**Raleigh/Wake City-County**

**Bureau of Identification**

**Crime Laboratory Division**

**FORENSIC SCIENCE QUALITY MANUAL**

**2020**



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# **Glossary**

**Accreditation Cycle** − the period of time between the date accreditation is granted and the date accreditation expires.

**Administrative Case File Review** − a detailed review of the case records for consistency with CCBI Crime Laboratory Division policy and editorial precision.

**Administrative Documentation** − records such as evidence forms, description of packaging and seals, laboratory examination requests, correspondence sent/received, and other pertinent information.

**Administrative Transfer** − retrieval of evidence from an employee’s custody when the employee is not available to transfer it him/herself.

**AFIS** − Automated Fingerprint Identification System.

**Amended Report** − a report issued when changes are required to a previously-issued report.

**Analytical Data** − all technical records used to formulate a CCBI Crime Laboratory Division report such as notes, worksheets, graphs, spectra, printouts, computer data files, photographs, and photocopies.

**Analyst** − an individual who conducts and/or directs the analysis of forensic casework or database samples, interprets data, and reaches conclusions.

**Management Review** − yearly examination to ensure that the current quality system is effective and that management can be confident that all measures taken provide the highest quality service.

**Associations** − the terms used to describe the strength of the relationship between items examined and forensic conclusions reported.

**Audit** − a review conducted to compare the various aspects of the CCBI Crime Laboratory Division’s performance with a standard for that performance.

**Calibration Certificates** − reports issued by competent external calibration services that demonstrate measurement capability and traceability for the equipment serviced.

**Case File** − a file folder holding all case records. The case file can contain Examination Documentation (see definition below) from multiple forensic disciplines.

**Case Record** − administrative and technical records generated or received by the CCBI Crime Laboratory Division pertaining to a particular case.

**Category of Testing** – a specific type of analysis within a discipline of forensic science.

**CCBI** – Raleigh/Wake City-County Bureau of Identification.

**Certification of Competency** − written notification issued by CCBI top management to an employee indicating completion of an approved training program or assessment of equivalent experience for a forensic discipline or category of testing.

**Chain of Custody** − documentation of all transfers of evidence from receipt by the CCBI Crime Laboratory Division to return to the submitting agency.

**Competency Test** − a written, oral, and/or practical test or series of tests designed to evaluate a person’s ability to perform work in any category of testing prior to the performance of independent casework.

**Computer Forensics** – a category of testing of Digital & Multimedia Evidence that involves the examination, analysis, and/or evaluation of digital evidence.

**Control (control sample)** − a test performed in parallel with samples and designed to demonstrate that a procedure worked correctly; a standard of comparison for verifying or checking the finding.

**Controlled Document** − a document that is issued and distributed in a trackable manner.

**Controlled Substances** (forensic science discipline) – the identification of controlled drug substances either in legal or illicit forms.

**Corrective Action** – course of action to be taken to minimize the impact of nonconformity and prevent its recurrence.

**Corrective Action Request (CAR)** – document detailing the course of action taken to minimize the impact of a nonconformity and prevent its recurrence.

**Crime Laboratory Assistant Director**– an individual, irrespective of other responsibilities, who has the defined authority and obligation to ensure that the requirements of the quality system are implemented and maintained.

**Crime Laboratory Report** – a document which details the results of the analyses performed on specified items of evidence, administrative information being communicated, or evidence submissions being returned only partially worked (Stop Work). This document will be signed or have an electronic equivalent.

**Critical Consumables/Supplies/Services** – consumables, supplies, and services which

reliability must be verified prior to use Critical consumables, supplies, and services are identified in unit technical procedures in which they are utilized, or imposed by the accrediting body.

**Customer** − a person or organization seeking the testing services of the CCBI Crime Laboratory Division. Also referred to as a contributor or submitting agency.

**Digital and Multimedia Evidence** (forensic science discipline) – Digital Evidence: The analysis of evidence stored or transmitted in binary form. Multimedia Evidence: Analog or digital media, including but not limited to magnetic and optical media, and/or information contained therein (includes categories of testing such as computer forensics).

**Discipline** – a major area of forensic casework dealing with similar tests, examinations, or comparisons.

**DWI Blood Chemistry** (forensic science discipline) – analysis of blood samples for ethanol concentration and the presence of illicit drugs.

**Evidence** – anything that provides factual information about an alleged criminal violation.

**Evidence Audit** – the physical accounting of evidence and a comparison of the physical accounting with chain of custody.

**Evidence Tracker** – an electronic document designed to record and track cases that contain evidence items.

**Evidence Transfer** − a change of possession of evidence that is documented.

**Evidence Vault** – a secured room or rooms for the storage of evidence.

**Executive Management** – This includes the Director and the Assistant Directors of CCBI

**External Proficiency Test** – a test prepared and provided by a source external to the CCBI Crime Laboratory Division.

**Impartiality** – treating all parties fairly, justly and equally, with the presence of objectivity.

**Internal Proficiency Test** – a proficiency test not provided by an external entity for review used as a quality assessment sample.

**International System of Units (SI)** – the standard set of basic units of measurement used in scientific literature worldwide. The fundamental quantities are length (meter), mass (kilogram), time (second), electric current (ampere), temperature (kelvin), amount of matter (mole), and luminous intensity (candela).

**Key Management**–Includes the Forensic Managers, Supervisors, and Technical Leaders within the CCBI Crime Laboratory Division.

**Laboratory Examination Request** – the type of analysis required on evidence submitted for testing whether a major area or testing category.

**Latent Print** (forensic science discipline) – comparison of latent and/or patent print impressions.

**Management System** – the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly.

**Manager** – a person with the responsibility for directing and controlling an organizational unit or program. Designated in the CCBI management system as Supervisor.

**Method** – the course of action or technique followed in conducting a specific analysis or comparison leading to an analytical result.

**Nonconformity** –the nonfulfillment of an expectation or requirement of CCBI policy or

procedure or an accreditation standard related to the laboratory quality system.

**Notes** – records of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photographs, sketches, and other documents generated which are used to support the Analyst’s conclusions. See also “Examination Documentation” and “Technical Record.”

**Performance Verification** – the confirmation that a technique, equipment, or reagent is functioning properly and/or is appropriate for its intended use.

**Preventive Action Request (PAR)** – document detailing a course of action to prevent nonconformities from occurring, and to monitor its effectiveness.

**Procedure** – the manner in which an operation is performed; a set of directions for performing an examination or analysis; or the actual parameters of the methods employed.

**Proficiency Testing** – an evaluation of the continuing capability of Analysts, technical support personnel, and the performance of the CCBI Crime Laboratory Division, against pre-established criteria, by means of comparisons.

**Protocol** – detailed instructions for the performance of a CCBI Crime Laboratory Division service or some aspect of a CCBI Crime Laboratory Division service.

**Quality Assurance** – those planned and systematic actions necessary to provide sufficient confidence that a CCBI Crime Laboratory Division’s product or service will satisfy the requirements for quality.

**Quality Audit** – a management tool used to evaluate and confirm activities related to quality.

**Quality Control** – the internal activities used to monitor the quality of analytical data or results as compared to specified criteria.

**Quality Manual** – a document stating the quality policy and describing the various elements of the quality system and quality practices of the CCBI Crime Laboratory Division. The Forensic Science Quality Manual is the “Quality Manual” for the CCBI Crime Laboratory Division.

**Quality System** – see “Management System”

**Reference Material** – items or collections of materials or data purchased or encountered in casework which are maintained for identification, comparison, or interpretation purposes, e.g. mass spectra, drug samples.

**Reference Standard** – a standard used for calibration of equipment or instrumentation whose properties are traceable to the International System of Units (SI).

**Root Cause Investigation** – means of determining the reason for a nonconformity.

**Seal** – a closure that prevents loss, cross-transfer, or contamination while ensuring that attempted entry into the container is detectable. This may include a heat seal or tape seal with the initials of the person creating the seal being placed on the seal or across the seal onto the container when possible. A container is “properly sealed” only if its contents cannot readily escape and only if entering the container results in obvious damage/alteration to the container or its seal.

**Technical Procedure** – procedures and/or protocols developed for analyses, examination, comparison, or identification that guides the work processes in a forensic discipline.

