.6

The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.

7.9.7

Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming Work

7.10.1

Established procedures are followed when substantive examination nonconformity is identified. Responsibilities and Authorities for management of nonconforming work are designated below:

Lab Director	QA Manager/TL/NIBIN Administrator	Lab Management	All Lab Personnel
Assess the approach of the Quality Inquiry and make final determination of Quality Inquiry closure or Corrective Action initiation	Assess possible quality affecting non-conformities and recommend Quality Inquiry closure or Corrective Action initiation.	Immediately direct possible quality affecting non-conformities to the responsible Quality Assurance Manager or Technical Leader.	Identify and bring to the attention of laboratory management recognized possible quality affecting non-conformities.
Review and closure of the completed Quality Inquiry Corrective Action process.	Responsible for documentation, document retention and related activities. Technical Leader shall document approval of any directed Corrective Action related to forensic DNA testing or CODIS prior to implementation NIBIN Administrator shall document approval of any directed Corrective Action related to NIBIN.		
	Assist with fact gathering; communicate outcomes and corrective actions to staff		

- When laboratory activities or results do not conform to the established procedures or customer agreements, an evaluation of the significance of any nonconforming work is made and documented. Documentation includes the risk

level, impact analysis, decision on whether to accept the nonconforming work, whether to notify the customer, and whether work may resume. Necessary actions are defined based upon the following established risk levels:

Impact	Likelihood to reoccur	Overall Risk Associated
Low	Low	Low
Low	Medium	Medium
Low	High	High
Medium	Low	Medium
Medium	High	High
High	Low	High
High	Medium	High
High	High	High

- Low- monitored by Laboratory Management and appropriate corrections are made with documented supervisor approval. Correction is taken immediately, together with any decision regarding the acceptability of the nonconforming work. Examples include:
  - Transcription, transposition or other administrative non-conformity
  - Administrative misidentification of examination results or case file information
  - Non-conforming documentation (Examples: failure to use properly controlled documents; insufficient or incomplete examination documentation; failure to document quality assurance related activity)
  - Testimony criteria evaluated as “no”, or otherwise communicated to the BCI laboratory as unsatisfactory

- Medium- monitored by Laboratory Management in consultation with QA Manager/TL. A Quality Inquiry is initiated to assess the concern and determine whether Corrective Action is warranted.

- High- Immediately brought to the attention of the QA Manager/TL. A Quality Inquiry is initiated. Examples include:
  - Issues related to the integrity of the evidence such as custody, sealing, destruction, loss, etc.
  - Issues that would impact materially on the investigative and/or probative value of the results reported and unfairly jeopardize the rights of an individual (Examples: erroneous identification or exclusion of an individual; misidentification of a controlled or

non-controlled substance; erroneous identification or exclusion of comparative impression evidence; erroneous identification or exclusion of trace evidence materials; etc.)
- Failure to identify or exclude when there is sufficient information available where a qualified individual would normally come to the proper conclusion
- Destruction of any technical records from the laboratory case file
- Substantive non-conformities made in proficiency test reporting to the test provider, such as technical errors; erroneous identification or exclusion; erroneous classification or characterizations; etc.
- A pattern of quality problems from a single source (instrument or individual)

7.10.2

The laboratory shall retain records of nonconforming work and actions taken, in accordance to established AGO Record Retention schedules.

7.10.3

Where evaluation indicates that the nonconformity could recur or there is doubt about BCI laboratory compliance with its own policies/methods/practices, corrective action as described in this manual are promptly followed.

7.11 Control of Data and Information Management

7.11.1

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

7.11.2

Computers and automated equipment used for acquiring, processing, recording, reporting, storing or retrieving test data are shown to meet the following requirements before use:

- Internally developed software, or substantial modification to commercial software is validated and documented.
- The integrity and confidentiality of data are protected in accordance with the BCI Management system.

Operating conditions and maintenance are such that computers and automated equipment function properly.

Prior to implementation of commercially available software, such as PopStats™, GeneMapper® or new LIMS applications, the AGO's Information Technology Services section in conjunction with laboratory staff will validate or performance check to ensure the laboratory application range is within the manufacturer's designated specifications.

7.11.2.1

A software validation plan must be established for BCI-developed software providing direction for parameter evaluation and parameter acceptance criteria to determine if the software is fit-for-purpose. Records of the validation must be retained.

7.11.3

Electronic transmission of laboratory report copies via telephone, fax, or e-mail is permissible under the information protection and control conditions described in this manual.

The laboratory information system(s) (*LIMS*) shall:

a) Be protected from unauthorized access. *Each LIMS User account is created with a designed User Group and Section Settings appropriate for the employee. LIMS User Groups include:*

User Group Name	*Lab Staff*
Evidence Intake	*EITs*
General Forensic Analyst	*Lab Technicians, Forensic Scientists*
HIT General Forensic Analyst	*LDIS Admins, CODIS EITs, CODIS Forensic Scientists, CODIS Lab Management*
LIMS Administrator- Limited	*Lab Management*
LIMS Administrator	*Designated ITS*
Password Reset Only	*OHLEG Support, AGO ITS*
Read Only	*External assessors, BCI Admin staff, BCI Cold Case Unit, BCI Lab Externs*
PLC Support	*External- LIMS vendor customer support*

b) Be safeguarded against tampering and loss;
Each user has unique credentials to log into LIMS. Additionally, evidence transfers involving an individual require entry of LIMS credentials. Each User Group's settings include limited permissions to safeguard and prevent tampering and loss.

User Group Name	*Key permissions*
Evidence Intake	*Update Department Case number, Update Department Code*
General Forensic Analyst	*Basic LIMS functions for casework activities*
HIT General Forensic Analyst	*Basic LIMS functions for CODIS-related activities*

LIMS Administrator-Limited	*Update section permissions, update department configuration details, audit Log access, re-enable user accounts, delete sub-items created in error, custody edits, update Prelog service request questions, update report wording options in Matrix, update admin config code tables*
LIMS Administrator	*Batch-related custody edits via Custody Command Center, Updates to Web Ctrl Codes, Updates to Dept Ctrl Codes, LIMS SQL Queries, Report Templates (ini), PUBL notification updates, develop crystal reports*
Password Reset Only	*Basic department code configuration only*
Read Only	*Records may be printed, but no edits/deletions*
PLC Support	*Full LIMS Admin*

c) Be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
d) Be maintained in a manner that ensures the integrity of the data and information; *The LIMS data undergoes a full backup once a week, and an incremental back up each day.*
e) Include recording systems failures and the appropriate immediate and corrective actions. *Significant LIMS setting updates and troubleshooting is recorded in an AGO ITS Work Order, where the Lab QA Manager is copied.*
    - *Designated ITS staff work with lab staff to identify the issue, determine the cause, and implement corrections.*
    - *All LIMS updates proposed are reviewed with Senior Lab Management prior to implementation in LIMS Production.*
    - *The approved changes are tested in the LIMS Test environment prior to deployment in LIMS Production.*
    - *The changes made by the LIMS Admin must be documented and retained.*

7.11.4

When the laboratory information management system is managed off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5

The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

7.11.6

Manual calculations, data transcriptions and data reductions relevant to examinations that are subject to human error are systematically checked for accuracy through the application of required technical and administrative review.

7.11.6.1

The case record must indicate the check was performed and who performed the check. Whenever possible, this check is not performed by the person who performed the calculation(s) or the data transfer.

8 Management System Requirements

8.1 Options

The BCI laboratory will ensure the integrity of the evidence in its custody to protect the interests of the laboratory and its clients. This will be accomplished by prescribing rules for transporting, receiving, handling, protecting, storing, retaining and returning evidence, and by documenting the chain of custody to provide for the generation of legally admissible chain of custody records.

8.1.1 General

These practices apply to all BCI laboratory employees, test items and submissions at all locations.

8.2 Management System Documentation

8.2.1

The BCI laboratory is committed to its quality management system as outlined in this manual, supporting laboratory practices, DNA and CODIS Quality Manuals, the Laboratory Safety Manual and all unit method and training manuals.

- Notifications of updates to management system documents are communicated to staff by the QA manager or Technical Leader, as appropriate.
- The laboratory staff documents their review and understanding of the document(s) via electronic signature in the electronic record management system.

The primary objectives of the BCI laboratory quality management system are:

- To assure that laboratory testing results provided to its customers are reliable and scientifically sound.
- To ensure the use of scientific methods that are valid, dependable, reproducible, and adequate for the intended purpose.
- To establish formal methods of quality assurance within the laboratory through the implementation of recognized standards for good laboratory practice.
- To monitor the routine operational performance of units within the laboratory.
- To maintain national and international recognition through compatibility with the requirements of relevant standards of service.
- To promote continual process improvement.
- To maintain evidence integrity

8.2.1.1

Requirements for the BCI laboratory management system must be met in writing when the following words are used: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, and specify.

8.2.2

The policies and objectives address the competence, impartiality and consistent operation of the laboratory.

8.2.3

Evidence of laboratory top management's commitment to the quality management system and its continual improvement is demonstrated by their participation in annual management system quality reviews, internal audits, quality document reviews, and other quality control procedures as defined throughout the BCI laboratory's quality management system.

Quality management system documents are regularly reviewed and updated as necessary to continuously improve the effectiveness of the quality management system. When conditions having an adverse impact on the quality management system are identified, appropriate changes are made and/or corrective actions implemented.

8.2.4

BCI laboratory quality management system documents are comprised of universal laboratory policies and practices; discipline specific policies and methods; and task specific supporting form documents.

Overall BCI laboratory quality policy is set forth in this manual. Additional DNA and CODIS specific policies may be found in those quality manuals. In areas of overlap, the more stringent policy is followed.

Laboratory practices provide comprehensive procedural detail for the implementation and regulation of multilayered quality policies referenced in this manual.

Technical method manuals in each laboratory discipline direct the examination /analytical process. Training manuals in each laboratory discipline prepare forensic scientists for proper implementation of technical methods included in their respective method manuals.

Quality system form documents support quality policies or technical methods through the consistent application and recording of specified information.

Quality document control policies are addressed in this manual.

8.2.5

These documents are readily available electronically to all BCI laboratory personnel via the agency intranet and the electronic records management system. Additional quality management system documents such as worksheets, log forms, technical review forms, instrumentation manuals, etc. are available electronically or in hard copy form.

8.3 Control of Management System Documents

8.3.1

BCI laboratory manages the documents that comprise its quality management system. Laboratory documents that specify quality requirements or prescribe quality affecting activities must be controlled to ensure that they are adequate, approved for use, properly issued and acknowledged, and that only the current versions are in use. Copies created from controlled documents are designated uncontrolled.

The laboratory recognizes the necessity to control quality affecting information directed toward, or solicited from its customers. These may include submission information letters; protocols; interaction policies; quality inquiries; customer reviews; etc. All iterations will be retained in accordance to established record retention policies ~~PowerDMS~~. Affected staff will be notified of their distribution targets. Record of revision or removal from distribution will be recorded and superseded versions will be archived in accordance with these practices.

Externally produced documents containing laboratory required specific procedure or instruction, such as equipment manuals or software containing information deemed

critical to the quality of the work product are identified as controlled through inclusion on the laboratory controlled document list and may be specified in the applicable method. Externally produced quality documents, such as specific accreditation program requirements, will be controlled and made available to laboratory staff via PowerDMS.

Equipment manuals retained only for general reference purposes are not subject to the document control requirements specified in these practices. (In this context, "general reference purposes" means laboratory personnel are not required by the BCI laboratory to follow specific quality affecting procedures or work instructions contained in those manuals.)

Externally produced document control is also not necessary if laboratory required quality affecting content is otherwise reflected in a controlled internally produced quality document.

Supporting software applications that have no direct effect on the quality of the work product (such as Microsoft Office Suite applications, LIMS, PowerDMS, etc.) are not subject to laboratory control requirements.

8.3.2

To ensure controlled documents are uniquely identifiable they will include the Ohio BCI name or approved agency branding; a unique document name or title; issuing authority; an effective date and revision number.

Prior to implementation, all laboratory quality management system documents are thoroughly reviewed, approved for release and made available for use by employees as specified below under the issuing authority of the LD, QA Manager or Technical Leader. Controlled document approval records, including approver identities and approval dates, will be retained in PowerDMS.

- BCI Laboratory produced quality documents will be prepared by personnel with adequate expertise in the subject matter. The document must correspond to the complexity of the activity being performed as well as the background of the intended user. The document must include enough detail and specificity to ensure that the activity conforms to quality requirements.

- The Laboratory Director is responsible for review and approval of all laboratory produced quality system manuals and practices to ensure they meet operational needs and comply with applicable AGO and BCI agency requirements. Changes and the current revisions status of documents are identified.

    - The Quality Assurance Manager is responsible for review and approval of all laboratory produced manuals and forms with comprehensive

laboratory applications (e.g. Laboratory Quality Assurance Manual, Safety Manual); all laboratory practices; and discipline specific manuals for Drug Chemistry, Firearms, Latent Prints, Questioned Documents, Trace Evidence and Evidence Receiving to ensure they meet the quality requirements of the ANAB accreditation program, and the Ohio BCI laboratory quality management system.

- The DNA Technical Leader is responsible for review and approval of all laboratory produced manuals and forms with comprehensive laboratory applications, all practices, and discipline specific manuals for DNA and Forensic Biology to ensure they meet the quality requirements of the ANAB accreditation program, applicable FBI Quality Assurance Standards, National DNA Index System Procedures and the Ohio BCI laboratory quality management system.

- The CODIS Technical Leader is responsible for review and approval of all laboratory produced manuals and forms with comprehensive laboratory applications, all practices, and discipline specific manuals for CODIS to ensure they meet the quality requirements of the ANAB accreditation program, applicable FBI Quality Assurance Standards, National DNA Index System Procedures and the Ohio BCI laboratory quality management system.

- The MPS Technical Leader is responsible for review and approval of all laboratory produced manuals and forms with comprehensive laboratory applications, all practices, and discipline specific manuals for MPS to ensure they meet the quality requirements of the ANAB accreditation program, applicable FBI Quality Assurance Standards, National DNA Index System Procedures and the Ohio BCI laboratory quality management system.

- The NIBIN Program Administrator is responsible for review and approval of all laboratory produced manuals and forms with comprehensive laboratory applications, all practices, and discipline specific manuals for NIBIN to ensure they meet the quality requirements of the ANAB accreditation program, applicable MROS and the Ohio BCI laboratory quality management system.

- The Quality Assurance Manager is responsible for publishing internally produced documents in PowerDMS; creating review/approval workflows in PowerDMS; and notifying assigned laboratory staff of the new or revised document.

  - Current revisions of Lab Methods Manuals and Laboratory Submission policies are published to the public AGO Webpage by the Quality Assurance Manager, or designee.
  - BCI customers are notified of updated Laboratory Submission policies prior to the effective date whenever possible.

- Affected staff is required to review the document and acknowledge receipt in PowerDMS as directed by the Quality Assurance Manager. Testing may be included as an element of the review process to verify review and assess comprehension.

- The Quality Assurance Manager will ensure a copy of any superseded version of a controlled internally produced quality system document is archived and retained indefinitely in PowerDMS. Archived versions are only accessible by a PowerDMS administrator. Replaced externally produced controlled documents will be designated as archived versions in PowerDMS so as to preclude improper use and are retained by the laboratory unit.

The Quality Assurance Manager is responsible for retaining a master list of controlled documents. The master list is available to all laboratory staff in PowerDMS. PowerDMS is a paperless distribution, organization and maintenance system for prepared documents. It is a web-based software application, accessible through the AGO intranet system. Access is restricted by agency logon requirements, individual password protection and PowerDMS administrator security controls.

All internally produced laboratory quality documents, including their associated control activity records, reside in PowerDMS. Following approval, an equipment manual or other externally produced quality document will be made available to the affected staff. Staff will be notified through issuance of the applicable method specifying the externally produced controlled document or notification of the amended master list of controlled documents.

Quality management system documents are periodically reviewed and revised as necessary to ensure continued suitability and compliance with applicable requirements. Review schedules and record of review are retained in PowerDMS and/or the master list of controlled documents.

Substantive additions to internally produced manual and practice revisions are italicized and deletions struck through, additional change highlight mechanisms are permitted. Additions revert to standard font and struck through characters are deleted in the succeeding document revision. The changes shall be identified in the document or in an attachment to the final version of the document. It is recognized, some manual or

practice revisions are too extensive for effective use of the change indicators specified above. Revisions identified as replacing the prior version, or specified segments in their entirety are permitted. Those revisions will be so identified at the beginning of the document or the applicable segment.

Internally produced controlled laboratory form revisions are not subject to the change indicators specified for laboratory manuals and practices. Each revision replaces the prior version in its entirety.

Revisions to externally produced quality documents made by the manufacturer/vendor are subject to the same control requirements as the original version.

PowerDMS design allows only active controlled document accessibility to laboratory staff, precluding the use of invalid or obsolete internally produced controlled documents. Additionally, the issuer will ensure any prior version the externally produced quality document may be replacing is removed from the point of use, or clearly marked as an archived copy. It is the responsibility of all laboratory staff to ensure any reproduction of a controlled document in their possession is destroyed upon the Effective Date of the succeeding version or replacement.

An audit trail of user activity within the system is recorded. Laboratory prepared quality management system documents are uniquely identified. Each internally produced controlled document is uniquely identifiable by the combination of its assigned name and revision number and/or effective date. With specified exceptions, each internally produced controlled quality document page will display the following identifying information:

- **Ohio BCI name or recognized branding**
- **Document name-** Document category, discipline identifier and description of subject.
  Example: **LM** (document category) **-DNA** (discipline) **–Methods** (subject)

Document Category	Description
Laboratory Manual (LM)	To include laboratory and discipline specific quality assurance manuals; discipline specific laboratory method, training and administrative manuals; and the laboratory safety manual.
Laboratory Practice (LP)	To include this and other detailed laboratory policy/procedure documents designed to augment the Laboratory Quality Assurance Manual and address specific requirements of the ANAB accreditation program.
Laboratory Form (LF)	To include documents which specify a quality impacting procedure; schedule; required observation; or recording method. Laboratory Form examples include examination worksheets; reagent preparation logs; equipment maintenance and calibration logs; review forms; checklists; and others.
Laboratory Training (LT)	To include documents or presentations which are designed to provide brief supplemental training to laboratory staff regarding

	safety and other quality impacting policies and procedures.

- **Issuing authority-** All internally produced laboratory manuals and practices are reviewed, approved and issued under the authority of the BCI Laboratory Director. Internally produced laboratory forms applicable to general quality assurance; safety; or the Drug Chemistry/Firearms/Latent Prints/Questioned Documents/Trace Evidence disciplines are reviewed, approved and issued under the authority of Quality Assurance Manager. Internally produced laboratory forms applicable to the DNA discipline are reviewed, approved and issued under the authority of DNA Casework Technical Leader. Internally produced laboratory forms applicable to the CODIS discipline are reviewed, approved and issued under the authority of the CODIS Technical Leader. Internally produced laboratory forms applicable to the MPS discipline are reviewed, approved and issued under the authority of the MPS Technical leader.
- **Effective date**- Effective date is assigned by the Quality Assurance Manager based upon operational needs and logistical considerations. Effective date denotes the first day the document iteration is considered current and approved for use. The effective date also denotes the archival date of any immediately prior version of that document.
- **Revision number** - The revision number serves to distinguish closely related document iterations. A revision represents a substantive change to the prior document contents. Revision assignment is made by the Quality Assurance Manager in association with the document preparer. Original documents are assigned revision number zero (0), subsequent revision numbers are assigned sequentially.
- **Document pagination (Page _ of _) -** Each page of an internally produced laboratory manual, practice or form includes the page number and the total number of pages in the document. It is recognized internally produced laboratory forms may be elements of case files or other parent record compilations with their own pagination requirements. When used in those circumstances, both the form document and parent record pagination requirements apply.

8.4 Control of Records

8.4.1

The laboratory has established and retained legible records to demonstrate compliance of the requirements in the accreditation program.