**Technical Leader** – a designated employee authorized to perform and assigned forensic discipline level quality assurance and quality control responsibilities.

**Technical Management** – Includes the, Crime Laboratory Assistant Director, Forensic Managers ,Supervisors, and Technical Leaders.

**Technical Record** – Includes reference to procedures followed, tests conducted, standards and controls used, diagrams, printouts, photographs, observations, and results of examinations. See also “Notes.”

**Technical Review** – review of notes, data, and other supporting records which form the basis for the scientific conclusion(s).

**Testimony Review** – the observation and evaluation of the sworn testimony given by an employee as part of his/her normal job duties.

**Top Managerial Personnel –** Includes the Director and Crime Laboratory Assistant Director.

**Traceability** – ability to confirm measurements are accurate through an unbroken chain of comparisons to SI units of measurement.

**Training Objectives** – a description of a performance that an individual must exhibit to demonstrate competence.

**Training Program** – a written description of activities to be performed by a trainee status employee of the CCBI Crime Laboratory Division to achieve competence in a specific discipline.

**Uncertainty of Measurement** – expected range of variation between the recorded measurement and the actual value.

**Validation** – the process of demonstrating a method or technical procedure meets the requirements or performance parameters necessary for use in a particular forensic examination.

**Verification** – Verification is a procedure that checks the reliability of a previously validated method or technique used for the forensic examination of evidence.

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| January 1, 2020 | 1 | New 2020 FSQM  |
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# **Introduction**

The Raleigh/Wake City-County Bureau of Identification (CCBI) Crime Laboratory Division Forensic Science Quality Manual has been prepared to meet the requirement for accreditation of the International Organization of Standardization (ISO 17025:2017).

# **Mission Statement**

The Raleigh/Wake City-County Bureau of Identification Crime Laboratory is committed to delivering state of the art scientific analysis, while maintaining the highest level of integrity, impartiality, and professionalism to all communities in Wake County that we serve, thereby contributing to the citizens’ safety and due process of the judicial system.

# **Quality Policy Statement**

The Raleigh/Wake City-County Bureau of Identification is responsible for providing scientific analysis of evidentiary material upon the request of its customers, the criminal justice agencies of Wake County. The CCBI is dedicated to providing a defect-free service in a professional manner to those agencies. To this end, CCBI is committed to good professional practice and to the quality of its testing services to the customer via the following quality objectives:

* The performance of forensic analyses that are accurate, competent, consistent, impartial, thorough, timely, and meeting the need of the customer;
* Interpretation of analytical results without bias and free of internal and external influence;
* The presentation of the results of analysis and reports and testimonies that are clear, objective, balanced, and easily understood by its customers;
* The ongoing development of the skills and expertise of its employees;
* The advancement of the state of forensic science;
* Maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of the ISO/IEC 17025:2017 and assuring the quality of the laboratory results; and
* Continual improvement of the effectiveness of its management system through the use of this quality policy. Quality objectives are integrated into CCBI’s strategic plan, audit results, analysis of data, corrective and preventive actions, and management review.

CCBI management has developed and implemented an extensive quality system, as set forth in the CCBI Standard Operating Procedures, Crime Laboratory Division Forensic Science Quality Manual, the Crime Laboratory Administrative Procedures Manual, and Crime Laboratory Unit Technical Procedures, which incorporate the policies and procedures necessary to meet these commitments.

It is the policy of CCBI management that all operations performed in the CCBI Crime Laboratory Division facility will conform to the practices described herein. All CCBI Crime Laboratory Division employees, therefore, will be familiar with this document and its subordinate documents and will implement the contained policies and procedures in their work. Deviations from these practices require the express written permission of the CCBI Director.

# **CHAPTER 4**

## 4.1 Organization

**4.1.1**

The Raleigh/Wake City-County Bureau of Identification (CCBI) consists of the CCBI Crime Laboratory Division, Support Services Division, and Investigations Division. The CCBI provides examination of evidentiary materials to aid in the investigation, prosecution, and defense of criminal offenses, and the Investigations Division processes crime scenes for all jurisdictions in Wake County. These responsibilities are mandated under Chapter 535 of the North Carolina Public-Local Laws of 1937, North Carolina common law, and North Carolina General Statues §15A-401, §15A-402, and §162-14.

**4.1.2**

The CCBI will carry out all crime laboratory services in accordance with stated methods, the requirements of the customer, state statutes and regulations, federal regulatory authorities, the ISO 17025 standards, and any supplemental standards required by the CCBI Crime Laboratory Division accrediting organization.

**4.1.3**

The CCBI Crime Laboratory Division management system covers forensic operations by CCBI Crime Laboratory Division staff with offices and evidence processing areas located at the permanent facility located at:

3301 Hammond Road

Raleigh, NC 27603

Crime Laboratory personnel may provide technical field assistance for any investigation having original jurisdiction under the District Attorney of the Tenth Prosecutorial District and may respond to any geographic location necessary to carry out an authorized examination. Any response required outside of Wake County geographical boundaries requires approval from the Crime Laboratory Division Assistant Director and/or the CCBI Director.

Administrative work performed outside of the CCBI facility will be performed in conformance with the CCBI Crime Laboratory Administrative Procedures Manual and the CCBI Crime Laboratory Forensic Quality Manual.

**4.1.4**

The CCBI is designed as a forensic assistance agency for law enforcement agencies in Wake County. The Director serves as the agency’s chief executive officer and authorizes policy and procedure. Each division within CCBI is commanded by a Assistant Director who reports to the Director.

The CCBI Identification and Records Division incorporates Central Records, a civilian unit, and a criminal unit. Central Records maintains all case records according to a pre-described retention policy and state law. Civilian services include fingerprinting and records checks to the public for a variety of purposes including employment, citizenship, and personal reasons. The criminal unit is responsible for positively identifying persons arrested in Wake County, ensuring arrestee information is recorded, and obtaining arrestee fingerprints and photographs.

The CCBI Investigations Division consists of four squads of Agents with each squad reporting to a specific Investigations Supervisor. The duties of this division include forensic crime scene examination and the proper protection, collection, and identification of all evidence. In addition, the scope of the crime scene agent is to process evidence for latent prints, shooting reconstruction, and serial number restoration.

The CCBI Crime Laboratory Division is composed of the Latent Print Unit, Drug Chemistry Unit, DWI Blood Chemistry Unit, Digital Evidence Unit, Firearms Unit, Forensic Photography Unit, and Evidence Receiving Unit. The duties of the CCBI Crime Laboratory Division encompass controlled substance analysis, blood alcohol and blood controlled substance analysis, digital media examinations, latent print analysis, firearms analysis, photographic services, and evidence submission to the State Crime Laboratory. The Latent Print Unit Supervisors and Analysts of the other units report to the Assistant Director of CCBI Crime Laboratory Division.

The CCBI organizational chart shows the relationship between its divisions.

**4.1.4.1**

The CCBI Director and command staff personnel have responsibilities and authorities that are defined in their Position Description Questionnaires (PDQ’s) and listed in the Laboratory Administrative Procedures Manual. The Director organizes the Divisions to maximize operational effectiveness through proper delegation of authority.

**4.1.4.1.1**

The Director possesses the authority to delegate, make decisions, and enforce policies involving the three (3) Divisions.

**4.1.5**

The CCBI Crime Laboratory Division:

1. Provides its employees with the authority and resources needed to carry out their duties, including the implementation, maintenance, and improvement of the quality system. CCBI Crime Laboratory Division employees will identify and report departures from the quality system.
2. Ensures that there is no influence on the professional judgments of employees including any undue internal and external commercial, financial, or other pressures and influences that may adversely affect the quality of their work. Management has the responsibility and authority to take action on employee concerns within their Division. Any instances of undue influence on analytical findings or conflicts of interest will be reported to the Assistant Director or Laboratory Quality Technical Leader.
3. Has policies and procedures to ensure that the contributors’ confidential information is protected as described in CCBI Crime Laboratory Administrative Procedures Manual, CCBI Standard Operating Procedures, and the CCBI Report Writing Manual.
4. Provides guidance concerning any situations that could diminish confidence in its competence, impartiality, judgment, or operational integrity and management shall continually strive to identify risks to its objectivity. Work shall be performed in an environment free from undue pressure that might influence technical judgment. Employees shall not engage in activities that may diminish confidence in CCBI’s competence, impartiality, judgment, or operational integrity. All conflict of interest concerns and situations that could cause impartiality or undue pressure that adversely affects the quality of the work shall be brought to the attention of the Assistant Director or Laboratory Quality Technical Leader.
5. Has an organizational chart showing the structure and relationships of all operations of the CCBI.
6. Specifies the responsibility and authority of each employee of the CCBI Crime Laboratory Division. Each CCBI Crime Laboratory Division employee will be accountable to only one (1) immediate supervisor per function.
7. Provides adequate supervision of all employees, including trainees. Employees responsible for supervision will be familiar with the purposes, methods, and Technical Procedures of examinations conducted in their area of expertise and the assessment of results.
8. Has technical management responsible for oversight and provision of resources to ensure the reliability and integrity of CCBI Crime Laboratory Division operations.
	1. Each unit will have at least one (1) Technical Leader who has technical management responsibility within that unit.
9. Has a Crime Laboratory Assistant Director that reports to the Director. The Crime Laboratory Assistant Director ensures the quality system is implemented and followed at all times.
10. Has designees appointed in the Administrative Procedure for Management Continuity and Administrative Procedure for Laboratory Command.
11. Has CCBI Crime Laboratory Division employees that are aware of the importance and relevance of their activities and how they relate to the objectives of the quality system.

**4.1.6**

Management shall ensure that appropriate communication processes such as staff meetings and email messages are established within the CCBI Crime Laboratory Division and that communication takes place regarding the effectiveness of the management system.

**4.1.7**

The CCBI Crime Laboratory Division has a health and safety officer with the responsibility and authority for ensuring that the health and safety program described in the CCBI Standard Operating Procedures is implemented and followed at all times.

## 4.2 Management System

**4.2.1**

CCBI will develop and maintain a management system to include a Crime Laboratory Quality Assurance Program. This program will include technical and operational guidelines for each forensic discipline as well as guidelines for evidence management, records retention, analytical data and administrative documentation, CCBI Crime Laboratory Division reports, case file review, testimony review, proficiency testing, and training and continuing education.

The CCBI quality system documentation includes the Forensic Science Quality Manual, Laboratory Administrative Manual, Laboratory Unit Technical Procedures, and training manuals. These documents will be available on a CCBI network location for employee review. Additional quality system documents such as instrumentation manuals will be available in the laboratory units.

**4.2.2**

CCBI is committed to protecting and serving the citizens of Wake County, North Carolina, by providing quality CCBI Crime Laboratory Division services. The [Quality Policy Statement](#QualityPolicyStatement) is one of the most important documents in this Forensic Science Quality Manual. It is issued under the authority of the Director and shall be reviewed annually during the management review. The quality statement in the front of this manual addresses subcategories a-e.

**4.2.3**

CCBI and its management are committed to professional excellence. The entire staff of the CCBI Crime Laboratory Division shall adhere to the spirit and intent of a quality program that is described in this manual, in the Mission Statement, and in the Quality Policy Statement. Management will communicate with CCBI Crime Laboratory Division employees regarding the development, implementation, and continuous improvement of the quality system.

**4.2.4**

The CCBI Crime Laboratory Division is committed to carrying out its testing activities to meet the needs of its customers to the maximum extent possible considering the resources available. Management will continually improve the effectiveness of the management system by setting and achieving goals and objectives that are specific to the organization, that are measurable and attainable, and that meet all statutory and regulatory requirements. Management will advise CCBI Crime Laboratory Division employees of the importance of addressing contributor requests and complying with any relevant statutory and regulatory requirements.

**4.2.5**

The CCBI Crime Laboratory Division’s policies and procedures are set forth in the following manuals: CCBI Standard Operating Procedures Manual, Forensic Science Quality Manual, Laboratory Administrative Procedure Manual, and Laboratory Unit Technical Procedures. The CCBI Standard Operating Procedures establishes the formal structures by which CCBI and its components are arranged, defined, directed and coordinated. The Forensic Science Quality Manual is subordinate to CCBI Standard Operating Procedures and been prepared to meet the requirements for accreditation of the International Organization of Standardization (ISO 17025:2017). The Laboratory Administrative Procedures Manual establishes administrative procedures applicable to the CCBI Laboratory and are subordinate to CCBI Standard Operating Procedures. Laboratory Unit Technical Procedures establish technical procedures utilized by the forensic disciplines in the CCBI Crime Laboratory to conduct forensic examinations.

**4.2.6**

To be successful, the CCBI Crime Laboratory Division quality system must have the complete support and commitment of all employees. This section describes CCBI Crime Laboratory Division technical management and the Crime Laboratory Assistant Director’s responsibilities for implementing the quality system.

The CCBI Management comprised of the Director and Assistant Directors will support and promote the quality system; ensure conformance with ISO/IEC 17025 Standards and any requirements of the laboratory accrediting body; ensure that the policies and procedures within the quality system are implemented within the CCBI Crime Laboratory Division; ensure that CCBI Crime Laboratory Division employees understand and apply current policies and procedures to appropriate situations; and ensure that corrective and preventive actions are taken and documented to resolve deficiencies if they are found.

The Crime Laboratory Assistant Director will serve as the CCBI Crime Laboratory Division’s quality manager; ensure conformance with ISO/IEC 17025 Standards and any requirements of the laboratory accrediting body; ensure that all quality assurance programs function in accordance with CCBI Crime Laboratory Division goals and objectives; ensure that the policies and procedures within the quality system are documented; advise key management regarding the development, implementation, and maintenance of the quality system; coordinate the development and revision of the quality system; and ensure that corrective and preventative action is taken and documented to resolve deficiencies if they are found.

Forensic Managers and Supervisors will support and promote the quality system; ensure conformance with ISO/IEC 17025 Standards and any requirements of the laboratory accrediting body; communicate the quality system and related policies and procedures to all employees under their supervision; ensure that the policies and procedures within the quality system are adhered to; appropriately delegate authority to implement the quality system; ensure that all unit employees receive necessary training and are qualified for their assigned work; ensure the completeness of case files and supporting case documentation; and ensure that corrective and preventative action is taken and documented to resolve deficiencies if they are found.

The Technical Leaders will support and promote the quality system; assist in conducting audits to ensure compliance with the policies and procedures within the quality system in their disciplines and categories of testing; advise management regarding issues specific to their disciplines and categories of testing; and recommend corrective and preventative action specific to their disciplines and categories of testing.

**4.2.7**

Top management will review proposed revisions to the CCBI Crime Laboratory Division quality system to ensure that the integrity of the system is maintained when changes are implemented.

## 4.3 Document Control

**4.3.1 General**

The CCBI Crime Laboratory Division’s quality system documentation is comprised of policies and procedures. The authority to approve, issue, and revise quality system documentation is defined in the CCBI Standard Operating Procedure for Document Control and Management.

The CCBI Crime Laboratory Division has established and will maintain procedures to control all documents that form part of the CCBI management and quality systems. Documents that specify quality requirements or prescribe quality-affecting activities will be controlled to ensure that they are adequate, approved for use, and the most current version of those documents. All documents and records will be included on a master list.

The document control procedures will:

* Define what is and is not included in the document control program.
* Ensure that authorized versions of the documents are located in the appropriate locations.
* Outline the process for creation, approval, distribution, review, revision, removal, and archiving of documents. This procedure addresses the control process for handling and maintaining quality system documents in both digital and paper media, relating to the requirements of ISO 17025.

Any instrument manuals provided by the manufacturer are considered to be general reference sources only and will not be used directly for casework. As such, they are not a part of CCBI’s document control program unless specifically referred to within unit Technical Procedures.

**4.3.1.1. Responsibilities of Management in the Document Control System**

CCBI management has designated a Document Custodian for all controlled documents. It is the responsibility of the Document Custodian to ensure the following:

* Internal documents are formatted correctly
* Amendments are published and appropriate staff notified in a timely manner
* The master list of quality system documents and the electronic archive file are maintained
* All forms associated with official documents are maintained

**4.3.2 Document approval and issue**

**4.3.2.1**

Prior to implementation, all CCBI Crime Laboratory Division quality system documents will be thoroughly reviewed, approved for release by authorized personnel, and made available for use by employees.