8.4.2

The BCI laboratory has established procedures for the identification, collection, organization, accessibility, filing, storage, maintenance and disposal of both quality and technical records as indicated below.

8.4.2.1 Identification, Collection and Organization

The chart below identifies the quality and technical records and designates the organization, filing, access & storage policies implemented in the laboratory.

All BCI laboratory quality and technical records are legible and readily retrievable at appropriate BCI or approved off-site facilities.

Record	Identification/ Organization	Collection/ Filing	Access	Storage	Maintenance	Retention
Case Files	BCI Case #	Lab Staff	Lab Staff	Paper/ Electronic	Updated as necessary	BCI-LAB-~~23, 25,~~ 26
Equipment Records	Equipment Model, ID	Scientists, Lab Technician	Lab Staff	Paper/ Electronic	Updated as necessary	BCI-LAB-~~-~~27
Lab Accreditation Records	Organization charts/ date	Lab Management designee(s)	Lab Staff	Paper/ Electronic	Updated as necessary	BCI-LAB-24
	Management review records/ date					
	Purchasing records/date					
	Audit reports/ lab, date	QA Manager	LD*, QA, TL		N/A	
	Testimony monitoring records/ staff, year	QA Manager	LD*, QA, TL		N/A	
Quality Records	Proficiency test summary record/ date	QA Manager, TL	LD*, QA, TL	Electronic	Updated as necessary	BCI-LAB-25
	Proficiency test records/ staff, test type, year	QA Manager, TL	LD*, QA, TL	Electronic	N/A	
	Validation studies/ date	QA Manager, TL, ~~R&D~~	LD*, QA, TL, R&D	Electronic	N/A	
	Training records/ staff	Lab Staff	Lab Staff	Paper/ Electronic	Updated as necessary	
	QI-CA records/ year	QA Manager	LD*, QA, TL	Electronic	Updated as necessary	
	Preventive action records/ year	QA Manager	LD*, QA, TL	Electronic	Updated as necessary	
	Archived policy/procedures/ manual name, revision	QA Manager	LD*, QA, TL	Electronic	N/A	
	Safety Records/ Year	*Safety Coordinator*, ~~QA Supervisor,~~ *Safety Officers*	LD*, QA, TL	Paper /Electronic	Updated as necessary	

*Accessible to staff designated by the Lab Director

8.4.2.2 Access and Storage

Access to BCI laboratory quality records is controlled under the authority of the LD, QA Manager and Technical Leader.

Access to BCI laboratory technical records stored on-site is controlled according to Bureau Directive 6.2 (Facility Security) and location specific laboratory security policies. The London BCI Laboratory is responsible for Long term storage of technical records. The custody of the technical record is documented in our LIMS record. Technical records created prior to 2002 are stored and labeled with the year and associated case offense. When a discovery request or subpoena is received for a technical record created prior to 2002 that is not already entered in LIMS, the case is back-entered in the LIMS and a scanned record of the paper file is uploaded to the image vault.

Access to BCI laboratory technical records stored off-site is controlled by vendors who demonstrate secure access to records and environmental controls approved by the Laboratory Director (or designee).

Electronic records on the LIMS and any others retained on affiliated agency servers are protected and routinely backed up by the Ohio Attorney General's Information Technology Division (IT). Access to these records is restricted.

8.4.2.3 Maintenance and Retention

Record retention times are established by the Ohio Attorney General's Office Records Management Section in accordance to Ohio Revised Code (ORC), laboratory policy, and/or ANAB program requirements.

Records are disposed of in accordance to the established retention schedules at the direction of laboratory management. AGO Record Management section approval must be received prior to destroying records.

- Paper case records are disposed of using a secure shred approach
- Electronic case records are removed from LIMS with the assistant of ITS.

If an original record, paper or other media is captured as an electronic record, and the original record will be destroyed, the laboratory personnel responsible for preparing the electronic record shall ensure that the electronic record is complete prior to destruction of the original record.

8.5 Actions to Address Risks and Opportunities

8.5.1

The BCI laboratory uses policies, planning objectives, audit/assessment results, data analysis, corrective actions, customer feedback, and performance review mechanisms to continuously improve the effectiveness of the quality management system.

Risks and opportunities associated with the laboratory activities give assurance that the management system achieves its intended results; enhances opportunities to achieve the purpose and objectives of the laboratory; prevents, or reduces undesired impacts and potential failures in the laboratory activities; and improves processes.

8.5.1.1

Risks and opportunities related the health and safety are considered.

8.5.2

When risks and/or opportunities are identified, the laboratory plans actions to address them and how to integrate and implement actions into its management system. The effectiveness of the actions is evaluated during internal auditing activities.

8.5.3

Actions taken to address risks and opportunities are proportional to the potential impact on the validity of laboratory results.

8.6 Improvement

8.6.1

The laboratory identifies and selects opportunities for improvement and implements any necessary actions. These can be identified through the review of operational procedures, use of policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and/or proficiency testing results.

8.6.2 **Customer Feedback**

The BCI laboratory seeks feedback from its customers. Customer feedback may be gathered through formal and informal mechanisms, including:

- Testimony evaluation
- Customer satisfaction surveys
- Meetings
- Conversation
- Complaint

The feedback is analyzed and used to improve the management system, laboratory activities, and customer service.

8.7 Corrective Actions

8.7.1

These practices include designation of authorities for implementing a corrective action when nonconforming work or departure from policies and procedures in the quality management system or technical operations are identified.

- The QA Manager or responsible Technical Leader will initiate documentation of the process through the use of the Quality Inquiry Corrective Action Form. Form documentation shall be sufficient to describe the quality concern, impact assessment and should include the following details whenever possible:
  - BCI case number(s) involved
  - BCI Laboratory involved
  - Date(s) of occurrence
  - Any indications of systemic quality concerns
  - Root causal factor(s)
  - Subsequent actions taken
  - The results of any corrective actions

- Quality Inquiry is the fact gathering and initial impact assessment piece of the QICA process. It is directed by the QA Manager or appropriate Technical Leader and is designed to ensure all relevant information about the non-conformity is thoroughly reviewed and consistently assessed. This assessment may include review of case records, equipment records, training records, etc. in order to identify the impact of the non-conformity. The QA Manager or appropriate Technical Leader will make recommendation to the Laboratory Director if Corrective Action is indicated or the process closed. If corrective action is required, this includes a root cause analysis and action step identification.

  - Root cause analysis should consider various factors such as human error, environmental conditions, and systematic factors. The factors considered and the assessment details regarding the root cause analysis will be recorded on the QICA form. Root cause conclusion(s) will be recorded on the QICA Form.
  - Following determination of the impact, appropriate personnel select, document and implement the action(s) most likely to eliminate the nonconformity and to prevent recurrence. Corrective action steps are identified as appropriate to the magnitude and risk of the nonconformity.

This must be completed within 30 days of the Quality Inquiry notification. Corrective Action steps not completed by the estimated completion date may be reviewed with the affected staff members. Subsequent progress meetings may be conducted, as necessary, until Corrective Action step completion. The QA Manager or responsible Technical Leader may modify action steps and timelines during the process to more effectively achieve corrective action goals. Approval will be documented on the QICA Form via Laboratory Director acknowledgement of 'Corrective Action indicated' by the QA Manager or Technical Leader. Upon approval(s), all affected parties shall be notified and the plan enacted.

- If necessary, the customer is notified and work is recalled. The QA Manager or Technical Leader may require one or more of the following notification practices, depending on the impact of the QICA:
    - Remarks in the BCI case record
    - Notification to the submitting agency and/or prosecutor's office
    - An amended laboratory report
    - Written notification to ANAB
    - Written notification to the affected agency

- The individual(s) designated responsible for managing the Corrective Action steps will notify the QA Manager or responsible Technical Leader when the Corrective Action steps are complete. As available, objective evidence of completion will be included. The QA Manager or Technical Leader will verify completion and signify the action steps as complete on the QICA Form. The Laboratory Director will review and signify the QICA process as complete on the QICA Form. All affected parties will be notified of closure. The QA Manager or Technical Leader authorizes the resumption of normal work, as applicable.

- Designated responsible laboratory management, in association with the QA Manager or Technical Leader, monitor and verify the corrective actions taken are completed and effectively resolve the issue. A nonconformity may require additional audit to assess compliance with BCI laboratory policies and practices. The LD, QA Manager or Technical Leader determines if further audit is required. If conducted, the audit will be done in a timely manner and will be in accordance with this manual.
- If necessary, risks and opportunities identified during planning will be implemented.
- If necessary, changes to the management system will be made.

8.7.2

Corrective action(s) most likely to eliminate the nonconformity and to prevent recurrence are selected. Corrective action steps are identified as appropriate to the magnitude and risk of the nonconformity. Examples include:

- Analytical/interpretative non-conformity Corrective Action steps may include, but are not limited to:
  - Remedial training
  - Removal from casework
  - Completed casework review
  - Recall and re-examination of completed casework
  - Re-examination of future casework
- Systemic non-conformity Corrective Action steps may further include, but are not limited to:
  - Procedural amendment
  - Reissue of existing policy or method
  - Work environment modifications
- Administrative non-conformity Corrective Action steps may further include, but are not limited to:
  - Re-examination or correction by the original examiner and a quality assurance re-examination by another qualified examiner
  - Self-technical reviews
- Proficiency Test non-conformity Corrective Action steps may further include, but are not limited to:
  - Another proficiency test examination with a different sample
- Testimony non-conformity Corrective Action steps may further include, but are not limited to:
  - Testimony training
  - Direct observation of subsequent testimony
  - Professional appearance training

8.7.3

BCI Laboratory retains records as evidence of the nature of the nonconformity, cause, and subsequent actions taken and the results of any corrective action in accordance to established AGO retention schedules.

8.8 Internal Audits

8.8.1

Laboratory Practices for Internal Audit are followed when conducting scheduled audits to verify that operations conform to the requirements of the BCI laboratory quality management system, the ANAB accreditation program, FBI Quality Assurance Standards, ATF Minimum Requirements for Operating Standards, and NDIS Procedures.

Audits are performed to measure and evaluate the effectiveness of the quality management system, remediate any identified nonconformity, and to recommend improvements for BCI laboratory operations. The QA Manager or Technical Leader is responsible for planning and organizing internal audit as required by standard. Internal audits are performed by trained and qualified personnel who are, to the extent possible, independent of the specific activity being audited.

8.8.1.1 At a minimum, an internal audit is conducted annually. The laboratory may elect to conduct a series of audits, where the entireties of the audits address the requirements of the quality system. Overall, annual internal audits occur between 9 and 12 months after the previous internal audit was completed.

8.8.2

When an audit identifies nonconformity, the responsible QA Manager or Technical Leader addresses the nonconformity according to the Laboratory Practices for Internal Audit. If laboratory results have been affected, customers are notified in writing.

Internal audit records include disciplines and activities audited, audit findings, action items, and any resultant corrective actions are recorded in accordance with Laboratory Practices for Internal Audit.

The effectiveness of any corrective action resulting from internal audit identified nonconformity is verified and documented in accordance with Practices for Internal Audit.

8.9 Management Reviews

8.9.1

In conjunction with the QA Manager, Technical Leaders, and other appropriate laboratory management, the LD is responsible for evaluating the laboratory quality management system and testing activities to ensure their continued suitability and effectiveness. This management review is used as the foundation for future development of the quality management system, as well as an opportunity to identify any necessary changes or improvements to the quality management system.

The LD will be responsible for scheduling the meeting, notifying the participants and setting the agenda.

8.9.1.1

Quality management system reviews are conducted at least once per calendar year at a minimum; however, ideally the audits are conducted in a series of various scopes

throughout the calendar year. The regularly scheduled annual quality management system review is conducted within 9 to 12 months after the previous annual review.

8.9.2

This review will include input from Lab Management regarding the following information:

- Changes in internal and external issues that are relevant to the laboratory;
- Fulfilment of objectives;
- Suitability of policies and procedures;
- Status of actions from previous management reviews;
- Outcome of recent internal audits;
- Corrective actions;
- Assessments by external bodies;
- Changes in volume and type of the work or in the range of laboratory activities;
- Customer and Personnel Feedback;
- Complaints;
- Effectiveness of any implemented improvements;
- Adequacy of resources;
- Results of risk identification;
- Outcomes of the assurance of the validity of results; and
- Other relevant factors, such as monitoring activities and training

8.9.3

Management review findings identified are documented. Follow up actions are documented and assigned to staff with an established schedule. Actions related to the following decisions are recorded:

- The effectiveness of the management system and its processes;
- Improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- Provision of required resources;
- Any need for change

The QA Manager will assign any directed follow-up, as needed, and ensure its completion.

9 Appendix- Laboratory Practices for Laboratory Relocation

9.1 Purpose

Laboratory personnel must ensure that integrity of evidence, reagents and testing equipment is maintained during and following a physical relocation of a laboratory. Proper storage and transport of records must be considered. It is also essential that the safety of laboratory personnel be ensured during all phases of the relocation.

9.2 Relocation Schedule

BCI Laboratory Management will determine a relocation schedule and document the details on the Laboratory Relocation Checklist (see attached laboratory form).

9.3 Evidence Return

Any examined evidence should be returned to the submitting agency prior to the relocation. The evidence may be picked up by the agency or delivered by a BCI Evidence Security Officer (ESO). Any ESO evidence deliveries will be scheduled by the BCI ESO supervisor.

1. Evidence Receiving will scan the barcodes of the evidence to "Return to Department" and will print hard copy evidence release receipt(s).

2. Each agency's evidence will be packaged in convenience containers such as sealed plastic bags or totes. The ESO will document the number of convenience containers received from the lab for each delivery trip.

3. The ESO will transfer all returned evidence and correlating evidence release receipt(s) in a secure transfer vehicle. The convenience container quantity will be verified by the law enforcement agency receiving the evidence.

4. The law enforcement agency will sign the evidence release receipt(s) upon receipt of the evidence.

5. The ESO will forward all signed evidence release receipts to the evidence receiving staff.

6. The laboratory support staff will scan/PDF the completed form into each LIMS case entry.

9.4 Evidence Relocation

All evidence with pending laboratory assignments will be securely relocated to the new facility. A BCI employee who is independent of the evidence receiving staff will conduct inventories to ensure a complete transfer of all evidence.

1. Laboratory staff will provide a LIMS-generated custody report for each storage location in the property room(s).

2. The BCI employee will manually inventory each location. Any custody discrepancies will be documented and updated in LIMS prior to the relocation of the evidence.

3. Each storage location represents a specific LIMS barcode custody location. A large plastic convenience bag will be labeled with the custody location name. All evidence barcodes will be scanned to a temporary Evidence Transfer location. The contents of each box will be placed in the labeled plastic convenience bag, heat sealed to ensure evidence integrity during the relocation.

4. The shelving system will be installed at the new facility and all labeled property room shelf boxes will be placed on the shelves.

5. The evidence will be securely relocated via a BCI employee to the new facility.

6. The convenience bags will be opened, scanned to the appropriate property room custody location and stored at the new facility.

7. Laboratory staff will create a LIMS-generated custody report for each storage location in the new facility.

8. The BCI employee will manually inventory each location for consistency. Any custody discrepancies will be documented and brought to the attention of the Quality Assurance Manager and appropriate Laboratory Management.

9.5 Case Files

Any case files that meet the laboratory's retention schedule for off-site archival storage will be boxed and picked up prior to the relocation.
All other case files will be relocated to the new facility. Cases files will be removed from the current storage location, and placed in a box labeled with the laboratory case number range. The boxes will be relocated by a BCI employee(s) to the new facility.

9.6 Quality Assurance Records

Instrument maintenance, calibration and QC logs will be boxed according to each laboratory section by the appropriate FSC.
The relocation of individual Quality Binders (or however named) is the responsibility of the forensic scientists.

9.7 Reference Collection Relocation

All specimens included in the reference collection are labeled according to section specific methods. In order to ensure a complete transfer of collection specimens, the following actions are completed:

1. Inventory the reference collection prior to the relocation.

2. Ensure that any firearms reference collection specimens are unloaded and safe for transport.

3. Package the collection specimens using convenience containers, appropriate for the size/weight of the specimen. Any Drug Standards will be packaged to prevent loss or contamination. The contents of the Drug Standards will be weighed at the new laboratory to confirm the approximate weight is maintained at the new laboratory and documented on the appropriate inventory.

4. The reference collection will be transported to the new lab via a BCI employee.

5. Re-inventory the reference collection at the new facility. The original inventory will be printed and used as a checklist to document the secondary inventory.

9.8 Equipment Packaging

Any equipment that is taken out of service must be clearly labeled as such. Date of removal from service, reason for removal and date of return to service is documented in the equipment maintenance log.

Any laboratory/office equipment that is to be transferred to another AGO office will be arranged prior to the relocation. Details will be documented on the Laboratory Relocation Checklist.

Any laboratory equipment that is to be relocated to the new facility will be prepped and packaged under conditions defined by the manufacturer. All equipment will be cleaned and inspected for damage before and after the relocation. Any associated computers or components' cable connections will be documented or photographed for reference during setup in the new facility.

Instrument	Special Handling Considerations
Comparison Microscopes	Remove lenses and accessory attachments.
Compound Microscopes	Raise nosepiece to its furthest position upward, place the dust cover over the scope, secure the electrical cord, support the base, avoid abrupt motions/vibration
Stereo Microscopes	Raise nosepiece to its furthest position upward, place the dust cover over the scope, secure the electrical cord, support the base, and avoid abrupt motions/vibration. Do not disassemble.
Latent Prints Hood/Super Glue Chamber	Handle with care.
GC/MS and GC/FID	Tower, auto sampler, and column should be removed prior to transport. GC/MS: Handle with care -Separate GC from MS and cover plug on MS -Separate rough pump and drain prior to transport -Remove diffusion pump (as applicable)
Genetic Analyzers	Remove capillary array and consumables Refer to manufacturer's instructions for instrument shutdown
Robotics	Refer to manufacturer's instructions for instrument shutdown Handle with care.
FTIR	Handle with care.

Alternate Light Source	Secure light, goggles and accessories in carrying case
Cameras	Handle with care, use carrying case when possible.
Centrifuges	Install transport safety devices; do not tilt on its side. Transport in original packaging when possible.
Hot plates/Stirrers	Allow to cool to room temperature before transport.
Balances	Transport in original packaging when possible. If balance model has glass enclosure, avoid placement where any stress is introduced to avoid breaking glass during transport.
Vortexes	Avoid pressure to vortex head in transport.
Water purifier	Drain prior to transport.

9.9 Equipment Relocation

Large laboratory equipment will be transferred to the new facility by an insured vendor. The packaged equipment will be labeled with a number, which is associated with a specific location for delivery in the new facility. Laboratory equipment that is currently under warranty will be prepared, packed, and relocated by the vendor.

9.10 Chemical Packaging

Commercial reagents and chemicals and reagents prepared by the BCI laboratory are labeled as described in the Quality Assurance Manual. Any expired reagents, individual aliquots of chemicals, chemicals not applicable to current testing methods, or chemicals stored in low quantities will be properly discarded prior to the relocation date. Hazardous chemical waste pick-up will be scheduled after the relocation is complete. Chemical gases will be picked up by the vendor after the relocation is complete. New chemical gas tanks will be delivered to the new facility.

A chemical inventory will be verified prior to the move. The inventory list will include the chemical name, manufacturer (if applicable), approximate volume, storage conditions and hazard class (as applicable).

Chemicals and reagents will be protected from loss and contamination during the packaging process. Screw cap containers will be secured with Para film, as appropriate. Liquids stored in glass bottles will be packaged in KPAKs and heat sealed. Bubble wrap, Styrofoam and other packing supplies will be used to secure containers during the relocation, as appropriate.