The CCBI Standard Operating Procedure for Document Control and Management contains provisions for identifying the current revision of documents, for distributing quality system documents, and to preclude the use of invalid and/or obsolete documents.

**4.3.2.2**

The CCBI Standard Operating Procedure for Document Control and Management ensures:

* Current revisions of appropriate documents will be available where critical operations are performed
* Quality system documents will be annually reviewed and revised as necessary to comply with applicable requirements
* Invalid or obsolete documents will be promptly removed
* Archived quality system documents will be marked as such to preclude their use
* All quality system documents will name the issuing authority

**4.3.2.3**

CCBI Crime Laboratory Division-prepared quality system documents are uniquely identified according to the requirements of the Standard Operating Procedure for Document Control and Management. This identification includes the document title, date of issue, revision number, unique document identifier, and page numbering including total number of pages. The issuing authorities are also identified in the document.

**4.3.3 Document changes**

**4.3.3.1**

Revisions to CCBI Crime Laboratory Division-prepared quality system documents will be subject to the same review, approval, documentation, and issuance requirements as the original document. Revisions to externally produced quality documents will be subject to the same review and approval as the original document. Changes to policies, practices, procedures, and training program manuals will be described in the revision history portion of the document. Additionally, appropriate personnel will have access to any information necessary to conduct the review and approve the revision.

**4.3.3.2**

Revised or new text will be identified in the document according to the Standard Operating Procedure for Document Control and Management.

**4.3.3.3**

Amendment of documents pending the re-issue of the documents shall be made in accordance with CCBI Standard Operating Procedure for Written Directives. The CCBI Crime Laboratory Division does not permit the amendment of documents by hand.

**4.3.3.4**

The Standard Operating Procedure for Document Control and Management also applies to documents maintained in computerized systems.

## 4.4 Review of requests, tenders, and contracts

**4.4.1**

Prior to examination of evidence, CCBI Crime Laboratory Division personnel will evaluate the request to ensure that the CCBI Crime Laboratory Division has the capability and resources to perform the services that are being requested.

**4.4.2**

Records of reviews shall be maintained according to the Laboratory Administrative Procedure for the Review of Requests, Tenders, and Contracts for Laboratory Services.

**4.4.3**

Reserved for Future Use.

**4.4.4**

Contributors submitting evidence to the CCBI Crime Laboratory Division agree to the terms and conditions for analysis as outlined in the CCBI Evidence Submission Guide and denoted on the Laboratory Examination Request form or by a request for CCBI Crime Scene Services.

**4.4.5**

Any changes to customer contract will be communicated to all affected personnel as stated in the Laboratory Administrative Procedure for the Review of Requests, Tenders, and Contracts for Laboratory Services.

## 4.5 Subcontracting of Tests and Calibrations

**4.5.1**

When laboratory work activities are to be performed by an external provider, the work shall be placed with a competent provider. Competency may be demonstrated by one or more of the following:

* + - 1. Compliance to ISO/IEC 17025 with respect to the specific laboratory work activity being sought.
			2. Requisite education, experience, knowledge, skill, or ability to perform the specific laboratory work activity being sought.

**4.5.2**

Activities performed by external providers shall undergo review and approval prior to incorporation into CCBI Crime Laboratory work activities.

**4.5.3**

A contract, Memorandum of Understanding, CCBI Requisition Form, curriculum vitae, or equivalent instruments will document the necessary requirements for work activity performed by an external provider.

## 4.6 Purchasing Services and Supplies

**4.6.1**

Wake County purchasing guidelines govern the procurement of products and services for the CCBI Crime Laboratory Division. The CCBI Crime Laboratory Division follows the Laboratory Administrative Procedure for Purchasing, Receipt and Storage of Laboratory Consumables, Services, and Supplies.

**4.6.2**

CCBI Crime Laboratory Division units will ensure supplies, reagents, and consumable materials that affect the quality of the examinations are not used in casework until they have been evaluated for compliance with Laboratory Unit Technical Procedure requirements and/or specifications in the purchase requisition. Records of compliance evaluations will be maintained.

**4.6.3**

CCBI Crime Laboratory Division units will ensure that purchase requisitions contain specifications of consumables, supplies, and services ordered if they affect the quality of testing. The requisitions will originate from or be reviewed and approved by the applicable unit Technical Leader or designee prior to ordering to ensure compliance with unit criteria.

**4.6.4**

The CCBI Crime Laboratory Division will evaluate suppliers of critical consumables, supplies, and services which affect the quality of the test in a manner that is fundamental to the quality of the test. Their reliability (competence) must be verified prior to use or affect the quality of the test in a manner that is fundamental to the quality of the test and their reliability is not verified as part of the quality control checks performed in association with the test. These critical consumables, supplies, and services will be identified in the technical procedures in which they are utilized. Records of vendor evaluations and a list of approved vendors will be maintained on the CCBI network location.

## 4.7 Service to the Customer

**4.7.1**

CCBI employees will confidentially communicate with customers as needed to clarify their requests and to answer any questions concerning the status of their requests.

All case records are confidential. Laboratory results will not be released outside CCBI except as described below:

* Preliminary findings and investigative lead information may be released to the submitting law enforcement agency, to the prosecuting attorney’s office, or during deposition. Appropriate documentation of what information was released and to whom will be included in the case record.
* Final results, conclusions, or reports will only be released to prosecuting attorneys and

the submitting agency unless directed by the court, by the submitting agency, or authorized by the prosecuting attorney. Results may also be released by the appropriate authority in response to discovery requests or court orders.

**4.7.2**

The CCBI seeks feedback from its customers through annual performance measures review with Wake County law enforcement agencies and testimony review forms.

## 4.8 Complaints

As part of the CCBI Crime Laboratory Division’s commitment to provide reliable forensic examinations, the CCBI Crime Laboratory Division will take appropriate steps to address valid complaints regarding its services as stated in the Laboratory Administrative Procedure for the Resolution of Complaints.

**4.8.1**

CCBI Crime Laboratory Division employee complaints concerning quality-related aspects of the CCBI Crime Laboratory Division management system shall be addressed as stated in the Laboratory Administrative Procedure for the Resolution of Complaints.

##

## 4.9 Control of Nonconforming Testing

**4.9.1**

If a nonconformity occurs during the examination process, the Laboratory Administrative Procedure for Corrective and Preventive Action will be followed. The procedure designates:

* actions to be taken by technical management
* evaluation of the significance of the nonconforming work
* the investigation if similar non-conformities exist or could occur
* timely implementation of corrective actions
* notification of the customers when necessary
* responsibility for authorizing the resumption of work

There are times when deviating from policies and/or procedures is necessary. These exceptions will be controlled to ensure that quality is not compromised. The CCBI Standard Operating Procedure for Written Directives specifies the requirements for requesting and approving exceptions.

**4.9.2**

Where the evaluation indicates that nonconformity could reoccur, the corrective action policy outlined in 4.11 shall be promptly followed.

## 4.10 Improvement

The CCBI Crime Laboratory Division uses policies, objectives, audit results, data review, corrective actions, preventive actions, and management reviews to continuously improve the effectiveness of the quality system.

## 4.11 Corrective Action

**4.11.1 General**

Technical Leaders and Supervisors may identify conditions or situations where corrective actions may be required. Any employee identifying a potential situation where a corrective action may be required will notify a Supervisor or Technical Leader. All discrepancies and occurrences of non-compliance will be properly noted, reported, and promptly reviewed. The intent of a corrective action is to prevent the recurrence of the nonconformity that affects the quality of work performed within the CCBI Crime Laboratory Division.

**4.11.2 Cause analysis**

Any corrective actions must begin with an investigation into the root cause of the problem.

**4.11.3 Selection and implementation of corrective actions**

The corrective action implemented shall be appropriate to the magnitude and risk of the problem. Any required changes will be documented and implemented.

**4.11.4 Monitoring of corrective actions**

Any required changes will be monitored to ensure effectiveness.