Chemicals and reagents will be packaged to separate acids and bases. Appropriate protective apparel and equipment will be in use for the packaging, transfer and delivery of all chemicals and reagents to the new facility:

- Proper footwear- sandals, perforated shoes, open shoes and bare feet are prohibited
- Disposable laboratory coats – to ensure skin contact with chemicals and reagents is avoided
- Disposable gloves- to prevent contamination from chemicals

- Face masks-to prevent inhalation of hazardous chemicals
- Thermal resistant/ insulated gloves- to prevent skin contact when handling liquid nitrogen
- Safety goggles- to protect from chemical splash/contact burns

Storage conditions will be maintained during the relocation of chemicals and reagents:

- Frozen-stored in Styrofoam boxes with thermometer and ice packs, contents will be secured with bubble wrap as applicable
- Refrigerated- stored in coolers with thermometers, appropriate for the weight/type of container, contents will be secured with bubble wrap or Styrofoam as applicable
- Room Temperature- stored in boxes or totes, appropriate for the weight/type of container, contents will be secured with bubble wrap or Styrofoam, as applicable

9.11 Chemical Relocation

The new facility must be stocked with first aid kits, spill kits, proper disposal containers and other safety essentials prior to delivery of the chemicals and reagents.

Chemicals and reagents will be relocated in multiple trips, avoiding moving packaged acid and bases together. The contents of each trip will be detailed on a manifest that includes: all chemicals and reagents included in the trip, emergency contact information, and a summary of any applicable hazard classes in the shipment. All SDS sheets and reagent preparation forms will be readily accessible during the relocation. The vehicle used for transport will be equipped with the following safety supplies: personal protective equipment, first aid kits, and spill control materials.

All chemicals and reagents will be re-inventoried to ensure proper storage conditions at the new facility.

9.12 Facility Evaluation and Preparation

The Laboratory Safety Officer and BCI Laboratory Management are responsible to ensure that the following environmental elements of the new facility are appropriate for forensic laboratory use:

- Temperature/HVAC- must hold required temperature range for a 24 hour period
- Refrigerator/Freezer- must hold required temperature range for a 24 hour period
- Safety Showers/ eye stations- appropriate flow and drainage
- Fire extinguishers/ Fire suppression system – verify availability and operating properly

- Ventilation hoods- ensure proper inward flow of air and certification is documented
- Electrical/Back-up Generator- verify operating properly
- Laboratory Security Access- verify security settings allow only appropriate laboratory staff

9.13 Testing Reliability

All critical laboratory equipment will be calibrated and/or performance checked prior to use in casework. Requirements for instrument calibration are described in the applicable discipline methods manual or instrument calibration/maintenance record(s).

1. Balances will be re-calibrated.
2. Measurement uncertainty recalculations will begin promptly after balance calibrations are performed in the Drug Chemistry section. A minimum of eight measurements per scientist will be documented over a five-day period.
3. Microscope optics will be re-aligned and the stages, sub stages and objectives will be re-centered (as applicable) prior to use in casework.
4. Water purification system will be assessed according to manufacturer's recommendations prior to use in casework.
5. All critical reagents are evaluated prior to use in casework.
6. All laboratory spaces and equipment will be cleaned prior to performing casework, in order to prevent contamination.

9.14 Safety

The Laboratory Safety Officer will ensure that the staff is trained on the safety elements of the new facility as soon as appropriate. This training may include the following details: review of evacuation route and emergency exits, safety showers and eye wash locations, protective equipment storage locations, fire extinguisher locations and proper waste disposal.

9.15 Notification of Successful Relocation

ANAB and CALEA representatives will be notified of the successful relocation within 30 days. All laboratory customers will be notified by methods detailed in the Laboratory Relocation Checklist. AGO office correspondence and LIMS software laboratory record templates will be updated to reflect the new laboratory address.

9.16 Post Relocation Report

During the relocation, BCI laboratory staff will document challenges, successes, and failures, along with any quality inquiries.

After completion of the move, the Quality Assurance Manager will compose a post-relocation report to document compliance with the Laboratory Relocation Plan.

9.17 References

1. Federal Motor Carrier Safety Administration. www.fmcsa.dot.gov/regulations/hazardous-materials/.
2. ISO standard 17025
3. ANAB ISO/IEC 17025 Forensic Science Testing Laboratories Accreditation Requirements.

10 Appendix- Laboratory Practices for Internal Audits

10.1 Purpose

Internal audits are self-evaluations conducted to verify continual operational conformance with BCI laboratory quality management system requirements and the ANAB accreditation program.

10.2 Scope

These practices are applicable to internal audits performed in any of the BCI laboratories as directed by the QA Manager, Technical Leaders, or top management of the Ohio Attorney General's Office.

10.3 Responsibilities

10.3.1 Laboratory Director

Review and approve proposed remedial actions, including follow-up verification activities, prior to their implementation.

10.3.2 Quality Assurance Manager or Technical Leader

- Will have successfully completed an ANAB Auditor or Assessor Training Course or comparable professional training.
- Ensure internal auditors are adequately trained to properly perform an effective audit.
- Prepare the annual internal audit schedule.
- Ensure annual internal audits are organized and conducted.
- Select and ensure that the audit team leaders and auditors meet the applicable training standards, as defined below.
- Prepare the audit checklist, if used.
- Review all audit findings and propose remedial actions.
- Ensure directed remedial actions are completed, adequate supporting documentation is provided, and all necessary audit related documentation is archived.
- Determination and notification of audit closure.
- Ensure annual accreditation audit reports are prepared and submitted as directed by ANAB.

10.3.3 **Team Leader**

- Read and understand the requirements that are being evaluated in the audit.
- Coordinate the activities of the assigned auditors as necessary to address the scope of the audit.
- Conduct a pre-audit team meeting, if necessary.
- Conduct the on-site audit close-out meeting.
- Ensure any audit checklists used are complete and provided to the Quality Assurance Manager or Technical Leader.

10.3.4 **Auditor**

- Read and understand the requirements that are being covered in the audit.
- Collect audit data, as directed, through reviewing documentation, interviewing personnel, observing operations, and observing conditions and facilities.
- Document the audit results as directed.
- Ensure any audit checklist used is complete and provided to the team leader.

10.4 Audit Practices

10.4.1 **Frequency and Scope**

At a minimum, internal audits are conducted annually.

The scope of audit may include verification of laboratory conformance with specified ANAB accreditation standards; internally defined quality requirements; discipline method and training manual requirements; safety requirements; applicable Bureau Directives; or any other aspect of the laboratory quality management system. The Quality Assurance Manager or Technical Leader is responsible for informing all affected laboratory staff of the scope of the audit prior to its commencement.

Internal Audits must include direct observation of a sampling of testing within each discipline.

During a four-year accreditation cycle, each year's internal audit plan will include one or more of the following special audits, at the discretion of the Quality Assurance Manager:

- Key Log Audit –a full audit of designated laboratory staff's keys/access
- Equipment Audit- a full audit of a designated laboratory section(s) equipment
- Controlled Document Audit- a full audit of a designated laboratory section's active controlled documents
- Evidence Submission Audit- an audit of compliance to designated established submission policies

10.4.2 **Scheduling**

The Quality Assurance Manager or Technical Leaders are responsible for scheduling annual internal audits and notifying all affected laboratory staff. These audits will be conducted between 9 and 12 months after the previous internal audit was completed.

10.4.3 **Team selection**

The Quality Assurance Manager or Technical Leader select the audit team leader or may serve as the team leader. The Quality Assurance Manager or Technical Leader select qualified auditors, as needed to assist in performing the audit.

- Wherever possible, the team leader will have successfully completed an ANAB Auditor or Assessor Training course or comparable professional training.
- Team auditors will have successfully completed the ANAB or ASCLD/LAB Auditor or Assessor Training course or BCI laboratory internal auditor training.
- Audit team leaders and auditors should not participate in audits for units over which they have first level supervisory authority, or are a regional unit member, whenever possible.

10.4.4 **Documents**

The Quality Assurance Manager or Technical Leader is responsible for providing training, instruction, and guidance, as necessary, prior to conducting the audit.

Auditors are responsible for reading and familiarizing themselves with the audit document and any prepared checklist, as well as any additional documents containing requirements for which conformance are being evaluated.

The Quality Assurance Manager or Technical Leader ensures that the proper audit document is selected and, if necessary, a working checklist is prepared. The checklist should be organized in such a way as to prompt the auditor to observe operations and review necessary documentation. Interview questions designed to evaluate conformance may also be provided by the Quality Assurance Manager or Technical Leader.

10.5 Audit Procedure

10.5.1 **Audit Roles**

Auditors will collect sufficient data of BCI Laboratory unit operations specified in the scope of the audit by conducting a review of documentation, interviews with personnel, and observations of operations, conditions, and facilities.

The Team Leader will review the data provided by the auditors. Any potential non-conformities will be documented and brought to the attention of the Quality Assurance Manager or Technical Leader. Documentation will include a statement of the non-conformity, the discipline(s) affected, any associated BCI Laboratory case numbers, and a citation to the specific accreditation standard or quality system requirement.

10.5.2 **Audit team meeting**

The audit team may meet, as necessary, to review the audit data or the progress of the audit. The audit team will seek to resolve any team question or disagreement prior to the close-out meeting.

10.5.3 **On-site audit conclusion**

The audit team leader is responsible for conducting a close-out meeting to inform the auditee (defined as the direct supervisor or designate of the unit audited) of the preliminary results. This meeting will be held as soon as possible following the audit.

The auditee is responsible for informing the team leader of any disagreement with the preliminary results. These issues should be resolved, as much as possible, before the on-site audit is concluded. At the discretion of the team leader, identified nonconformities may be corrected prior to the conclusion of the on-site audit.

Unresolved disagreement between the auditee, team leader, or auditors will be arbitrated by the Quality Assurance Manager or Technical Leader.

10.6 Audit Closure

10.6.1 **Summation**

The Team Leader is responsible for gathering notes, checklists, direct evidence and other pertinent information for the purpose of compiling a summary to the QA Manager or Technical Leader. The summary consists of possible identified nonconformities, or other quality related observations that may require remediation or further consideration.

10.6.2 **Assessment**

The QA Manager or Technical Leader is responsible for assessing the summary results and identifying any necessary remedial action.

The QA Manager or Technical Leader is also responsible for the identification of follow-up activities designed to verify the effectiveness of the remedial actions taken.

The Laboratory Director is responsible for review and approval of recommended remedial actions and follow-up verification activities.

10.6.3 **Remediation**

Laboratory Director approved remedial actions are presented to the auditee. It is the responsibility of the auditee to remediate nonconformities as directed and provide documentation of compliance to the QA Manager or Technical Leader, wherever possible.

10.6.4 **Verification**

Follow-up activities identified to verify effectiveness of the remedial actions are initiated under the direction of the QA Manager or Technical Leader. Results of those activities are documented and retained as per practice.

10.6.5 **Notification**

The QA Manager or a Technical Leader is responsible for determining all remedial actions, including verification activities are complete, and the audit concluded. The QA Manager or Technical Leader is responsible for notifying the Laboratory Director and the auditee of audit closure.

11 Appendix- Laboratory Practices for Measurement Uncertainty

- The laboratory reports measurement uncertainty (1) when values are reported for the weight of controlled substance evidence and (2) when values are reported for the % THC in controlled substance evidence

The estimations for measurement uncertainty may change when any significant parameters that affect the measurement result are varied. Estimations are recalculated upon changes in the affected equipment, personnel, and/or measuring process; following significant changes in laboratory facility; and following recalibration/certification of the measuring equipment.

The purpose of this laboratory practice is to provide a detailed procedure for the on-going collection of data, performance of subsequent calculations, evaluation of the results and reporting.

Applicable Statutes:
Ohio Revised Code Chapters 2925 (Drug Offenses) and 928 (Hemp and Hemp Products) include all applicable legislation; included Section 2925.51 (Evidence in Drug Offense Cases) specifies laboratory analysis and reporting requirements.

11.1 Scope
The BCI Drug Chemistry laboratory section previously applied the NIST 8-Step Process for estimating and reporting Measurement Uncertainty. The results of this initial study identified parameters that require on-going evaluation in order to assess the measurement uncertainty for the weight of controlled substance evidence. The results of the initial reproducibility study are retained by the QA Manager.

A re-calculation of the measurement uncertainty is initiated whenever one of the following laboratory changes occurs: relocation to a new laboratory facility, newly qualified staff begins casework or measuring equipment is newly installed, re-calibrated/re-certified.

11.2 Estimating Measurement Uncertainty (MU) for Weight of a Controlled Substance
Initial Measurement Process Reproducibility studies included approximately 200 measurements collected from the analysts working Drug Chemistry casework.

On-going measurement data should be collected weekly by each of the qualified analysts in the Drug Chemistry section. When an analyst re-locates to a different laboratory bench or balance, additional data should be collected.

Trainees should collect measurement data during the final month of their training period. At least two measurements should be collected per day.
11.2.1 Measurement Process Specifications

- The weighing vessel is placed on a balance, the balance is tared, and the measurement assurance check standard is immediately added to the weighing vessel without removing it from the balance. A single measurement is made where the weight is determined through a functional relationship based on the amount of force on the balance. The functional relationship can be expressed by the mathematical equation:

$$y=mx+b+/-U$$

- The weight is determined using balances with readabilities of 0.01 gram, 0.1 gram or 2 grams.
- Range of Measurement: Minimum balance load to maximum balance load. [y= the measurement result; m= slope or sensitivity of the measurement instrument linearity; x = the indication; b= bias; U = expanded uncertainty]
- Each qualified analyst documents measurement data using the previously established measurement assurance check standard set on each brand and model of measuring equipment. The measurement assurance check standards were designed to mimic case evidence commonly encountered in the Drug Chemistry section. The measurement assurance check standards are secured in heat-sealed plastic containers to prevent loss. The contents include:
    - Paper
    - Vegetation
    - Brown powdery substance
    - Capsules (non-controlled)

Uncertainty Component	Factors Considered
Measuring Equipment	Multiple equipment of the same model
Staff	Multiple analysts, Training, Experience, Time of Day, day of week, Interruptions, Workload
Test Method	Differences in centering of measurement assurance check standard on the balance
Facility	Temperature Variation, Air flow, Vibration, Humidity, Static Electricity, Location of balances in the laboratory buildings

11.2.1.1 Type B Evaluations
A Type B Evaluation is a method of evaluation of uncertainty by means other than the statistical analysis of a series of observations.

Uncertainty components assessed as Type B evaluations:

- Display resolution – impact of rounding at zero and at load value displayed
- Balance calibration uncertainty
- Balance linearity
- Balance bias

- Bias

Display resolution – rounding at zero and at load:
All measuring equipment in use are "single range" balances.
The display resolution of the Shimadzu balances is ~0.01 gram at both zero and at load.
The display resolution of the Mettler balances is ~0. 1 gram at both zero and at load.
The display resolution of the Ohaus balances is ~2 grams at both zero and at load.
The purpose of this uncertainty component is to account for the rounding that is automatically performed by the balance. Because rounding automatically occurs at both zero (taring) and at load, two components will be included.

- Equal to one half the display resolution = ½ of 0.01 g = 0.005g (Shimadzu balances)
- Equal to one half the display resolution = ½ of 0.1 g = 0.05g (Mettler balances)
- Equal to one half the display resolution = ½ of 2 g = 1g (Ohaus balances)

The measurement process reproducibility data may double-count variation separately quantified for the display resolution at zero and at load. Any double counting will result in an overestimation of the measurement uncertainty and as such is considered acceptable by the laboratory.

Balance calibration uncertainty: A review of balance calibration certificates from the accredited external calibration laboratory identifies the greatest expanded uncertainty.

This uncertainty may be provided as a static value or as a function (line, parabola, etc.) of the load on the balance. In cases where expanded uncertainty is provided as a function, suitable weight brackets may be used, using the maximum value of the uncertainty function in the given weight bracket as the value used in calculating measurement uncertainty for any measured weight within the bracket.

Balance linearity: The laboratory procedures to confirm the continued calibration status and ensure proper functioning of the balances have pre-defined performance criteria across the useable range of the balances used for these measurements.

Balance bias: Calibrated mass reference standards are used to confirm the continue calibration status of the balances. This provides the laboratory with an ongoing evaluation of bias.

11.2.2 Converting Quantities to Standard Uncertainties
The measurement unit is the gram expressed in decimal format, where the extended decimal value is later rounded to the appropriate number of significant figures.

Type A evaluation components:

Reproducibility data is recorded in the correct unit (gram) and format (decimal).

When a set of several repeated measurements have been recorded, the mean and the estimated standard deviation should be calculated for the data set.

Type B evaluation components:
Display resolution – rounding at zero and at load

This component is evaluated as a rectangular distribution- see appendix for calculation specifics.

Balance calibration uncertainty:
A review of the calibration certificates from the accredited external laboratory for all the balances used throughout the laboratory system identifies the greatest calibration expanded uncertainty.

Each certificate indicates this expanded uncertainty assumes a normal distribution, a coverage factor of k, where k correlates to the coverage probability of approximately 95% or 99%.

The uncertainty of the calibration certificate will be divided by the coverage factor, k, to arrive at a standard uncertainty- see appendix for calculation specifics.

Balance Linearity:
This component is evaluated as a rectangular distribution- see appendix for calculation specifics.

11.2.3 Calculating the Combined Standard Uncertainty

This estimation assumes that the uncertainty components are independent or uncorrelated and that the measurement result is the sum of a series of components. The combined standard uncertainty (u_c) is the positive square root of the variance of all components combined.

$$u_c(y) = \sqrt{\sum (c_i u_i)^2}$$

The laboratory recognizes the Type A measurement process reproducibility component may double count variation quantified individually by the Type B evaluation components. This double counting cannot be quantified. The laboratory recognizes any double counting will result in an acceptable over estimation of the measurement uncertainty.

~~11.2.4 Expanding the Combined Standard Uncertainty by Coverage Factor (k)~~
~~To expand the calculated uncertainty to 95.45% coverage probability the coverage factor k = 2 is used. To increase coverage probability to 99.73%, the coverage factor k = 3 is used.~~

~~In cases where a limited number of measurements have been taken (where the number of degrees of freedom less is than 200), the appropriate value of k will be selected from a Student's T table~~

~~The Drug Chemistry Measurement Uncertainty Estimation Form uses a budget table to display the expanded uncertainty calculations. This form is attached to this laboratory practice.~~

~~$U = k * (u_c)$~~

~~11.2.5 Measurement Uncertainty with a Calculated Weight~~
~~An overall weight may be estimated via an extrapolation of the average weight of a statistically significant number of packaging units (the "R" number). This practice is generally reserved for very large submissions. A new, critical component to the overall uncertainty is introduced by this technique — the uniformity in weight of the empty packaging units. Logically, if there is wide variability in the weight of the individual packaging units, there must be a greater uncertainty in a total weight calculated from extrapolating the average weight of a packaging unit.~~

~~In circumstances where a calculated weight is employed, the expanded uncertainty shall be determined as follows:~~

~~$$U = k\sqrt{n^2 u_c^2 + \sigma^2}$$~~

~~Where k and u_c have the same meanings as elsewhere in this document, n is the total number of measurement events needed to determine the total gross weight and the weight of the "R" number of packaging units, and σ is the standard deviation of individual weights of the "R" number of packaging units.~~

~~11.2.6 Reporting the Uncertainty~~
~~Report structure/content is controlled by the LIMS Drug Chemistry Matrix, ensuring consistent Drug Chemistry reporting throughout the BCI laboratory system. Upon approval of the new estimate, the updated measurement uncertainty estimates are configured into the LIMS Drug Chemistry Matrix. The LIMS Drug Chemistry Matrix is equipped with a pick list to insert the current Measurement Uncertainty estimations into a report draft for each balance type given either one or two measuring events.~~

~~The expanded measurement uncertainty value will be expressed as the quantity value, y, along with the expanded uncertainty, U, in the form y +/- U. The units of the measurement result and the expanded uncertainty will be the same and the values reported to the same significance. The reported uncertainty should not exceed 2 significant figures.~~

~~Reporting examples:~~
~~Off white substance – 0.23g +/- [Current Estimated MU (gram)] – found to contain Cocaine.~~
~~Vegetable matter – 1027.6g +/- [Current Estimated MU (gram)] – found to contain Marihuana (Cannabis).~~
~~Twenty-eight (28) packets of powder – 0.68 gram (Calculated weight) +/- [Current Estimated MU (gram)] – found to contain.~~

~~The report should also include remarks regarding the coverage probability. The following coverage probability statement may be used:~~

~~"Where applicable, an estimate to the measurement uncertainty associated with the weight of an item has been provided. The coverage probability in such instances is 95.45% (k=2)."~~

~~11.2.6.1 Rounding~~
~~If an overall weight is reported for an item containing two or more measuring events, then the uncertainty in each measurement must be accounted for in the reported overall uncertainty. In order to accurately calculate the combined standard uncertainty, a correlation coefficient that describes the relationship between the weighings must be determined. A conservative approach is to assume that the consecutive weighing events are completely positively correlated. Thus, the sum of each respective uncertainty should be reported, which will likely result in an overestimation of the uncertainty.~~

~~The analyst must refer to the current Drug Chemistry Measurement (located in the Labshare location) to ensure that the expanded numerical value is considered and appropriate rounding mechanisms are applied.~~

~~11.3 Estimating Measurement Uncertainty (MU) for THC Quantitation in cannabis related items~~
~~11.3.1 Measurement Process Specifications~~

- ~~The batch containing the sample run will have two linear, 5-point (or greater) calibration curves, with internal standard. One calibration curve will equate THC peak response to THC concentration; the other calibration curve will equate THCA peak response to THCA concentration. Consider the example below for THC.~~

$$\frac{I_{Sample,THC}}{I_{IS}} = m_{cal,THC} \, xC_{Sample,THC} + b_{cal,THC}$$

~~Where:~~

~~$I_{Sample,THC}$ is the THC peak response of the sample~~
~~I_{IS} is the peak response of the internal standard~~
~~$m_{cal,THC}$ is the slope of the THC calibration curve~~
~~$C_{Sample,THC}$ is the THC concentration of the sample~~
~~$b_{cal,THC}$ is the "y-intercept" (peak response ratio - intercept) of the THC calibration curve~~

~~Solving for the Concentration of the sample:~~

$$C_{Sample,THC} = \frac{\frac{I_{Sample,THC}}{I_{IS}} - b_{cal,THC}}{m_{cal,THC}}$$

~~Using this, the %THC for the sample is:~~

$$\%THC = \frac{C_{Sample,THC}\left(\frac{\mu g}{mL}\right) x \; Dilution \; (mL)}{mass_{sample} \; (mg) \; x \; 1000 \left(\frac{\mu g}{mg}\right)} x \; 100\%$$

~~Using the same technique with the pertinent THCA data will also generate a %THCA value. The total THC (the reported value) is given by:~~
~~Total THC = %THC + (0.877 x %THCA)(by definition, see ORC 928.01 (J)).~~

~~11.3.2 Traceability~~
~~The traceability for this measurement process is established through the calibration of the balances, pipettes, temperature kits and moisture analyzers used to perform the measurement, the mass reference standard weight sets used to confirm the continued calibration status of the balance, and the use of known drug standards for calibration curve development.~~

- ~~The calibration of the balances is performed annually by an external calibration laboratory that is accredited to ISO/IEC 17025, with a scope of accreditation that includes the specifics of the calibration performed.~~
- ~~Continued balance calibration is confirmed weekly using certified weight sets. Weight sets are regularly recertified by an external laboratory that is accredited~~

~~to ISO/IEC 17025, with a scope of accreditation that includes the specifications of the certification performed.~~

- ~~Balance calibration and weight set certification information is maintained by the affected unit and/or the QA Manager.~~
- ~~The calibration of the pipettes is performed annually by an external calibration laboratory that is accredited to ISO/IEC 17025, with a scope of accreditation that includes the specifics of the calibration performed.~~
- ~~Continued pipette calibration is confirmed monthly at the low and high end of the mechanical range.~~
- ~~The calibration of the moisture analyzer is performed annually by an external calibration laboratory that is accredited to ISO/IEC 17025, with a scope of accreditation that includes both the weighing accuracy and temperature. The heating element will be checked monthly with a certified SmartCal Test Substance. The sodium sulfate decahydrate reference will be checked weekly. The temperature kits are used to perform a monthly check of the moisture analyzers. The temperature kits are calibrated every two years by an external vendor to ISO/IEC 17025, with a scope of accreditation that includes the temperature.~~
- ~~Continued moisture analyzer calibration is confirmed monthly.~~
- ~~NIST Traceable certified glassware is used in quantitative casework procedures.~~
- ~~THC/THCA known drug standards records are retained by the affected unit.~~

~~11.3.3 Identification of Uncertainty Components~~

- ~~U(prep) – uncertainty associated with sample and standard preparation~~
  - ~~Uncertainty in standard concentration (x 2, THC and THCA)~~
  - ~~Uncertainty in pipette volume in standard dilution~~
  - ~~Uncertainty with volumetric flask in standard dilution~~
  - ~~Uncertainty in sample mass~~
  - ~~Uncertainty in pipette volume in sample extraction~~
  - ~~Uncertainty in moisture content~~

- ~~U(calib)- uncertainty associated with the calibration curve- generated from the linear regression data with each batch~~
- ~~U(rep)- uncertainty associated with method repeatability- generated from pertinent section of the method validation data~~
- ~~U(bias)-uncertainty associated with bias- generated from the spike recovery section of the method validation data~~

~~Staff:~~

- ~~Analysts from each laboratory~~
- ~~Training~~
- ~~Experience~~

- ~~Time of day, day of week, interruptions, workload~~

~~Test Method:~~

- ~~Differences in centering of measurement assurance check standard on the balance~~

~~Facility:~~

- ~~Temperature variation of laboratory and difference from the temperature during calibration~~
- ~~Drafts – air flow in the laboratory area of the balance or moisture analyzer~~
- ~~Location of measurement equipment in the laboratory buildings~~
- ~~Vibration~~
- ~~Humidity~~
- ~~Static electricity~~

~~11.3.4 Quantification of Uncertainty Components~~

~~11.3.4.1 Type A Evaluations~~
~~A Type A Evaluation is a method of statistical analysis regarding a series of observations.~~

~~The data results of the uncertainty components specified in the table below are evaluated to ensure the following criteria demonstrates fitness for purpose:~~

- ~~The data collected is a normal, non-skewed distribution~~

- ~~The data falls within 1, 2 and 3 standard deviations of the mean. The statistic that will be calculated is the standard deviation for each measurement assurance check standard on the balance.~~

~~Uncertainty Component~~	~~Factors Considered~~
~~Staff~~	~~Multiple analysts, Training, Experience, Time of Day, day of week, Interruptions, Workload~~
~~Test Method~~	~~Differences in centering of measurement assurance check standard on the balance~~
~~Facility~~	~~Temperature Variation, Air flow, Vibration, Humidity, Static Electricity, Location of balances in the laboratory buildings~~
~~U(Mass of Sample)~~	~~Multiple equipment of the same model~~
~~U(Moisture content)~~	~~Multiple equipment of the same model~~
~~U(Calib)~~	~~See below~~
~~U(Rep)~~	~~See below~~
~~U(Bias)~~	~~See below~~

~~**U(calib):** The standard uncertainty for the concentration of THC as a result of the calibration correlation being applied is given by the following relationship:~~

$$u(\overline{C_{Sample,THC}}) = \frac{s_{residual}}{m_{cal,THC}} \sqrt{\frac{1}{p} + \frac{1}{n} + \frac{([C_{Sample\ THC}]_i - \overline{x})^2}{\sum_{i=1}^{n}(x_i - \overline{x})^2}}$$

Where:

$$s_{residual} = \sqrt{\frac{\sum_{i=1}^{n}[\frac{I_{i,THC}}{I_{IS}} - (m_{cal,THC} \times x_i + b_{cal,THC})]^2}{n-2}}$$

$I_{i,THC}$ is the THC peak response of the i-th calibration standard

I_{IS} is the peak response of the internal standard

$m_{cal,THC}$ is the slope of the THC calibration curve

$b_{cal,THC}$ is the "y intercept" (peak response ratio – intercept) of the THC calibration curve

p is the number of repeated measurements for the given sample

n is the total number of standards used for plotting the calibration curve

$\overline{x}$ mean value of the concentrations of all the calibration standards

x_i concentration of the i-th calibration standard

Relative standard uncertainty u(calib)= $u(\overline{C_{Sample,THC}})/\overline{C_{Sample,THC}}$ This value is be calculated on a per-batch basis.

U(rep): A significant component of uncertainty is with the repeatability of measurements. This will be assessed based on repeated measurements of the same material collected in conjunction with the method validation.

This value will be reassessed as new analysts begin cannabis casework using data from their training mirroring the repeated measurements performed in the method validation.

U(bias): Was modeled after the similar section in the Eurachem guide, and taken from spike recovery measurements in the method validation.

This value will be reassessed as new analysts begin cannabis casework using data from their training mirroring the spike recovery measurements performed in the method validation.

U(sample mass): Will be calculated using both Type A and Type B evaluations and will revert to the procedures outlined in section 11.2.

~~11.3.4.2 Type B Evaluations~~
~~A Type B Evaluation is a method of evaluation of uncertainty by means other than the statistical analysis of a series of observations.~~

~~**U(Standard concentration):** standard preparation~~
~~A review of the THC and THCA standard certificates identifies the concentration expressed with an expanded uncertainty at the 95.45% confidence interval. A coverage factor of k = 2 is used and incorporates uncertainties from the corrected purity*, solution preparation, homogeneity, and long- and short- term stability.~~
~~*Note: Corrected purity is a measure that corrects for residue on ignition, chromatographic purity, and either loss on drying or Karl Fisher water titration and residual solvents]~~

~~These values will be reassessed whenever a new reference material is utilized. If the standard's certified concentration uncertainty has not changed, then no recalculation of overall uncertainty is needed.~~

~~U(dilution):~~
~~Appropriate factors will be included from the certificates of analysis of the various glassware and pipettes used in the preparation of the calibration standards and the samples.~~

~~At present, the uncertainty from volumetric flasks has been determined insignificant (more than an order of magnitude less impact than other components).~~

~~These values will be reassessed whenever equipment is switched (different pipettes) or new calibration standards are prepared (using different volumetric flasks).~~

~~11.3.5 Converting Quantities to Standard Uncertainties~~
~~Each individual quantity (for example, an uncertainty in pipette volume, measure in mL) will be rendered unitless by dividing the uncertainty by the volume utilized in the measurement.~~

~~11.3.6 Calculating the Combined Standard Uncertainty~~

~~This estimation assumes that the uncertainty components are independent or uncorrelated and that the measurement result is the sum of a series of components. The combined standard uncertainty (u_c) is the positive square root of the variance of all components combined.~~

$$u_c(y) = \sqrt{\sum (c_i u_i)^2}$$

~~The laboratory recognizes the Type A measurement process reproducibility component may double count variation quantified individually by the Type B evaluation components. This double counting cannot be quantified. The laboratory recognizes any double counting will result in an acceptable over estimation of the measurement uncertainty.~~

~~11.3.7 Expanding the Combined Standard Uncertainty by Coverage Factor (k)~~
~~To expand the calculated uncertainty to 95.45% coverage probability the coverage factor k = 2 is used. To increase coverage probability to 99.73%, the coverage factor k = 3 is used.~~

~~In cases where a limited number of measurements have been taken (where the number of degrees of freedom is less than 200), the appropriate value of k will be selected from a Student's T-table or using the related Microsoft Excel function (T.INV.2T).~~

~~The Drug Chemistry Measurement Uncertainty Estimation Form used a budget table to display the expanded uncertainty calculations. This form is attached to this laboratory practice.~~

~~$U = k * (u_c)$~~

~~11.3.8 Evaluation of the Expanded Uncertainty~~
~~The laboratory evaluates the estimation of uncertainty to ensure the following:~~

- ~~The estimation is void of calculation errors~~
- ~~Ensure the estimation is within the limits of acceptable expanded uncertainty~~
  - ~~The expanded uncertainty for a single measurement event should be less than 25% relative of the measured value.~~

~~11.3.9 Incorporation of MU into Quality Management System~~
~~The expanded measurement uncertainty will be updated in the following records to ensure the appropriate MU is reported:~~

- ~~The Equipment Records associated with any updated calibrations performed~~
- ~~Active Lab Forms associated with MU Calculations~~
- ~~LIMS Matrix Panel options for MU~~

~~11.3.10 Reporting the Uncertainty~~

~~The expanded measurement uncertainty value will be expressed as the quantity value, y, along with the expanded relative uncertainty, U, in the form y +/- y*U. The units of the measurement result and the expanded uncertainty will be percent and the values reported to the same significance, using traditional rounding rules. The reported uncertainty should not exceed 2 significant figures.~~

~~The report should also include remarks regarding the coverage probability. The following coverage probability statement may be used:~~

~~"Where applicable, an estimate to the measurement uncertainty associated with the weight of an item has been provided. The coverage probability in such instances is 95.45% (k=2)."~~

~~11.3.11 References~~

~~1. Tomić, T., Uzorinac Nasipak, N. & Babić, S. Accred Qual Assur (2012) 17: 291. https://doi.org/10.1007/s00769-011-0872-0.~~
~~2. EURACHEM/CITAC Guide CG 4. "Quantifying Uncertainty in Analytical Measurement". Third edition. https://www.eurachem.org/images/stories/Guides/pdf/QUAM2012_P1.pdf~~

~~11.4 References~~

~~ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty- Overview. AL-PD-3061 Ver 1.0 May 22, 2013.~~

~~ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty- ANNEX A. AL-PD-3062Ver 1.0 May 22, 2013.~~

~~ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty- ANNEX B. AL-PD-3063Ver 1.0 May 22, 2013.~~

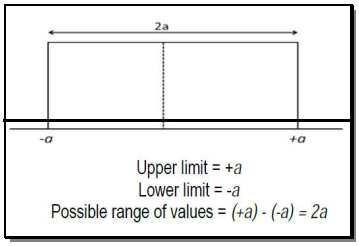
~~ASCLD/LAB Guidance on the Estimation of Measurement Uncertainty- ANNEX C. AL-PD-3064 Ver 1.0 May 22, 2013.~~

~~SWGDRUG Supplemental Document: SD-3. Quality Assurance/Uncertainty. Measurement Uncertainty for Weight Determinations in Seized Drug Analysis. 2011-07-07. 9. 14~~

~~11.5 Drug Chemistry Calculations~~

~~**Display resolution – rounding at zero and at load**~~

~~This component is evaluated as a rectangular distribution:~~



~~Standard uncertainty for rectangular distribution is calculated by:~~

~~Standard uncertainty = a/√3~~

~~**Outside limit = ½ the readability of the balance at zero**~~

~~For Examples:~~

~~Shimadzu = ½ (0.01 g) = 0.005 g~~

~~Shimadzu standard uncertainty = 0.005 g/ √3 = 0.0028867513 g~~

~~**Outside limit = ½ the readability of the balance at load**~~

~~Shimadzu = ½ (0.01 g)~~

~~Shimadzu standard uncertainty = 0.005 g/ √3 = 0.0028867513 g~~

~~**Balance calibration uncertainty:**~~

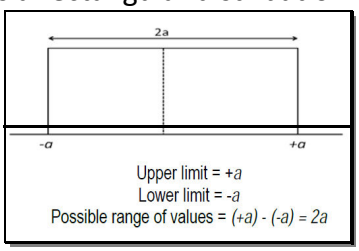
~~The uncertainty of the calibration certificate will be divided by the coverage factor, k, to arrive at a standard uncertainty. For example:~~

~~Calibration Uncertainty = 0.23103490 g~~

~~Standard Uncertainty= 0.23103490 g / 2.00 = 0.11551745 g~~

~~**Balance Linearity:**~~

~~This component is evaluated as a rectangular distribution:~~



~~**Outside limit**~~

~~Shimadzu = 0.02 g~~

~~Shimadzu standard uncertainty = 0.02 g/ √3 = 0.011547005 g~~

11 Appendix- Laboratory Practices for Evidence Handling

11.1 Purpose

The BCI laboratory will ensure the integrity of the evidence in its custody to protect the interests of the laboratory and its clients. This will be accomplished by prescribing rules for transporting, receiving, handling, protecting, storing, retaining and returning evidence, and by documenting the chain of custody to provide for the generation of legally admissible chain of custody records.

11.2 Scope

These practices apply to all BCI laboratory employees, test items and submissions at all locations.

11.3 Definitions

11.3.1 Evidence Defined

All items submitted to the laboratory for examination will be treated as evidence.

When a portion of the evidence is preserved for future/additional testing, it will be treated as evidence. Examples include: swabs collected from evidence, cuttings taken from evidence, casts, fingerprint lifts, extracted DNA, test fires and ESDA transparencies.

Digital or traditional photographic images that are the primary record of an analytical result (such as captured images of ninhydrin treated latent prints) shall be considered evidence, as they are likely not reproducible. Media on which the primary record images are archived will be treated as evidence.

11.3.2 Non-evidential Items Defined

Other materials, conditions or situations not specifically covered herein will be stored as work product. This includes test papers/mappings or other products and are not preserved for future testing, as defined above.

11.3.3 DNA database samples

DNA samples collected by law enforcement agencies pursuant to Ohio law and sent to the laboratory for entry into the DNA database are recognized as an exception to evidence, as defined above.

A database sample will not be used as evidence in a criminal case unless the offender is deceased, and no other samples are available for the individual.

Employee DNA elimination samples and profiles maintained in conjunction with the DNA database are not considered evidence.

11.3.3.1 Individual Characteristic Database samples

Individual Characteristic Database samples, such as finger and palm print exemplars of known individuals or their electronic image equivalents shall not be considered evidence. When individualization is made with such a sample, the electronic image equivalent used or a legible reproduction of the known exemplar must be retained in the case record.

Images entered and/or acquired from the NIBIN or footwear databases are not considered evidence. Comparisons leading to a reported conclusion must be performed using the evidentiary item represented by the image.

Though not treated as evidence, sufficient precautions and securities are exercised to ensure any individual characteristic database sample under control of the laboratory is protected from loss, cross transfer, contamination and/or deleterious change and in a manner that ensures their continued utility as comparative materials.

11.3.4 **Evidence images**

Digital or traditional photographic images taken in the laboratory and used as examination documentation are not evidence.

11.4 Evidence Reception Methods

11.4.1 **Acceptance**

BCI is authorized by the Ohio Revised Code to provide technical support, such as forensic laboratory services, and to otherwise cooperate with law enforcement agencies in Ohio in the investigation of criminal matters. Services may also be provided to investigating agencies outside Ohio, including federal agencies.

The BCI laboratory will not accept evidence in cases for which no criminal prosecution is intended unless specifically authorized by a laboratory manager.

Laboratory management may permit retesting *when previously tested by an outside lab* if the BCI laboratory is able to provide other, or more advanced forensic technologies that might offer additional distinguishing information. This policy does not apply to inter-laboratory cooperative quality assurance actions, such as verification.

The submitting agency is permitted to request an evidence submission policy exception or rush analysis. The requests should be brought to the attention of laboratory management.

Policy exception or rush request correspondence that occurs prior to the submission of evidence items (i.e. prior to LIMS case creation) should be documented in Sharepoint by laboratory management. Upon receipt of evidence, the EIT in Evidence Receiving will verify the approved request prior to accepting the evidence. Approved requests will be documented in the individual case record and the Sharepoint entry can be removed by AGO ITS after 6 months.

11.4.1.1 Rush Requests

Typically, rush requests are considered for upcoming trial dates or immediate threats to the community.

Drug Chemistry rush requests are limited to one item per case. Requests may be considered for approaching Grand Jury hearings where the suspect is in custody.