**4.11.5 Additional audits**

When conditions or situations require a corrective action, the Crime Laboratory Assistant Director will determine if an additional audit is necessary to assess the effectiveness of the corrective action. If an audit is required, the audit will be conducted in a timely manner.

## 4.12 Preventive Action

**4.12.1**

Any CCBI Crime Laboratory Division employee may identify conditions or situation where preventative actions may be required. Preventive actions are taken to prevent an occurrence of nonconformity. When improvement opportunities are identified, a plan shall be developed to take advantage of the prevention of nonconformity.

**4.12.2**

The Laboratory Administrative Procedure for Corrective and Preventive Action includes measures for verifying the effectiveness of any preventive actions that are implemented.

## 4.13 Control of Records

**4.13.1 General**

**4.13.1.1**

The CCBI Standard Operating Procedures for Records Management System Administration and Central Records Unit and the Laboratory Administrative Procedure for Laboratory Quality Record Retention and Case Records Contents, Management and Retention describe the requirements for the identification, collection, organization, accessibility, filing, storage, maintenance, and disposal of quality records and technical records.

**4.13.1.2**

All CCBI Crime Laboratory Division records will be legible, appropriately stored, and readily retrievable. Retention times for records will be determined the North Carolina Records and Retention Schedule for Sheriff’s Offices and/or the accrediting body.

**4.13.1.3**

CCBI Crime Laboratory Division case files shall be kept confidential, and access to CCBI Crime Laboratory Division case files is controlled according to the Administrative Procedures for Laboratory Case Record Contents, Management, and Retention and the Laboratory Administrative Procedure for Laboratory Reports. All other records are stored within secure areas in CCBI.

**4.13.1.4**

The Wake County Sheriff's Office supports and maintains CCBI’s primary records management system for all electronically maintained investigative, examination, or analytical test reports in Sungard’s® ONESolution RMS system, hereafter referred to as RMS. Access to these records is controlled by the RMS System Administrator. CCBI’s Standard Operating Procedure on Records Management System Administration outlines CCBI’s procedures for protecting and backing up records stored electronically.

**4.13.2 Technical records**

**4.13.2.1**

The CCBI Crime Laboratory Division will retain examination and administrative documentation as part of the case record for a defined period in accordance with the North Carolina Records and Retention Schedule for Sheriff’s Offices. Technical records will be such that another qualified Analyst could repeat the examination under conditions as close as possible to the original.

**4.13.2.2**

Examination notes will include observations, data, and calculations, where applicable. These notes will be recorded at the time the examination is performed and will be identifiable to the specific examination performed.

**4.13.2.2.1**

Technical records will contain the date(s) of examination according to the Laboratory Administrative Procedure for Laboratory Case Record Contents, Management, and Retention.

**4.13.2.3**

Mistakes that occur in case documentation or records will be corrected with an initialed single strike-out and the correction entered alongside. No part of case documentation or records can be erased or otherwise made illegible.

**4.13.2.3.1**

Any additions made to case documentation will be initialed and dated next to the addition by the employee making the addition.

**4.13.2.3.2**

In the case of electronically stored records, equivalent measures will be taken to track changes in original data. Examination records shall be considered completed prior to any technical or administrative review of the records.

**4.13.2.4**

The Laboratory Administrative Procedure for Case Record Contents, Management, and Retention will identify what documents will be maintained in the case record.

**4.13.2.5**

Technical records will be such that, in the absence of the Analyst, another competent Analyst could evaluate the examinations performed and interpret the data.

**4.13.2.6**

The CCBI Crime Laboratory Division case number and the Analyst’s handwritten initials will be on each page of the examination records.

**4.13.2.7**

When examination records are prepared by an individual other than the Analyst who interprets the findings, the individual’s handwritten initials will be on each page of the documentation representing his/her work.

**4.13.2.8**

The CCBI Crime Laboratory Division case number and initials of the individual that generated or received the document will be on each page of the administrative documentation in the case record. When information is recorded on both sides of administrative documentation, each side will be labeled with the CCBI Crime Laboratory Division case number.

**4.13.2.9**

The CCBI Crime Laboratory Division case number for each case for which data was generated shall be appropriately recorded on the printout when data from multiple cases is recorded on a single printout.

**4.13.2.10**

When information is recorded on both sides of technical documentation, each side will be initialed and labeled with the CCBI Crime Laboratory Division case number.

**4.13.2.11**

Paper case file records shall be prepared in ink or in a manner that is permanent in nature.

**4.13.2.12**

When an independent check on a critical finding is carried out, it will be conducted by another competent Analyst and documented in the case file.

**4.13.2.13**

Abbreviations and notations will be acceptable if they are clearly documented and comprehensible. CCBI Crime Laboratory Division Unit Technical Procedures will contain a list of common abbreviations and/or symbols that are used by their personnel.

## 4.14 Internal Audits

**4.14.1**

The Laboratory Administrative Procedure for Annual Quality Audits will be followed when conducting scheduled audits to verify that operations conform to the requirements of the CCBI Crime Laboratory Division quality system*,* ISO/IEC 17025 Standards, and any requirements of the laboratory accrediting body.

Audits are performed to measure and evaluate the effectiveness of the quality system; to verify the effectiveness of corrective actions; and to recommend improvements for CCBI Crime Laboratory Division operations, taking into account the importance of the laboratory activity, any changes affecting the laboratory, and the results of previous audits.

An annual audit will be conducted in each unit of the CCBI Crime Laboratory Division to verify that its operations continue to comply with the discipline and CCBI Crime Laboratory Division quality system policies and procedures. The CCBI Crime Laboratory Assistant Director or designee is responsible for planning and organizing audits. Such audits are carried out by trained auditors in the CCBI Crime Laboratory Division that are independent of the discipline being audited.

**4.14.1.1**

Internal audits will be conducted, at a minimum, on an annual basis according to the Laboratory Administrative Procedure for Quality System Audits and Reviews

**4.14.1.2**

Internal audit records will be retained for at least five (5) years or as required by the laboratory accrediting body, whichever is longer.

**4.14.2**

When an audit identifies a nonconformity, it will be addressed according to the Laboratory Administrative Procedure for Corrective and Preventive Action. When necessary, the CCBI Crime Laboratory Division will notify contributors, in writing, if CCBI Crime Laboratory Division results have been affected.

**4.14.3**

A Quality Audit Report Form will be issued for every internal audit according to the Laboratory Administrative Procedure for Quality System Audits and Reviews.

**4.14.4**

Follow-up audit activities will be documented, implemented, and monitored to ensure effectiveness of any corrective action taken.

## Management Reviews

The CCBI Crime Laboratory Division’s Assistant Director, in conjunction with top management, will conduct an annual review of the laboratory’s management system and testing activities according to Laboratory Administrative Procedure for Management Reviews to ensure there is continued suitability and effectiveness of the quality system and risk and opportunities are evaluated. In order to:

* give assurance that the management system achieves its intended results,
* enhance opportunities to achieve the purpose and objectives of the laboratory,
* prevent or reduce undesired impacts and potential failures,
* achieve improvement.

This management review will be used as the foundation for future development of CCBI Crime Laboratory Division goals and objectives as well as for planning any necessary changes or improvements to the quality system.

**4.15.1.1**

Management reviews will be conducted at least once per calendar year.

**4.15.1.2**

Management reviews will be documented and retained by the CCBI Crime Laboratory Assistant Director or designee for five (5) years or for a period required by the laboratory accrediting body, whichever is longer.

**4.15.2**

An annual review is required to ensure that management can continue to be confident that all measures taken provide the highest quality service. Management will carry out any necessary actions as a result of the annual review in an appropriate and agreed upon time frame.

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| **Revision History** |
| **Effective Date** | **Version Number** | **Reason** |
| January 1, 2020 | 1 | New 2020 FSQM |
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# **Chapter 5**

## 5.1 General

**5.1.1**

The CCBI Crime Laboratory Division ensures correct and reliable forensic examinations by using adequately trained employees, appropriate facilities, validated Technical Procedures, properly maintained and calibrated equipment and instrumentation, and by maintaining the integrity of evidence. When applicable, traceable reference standards and materials and suitable sampling procedures are utilized.