DNA analysis rush requests can be turned over within days, if the request meets the following criteria:

- The perpetrator is unknown
- Violent crime against a person
- Evidence must be directly related to the crime
- Evidence consists of body fluids (no touch DNA evidence)

11.4.2 **Evidence Receipt**

Evidence may be received for analysis at any of the three full service laboratories in London, Richfield and Bowling Green, Ohio, or at designated, regularly scheduled remote submission locations.

Evidence shall be submitted during normal business hours unless specifically authorized by laboratory management.

11.4.2.1 Hand Delivery

Evidence may be received via hand delivery from a submitting agent to a member of the Evidence Receiving staff. Evidence may be similarly received, as necessary, by other appropriately trained laboratory personnel.

11.4.2.2 Electronic Delivery

Digital Images of evidence may be received via e-mail from a submitting agency. The person receiving the email should retain the image by either printing the digital image or saving a copy to media such as a DVD. The evidence item should be added to LIMS as part of a new case record or an existing case record (as appropriate). The email should be printed and marked with the BCI case number, date, and the initials of the receiving employee and placed in the case record. A submission sheet will be issued to the submitting agency.

The retained image custody will be tracked in LIMS and eventually returned to the submitting agency.

11.4.3 **Submission designations**

Each submitting agency investigation is independently entered into LIMS as a separate case. For instance, evidence submitted on the same suspect for a separate offense or a separate date of offense will each be a new submission, not an additional submission, and will receive a separate case number. Exceptions are permissible upon request from the submitting agency.

Each new case will be checked to ensure it is not an additional submission or a resubmission using one or more of the following methods:

- The packaging will be inspected for an indication of being previously worked, such as, the presence of existing LIMS barcodes and prior seals and/or markings from BCI laboratory staff
- The submitting officer will be asked whether it is a new case, additional submission, or a resubmission
- ~~A query of the names will be made through the LIMS~~
- LIMS will detect and display a prompt regarding cases identified with duplicate agency case numbers during the entry process

11.4.3.1 New submissions

The original submission on an individual case will receive a unique BCI case number, as described in these practices.

11.4.3.2 Additional submissions

Additional evidence submissions are defined as new item submissions that have not been previously submitted on an individual case. The submission will be entered under the previously assigned BCI case number, except as specified above.

If an item is an additional submission to more than one case (cross reference) it will be assigned to all associated case numbers.

If an additional item is submitted on a case, the original scientist(s) for the relevant unit(s) should receive the assignment(s), whenever possible.

11.4.3.2.1 Additional submission procedure

If a report has been written by the relevant unit, the original case scientist will receive the assignment for the additional item(s), whenever possible.

If there is an open assignment for a relevant forensic scientist that scientist will receive the resubmission assignment. If there was not a previous assignment for that unit an assignment will be made for the required unit. Laboratory management may be consulted as necessary to assign a case scientist. *See the LIMS.Net Guide for the procedure.*

- ~~If an agency case number is provided, enter the additional submission via the "Quick Create" function. Otherwise:~~
  - ~~Open the existing LIMS case, browse to the "Submissions" tab and select the "Add" icon.~~
  - ~~Enter the submission type, tracking number (if applicable), and submitted by information into the fields. Click "Save".~~
  - ~~Browse to the Items tab.~~
  - ~~Select "Add" and enter the appropriate item type, packaging and description.~~
- ~~Click "Save".~~
- ~~Browse to the "Assignments" tab and click "Add". Select the appropriate assignment type and select the associated item numbers.~~
- ~~Click "Save."~~
- ~~Browse to the "Submissions" tab, edit to include any comments/remarks, and then select the "Receipt" icon to print a submission sheet. Provide a copy of the submission sheet to the submitting officer.~~

11.4.3.3 Resubmissions

Resubmissions are defined as those containing previously submitted and returned items of an individual case that require additional analysis and/or comparison. Resubmitted evidence will be entered under the original BCI case number. *See the LIMS.Net Guide for the procedure.*

~~Evidence resubmitted to the laboratory in new packaging should be entered in LIMS by designating the item number as "<insert original item number>_ resub". Any~~

~~discrepancies discovered regarding the contents will be disclosed to the submitting agency on the laboratory report.~~

Evidence resubmitted to the laboratory by an agency other than the original submitter shall be entered under a new BCI case number. The new case number can then be linked to the original case in LIMS. Alternatively, if the additional submission is re-submitted by the prosecutor's office in preparation for trial for the same investigation, then the evidence may be documented under the original case number and a comment may be added to the submission record in LIMS.

~~12.4.3.3.1 Resubmission procedure~~

- ~~The original submission is reviewed to verify the item, case type, and agency case number.~~
- ~~The procedures for entering these cases in the LIMS are as follows:~~
  - ~~Open Quick Create, enter case information exactly as it appears in the original submission, the case is then populated in the Quick Create fields.~~
  - ~~Open the Returned Items tab in Quick Create.~~
  - ~~Scan the item barcode label for the resubmitted item.~~
  - ~~Add the assignment to the "section" field.~~
    - ~~If a report has been written by the relevant unit, the original case scientist should receive the assignment, whenever possible.~~
    - ~~If there is an open assignment for a relevant forensic scientist that scientist will receive the resubmission assignment. If there was not a previous assignment for that unit an assignment will be made for the required unit.~~
    - ~~Laboratory management may be consulted as necessary to assign a case scientist.~~
- ~~Click the Quick Create button to complete the resubmission.~~

11.4.4 **Typical Evidence Submissions**

Each evidence submission must be evaluated by the Evidence Receiving staff in regard to the laboratory services offered by BCI, and appropriate packaging /labels /seals /*storage conditions*.

11.4.4.1 Packaging

All evidence received by the BCI laboratory will be packaged to ensure that it can be safely handled and to protect it from loss, cross transfer, contamination and/or deleterious change.

All evidence that is not properly packaged on submission will receive additional packaging by the submitting officer or Evidence Receiving personnel prior to being received (whenever possible).

Potentially hazardous evidence (such as firearms, knives, and other sharp implements), or items containing potentially hazardous materials (such as unbroken mercury thermometers, chemical containers, etc.) must be packaged and/or marked for safe handling and stored in a manner to ensure individual safety. All knives and other sharp instruments will be packaged in a puncture-resistant container.

Guidance from laboratory management or the appropriate laboratory unit should be requested as necessary.

11.4.4.1.1 General packaging requirements

All evidence will be contained in a package that is suitable using the following guidelines:

- Small evidence must be submitted in a package that is a minimum of ~ 5x7 inches in size. Please note that drug chemistry evidence is an exception; small items are placed in containers during evidence submission that exceed these dimensions.
- The size of the container must be of sufficient size to accommodate and ensure the item(s) can be re-packaged with a proper seal.
- The strength of the container must be sufficient to hold the weight of the item(s).
- The evidential area(s) of large items may be protected and properly sealed to avoid packaging the entire item (e.g. long handled tools, doors, etc.).
- Exceptions to the packaging practices described below are permitted, as necessary, to accommodate size, condition or analytical requirements of the submitted evidence.
- Wet items, (i.e. clothing, vegetation) should be dried before being packaged. Wet items may be submitted to the laboratory, upon laboratory management approval.
- If a bone is received dry in a paper bag, it should remain in this packaging and may be placed on a shelf in the main property room. If the bone is submitted wet or frozen, then the item should be packaged in plastic (if not already in a waterproof container) and placed in a freezer.
- Evidence collected from different areas/sources should be packaged separately to avoid cross contamination and labeled accordingly.
- Multiple known standards collected from a single person should be listed as a single item and packaged as one item or one container. Whenever possible, the type of standard should be disclosed by the submitting agency (e.g. victim, elimination, or suspect standards).

11.4.4.1.2 Plastic packaging

- Separately identified money and valuable evidence will be packaged in plastic and heat sealed.
- Drug evidence will generally be packaged in plastic and heat sealed.
- The following evidence types will be packaged in plastic, heat sealed and may be stored at reduced temperatures (i.e. refrigerator or freezer): Khat, condoms, products of conception, edible drug evidence and evidence with suspected bug infestations
- Arson evidence may be packaged in arson-specified Nylon plastic bags or metal cans.

11.4.4.1.3 Paper packaging

- All biological evidence should be packaged in paper, except as listed above or an exception is approved by DNA Lab management.
- Original documents evidence should be packaged in paper.
- Marijuana cultivation cases and other large bulk evidence submissions may be packaged in paper, as necessary.

11.4.4.2 Incoming Evidence Seals

All evidence received by the BCI laboratory will be sealed to ensure that it is protected from loss, cross transfer, contamination and/or deleterious change and such that opening an item causes obvious damage or alteration to the packaging and/or its seal.

The receiver must ensure the submitter has sealed the item to sufficiently meet the requirements above and has initialed the outermost package seals for which they are responsible.

11.4.4.2.1 Seal correction

Evidence received by the laboratory that has not been properly sealed will be sealed and initialed by the submitting officer whenever possible or by the laboratory personnel receiving the evidence.

Unmarked seals will be corrected before being received into evidence.

The employee receiving the evidence may correct a seal by placing a piece of tape perpendicular to the original tape seal and initialing across the supplemental tape seal. Across the seal is defined as half on and half off for tape seals and directly across a heat seal.

If the condition warrants, the item may be placed into a new package and properly sealed.

11.4.4.3 Marking/Labeling Incoming Evidence

Evidence marking serves to identify items before and after examination, while in storage, and for purposes of disposition. Post-examination evidence markings consist of the BCI laboratory case number, item number and the examiner's initials.

As each item is received, it may be initially marked with a handwritten item number. Each item package will be permanently marked with the case and item number using a LIMS barcode label in the presence of the submitter, whenever possible.

Whenever possible, the label should be placed near any existing handwritten item number and in a location that is visible during storage (i.e. ends or sides of boxes, near the upper right corner of envelopes, etc.)

No evidence or evidence package should display more than one viable BCI LIMS barcode label. Shared proficiency test samples or custody correction LIMS Container barcodes are the exception.

- Shared proficiency test samples- may display barcodes from multiple case numbers which are applied to track the handling of a proficiency sample for each scientist assigned.

- Custody correction LIMS container- may be created to force sub-items with a broken chain of custody to appropriately follow a parent item chain. These LIMS container barcodes should be placed near the item number barcode to ensure visibility. Evidence transfers must include a scan of both the item number barcode and the LIMS container barcode in order to accurately reflect the internal chain of custody.

11.4.4.3.1 Labels on DNA Reference Standards

DNA reference standards must be labeled with the name of the individual who the sample was collected from (e.g. “swabs from John Doe”, “pants from Jane Doe”, or “DNA standard from John Doe”).

11.4.4.3.2 Labels on Drug Evidence

Drug Evidence related to possession criminal investigation submissions must be labeled with the name of the suspect involved.

11.4.4.4 *Storage Conditions*

Dry evidence is routinely stored at room temperature. If moisture is observed inside plastic packages, the evidence may be stored in the refrigerator or freezer.

Additionally, any active bug infestations observed will be handled as follows:

- *Temporarily secure the evidence in a heat-sealed plastic.*
- *Store the evidence in the freezer for at least 5 days prior to performing laboratory examinations*
- *Staff in contact with the infested evidence should place their laboratory coat and/or clothing in heat-sealed plastic immediately to prevent further exposure*
- *The Laboratory Supervisor will notify the investigating department of the actions taken to the evidence. In some circumstances, it may be necessary to notify departments related to evidence stored in close proximity to the infested evidence.*
- *If items known to have bed bug exposure at submission see procedure in 12.10 for evidence storage considerations*

Evidence submitted with lithium batteries enclosed will be stored in a flammable cabinet.

Evidence collected from a clandestine laboratory may be stored in flammable cabinet.

11.4.5 **Containers**

Containers, such as boxes or bags, may be used to facilitate internal evidence handling practices.

Circumstance	**Container Package Examples**	**Container Labeling**	**Container Seal**
Grouping/tracking multiple items from	Plastic zipper bag	LIMS container barcode	Yes- upon placing the container in a

one case to facilitate evidence transfers (e.g. DNA sub-item containers)			return storage location
Security/Safety Purposes (e.g. Drug Chemistry evidence)	KPAK, plastic bag	LIMS container barcode	Yes, to minimize handling of internal contents
To avoid loss of small package from one case; only one item per container (e.g. Fired casing packaged in small coin envelope)	Clear plastic bag (larger than ~ 5 x 7")	None- Item barcode only	Yes, to prevent loss
BCI bulk transport of multiple items from multiple cases *	Plastic, Banker Box, Tote, etc.	No LIMS container barcode	No- individual items contained are sealed

* The container packaging may be discarded after use

Containers created during evidence submission must be sealed and initialed by the submitting officer. Containers created by laboratory staff must be sealed by laboratory staff (with appropriate markings) upon return to department.

11.4.6 **Laboratory Services Offered at BCI**

The BCI laboratory facilitates the operation of the laboratory through defined evidence acceptance and testing protocols.

11.4.6.1 Drug Chemistry

- Identification of potential controlled substances
- Quantitation of THC content (*vegetation and oil)*

Drug Chemistry evidence shall be heat sealed in a plastic container. Exceptions due to size or condition (e.g. moisture) are permitted.

Considerations that may affect the submission:

- Residues and drug paraphernalia will not be accepted for analysis unless there are no other items in the case to be tested, for the listed subject.

- The anticipated degree of the offense and the approximate gross weight of the substance should be provided by the submitter; A minimum of ~*3* ~~5~~ grams and anticipated pursuit of Felony ~~1 or Felony 2~~ charges is required for all THC Quantitative lab requests.

- ~~Pills will be separated into like populations prior to testing. Generally, only one pill per population will be tested.~~

- Different types of drugs should be packaged separately and submitted as different items (i.e. tablets packaged separately from bags containing powder). In addition, tablets should be separated by markings into separate items prior to submission.

- Whenever possible, the liquid from syringes should be transferred into a small vial prior to submission to the laboratory. If the syringe does not have a needle intact, the barrel may be submitted to the laboratory and treated as a residue evidence item.

- Syringes with needles attached must be packaged in a sharps container which is clearly marked "Bio-hazard". The syringe <u>will not</u> be accepted at BCI and the submitter may be referred to a toxicology lab if:
    - Liquid is in the syringe is red in color
    - There is no liquid in the syringe <u>and</u> the offense is not death-related

- ~~After removing the cap and dispensing a portion of the contents for analysis, the syringe cap will be replaced using a one-handed technique or a syringe re-capper safety device.~~

- Marijuana must be dried before being submitted to the laboratory to prevent mold growth. If circumstances dictate, accommodations may be made to dry a limited amount of marijuana.

- Fresh Khat evidence must be stored frozen.

- All Clandestine lab evidence that is accepted must be safely packaged. Liquid evidence may contain flammable solvents, and should be labeled with "flammable" stickers upon receipt and stored in the secure hazardous chemical storage cabinet.

- Bulk solvent containers (i.e. propane tanks, fuel canisters, fire extinguishers, etc.), gas generators with tubing attached, multi-layered liquids, liquids with apparent lithium (i.e. black specks) will not be accepted by the BCI laboratory. Cold pack submissions should be avoided whenever possible. Personal protective equipment such as gloves, masks and/or goggles should be worn when handling due to:
    - Strong acids and bases that can injure flesh and eyes

- Cold Packs contain ammonium nitrate, which can cause skin burns if exposed
- ~~When analyzing evidence, ensure proper ventilation in the lab space. Examination in the fume hood is recommended, as the evidence may contain noxious fumes, the potential for spills and for explosion.~~

11.4.6.2 Firearms

- Bullets and/or cartridge cases comparisons
- NIBIN requests
- Serial number restoration, upon request

Firearms should be packaged in boxes. If the evidence receiving personnel are advised that a firearm is loaded, authorized staff will make the firearm safe whenever possible. If the condition of the firearm does not allow it to be unloaded, then the packaging shall be marked “Loaded Firearm”.

Considerations that may affect the submission:

- Cartridge cases found inside firearms will not be compared.
- Serial number restoration will only be conducted upon request.
- Investigations classified as “Questioned Death” will require clarification regarding case circumstances before analysis is conducted.
- Test fire submissions should be accompanied with the make, model and serial number of the firearm to which they were generated from.
- Firearms will only be test fired for cases in which fired cartridge cases and/or bullets are also submitted as evidence for comparison, and exceptions may be made for those submitted for DNA swabbing and NIBIN entry.
- Whenever firearms are submitted that are submerged in a fluid, such as water or oil, the evidence examination should be prioritized to prevent development of rust.

11.4.6.3 Latent Prints

- Latent Print comparisons
- Latent Print processing
- AFIS search requests

Latent print evidence will typically be packaged in paper, except for drug evidence which will be packaged in plastic. Latent lifts may be packaged together and each individual lift should be labeled as to where it was collected from.

Digital Latent Print evidence should include a scale and it is preferred to be submitted in a .TIFF format.

Considerations that may affect the submission:

- Fired and unfired cartridges (rounds), tools foreign to the scene, baggies containing unknown powder, lug nuts, padlocks, money and syringes will not be accepted for Latent Print examination
- If a probative identification is made to a subject, additional items will not routinely be examined, unless circumstances dictate the need for additional analysis (i.e. multiple perpetrators).
- Evidence submitted for violent crimes will generally have both DNA and Latent Prints assignments created, with the exception of beverage containers, to ensure that a co-examination of the evidence is performed. The evidence type, case circumstances, and current laboratory testing methods will be considered in order to determine the best workflow for the evidence.
- Evidence submitted for non-violent crimes will be assigned initially to one unit only.
    - *DNA* ~~FB~~ Assignments: tools brought to the crime scene by subject/beverage containers/lighters; firearms; A LP assignment will only be created if ridge detail is observed during the initial examination and no individual was identified during DNA testing
    - LP Assignments: items moved/handled at the crime scene, lifts, etc.

11.4.6.4 Questioned Documents

- Handwriting and/or hand printing comparisons
- Alterations and/or obliterations
- Processing for indented writing
- Mechanical printing comparisons
- Scratch-off Ohio Lottery Tickets Quality Assurance Testing

Considerations that may affect the submission:

- Document examinations are only conducted at the London BCI laboratory.
- Questioned Document evidence may be in the form of original documents or copies, this distinction should be acquired upon receipt of the evidence.
- Evidence submissions for handwriting examinations should indicate whether the evidence package contains questioned or known writing.
- The standards should be written on the same type of document (i.e. check) with the same type of writing instrument and the same style (i.e. print to print or cursive to cursive) as the questioned writing.

- Digital BMV or other electronic signatures are not sufficient reference standards

11.4.6.5 Trace/GSR

- Footwear and tire impressions
- Hand stubs-GSR
- Clothing or other surface stubs-GSR

Considerations that may affect the submission:

- BCI will test Gunshot Primer Residue (GSR) test kits from shooting subjects only. There will be no analysis for gunshot primer residue on samples from shooting victims.
- GSR samples from objects such as vehicles, bedding and home furnishings will not be tested.
- Digital Impression evidence should include a scale and it is preferred to be submitted in a .TIFF format.
- Evidence submissions for trace examination comparisons should indicate the source of the sample and whether the evidence package contains questioned or known samples.
- When a case is submitted with evidence for DNA/LP and Trace Evidence examination, the trace evidence assignment will only be created if the DNA/LP assignment does not generate an association to an individual.

11.4.6.6 ~~Forensic Biology/~~DNA

- Mitochondrial DNA testing will be processed by the CODIS MPS Section when needed for analysis of unidentified human remains and samples associated with a missing person or a relative of a missing person.
- Evidence that contains potential body fluids or cellular material (sexual assault kits, clothing, weapons, bedding, etc.)
- Human remains for identification purposes
- Fetus/product of conception, along with comparison DNA standards
- Additional submissions that only contain DNA standards

Considerations that may affect the submission:

- Touch evidence will be processed by the ~~Forensic Biology~~ *DNA* section only if it has not been previously processed by another discipline, with the exception of clean/sterile processing methods previously conducted. BCI defines touch DNA evidence as an item that has had brief skin contact. This does not include items that may contain saliva such as beverage containers, or cigarette butts or items that have undergone prolonged contact such as clothing or tools.

- Permission for consumption is required in capital cases when there is limited DNA available for testing if:

- 1) the investigation is a capital case
- 2) a subject has been named

- All rape kit submissions will be examined, regardless of investigation status.

- Items submitted for mitochondrial DNA testing will be processed by the CODIS MPS workflow.

- Providing reference standards from subject(s) and all individuals for elimination at the time of case submission will reduce the time to obtain a final report.

- Criminal parentage or unidentified human (remains) case submissions must include a buccal swab standard from mother/alleged mother, father/alleged father, and the child or product of conception (stored frozen, no preservatives). No partial submission will be accepted, unless case circumstances dictate (such as deceased mother, questionable maternity, or father is unknown).

- Samples from homicide and sexual assault cases will be completed in a timely manner. If the DNA turnaround time were to increase to 60 days or greater for all case types, BCI will prioritize homicides and sexual assaults.

11.4.7 **Detailed Narrative of Case Facts**

A submitting agency must provide a description of evidence included in the lab submission and a synopsis/narrative must be provided for all submissions to inform the Forensic Scientists of:

- How the evidence relates to the crime in question
- To whom the evidence belongs
- Where the evidence was located

This administrative document will be scanned to the LIMS image vault in the case record.

11.4.8 **External Evidence Tracking Systems**

BCI Laboratory is responsible for maintaining the continuity of external evidence tracking systems for sexual assault evidence collection (SAEC) kits, at the direction of the AGO.

11.4.8.1 SAEC Kit Tracking Procedure

1. Identify the SAEC tracking barcode on the kit.
2. When logging the evidence into *Prelog* ~~LIMS~~, ~~add~~ the *officer is required to enter the* OHR tracking number *attribute for Sexual Assault Kits logged in the case* ~~in~~

~~the "location field"~~. For example, OHR-000665. This will enable a search in LIMS by the SAEC Kit tracking number.

3. Each day you receive kits with SAEC tracking barcodes, update the kit tracking site: https://sakt.ohioattorneygeneral.gov/login, using the individual BCI Laboratory account login.
4. Record receipt of the SAEC kit.
    a. click on the SAEC Kit tracking number or the 3 dots to the right
    b. click on 'receive kit' in the upper right corner
    c. 'from' field – type the agency name or use drop down
    d. 'received date' – use calendar to enter the date the kit was received at BCI
    e. click receive
5. Record the deposition of the SAEC kit, when returned to the submitting agency:
    a. click on the SAEC Kit tracking number or the 3 dots to the right
    b. 'completed date'- this is the date you are returning evidence to the department
    c. 'DNA database entry'- select "n/a", click save
    d. select the investigating LEA name
    e. 'sent date' this is the date you are returning evidence to the department

11.5 Atypical Evidence Types

It is recognized that submissions will be presented that are outside of the BCI laboratory's standard acceptance guidelines. Laboratory Management will be contacted if there are any questions about the type of evidence, requested examinations, or authority of the submitting agency.

Atypical evidence types are those items that present a known concern for the safety of the BCI laboratory staff and environment and/or are outside the accredited testing services of the BCI laboratory. These evidence types include, but are not limited to, the following:

11.5.1 Weapon of Mass Destruction

Weapons of Mass Destruction that are presented in the form of unknown powders are those substances suspected as being something other than a controlled substance (e.g. anthrax). Suspected Weapons of Mass Destruction will not be accepted for analysis.

Laboratory management must be immediately notified if this type of case is presented to Evidence Receiving. The submitter may be referred to the Ohio Health Department or the Federal Bureau of Investigation.

11.5.2 **Explosive Evidence**

Explosive device evidence must be approved by Laboratory Management. Any explosive analysis requests may be referred to the State Fire Marshal's Forensic Laboratory. Alternatively, latent lifts or swabs collected from the evidence may be submitted by the submitting agency.

11.5.3 **Currency submissions**

Currency submissions contain items identified as, or items that include bank notes and/or coinage. Customer identified currency submission amounts should be specified in the item description or otherwise documented in the case record. Examination and return of $5,000 (U.S., or equivalent amount in other currency types) or greater currency containing items should be prioritized.

Currency of any value identified during the examination process should be noted in the case documentation. Laboratory management will be immediately notified of any discrepancy between the customer identified currency amount and the actual amount as determined by BCI inventory. Laboratory management is responsible for notifying the customer of the discrepancy. Actions will be documented in the case record.

Items containing $5,000 (U.S., or equivalent amount in other currency types) or greater are subject to heightened security measures, as follows:

- If the currency is packaged within an item, but not required for examination, it should be removed from the item (if practicable), repackaged, returned to the submitting agency, and these actions recorded in the case record.
- Currency should be further secured in heat sealed bags at submission. During examination, the currency should be sub-itemized so that it is readily available for return to the submitting agency.
- Laboratory management should be notified of items containing unusually high currency values. Items may be stored in a restricted access property room safe for added security.
- Upon discovery (whether during submission or examination), currency of $5,000 or greater must be inventoried and recorded on a Monetary Evidence form by the BCI laboratory employee initially opening the item. This action will be witnessed by the submitter or a second BCI laboratory employee.
    - Note: Temporary storage of monetary evidentiary items regarding BCI Investigation are excluded from this inventory requirement, as the evidence is not being submitted for laboratory analysis purposes.
- The completed Monetary Evidence Receipt form(s) will be included in the case record.
- A copy of the completed form(s) will be issued to the submitting law enforcement agency, for their records. If the agency chooses to re-count the

currency during evidence return, this count will be witnessed by a BCI Laboratory employee and documented on the Monetary Evidence Receipt form(s).

11.5.4 **Valuable item submissions**

Valuable item submissions are related to evidence known to contain an item of extraordinary value (e.g. art work, collectables, jewelry, *active lottery tickets,* etc.) as indicated by the investigating agency. *Note: Lottery tickets submitted for quality assurance testing are void, and thus considered of no value.* When evidence submitted is valued at $5,000 or more, an immediate examination and return of a valuable item should be arranged when practical.

Evidence valued at $5,000 or more will be inventoried in the assigned laboratory staff's case notes and may be witnessed by a second BCI laboratory employee.

If valuables are discovered during the examination process, the following procedures will be followed:

- Laboratory management will be immediately notified.
- A sub-item will be created, described as valuable evidence, packaged separately, and placed with the parent item.
- The unique identifier markings may be placed on the proximal container to avoid damaging the valuable evidence item.

The submitting agency's representative may re-inventory the valuables before their return.

11.5.5 **Narcotic Identification Kit (NIK)**

Narcotic Identification Kit (NIK) is a destructive field test. A NIK cannot be used for further laboratory analysis and are not acceptable for submission.

A NIK should be removed from any packaging prior to being accepted by the BCI laboratory. The used contents of the kit are acidic, and may destroy the packaging and adjacent evidence.

If a NIK is discovered during the examination of evidence:

- Document in case notes that the kit was included with the evidence.
- Dispose of the hazardous waste, or consult with Safety Officer as needed.
- Remark on the disposition of the NIK in the laboratory report.
- Communicate the disposal of the NIK to the submitting agency.

11.5.6 **Photographic Film**

The laboratory does not accept photographic film for development.

11.6 Atypical Case Types

Atypical case types are those analysis requests that present a known concern for the safety of the BCI laboratory staff and environment, are outside the accredited disciplines of the BCI laboratory, or present other issues that may be detrimental to the operation of the BCI laboratory. They include, but are not limited to, the following:

11.6.1 **Arson cases**

Fire debris analysis for the presence of accelerants is not a BCI laboratory accredited testing category.

- Other than tests normally performed by BCI, arson case evidence may be referred to the State Fire Marshal's Laboratory.
- When arson evidence is received for BCI examination, it must be sealed in airtight containers (paint cans or arson specific Kapaks).
- Arson evidence may be submitted to the State Fire Marshal's in accordance to their established evidence submission policies.

11.6.2 **Non-criminal cases**

As a section of the Ohio Attorney General's Office (AGO), it may be necessary to provide assistance in cases that are not of a criminal nature. These requests may come directly from the AGO, an agency with compliance authority represented by the AGO, or agency assisting the AGO.

- Requests involving non-criminal cases will be immediately referred to laboratory management.
- Criminal cases that will not be prosecuted will be immediately referred to laboratory management.
- Criminal cases that are now being litigated civilly will be referred to laboratory management.
- Laboratory management will contact the Attorney General's legal staff as necessary.

11.6.3 **Linking Individuals Not Known (LINK) cases**

Unidentified Human Remains and Missing Persons investigations are incorporated into BCI's LINK program (Linking Individuals Not Known). DNA collections from unidentified human remains or personal items of a missing person are submitted for comparison to samples taken from relatives of missing persons in a database.

- The laboratory Evidence Receiving staff is responsible for the initial LIMS case entry and barcoding of evidence.

- If the BCI Identification Unit cannot identify an individual, the BCI Criminal Intelligence Unit representative opens a LINK number and the fingerprint exemplar is submitted to the lab.
    - Latent Print exemplar- LINK Case Type
    - The LIMS case will have an assignment type of "LP"
    - All known fingerprint exemplars should be submitted as a separate LIMS case from any prints associated with unidentified human remains, even if they are believed to have been linked.
    - In instances when only a digital image of the known fingerprint exemplar is provided, an item will be created in LIMS to facilitate reporting and internal tracking; however, a physical item does not need to be created. Once the comparison is complete, the exemplar barcode can be scanned item can be scanned to "Latent Print Exemplar" disposal code to complete the chain of custody. A physical item will not be returned to the department and an EIT can sign to complete the transaction.

- All DNA reference standards should be submitted as a separate LIMS case from any unidentified human remains, even if they are believed to have been linked.
    - DNA reference standards- LINK Case Type
    - Unidentified Human Remains- Criminal Case Type (e.g. Death Investigation, Questioned Death, Missing Person, etc.) should be changed to case type LINK.
    - The LIMS cases listed above will each have an assignment type of "LINK".
    - The CODIS section should be notified of the submission.

- A LINK number will be provided by a BCI Criminal Intelligence Analyst to the laboratory. The LINK number will be entered in the "Location" field of the LIMS case. If a National Crime Information Center (NCIC), National Missing and Unidentified Persons System (NamUS) or any other investigative tracking number is provided, record this information in LIMS case.

11.6.4 **DUI/OMVI cases**

The BCI laboratory does not conduct alcohol or drug tests on physiological fluids in DUI/OMVI cases. The submitter may be referred to a toxicology lab (i.e. Ohio State Highway Patrol Laboratory (OSHP) or a county coroner's laboratory).

~~12.6.5 Weapons of Mass Destruction (WMD) cases~~
~~The BCI laboratory does not accept suspected WMD cases (e.g. Anthrax).~~
- ~~The submitting agency may be referred to the Ohio Department of Health.~~

- ~~The FBI may also be contacted for examination of suspected WMD material.~~
- ~~Subsequent to the examination by the ODH or the FBI and after receiving written documentation that the case has been made safe by a level 3 Biological Laboratory, the case will be accepted for further examination by the BCI (i.e. DNA, latent prints, questioned documents, trace).~~

11.6.5 **Product tampering cases**

The BCI laboratory will only check for drugs in criminal cases. The submitter may be referred to the Ohio Department of Health for all other cases.

11.7 Laboratory Information Management System (LIMS)

All evidence submitted to the BCI laboratory shall be entered into the LIMS before any analysis is initiated.

Submitting customers shall provide an evidence submission receipt to facilitate the submission process for new case submissions. This may be accomplished by using the LIMS Pre-log program or a hard copy representation.

11.7.1 **BCI laboratory case number**

The LIMS shall automatically assign a BCI laboratory case number upon case creation. The BCI laboratory case number is a unique identifier for all submissions of physical evidence related to a single case as defined by the laboratory.

Laboratory management has the administrative authority to manually enter case numbers that are not in the LIMS.

11.7.1.1 BCI laboratory case number nomenclature

- The first two digits will signify the year of the original submission.
- The third digit will identify the BCI location receiving the original submission. Those designations are as follows:

1 - London
2 - Bowling Green
3 - Richfield
4 - Cambridge
5 - Jackson
6 – Youngstown
7- Athens
9 - Boardman

- The last series of digits will signify the sequential case number for that year at that location.

11.7.2 **LIMS case creation**

Laboratory personnel will be responsible for BCI laboratory case creation in the LIMS.

With the exception of the unique BCI case number and other automatically populated LIMS entries, the submitting agencies shall provide information as required for case creation, evidence submission and analysis requested.

All submission information must be reviewed for accuracy at the time of submission. Including but not limited to telephone number, *department case number,* submitting person's name, items packaging and description(s), and assignment(s).

Many of the entry fields can be populated manually or by use of a defined pick list. ~~If modifications are made to the department pick lists, ITS will be notified to ensure all affected LIMS databases are amended accordingly.~~

11.7.2.1 Case information entry

Auto-populated fields

The date, time, and day of submission fields are automatically populated by the LIMS. If required, laboratory management has the authority to edit this information.

Case type

The case type dictates the schedule for case record retention.

Department name and County

The county name is automatically populated by the LIMS by association to the department name selected.

Case officer

The case officer will be the name of person provided as the case investigator or contact person.

Submission type

The submission type refers to the mode used to convey the evidence to the BCI laboratory.

- Hand Delivered no signature- submitter not available
- Hand Delivered- submitting officer is physically present

- Certified Mail/DHL Express/Federal Express/ Mail/Priority Mail/United Parcel Service- evidence received via mailing service (Note: This only applies to Lottery Ticket submissions)

Tracking number

- The tracking number refers to a carrier's number for a package.
- It should be entered by scanning the barcode from the package label or alternatively, it may be manually entered.

Department/Agency case number

- An agency case number is an internal number used by an agency to track a specific case.
- If provided by the submitting agency that number will be entered to the LIMS.

Submitting officer

- The submitting officer will be the name of the person who transported the evidence to the BCI location.
- If the submitting officer is submitting the evidence on behalf of another agency, the name of the agency that the submitter is employed by should follow their name or it may be selected from the adjacent LIMS pick list.

BCI Special Agent

- The BCI Special Agent (S/A) submitting the evidence on behalf of an agency, or is the primary investigator of the case, then the S/A name may be selected from the adjacent LIMS pick list.

~~**Offense type**~~

- ~~The offense type field will not be entered into the LIMS record. This information is captured using the case type field and is considered duplicative.~~
- ~~Offense types entered using a Pre-log will be deleted by the Evidence Receiving personnel during submission.~~
- ~~Offense type may be used for CODIS, evidence re-exam cases, or other internal designations as deemed necessary by laboratory management.~~

Offense date

The offense date is the date of the crime or the date when the submitting agency was notified of the crime. It should be provided by the submitting agency, and if provided entered in the LIMS.

Location

The location ~~is the county~~ where the offense occurred and ~~will~~ *may* be listed in the location field. If the location county is different from the submitting agency's county (e.g. state, federal agencies) the county where the offense occurred will be entered as the location.

Case names

The case names are those persons' names known to be associated with that case. The following information should be provided by the submitting agency:

- Designate if a person is a Subject, Elimination or Victim in the case. (Only S or V will be selected from the LIMS pick list, never S/V.) Elimination should be selected for those persons whose standards are submitted and are not a Subject or Victim. If no victim information is provided, "State of Ohio" will be entered for drug and similar societal offenses, otherwise "Unknown" will be entered.

- The person's last name, first name, middle initial and appropriate last name suffix, e.g., Jr.
- If a subject's name is not known, "Unknown" must be entered as a subject's name. If the subject is later identified, the name may be added to LIMS, however the original "Unknown" entry should not be deleted.
- Sex
- Race
- Date of birth
- BCI number (SID number)
- All subjects must be entered with a custody status. "In custody" status will be given a priority 1 by the LIMS
- "Not in custody" or "Unknown" status will be given a priority 2 by the LIMS.

Mailing address

The mailing address field is the address for the submitting agency and is automatically populated by the LIMS.

~~**Phone number**~~

~~The phone number is the contact number of either the submitting agency or the case investigator. This information is automatically populated by LIMS. The receiving personnel will verify that the phone number is correct with the submitting officer and may edit the information, as necessary.~~

~~**E-mail**~~

~~The email field is the contact address of the case investigator. This information is used by OHLEG to issue notifications of electronic laboratory report availability.~~

Remarks/Comments

Remarks or comments are additional information not captured in the subsequent case entries. ~~That information may include:~~

- ~~The description of a "Trial Date" (e.g. trial, discovery, release, etc.)~~
- ~~Requests for special handling (i.e. protect for future examinations).~~

11.7.3 **Itemization**

11.7.3.1 Evidence item numbers

The numbering of individual pieces of evidence is the principal means for maintaining the chain of custody within individual cases. Item numbers are sequentially assigned by the LIMS under the corresponding unique BCI laboratory case number.

11.7.3.2 Container Numbers

Containers may be created within the LIMS to enhance the control and/or association of items within an individual case.

A container number must be entered into the LIMS and corresponding items selected to enable its use.

11.7.3.3 Cross-referenced items

Cross referenced items are those physical evidence items that will be examined in association with two or more individual cases. ~~The procedure below does not apply to cross referenced data analysis (e.g. DNA comparisons)~~

- The *Big View* ~~Link~~ button within the LIMS will be used to enable this process. *See the LIMS.Net Guide for the procedure.*
- ~~Each case to be linked must first have an assigned case number in the LIMS.~~
- ~~The following steps will be followed to link cases:~~
    - ~~Under the Items tab, select the "Link" icon~~
    - ~~Scan the barcode for the item to be linked. If necessary, edit the submission number to coincide with the other items received at that time.~~

11.7.4 **Packaging descriptions**

The packaging description entered during evidence submission will reflect the visible outer package. Internal item packaging descriptions may be added by a forensic scientist, as necessary.

11.7.5 **Item descriptions**

Item descriptions are general details associated with each submitted item. When possible, item descriptions should include details such as who and/or where it is from (e.g. bedding from Jane Doe's bedroom), and any other pertinent information that would further distinguish between multiple items submitted in the case.

Item descriptions should be limited to general terms (i.e. shirt, pants, coat, shoe, boot, etc.). Weights, quantity, or suspected identity information offered by the submitting customer will not be included in the item description. Description details such as color, brand, size, or condition will not be included, unless the detail allows for a distinction between multiple items submitted for a case.

Item descriptions may be amended in LIMS at the discretion of the assigned forensic scientist with information obtained upon observation, or from the case investigator and/or packaging. Amended information will be documented in the case examination notes and/or conversation record. Item description amendments should be made to the LIMS field so that it displays consistently on all issued laboratory reports from the laboratory.

11.7.6 **Item types**

Item types are entries used for tracking and statistical analysis of the LIMS data. *General* Item types will be routinely listed, *as follows:*

Item Type	Description	Required Attribution Information
CODIS Hit Verification Standard	DNA standard submitted because of a CODIS lead	 - Name association
DNA Evidence	Clothing, weapons, beverage containers, etc.	
Firearm Evidence	Firearms, magazines, cartridge cases, etc.	
GSR Kits	Gunshot Residue collection stubs	 - Name association
Known DNA standard	DNA standard submitted to compare to DNA Evidence	 - Name association
Known Exemplar	Fingerprint card from a known individual to compare to latent print evidence	 - Name association
Latent Print Evidence	Latent lifts from the crime scene, evidence touched/handled at the	

	crime scene	
Questioned Document Evidence	Unknown handwriting, forged writing, etc.	
SAEC Kit	Sexual Assault Kit	 - Name association  - Item attributes for SAK Tracking Number
Strangulation Kit	Strangulation DNA Evidence Collection Kit	 - Name association
Test Fires from Known Firearm	Test fires from a known gun submitted for NIBIN entry purposes	 - Item attributes for NIBIN entry
Trace Evidence	Footwear impression, tire impression, etc.	
Unknown Substance	Suspected controlled substance; includes powders, vegetation, crystalline, etc.	 - Name association

~~"unit00" (e.g. DN00, L00, etc.) with the following exceptions:~~

- ~~Rape Kits – DN01~~
- ~~GSR kits – T02~~
- ~~CODIS Hit Verification DNA Standard - DNHV~~

When multiple units are assigned an item, choose the dominant unit for the item type (i.e. drugs to Chemistry, checks to Documents, firearms to Firearms, etc.).