**5.1.2**

In affected forensic disciplines, the CCBI Crime Laboratory Division will consider all factors contributing to the total uncertainty of measurement when developing and validating Technical Procedures, in the training and qualification of employees, and in the calibration and maintenance of the equipment it uses.

**5.1.3**

CCBI Crime Laboratory Division unit Technical Procedures will have documented procedures for routinely checking the reliability of its reagents.

**5.1.3.1**

Reagents prepared in CCBI Crime Laboratory Division units will be labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records maintained by the units will identify who made the reagent, the date of preparation or lot number, who tested the reagent, and the quality control check result(s). The quality control check will be performed before use or, if appropriate, concurrent with the test.

## 5.2 Personnel

**5.2.1**

Management will ensure that only qualified technical personnel conduct forensic examinations, confirm identifications and associations, review results, and issue reports. Personnel who are undergoing training will be appropriately supervised.

**5.2.1.1**

Each discipline and category of testing within the CCBI Crime Laboratory Division will have a documented training program that is used to develop an individual’s knowledge, skills, and abilities required to perform forensic examinations. The Laboratory Administrative Procedure for Training Programs will provide for maintaining the skills and expertise of personnel and provide for retraining, when needed.

Each Supervisor or Technical Leader will ensure that, at a minimum, each trainee successfully completes a competency test in the relevant discipline or category of testing prior to conducting independent casework. A trainee’s successful completion of the training program will be documented through CCBI Training Progress Reports and a final memorandum and certificate identifying the discipline and/or category of testing and his/her position as indicated in the Laboratory Administrative Procedure for Training Programs.

**5.2.1.2**

All CCBI Crime Laboratory Division Analyst training programs will contain training in the presentation of evidence in court.

**5.2.1.3**

Training shall include the application of ethical practices in forensic science, a general knowledge of forensic science, and all applicable civil and criminal laws and procedures.

**5.2.2**

Continuing education and training is addressed in the CCBI Standard Operating Procedure for Training /Certifications and Laboratory Administrative Procedure for Training and Continuing Education.

**5.2.3**

The CCBI Crime Laboratory Division uses qualified technical personnel who are employed by the CCBI. Supervision, training, and competence shall be documented for all contracted and additional technical and key support personnel.

**5.2.4**

The CCBI Crime Laboratory Division shall maintain active job descriptions for managerial, technical, and key support personnel. Job descriptions will exist in the form of a Position Description Questionnaire (PDQ). PDQ’s are accessible on a shared folder on the CCBI shared drive, and are also maintained in employee personnel files.

Management shall maintain a current Statement of Qualification (*curriculum vitae* or CV) for each Analyst and technical support staff and employees shall update the CV at least annually. Current CV’s will be maintained on the Staff CV’s folder on the CCBI shared drive.

**5.2.5**

The Director authorizes qualified employees to perform forensic examinations as described in the Laboratory Administrative Procedure for Certification of Competency. The CCBI Crime Laboratory Division will maintain records of an employee’s qualifications to include education, professional experience, competency test results, proficiency test results, and documentation of the successful completion date of the training program.

**5.2.6 Analyst Qualifications**

**5.2.6.1 Education**

**5.2.6.1.1**

Analysts working in the Drug Chemistry discipline of forensic science will possess a baccalaureate or an advanced degree in a natural science, criminalistics, or a closely related field.

**5.2.6.1.2**

Analysts working in the DWI Blood Chemistry Unit will possess a baccalaureate or an advanced degree in a natural science, toxicology, criminalistics, or a closely related field.

**5.2.6.1.3**

Reserved for Future Use.

**5.2.6.1.4**

Analysts working in the Latent Print Unit and Digital Evidence Unit will meet the educational requirement(s) specified in their PDQ.

**5.2.6.2 Competency Testing**

**5.2.6.2.1**

All Analysts must satisfactorily complete a competency test prior to assuming casework responsibilities in the CCBI Crime Laboratory Division. Previously trained Analysts, regardless of education or past work experience, shall satisfactorily complete a competency test in each category of analysis prior to assuming casework responsibilities.

**5.2.6.2.2**

Competency testing of employees shall include at a minimum:

* Examination of unknown samples to cover the anticipated spectrum of duties and to evaluate the ability to perform proper analyses;
* Preparation of a written report to demonstrate the ability to convey results and/or conclusions accurately; and
* Completion of a written or oral examination to assess knowledge of the discipline, analysis, or task being performed.

**5.2.7**

The CCBI Crime Laboratory Division provides access to forensic science resources such as relevant books, journals and literature, and internet access to relevant forensic resources.

## 5.3 Facilities and Environmental Conditions

**5.3.1**

CCBI Crime Laboratory Division facilities will be such as to permit the accurate performance of forensic examinations. Units and management will ensure that the environmental conditions do not adversely affect the quality required of any measurement. Any environmental conditions that can affect the results of examinations will be described in the appropriate Laboratory Unit Technical Procedure.

All examinations require normal CCBI Crime Laboratory Division environmental conditions unless noted in a Laboratory Unit Technical Procedure. Extreme care will be taken when sampling and/or examinations are undertaken at sites other than a permanent CCBI Crime Laboratory Division facility.

**5.3.2**

If environmental conditions could affect the quality of an examination, units will monitor, control, and record those conditions as required by Laboratory Unit Technical Procedures. Examinations will be stopped when the environmental conditions jeopardize the results.

**5.3.3**

CCBI Crime Laboratory Division management will be responsible for maintaining effective separation between incompatible activities to prevent cross-contamination.

**5.3.4**

Access to and use of all examination areas in the CCBI Crime Laboratory Division is controlled and limited to those individuals authorized by the Director.

**5.3.4.1**

CCBI Crime Laboratory Division procedures and/or practices for security are found in the CCBI Standard Operating Procedure for Facilities Access and Security.

**5.3.5**

The CCBI Crime Laboratory will comply with the Wake County Safety, Security, and Loss Prevention Manual and CCBI Standard Operating Procedures outlining good housekeeping measures. Special housekeeping procedures will be addressed in Laboratory Unit Technical procedures when necessary.

**5.3.6**

The CCBI Standard Operating Procedures document the CCBI Crime Laboratory Division’s health and safety program.

## 5.4 Test and calibration methods and method validation

**5.4.1 General**

Laboratory Unit Technical Procedures as well as validations are a key element in establishing and maintaining quality within the CCBI Crime Laboratory Division. It is the policy of the CCBI Crime Laboratory Division for units to have and use written procedures for all examinations within their scope.

These procedures include, when necessary and relevant, handling, transfer/transport, storage, and preparation of evidence to be examined; sampling; calculations, including any statistical techniques for the analysis of examination data; uncertainty of measurement; limitations of the procedures including any environmental conditions affecting quality. All Laboratory Unit Technical Procedures used in the CCBI Crime Laboratory Division will be reviewed, approved, and controlled prior to implementation.

Units will have procedures and/or instructions for operating CCBI Crime Laboratory Division equipment where the absence of such instructions would jeopardize the results of tests. Procedures will also exist for handling and preparing evidence for examination to ensure the quality of the results. Any deviations from a Technical Procedure will follow the Exception to Policy Approval Process section of the CCBI Standard Operating Procedure for Written Directives.

Units will be responsible for maintaining their Laboratory Unit Technical Procedures and ensuring the procedures are up-to-date and readily available to appropriate employees.

Technical Procedures may specify the use of appropriate standards and controls. Any standards or controls used will be recorded in the technical records.

**5.4.2 Selection of methods**

Analysts will select appropriate technical procedures to meet the needs of the contributor while taking into account the nature of the evidence and the facts of the case. These technical procedures should be consistent with procedures published in international, regional, or national standards, by reputable technical organizations, in relevant scientific texts or journals, or as specified by the manufacturer of the equipment or developed by the CCBI Crime Laboratory Division.

If the CCBI Crime Laboratory Division uses a technical procedure, it will use the latest version when possible. The technical procedure will be supplemented with additional details to ensure consistent application.

The CCBI Crime Laboratory Division will confirm that it can properly use a technical procedure prior to introducing it for forensic examinations. The confirmation will be repeated if the technical procedure changes.