11.7.7 **Laboratory unit assignments**

A unit assignment is an analysis assignment for each submitted item to at least one functional component of the laboratory. If items are submitted without a unit assignment association, it will require additional information from the submitting agency or the item will not be accepted.

It shall be the responsibility of the laboratory staff member receiving evidence to ensure that each item has a viable unit assignment corresponding to the BCI laboratory's provided service and to ensure clear documentation when necessary requisite items have multiple unit assignments. The following represents typical unit assignment requests. It is not intended to be a comprehensive list. Assignments will be made to direct evidence to the unit(s) that best satisfy the needs of the customer.

Assignment Type	Circumstance
CCU	DNA Cold Case
CHEM	Controlled substances
QNT	THC Quantitative testing
DNA	*Evidence intended for DNA testing;* DNA standards only submissions
~~**FB**~~	~~Evidence intended for DNA testing (this may accompany a DNA standard)~~
CODN	DNA Proficiency Tests
COFB	Cold case investigations
~~**FHL or CODS**~~ ***COD***	LDIS tracking
~~**OHL or CODS**~~ ***COD***	SDIS tracking
~~**MITO**~~	~~LINK cases, DNA standards from relatives of missing persons, human remains- to be sent to UNT for processing~~
LINK	LINK cases, DNA standards from relatives of missing persons, human remains- to be processed at BCI by the CODIS MPS section
QA	Documents- Lottery Quality Control
DOC	Questioned Documents
FA	Firearms
FACC	Firearms Cold Case
FAM	Familial
GG	Genetic Genealogy
MS	Make FA safe for co-assignments
NIBN	NIBIN entry only
LP	Latent Prints
LPCC	Latent Prints Cold Case
TRAC	Trace Evidence
TRCC	Trace Evidence Cold Case
GSR	Gunshot residue
SPRJ	Post-Conviction DNA Case
OUTN	Outsourced NIBIN Case
OUTC	Outsourced Chemistry Case (Qualitative)
OUTQ	Outsourced Chemistry Case (Quantitative)
OUTM	Miami Valley Crime Lab Casework
OUTS	Outsourced DNA Casework
OPER	Operability (NIBIN/Firearms)

Any Cold Case associated assignment type alerts Laboratory Supervisors to notify the Cold Case Unit Representative to ensure any BCI agent assigned to the case gets the information in addition to the submitting agency's case investigator. Additionally, this notification prompts the Cold Case Unit to verify that appropriate outreach and investigative review has been completed.

11.7.8 **Case Administrative Records**

Administrative records, such as the detailed narrative of case facts (i.e. incident report/synopsis) provided during submission *may be scanned directly into the individual case record during evidence intake via Quick Create. Note: The desktop scanner optimal settings are 200 dpi for administrative records. If an administrative record is added to the case record outside of evidence intake, then the record must be marked with the BCI case number.* ~~are marked with the BCI case number~~.

If evidence listed on the agency submission paperwork is not accepted because it does not meet the established BCI policy, then the BCI staff member shall strike it out, initial the *submission* paperwork, *and include a reason for not accepting the evidence.*

A PDF format should be used to scan submitter administrative records to be included in the case record.

LIMS case attachment procedure:

1. Open the corresponding case in the LIMS.
2. General attachments will be imported as follows:
    a. Select Case Information tab (*Note: attachments may be linked to other tabs at the discretion of the user; i.e. Case conversation)*
    b. Select Documents button
    c. Select *Upload* ~~Attach~~ button
    d. Attach file from its current location

3. Item specific attachments will be imported as follows:
    a. Select Items tab
    b. Select corresponding item number
    ~~c. Item 0 will be used for all administrative documents~~
    d. Specific Item number will be used for photographs, when possible
    e. Open image vault *by clicking on the paperclip icon.* ~~using the F11 key~~
    f. Attach file to the Item from its current location

11.7.9 **Submission receipt**

The customer is formally notified of the testing agreement, including possible use of a subcontractor, and the necessity for submission review and acknowledgement through language included on each submission receipt. This language should be emphasized with customers who may be unfamiliar with the agreement at submission.

11.7.9.1 Submission review procedure

Review leading to an agreement for testing between the customer and the BCI laboratory is done in a practical and efficient manner prior to the commencement of work. Review at evidence submission is designed to ensure the following:

- The items submitted and testing identified on the submission receipt are accurate to the best of the reviewer's knowledge.
- The laboratory has the capability and resources to meet the customer requests.
- The tests selected are appropriate and capable of meeting the customer requirements.

Substantive differences between the request and the testing to be provided will be resolved before alternatively identified work commences.

Proposed testing must be acceptable to both the customer and the BCI laboratory.

11.7.9.2 Record of review and test agreement

Acknowledgement of review and acceptance of the testing agreement for hand delivered evidence submissions is signified by the customer signature as recorded by the following method:

1. Upon case creation for hand delivered evidence submissions a signature box will appear in LIMS.
2. The customer is instructed to sign the LIMS signature pad.
3. The customer signature is recorded in the LIMS case record and displays on the LIMS submission receipt.
4. The BCI laboratory, as facilitated by the LIMS software, permits the option of test agreement and review acknowledgement of multiple case submissions by a customer at one time with a single signature. That signature is recorded in each case record and displays on each case submission receipt.

Record of review of the testing agreement for lottery ticket evidence submissions received by mail, or otherwise submitted in the absence of a customer representative, is accomplished by the following method:

1. The case creator is responsible for review ensuring the LIMS submission receipt is an accurate transcription of the customer provided information; and the laboratory has the capability to meet the customer testing requests.
2. Any apparent discrepancy or requested testing concern will be addressed with the customer prior to case creation. Those interactions will be included in the case record.
3. The submission receipt(s) will be directed to the submitting agency ~~with a submission notification letter designed~~ to ensure the customer is aware of the testing agreement; necessity for customer submission receipt review; and obligation to contact the laboratory should a concern be identified.

~~If a BCI Special Agent submits the evidence, a copy of the BCI LIMS submission receipt will also be mailed to the requesting agency. If an assigned BCI Special Agent is provided by the submitting agency, a copy of the BCI LIMS submission receipt should also be e-mailed to the BCI Special Agent.~~

11.7.10 **Corrected submissions**

It is recognized case or evidence information may be incorrectly provided or transcribed at case creation. Corrected copy submission sheets shall be made under the following practices:

- Evidence Receiving staff is responsible for a significant "Item Description" or "Name" entry error and the error is detected after the receipt has been provided to the submitting agency.

  An "item description" or "name" entry is considered significantly discrepant when the description cannot be reasonably generalized as the same. For example, a submission sheet item description of "vegetation" where the package is labeled "suspected marijuana" is not considered a significant discrepancy that requires a corrected submission sheet.

  In regards to names, a submission sheet item description of "Jon Smith" where the package is labeled "Jonathon Smith" is not considered a significant discrepancy that requires a corrected submission sheet. "Unknown" is a place holder, and if not included, a corrected submission is not required.

  If the Evidence Receiving staff enters the wrong name or if the submitting agency provides the wrong name, a corrected submission sheet must be made.

  Note: If the submitting agency later developed additional names for inclusion in the case record, this does not require a corrected submission sheet. Likewise, if the submitting agency does not initially provide the names during evidence submission, and later notifies the laboratory to add them, this does not require a corrected submission sheet.

- The submitting agency's case number is updated after the receipt has been provided to the submitting agency. In addition to the issuance of the corrected copy submission sheet, the LIMS barcodes must be updated to reflect the correct agency case number. *See the LIMS.Net Guide in PowerDMS for more information.*

- A laboratory discipline assignment amendment is required, including the change of the originally assigned discipline or addition of a discipline assignment

Note: Some laboratory disciplines utilize a variety of assignment types in order to track a specific workflow. A change between assignment types within the same discipline does not require a corrected submission sheet. For example, a change of the date of offense/incident may require a "CCU" assignment to be created. The reason for the change should be documented in the case record; however, no corrected submission sheet is necessary.

Evidence information discrepancies discovered by the laboratory staff during examination may be addressed under the following practices:

- General Case Information (such as Date of Offense, Investigating officer, Contact information, etc.) may be amended with expressed request or permission of the submitting agency. Submitter request or authorization information must be included in the case record.

- When Evidence Receiving is responsible for a typographical error regarding a Name(s) or Item Description(s), documentation of the change may be resolved by noting the change in the case conversation record and the case examination documentation. A typographical error can be confirmed by comparison between the evidence markings and the submitting agency's paperwork or by correspondence received from the investigating officer.

  Note: Typographical errors regarding names may include, but are not limited to, misspellings or erroneous entry of the last name in the field for the first name (or vice versa).

- Evidence discrepancies observed during examination will be documented in the associated examination documentation. The laboratory report "submitted information section" will clearly reflect the discrepancy.

11.7.10.1 Corrected Copy Submission Sheet Procedure

From the case in LIMS.Net, click on the "Submission" tab:

1. *Click "Receipt"*
2. *In the pop-up window, click "generate new"*
3. *Type the reason for regeneration, click "OK"*
4. *The corrected submission sheet will automatically include the person who created it and the date.*
5. *The regenerated submission receipt ~~it~~ is automatically available to the law enforcement agency via Prelog.Net.*

Note: If you edit an item description on the Items Tab in LIMS.Net, this will appear on the re-generated submission receipt, as you would expect. If you add/remove an Assignment type, this needs to be clearly stated in the "reason for regeneration". The grid on the new submission sheet does not update to reflect assignments changed once the submission has been accepted in Evidence Receiving.

6. ~~The original submission sheet will be marked to clearly indicate the mistake. A PDF of this document will be attached to the LIMS Image Vault in the case record.~~
7. ~~Enter the correct information into LIMS.~~
8. ~~The corrected submission receipt will be identified by adding "CORRECTED COPY", date and the initials of the person creating the corrected copy to the Comments field.~~
9. ~~Copies of the corrected submission receipt will be provided to the submitting agency and distributed to all originally and any subsequently assigned laboratory disciplines for inclusion in their case records.~~

11.7.11 LIMS not operational

Evidence will continue to be accepted in the event of a LIMS outage.

Evidence will be accepted by use of one or more of the following methods:

- A computer may be used by accessing the LIMS Pre-log program in OHLEG.
- A submission receipt may be completed by hand.
- Mark each item with an item number.
- Place all case related items and a copy of the submission receipt in a convenience container and seal.
- Place the convenience container in the property room for temporary storage.

LIMS restored

- Enter the case information into the LIMS.
- Edit the submission date and time, and add a comment (i.e. LIMS down, power outage).
- After each completed submission, label the evidence for each case.
- Re-locate the evidence in the appropriate property room for long-term storage.
- Complete the submission process in a normal manner.
- ~~Mail a copy of the submission receipt to the submitting agency.~~

11.8 Evidence Transfers

11.8.1 Internal Evidence Transfers

All evidence transfers internal to BCI shall be tracked in LIMS. The LIMS record shall detail each person relinquishing/taking possession of an item of evidence and, for

administrative custody, the location of that item. The LIMS record constitutes the official chain of custody record for those transfers. It is comprised of the following:

- A signature, or equivalent identification, of the person receiving or relinquishing evidence
- Electronic signatures for Return to Department
- Secure passwords confirming the individual's identity in LIMS
- Dates of transfer(s)
- A unique identifier of the evidence, including the BCI laboratory case number and item number

~~All individual evidence transfers must be made by scanning the actual LIMS barcode, as opposed to using the manual transfer custody feature in LIMS, unless approved by laboratory management, such as mass transfer practices.~~

11.8.2 Intra-Laboratory Evidence Transfers

Evidence may be transferred between BCI Laboratories/Reception sites by BCI ESO. The evidence transport is tracked in LIMS using the designated ESO Evidence Location, under the Custody of Evidence Transfer. Additional transfer practices are included in the BCI Bureau Directive – Evidence Security Officer Protocol.

All evidence will be transferred to an employee at the receiving facility within the LIMS according to normal procedures.

Applicable case file *travelers* ~~folder(s)~~ should accompany evidence to be worked, *where applicable*.

The *assignment* lab code (i.e. L, BG, or R ~~or Y~~) ~~and assigned analyst~~ are updated within LIMS for each associated case.

Following completed laboratory examination of intra-laboratory transferred evidence, it may be returned in accordance with standard practices, or transferred back to the original BCI facility for subsequent return.

11.8.3 Mass Transfer *via Bulk Containers*

The purpose of mass transfer is to quickly and securely transfer evidence from one location to another with minimal scanning. It allows Evidence Receiving to prepare transfer shipments for the Evidence Security Officers by utilizing sealed totes. This provides greater integrity for the evidence being transferred from one location to another.

11.8.3.1 Mass Transfer Totes

The Evidence Security Officers transfer evidence between BCI Evidence Receiving locations. Their daily routes are assigned by laboratory management and may change due to priority. The evidence they transfer is secured inside a sealed plastic tote. ~~The totes are color-coded and uniquely numbered to reflect a specific transfer route.~~ Each tote is *labeled with a Bulk Container barcode.* ~~specifically named in LIMS as a numbered Evidence Storage/Evidence Transfer location~~. ~~Further, each tote is labeled with three unique LIMS barcodes: one EVTR barcode and two different evidence storage location barcodes.~~

~~For example, Tote #001 is used for evidence transfer between London and Richfield. There is one barcode label for the London Evidence Storage Location (ESL) and one for the Richfield Evidence Storage Location (ESR). These labels are affixed to the inside surface of the folding lids so that they are only visible when the tote is open. The third barcode label is affixed to the outside surface of the lids and is only visible when the tote is closed. This barcode is the EVTR location. There are currently 56 totes labeled with EVTR locations.~~

11.8.3.2 Mass Transfer Procedure

~~Since each tote has three different barcode labels, it is important to scan the evidence in the tote to the correct barcode label. Before a tote is sealed for transfer, it is considered to be a "Storage" location.~~

1. Any evidence in the tote shall be scanned to the *bulk container* barcode *affixed to the tote* ~~that coincides with the tote's current storage location~~.
2. ~~The contents shall be verified by the receiving location. The ESO shall not have direct contact with evidence inside the tote. For example, Tote #001 travels between London and Richfield. It has three barcodes on it: one London Storage (ESL), one Richfield Storage (ESR), and one Transfer (EVTR). While Tote #001 is physically in London, all evidence placed into this tote shall be scanned to the London Storage (ESL) barcode.~~

3. Close the tote and seal using a plastic fastener, such as a zip tie. The LIMS user who seals the tote is responsible for the accuracy of the tote's contents as long as the seal is not broken upon receipt at the destination.

4. *The bulk container barcode is scanned to the Evidence Transfer barcode.*

5. ~~Launch the LIMS mass transfer software utility and scan the affixed EVTR barcode on the tote.~~
    a. ~~Scan the location barcodes or manually search to populate the "Source" and "Destination" fields.~~

~~b. Click "Transfer" on the bottom left to transfer all evidence from "Source" to "Destination" location. A window will pop up stating "Items were transferred" with an "OK" box to close.~~

6. Once a transfer tote is received at an Evidence Receiving destination, *scan the bulk container barcode to an evidence storage location.* It can either be opened and the evidence properly distributed or it can remain sealed and the entire contents can be mass transferred to the barcode storage location affixed on the tote.

11.8.4 **LIMS evidence custody update/correction**

Only laboratory management has the authority to make a manual evidence custody entry or amendment in LIMS. *See LIMS.Net Guide in PowerDMS for more information.*

When LIMS is unavailable, case notes shall be used to record internal transfers of evidence. The information shall be updated in LIMS as soon as it becomes available.

Laboratory staff shall direct LIMS evidence custody correction requests to laboratory management via e-mail. Correction request e-mails and other applicable communications shall be entered into the respective case LIMS conversation record.

11.8.5 **Evidence custody records prior to the LIMS**

Prior to the LIMS installation in 2002, various methods of recording the custody of evidence were employed by each laboratory location.

11.8.5.1 London

- Property cards prior to 1999 – returned property cards filed by county and/or agency most recent case number first.
- Evidence Control Documents (ECDs) 1999 to November 2002 - returned property ECDs are filed in binders by case number.

11.8.5.2 Bowling Green

- Submission sheets prior to 1999 - signed submission sheets for returned evidence are filed in corresponding case files.
- ECDs 1999 to October 2002 - returned property ECDs are filed in the corresponding case files.

11.8.5.3 Richfield

- Submission sheets prior to 1999 - Signed submission sheets for returned evidence are filed in corresponding case files.
- ECDs 1999 to October 2002 - returned property ECDs are filed in the corresponding case files.

11.8.5.4 Cambridge

- All Cambridge records were transferred to London in June, 2009
- Property cards prior to 1999 - returned property cards are filed in the corresponding case files.
- ECDs 1999 to November 2002 - returned property ECDs are filed outside the case files.

11.8.5.5 Youngstown

- ECDs 1999 to November 2002 - returned property ECDs are filed in the corresponding case files.

11.8.6 **Evidence custody transfer for verification**

LIMS documented evidence custody transfer is not required for the purpose of verification (or similar internal review) provided the original forensic scientist maintains functional control of the evidence.

LIMS documented evidence custody transfer is required when the original forensic scientist relinquishes functional control, such as verifications requiring overnight evidence retention by another BCI scientist at a different laboratory.

11.8.7 **Vendor laboratory evidence transfers**

LIMS entry:

- The vendor laboratory's name should be entered as a LIMS Location.
- The location will be within the Custody field as "Vend – Outsourced Cases".

Custody transfer:

- The evidence is transferred to the vendor laboratory within the LIMS according to normal procedures.
- Returned evidence from the vendor laboratory is transferred to its property room location within LIMS.
- Returned evidence is placed in a property room according to normal procedures.

11.8.8 **Evidence in Process**

Only BCI laboratory employees and escorted visitors are allowed in the area of open evidence. The laboratory employee with custody of open evidence is responsible for preventing its loss, contamination, or deleterious change. In the event that evidence is missing from a work area, the policy on Missing Evidence (included in these practices) should be followed.

11.8.8.1 Opening sealed packaging

Laboratory personnel open sealed packaging at a location other than the original seal, whenever possible.

The examining forensic scientist must document the date that each item was opened and the contents of the evidence package.

11.8.8.2 Marking examined evidence

Persons directly examining and/or processing an item of evidence will place the following directly on the evidence, where practicable:

- Examiner initials
- Item identifier
- BCI laboratory number or a derivative thereof. If a derivative is used, the primary container must bear the full BCI laboratory number.

When initialing or labeling, care must be taken not to mark the item of evidence in such a manner as to affect another examination. Therefore, if the item does not lend itself to marking, the proximal evidence container must be labeled with the required markings.

11.8.9 **Subdividing evidence**

There may be times during the examination process that an item of evidence needs to be subdivided and uniquely identified. A forensic scientist may subdivide an item, as necessary, for the purpose of physical separation and independent tracking, or simply as a mechanism to differentiate within the case.

Items created and used or those that could be used for testing are uniquely identified and tracked (i.e. ESDA lifts, test-fired ammunition, latent print lifts, photos, trace evidence, DNA extracts). Portions of test items that are not preserved for future testing/consumed during testing do not require tracking.

11.8.9.1 LIMS sub-item creation

A LIMS sub-item must be created and adhered to evidence when a subdivided evidence item component must be separated and uniquely identified for independent tracking. Once a sub-item barcode is printed, LIMS no longer associates its chain of custody with the parent Item. Therefore, if a sub-item barcode is printed by mistake, the "Clear Label" function can be utilized to correctly re-associate the sub-item chain of custody.

Sub-item numbers should be generated using the item number from which the sub-item originated, followed by a decimal point and a new sequential number. ~~A notation of "s" may be used for naming slides prepared from evidence.~~ Sub-items from previously created sub-items are permitted. Sub-item numbering examples:

- First sub-item of item 1, is 1.1 followed by 1.2
- First sub-item of item 2 is 2.1 followed by 2.2
- First sub-item of item 1.1 is 1.1.1 followed by 1.1.2

LIMS sub-items shall be treated as evidence.

11.8.10 **Repackaging/resealing/marking completed evidence**

Laboratory personnel are responsible for properly repackaging and resealing items and/or LIMS containers before return to the property room.

Evidence repackaging and resealing must be adequate to ensure that the item is protected from loss, cross transfer, contamination and/or deleterious change; and such that opening the item causes obvious damage or alteration to the packaging and/or its seal.

If the original packaging is inadequate for effective repackaging, new package material may be used. The original packaging should be placed inside the new packaging for the item.

The responsible laboratory employee shall initial across their seals with a permanent marker. Across the seal is defined as half on and half off for tape seals and directly across for heat seals.

Outer packaging plastic bags should be heat-sealed, when possible. If it is not possible to heat seal a plastic bag, packaging tape should be used to ensure the integrity of the seal.

The integrity of the tape must correspond to the type of packaging:

- Packaging or binding tape will be used to seal paper bags and large boxes.
- Perpendicular tape seals will be applied for reinforcement purposes when the paper bag seal results in gapping.

- Tamper proof or evidence tape alone will not be used to seal brown paper bags, envelopes, or small boxes. It is appropriate to use tamper proof tape perpendicular to the packaging tape on brown paper bags.

The following materials should not be used for sealing evidence:

- Cellophane ("Scotch") tape
- Masking tape
- Duct tape
- Staples, if packaging includes staples, the staples must be removed before being received into the laboratory.

The examining forensic scientist should document the date that each item was permanently resealed in the examination documentation.

Any applicable safety-related stickers or markings should be applied to ensure safe handling.

11.9 Multi-discipline interactions

Evidence may be submitted to the laboratory with assignments for multiple disciplines. Each associated discipline will be assigned accordingly in LIMS.

Case examination documentation for all assigned disciplines should include notations of co-examinations and details of any clean techniques utilized to ensure the integrity of the evidence. The chain of custody includes any transfers of evidence between storage locations and laboratory staff.

In order to ensure the integrity of the evidence for all analysis requested, appropriate PPE must be worn.

The assigned scientists will discuss the item description, case approach and plan to co-examine the evidence. This correspondence should be documented in the individual case record. The following practices are examples of commonly encountered co-assignments that should be utilized. Other co-assignments scenarios exist.

11.9.1 Firearm Evidence

All firearms will be handled as if they are loaded at all times, regardless of any available information on the condition of the firearm.

- All firearms will be examined by authorized staff assigned to the Firearms/*NIBIN* unit prior to being worked by another unit to ensure they are unloaded and safe to handle.

- All firearms will be rendered safe before being returned to the submitting agency.
- The authorized staff should mark the package indicating it is safe and include their initials and date of examination in an easily viewable location.

Swabbings from firearms may be processed in accordance with the current submission policy.

Upon submission of a firearm with a request for DNA swabbing and a firearms assignment, at a minimum, FA and ~~FB~~ *DNA* assignments will be made for the item(s). In addition, a LP assignment request must be approved by Lab Management.

Swabbing firearms and related components will routinely be performed by a scientist from the ~~FB~~ *DNA* section; however, laboratory management may have authorized staff perform the swabbings based on the caseloads for the respective sections.

1. The authorized staff will render the firearm safe, using caution to avoid normally handled areas. If no further FA testing is required, the FA or MS assignment will be admin closed by the FA laboratory supervisor.
2. If a LP assignment exists, the scientist from LP and the scientist performing the swabbings will either discuss the case approach or plan to co-examine the firearm.
3. A case synopsis should be reviewed for any special case circumstances regarding the suspect/victim's interactions with the firearm (For example, whether subject/victim grabbed barrel of weapon). The authorized staff should collect swabbings with Stain Extraction Buffer (SEB) from the following surfaces and/or any special circumstances identified in the case synopsis:
   a. Pistols (see Figure 1):
      1. One swab of the trigger/interior trigger guard
      2. One swab of the textured and smooth areas of the grip
      3. One swab of the back area of slide
      4. One swab from textured buttons/levers, including slide release, magazine release, safety, etc.
      5. One swab of the front sight area

Figure 1 Pistol

b. Revolvers (see Figure 2):
    1. One swab of the trigger/interior trigger guard
    2. One swab of the textured and smooth areas of the grip
    3. One swab of the cylinder and textured buttons/levers, including the safety, hammer, ejector rode, etc.
    4. One swab of the front sight area

Figure 2 Revolver

c. Pump Shotgun (see Figure 3)
    1. One swab of the trigger/interior trigger guard
    2. One swab of the grip area
    3. One swab of the forend/pump. If a bolt action shotgun, alternatively swab the bolt lever
    4. One swab of the textured buttons/levers
    5. One swab of the front sight area
    6. One swab from the scope eyepiece and scope dials (if applicable)

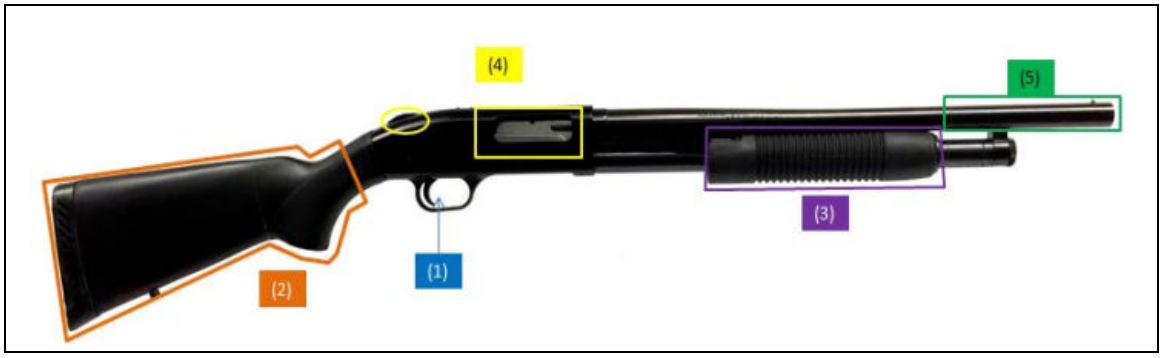


Figure 3 Pump Shotgun

d. Rifle (see Figure 4)
    1. One swab of trigger/ interior trigger guard
    2. One swab of grip area
    3. One swab of forend
    4. One swab of textured buttons/levers (magazine release, safety, bolt release, charging handle)
    5. One swab of barrel
    6. One swab of stock
    7. One swab from magazine

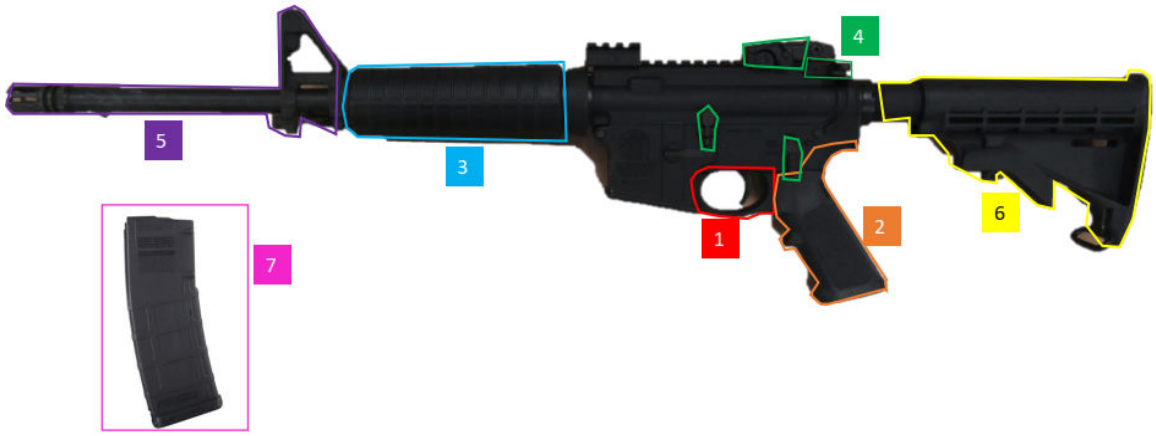


Figure 4 Rifle

e. Magazine (see Figure 5)
    1. One swab of the body
    2. One swab of the base

Figure 5 Magazine

1. The collected swabs should then be allowed to dry, tip upright.
2. After examination is complete, the evidence will be sealed and returned to the FA property storage location via a FA scientist.

11.9.1.1 Cartridges

Fired and unfired cartridges (i.e. rounds) will not be accepted for LP examination. If cartridges are enclosed in the magazine, the following approach may be used:

1. If LP examination is necessary, the LP scientist will process the magazine with the cartridges enclosed using sterile technique.
2. If DNA testing is necessary, the ~~FB~~ *DNA* scientist will remove the cartridges and collect one swab using Stain Extraction Buffer (SEB).
3. One swab of ~10 cartridge cases based on location of collection and caliber.

11.9.2 **Drug Evidence**

Any drug-related DNA evidence from the Drug Chemistry Vault requiring DNA swabbing is to be pulled by a Drug Chemist and not an EIT as outlined below.

- *The chemist will review the submission form and case facts, and evaluate the case for any potential evidence sampling safety concerns.*
- *DNA evidence that has a potential safety concern (which may or may/not include a Chemistry assignment) is to be retrieved from the Drug Chemistry Vault by a Chemist.*
- *If the Chemist deems the evidence safe to process outside of the Drug Chemistry lab, the Chemist will add an entry into the case conversation record, transfer the evidence to the DNA Scientist, and sampling can*

proceed in the DNA laboratory space. This safe evidence may include cannabis related items and vape pens, where the potential for drug exposure and the need for Narcan is reduced.

- *If the evaluation identifies bags with powders, scales, spoons, pipes, etc., this evidence must be worked by the DNA Scientist in a safe, clean space within the Drug Chemistry section and a Chemist will be consulted.*

~~Swabbings from drug packaging or paraphernalia may be processed. This examination takes place in the Drug Chemistry Lab, to ensure safe handling of the item. A forensic scientist assigned to the Chemistry Unit will work alongside authorized staff assigned to the DNA section to ensure the associated drug packaging is sampled using clean technique and preserved if able. Alternatively, a forensic scientist assigned to the Chemistry Unit will ensure clean technique in any collection of samples for DNA from the packaging and notate the state of preservation.~~

Drug evidence will routinely be examined by the forensic scientist assigned to the Chemistry Unit prior to being working in Latent Prints to ensure that any potential safety hazards are identified and can assure that associated drug packaging, paraphernalia or scales are safe to process for Latent Prints. The Drug Chemistry Forensic Scientist must notify the Latent Print Forensic Scientist of the substances identified in their testing. In the instance where outer drug packaging is examined by Latent Prints Forensic Scientist first, the initial consultation is done in the Drug Chemistry lab to minimize potential exposure throughout the laboratory.

A Chem/LP Co-assignment may be created for paper submitted for drug related offenses (e.g. paper saturated with potential controlled substances). The evidence will be opened in the Drug Chemistry laboratory and co-examined to determine the appropriate sampling approach.

If saturated, Latent print processing will be performed on paper prior to Drug Chemistry sampling. Otherwise, the evidence will be processed in a way agreed upon between both LP and Chem. If a Questioned Document (QD) assignment exists, the QD scientist should create a quality comparison record prior to LP or Chem analysis whenever possible.

1. The Chem scientist will record weight.
2. The LP scientist should process the evidence using approved chemical enhancement techniques.
3. The Chem scientist should sample from the item.

11.9.3 **Beverage Containers**

For beverage containers where the suspect is suspected to have drunk from the container, the following approach will be used:

1. Only a ~~FB~~ *DNA* assignment will be created initially in LIMS.
2. One swab should be collected from the mouth area of the beverage container using Stain Extraction Buffer (SEB).
3. If no DNA profile is obtained and subsequent LP processing is needed sterile technique will be used, in order to allow for additional ~~FB~~ *DNA* sampling.

11.9.4 **Envelope Seals/Stamps**

If a Questioned Document assignment exists, the Questioned Documents (QD) scientist should create a quality comparison record (.TIF file) prior to LP or ~~FB~~ *DNA* analysis whenever possible.

1. If a seal is not an apparent self-adhesive seal, the ~~FB~~ DNA scientist should collect a swab from the inner seal using SEB.
2. If there is apparent writing across the seal, then the evidence seal should be preserved for QD analysis as appropriate. Otherwise, a portion/cutting from the seal may be retained at the discretion of the ~~FB~~ *DNA* scientist.
3. The sterile LP processing should routinely be performed by a scientist from the LP section prior to ~~FB~~ *DNA* sampling.

11.9.5 **Paper/Money**

A *DNA* ~~FB~~/LP Co-assignment will be created for paper submitted for violent crimes (i.e. bank robbery notes, etc.). DNA and Latent Print analysis will only be performed on money with the approval of laboratory management.

Latent print analysis will be performed on paper using clean processing technique. The following approach will be used:

If a Questioned Document assignment exists, the QD scientist should create a quality comparison record prior to LP or *DNA* ~~FB~~ analysis whenever possible.

1. The LP scientist should process the evidence using a reagent.
2. The LP scientist may apply heat to finish processing the evidence.

11.9.6 **Clothing**

The interior portion of the clothing (collar, underarms, interior gloves, etc.) may be swabbed by the *DNA* ~~FB~~ scientist prior to sampling from the exterior for GSR sampling if the *DNA* ~~FB~~ scientist has had no recent contact with a firearm.

11.10 Evidence Storage

Long-term evidence storage will be in a secured property room that prevents unauthorized access. Evidence stored in these property rooms will be maintained under proper seal, as specified in this document.

For temporary or other short-term storage, lockable cabinets; drawers; interior rooms; or otherwise access controlled areas will be used. At a minimum, high-risk evidence (i.e. guns and drugs) stored in cabinets, drawers or interior rooms will be locked for overnight temporary storage. These will be located in the forensic scientist's work area or other area with access limited under the authority of laboratory management. These areas are subject to unannounced evidence audits conducted by lab management.

Unsealed evidence will not be left unattended to ensure the integrity of the evidence, prevent loss and avoid contamination.

11.10.1 Biological evidence storage conditions

Type of Evidence	Storage Condition	
Dry Biological Stains Hair Buccal Swabs	Temperature Controlled	A storage condition in which temperature is maintained thermostatically between 15.5 °C and 24°C (60°F and 75°F)
Bones^ Urine Feces DNA Extracts Liquid/Wet stains	Frozen	A storage condition in which the temperature is maintained thermostatically at or below -10°C (14°F)
Liquid Blood	Refrigerated	A storage condition in which the temperature is maintained thermostatically between 2°C and 8°C (36°F and 46°F)

Source: The Biological Evidence Preservation Handbook (https://www.nist.gov/publications/biological-evidence-preservation-handbook-best-practices-evidence-handlers?pub_id=913699)
^Due to variable condition of bone evidence will be stored frozen

All evidence stored frozen must be packaged in plastic and heat sealed.

11.10.2 Additional storage considerations

Evidence in a forensic scientist's temporary storage must have an active LIMS assignment to ensure ongoing monitoring of evidence stored in the laboratory.

Evidence should be placed in the appropriate designated storage locations within each property room. ~~All drugs and firearms in the custody of the main property rooms will be stored in their specific rooms at all times.~~

11.10.3 Temporary Storage of BCI Investigation Evidence

Bulk evidence items or monetary seizures concerning a BCI Investigation may be stored temporarily in a secure laboratory property room, however this storage condition may not resume in excess of 30 days without documented approval from laboratory management.

Bulk evidence items must be secured under proper seal.

Monetary submissions must be enclosed in a secure lock box where access keys are limited to authorized BCI Investigations staff.

In order to accommodate after hours submissions at BCI facilities, S/A Supervisors will be allowed access to the property room, under the approval of the Laboratory Director. After hours evidence submissions will be stored in a designated location of the property room. Notification of the submission will be issued to the Laboratory Director or designee from the S/A Supervisor, in order to facilitate the subsequent submission entry into LIMS.

All temporary storage submissions will be recorded in LIMS, in order to track custody transfers. No associated laboratory assignment will be created.

11.11 Evidence Return

The disposition of the evidence will be included in the issued laboratory report.
Evidence should be returned to the submitting agency as soon as possible after the requested examinations are completed.

Evidence remains the property of the submitting agency and must be returned to that agency unless they authorize in advance to return elsewhere. Written authorization will be retained in the case record, verbal authorization will be documented in the LIMS case conversation record and/or the case examination documentation. Exceptions include:

- Evidence may be returned to the court or the appropriate county prosecutor without authorization from the submitting agency.
- DNA extracts will routinely be stored at BCI

The identity of the individual receiving the evidence must be known or verified.

Evidence shall be returned during normal business hours unless specifically authorized by laboratory management.

Monetary or otherwise valuable evidence may be re-inventoried prior to its return.

11.11.1 Submitting Agency

Evidence returns to the submitting agency, are documented in the LIMS using the comment field and an electronic or an original signature on the release receipt(s).

During the return of evidence, the Evidence Receiving staff should verify the electronic chain of custody transfer was complete by reviewing a LIMS custody inquiry record for the specific Evidence Return storage locations associated with the law enforcement agency in the property room.

If there is a discrepancy between the contents of the storage location and the LIMS custody inquiry record, then the Evidence Receiving Staff must review the items pending return prior to completing the return transaction. If the discrepancy is not resolved, the EIT must notify laboratory management.

The laboratory management will contact the submitting agency. If the evidence was found in the possession of the submitting agency, then its transfer is recorded in the LIMS case record(s), and no further action is required. However, if the submitting agency is unable to verify the location of the evidence, then refer to the policy regarding Missing Evidence in this document.

11.11.2 Court Transfers

All items transported to court must first be transferred within LIMS to the BCI employee. An Evidence Release Receipt is generated indicating those items to be returned. Every effort should be made to have a court representative or submitting agency employee sign the Evidence Release Receipt for all evidence that is transferred to the court. If this is not possible, the BCI employee must sign it noting the date and person, and court of record receiving the evidence.

The signed receipt will be scanned to the LIMS image vault and kept on file. A transfer within the LIMS will reflect the evidence was returned to the department with a written description of the transfer within the comment field.

11.11.3 BCI Special Agents

BCI Special Agents most often submit evidence on behalf of another agency. In some cases, BCI Special Agents investigate independently. Evidence submitted on such BCI cases is the property of BCI. Written authorization to return evidence to another agency will be retained in the case record.

11.12 Audit/Inspection

Evidence storage locations and evidence in the custody of the laboratory will be regularly audited and inspected as prescribed by the BCI Bureau Directives. Additional audits, inspections or evidence inventories may be conducted, as necessary.

11.13 Missing Evidence

11.13.1 Notification

Laboratory staff shall notify laboratory management immediately. Laboratory management should ensure that the evidence has not been returned to the department. Laboratory Management will notify the Laboratory Director and the Quality Assurance Manager with the following details (when possible):

- BCI Case Number, Item Number(s), Item Description
- Department Name
- Last known custody details of the item(s)

In addition, laboratory management should notify the Special Agent Supervisor (SAS) if evidence is misplaced during intra-laboratory evidence transport via Evidence Security Officers (ESOs).

11.13.2 Action Steps

- Laboratory management should immediately secure the work area when evidence is misplaced during examination in the laboratory.
- The Laboratory Director should provide instructions to the on-site laboratory management.
- The Quality Assurance Manager should initiate a quality inquiry investigation, as described in this manual.

11.13.3 Case Documentation

If the item is not located, the LIMS case record documentation will disclose the disposition of the evidence, and the submitting agency will be notified.

In addition, the laboratory report must disclose the disposition of the evidence.