Technical procedures developed or adopted by the CCBI Crime Laboratory Division, including standard procedures, will be used as appropriate. Customers accept and approve these technical methods by way of submission of the CCBI Laboratory Examination Request Form or whenever evidence is submitted to the CCBI Crime Laboratory by the CCBI Investigations Division staff subsequent to a request for crime scene services.

The reliability of a validated technical procedure that is new to the CCBI Crime Laboratory Division will be confirmed in-house against any documented performance characteristics of that procedure prior to first use. Validation Plans and records of Performance Checks conducted will be maintained by the Laboratory Unit.

**5.4.3 CCBI Crime Laboratory Division-developed methods**

When a unit develops a technical procedure, it will be a planned activity that is performed by qualified employees with adequate resources. Any significant changes occurring during the development of the procedure will be effectively communicated to all employees involved in the development process.

**5.4.4 Non-standard methods**

Units will use validated technical procedures; however, this does not preclude the Analyst from deviating from a procedure if the nature of the evidence precludes the use of a technical procedure. Changes to or deviations from a technical procedure must be within the bounds of good Crime Laboratory practice, documented, justified, and approved according to the Exception to Policy Approval Process section of the CCBI Standard Operating Procedure for Written Directives.

**5.4.5 Validation of methods**

**5.4.5.1**

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

**5.4.5.2**

New non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope and amplifications and modifications of standard methods must be validated prior to use to confirm that the methods are fit for the intended use. The Laboratory Administrative Procedure for Validation and Verification outlines the requirements for proceeding with the validation process. The validation must be as extensive as is necessary to meet the needs of the given application or field of application. Units will maintain validation records to include, but not limited to, the results obtained, the procedure used for the validation and a statement as to whether the method is fit for the intended use.

Minor upgrades to critical software in the digital evidence discipline shall be subjected to performance verification prior to use.

**5.4.5.3**

The range and accuracy of the values obtainable from new validated methods will be assessed to ensure that the procedure meets the requirements of the customer’s needs and application.

**5.4.5.4**

Prior to implementation of a validated method new to the CCBI Crime Laboratory Division, the method shall be subjected to performance verification prior to use. The reliability of the method shall be demonstrated “in–house” against any documented performance characteristics of that method, to include one or more of the following:

* calibration using reference standards or reference materials;
* comparison of results achieved with other methods;
* inter-laboratory comparison;
* systematic assessment of the factors influencing the result;
* assessment of the results based on scientific understanding of the principles of the method and practical experience.

Performance verification must, at a minimum, demonstrate that a representative set of reference materials has been carried through the process and yielded the expected results. The Laboratory Administrative Procedure for Validations and Performance Verifications outlines the requirements for proceeding with the performance verification process. Units will maintain performance verification records to include, but not limited to, the results obtained, the procedure used for the performance verification and a statement as to whether the method is fit for the intended use.

**5.4.6 Estimation of Uncertainty of Measurement**

**5.4.6.1**

The CCBI Crime Laboratory Division does not perform calibration services.

**5.4.6.2**

When a quantitative numerical measurement result for a measurement that matters is included in a laboratory report, the uncertainty of measurement (when established) shall be reported clearly. Laboratory Unit Technical Procedures shall include considerations for reasonably estimating the uncertainty of measurement by attempting to identify and combine all significant components of uncertainty. The estimation shall be based on knowledge of the performance of the method, the measurement scope, and shall make use of any previous experience and validation data. The degree of rigor in an estimation of uncertainty of measurement depends of factors such as:

* The requirements of the procedure.
* The existence of limits on which decisions on conformity to a specification are based.

Each Unit in which the estimation of the uncertainty of measurement is required shall maintain records of each estimation of uncertainty of measurement performed.

**5.4.6.3**

When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

**5.4.7 Control of Data**

**5.4.7.1**

All Analysts will ensure that manual calculations and data transcriptions and transfers relevant to examinations are checked for accuracy.

**5.4.7.2**

When computers or automated equipment are used for forensic examinations, units will ensure that:

* Computer software developed in-house is documented, evaluated, and validated prior to use;
* Procedures for protecting test data maintain the integrity and confidentiality of the data;
* Operating conditions and maintenance are such that computers and automated equipment function properly.
* All laboratory computers used for data entry or collection, data storage, and/or data transmission and data processing shall be password protected or otherwise secured to prevent unauthorized access

## 5.5 Equipment

**5.5.1**

The CCBI Crime Laboratory Division is furnished with, or has access to, all items needed for the correct performance of forensic examinations. In those cases where the Laboratory needs to use equipment outside of its permanent control, it shall ensure that International standards are met. All instruments and equipment having an effect on the accuracy or validity of forensic examination results will be properly maintained and calibrated or performance checked. Requirements for instrument calibration or performance checks and maintenance are specified in the Technical Procedures for each unit. The CCBI Crime Laboratory Division shall maintain an inventory of all equipment used to perform testing.

**5.5.2**

Equipment and its software used for the examination of evidence must meet the requirements of the relevant technical procedure. Before being placed into service, equipment will be calibrated and/or performance checked to verify that it meets the unit’s specifications.

**5.5.3**

CCBI Crime Laboratory Division equipment will be operated by qualified and authorized employees. Manufacturer’s manuals and up-to-date instructions for the use and maintenance of equipment will be available to the appropriate employees.

**5.5.4**

CCBI Crime Laboratory Division instruments, equipment, and their associated software used for forensic examinations and significant to examination results will be uniquely identified if practicable.

**5.5.5**

Records of each instrument and its associated software and firmware used for forensic examinations will be maintained according to the Laboratory Administrative Procedure for Equipment Records.

**5.5.6**

Procedures for appropriate use and planned maintenance of equipment to ensure proper functioning are found in the Laboratory Unit Technical Procedures.

**5.5.7**

Any instrumentation that is malfunctioning will be taken out of service and clearly labeled to prevent use until repairs are completed. Only when it is shown by calibration or a performance check to operate correctly will the instrument be returned to service. Units will determine the effect of the malfunction, if any, on test results and implement the Laboratory Administrative Procedure for Corrective and Preventive Action when necessary.

**5.5.8**

CCBI Crime Laboratory Division instrumentation requiring calibration will be labeled or otherwise identified to indicate the calibration status, when practicable. Methods for calibration shall be explained in the unit Technical Procedures.

**5.5.9**

Prior to its return to service, calibrations or performance checks must be satisfactorily completed by the appropriate unit on any instrument that goes outside the control of the CCBI Crime Laboratory Division.

**5.5.10**

When necessary, performance checks will be carried out on calibrated equipment according to the appropriate Laboratory Unit Technical Procedure.

**5.5.11**

Where instrument calibrations or performance checks produce a set of correction factors, the correction factors will be made available to appropriate employees.

**5.5.12**

Instrumentation used for forensic examinations, including both hardware and software, will be safeguarded from adjustments which would invalidate the test results. These safeguards include password protection, where applicable.

## 5.6 Measurement Traceability

**5.6.1 General**

Equipment used for forensic examinations will be calibrated or performance checked according to unit Technical Procedures prior to being put into service.

**5.6.1.1**

CCBI Crime Laboratory Division units have established calibration intervals for equipment/ instrumentation requiring calibration. Equipment/instrumentation calibration will be checked following service, shut down, or other substantial maintenance.

**5.6.2 Specific Requirements**

**5.6.2.1 Calibration**

The CCBI Crime Laboratory Division is not a calibration laboratory.

**5.6.2.2 Testing**

**5.6.2.2.1**

Units that perform internal calibrations of equipment/instrumentation will establish traceability by means of an unbroken chain of calibrations or comparisons linking the calibration standards to the relevant primary standards of the SI units of measurement.

When necessary, units can utilize competent external calibration services that can demonstrate measurement capability and traceability. The calibration certificates issued by these entities will contain the calibration results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification.

**5.6.2.2.2**

Measurements made by disciplines should be traceable to SI units. The link to SI units may be achieved by reference to national measurement standards.

Where traceability of measurements to SI units is not possible and/or relevant, units will establish traceability to other appropriate measurement standards such as certified reference materials or agreed methods and/or consensus standards.

**5.6.3 Reference Standards and Reference Materials**

**5.6.3.1 Reference Standards**

CCBI Crime Laboratory Division units will have procedures for the calibration of their reference standards to ensure that the calibrating organization provides traceability to SI units by a means of an unbroken chain of calibrations or comparisons linking the reference standards to the relevant primary standards of the SI units of measurement. Units will only use a reference standard for calibration purposes if it can be shown that any additional use will not invalidate it. When appropriate, reference standards will be calibrated before and after any adjustment.

**5.6.3.2 Reference Materials**

Reference materials will be traceable to SI units or to certified reference materials, where practicable. Internal reference materials will be checked to verify their suitability.

**5.6.3.2.1**

CCBI Crime Laboratory Division units utilizing reference collections for comparison or interpretation purposes will document, uniquely identify, and properly control such references.

**5.6.3.3 Intermediate Checks**

CCBI Crime Laboratory Division units will perform checks on reference, primary, or working standards as well as reference materials to maintain confidence in their calibration status in accordance with the appropriate Laboratory Unit Technical Procedures.

**5.6.3.4 Transport and Storage**

To protect the integrity of reference standards and materials, CCBI Crime Laboratory Division Unit Technical Procedures will address handling and use.

## 5.7 Sampling

Sampling plans are required when taking part of a representative sample of a substance, material, or item to provide for testing and reporting on the whole substance, material, or item.

**5.7.1**

The Drug Chemistry Unit will have a plan and procedure for the sampling of evidence included in the appropriate unit Technical Procedures. The sampling plan will address the factors to be controlled to ensure the validity of the examination results.

**5.7.2**

If the contributor or the nature of the evidence requires deviation or exclusion from the sampling plan described in the appropriate unit Technical Procedures, the deviation will be documented by the Analyst. This deviation will be recorded in detail in the technical records. The deviation will be carried out in accordance with the Exception to Policy Approval Process section of the CCBI Standard Operating Procedure for Written Directives.

**5.7.3**

The Drug Chemistry Unit will document appropriate sampling data and activities relating to the forensic examination process. Records will be maintained in the CCBI Crime Laboratory Division case file and will include the sampling procedure used, the identification of the individual performing the sampling, any relevant environmental conditions, diagrams of the sampling location as necessary, and, if relevant, the statistical basis for the sampling procedures.

## 5.8 Handling of Items of Evidence

**5.8.1**

The Laboratory Administrative Procedure for Evidence Handling gives guidance for the handling of evidence which protects the integrity of evidence, the interests of the CCBI Crime Laboratory Division, and the interests of the contributor.

**5.8.1.1**

The CCBI Crime Laboratory Division uses the CCBI Laboratory Examination Request form or the CCBI Evidence Inventory form to record all internal transfers of evidence from the time of receipt. These documents track the chain of custody for each evidence container submitted for analysis. This system includes a signature or equivalent identification of the person/location receiving the evidence, the date of receipt or transfer, and the unique identifier of the evidence.

**5.8.1.1.1**

When evidence is sub-divided in the CCBI Crime Laboratory Division, sub-items will be tracked to the same extent that the original items of evidence are tracked.

**5.8.1.1.2**

The CCBI Crime Laboratory Division shall ensure that evidence is packaged in a manner which protects its evidentiary value in accordance with the Laboratory Administrative Procedure for Evidence Handling.

**5.8.2**

The CCBI Crime Laboratory Division will identify items of evidence according to the Laboratory Administrative Procedure for Evidence Handling. These procedures ensure that items of evidence are uniquely identified and provide for sub-divided evidence.

Evidentiary items will be transferred within and from the CCBI Crime Laboratory Division according to the Laboratory Administrative Procedure for Evidence Handling. The unique identifier shall be retained throughout the life of the item in the CCBI Crime Laboratory Division.

**5.8.3**

Upon receipt of evidence, any departures from normal or specified conditions will be documented according to the Laboratory Administrative Procedure for Review of Requests, Tenders and Contracts for Laboratory Services.

The contributor will be contacted when the suitability of an item of evidence for examination is questionable or the request for examination is unclear. This communication will be documented in the case record communication log.

**5.8.4**

The CCBI Crime Laboratory Division will ensure the integrity of evidence by protecting items from loss, cross-transfer, or deleterious change during storage, handling, and preparation according to the Laboratory Administrative Procedure for Evidence Handling. Appropriate handling instructions provided with an item will be followed. When evidentiary items must be stored or handled under specified environmental conditions, these conditions will be maintained, monitored, and recorded.

**5.8.4.1**

Any evidence not in the process of examination must be protected from loss, cross-transfer, or contamination. Any such evidence will be stored in accordance to the Laboratory Administrative Procedure for Evidence Handling.

**5.8.4.2**

The time period for active examination shall not be open-ended and shall be based upon a justifiable expectation of frequent examination/analysis.

**5.8.4.3**

Each item of evidence will be marked to ensure that it is uniquely identified and traceable to the CCBI Crime Laboratory Division case number.

**5.8.4.4**

Digital or electronic photographic files to be forensically examined or utilized for reference purposes in a forensic examination may be placed on a physical storage device and submitted to the Crime Laboratory or submitted to the Crime Laboratory via the Internet though the CCBI secure URL.

Any physical storage device submitted to the Crime Laboratory which contains digital or electronic files to be forensically examined or utilized for reference purposes in a forensic examination will be treated as evidence and labeled with a CCBI case number and item number.

Digital or electronic photographic files submitted via the secure URL for forensic examination or reference purposes in a forensic examination will be stored in the Dataworks Plus DigitalCrimeScene (DCS) electronic crime scene management system. Digital or electronic photographic files submitted via the secure URL for forensic examination or reference purposes in a forensic examination will treated as evidence and assigned a CCBI case number and item number in DCS.

Digital or electronic photographic files otherwise uploaded into DCS and subsequently determined by a CCBI Laboratory Examiner to be required for evidentiary examination will be treated as evidence and assigned a CCBI case number and item number in DCS.

Subsequent printed or hard copy documents produced from a digital or electronic file assigned a CCBI case number and item number in DCS will be treated as a technical case record.

## 5.9 Assuring the Quality of Test Results

**5.9.1**

CCBI Crime Laboratory Division units will have quality control procedures for monitoring the reliability of forensic examinations. The resulting data will be recorded in such a way that trends are detectable and, where practicable, statistical techniques will be applied to the reviewing of the results.

**5.9.1.1**

Laboratory Unit Technical procedures shall specify standards and controls, and the use of standards and controls shall be recorded in the case record.

**5.9.2**

CCBI Crime Laboratory Division units will have procedures for evaluating quality control data against defined criteria. When quality control data are found to fall outside established criteria, appropriate corrective actions will be taken to prevent incorrect results from being reported.

**5.9.3**

Proficiency testing is an integral part of the CCBI Crime Laboratory Division quality system. It is one of many quality control measures used to monitor the CCBI Crime Laboratory Division’s own performance as well as to identify areas where improvement may be needed.

The CCBI Crime Laboratory Division proficiency testing program is documented in the Laboratory Administrative Procedure for Proficiency Testing. Proficiency testing applies to Analysts in each discipline and/or category of testing in which casework is performed.

**5.9.3.1**

CCBI Crime Laboratory Division units will follow CCBI-approved Technical Procedures when participating in proficiency testing programs to include verification, technical review, and administrative review.

**5.9.3.2**

The CCBI Crime Laboratory Division proficiency testing program will comply with the proficiency testing requirements of the accrediting body.

**5.9.3.3**

All Analysts who participate in casework activities will successfully complete at least one (1) internal or external proficiency test per calendar year per discipline.

**5.9.3.4**

CCBI Proficiency Testing Program will be performed according to the requirements of the accrediting body.

**5.9.3.5**

In addition to proficiency testing, the CCBI Crime Laboratory Division may also participate in interlaboratory comparisons to monitor its performance.

**5.9.4**

Consultation is a normal and acceptable practice in any professional environment. A consultation is a discussion or conference between a laboratory examiner assigned to a forensic examination and another laboratory examiner about any aspect of an examination while the examination is in process. A consultation intrinsically means no decision or conclusion has been reached by the assigned examiner, because the examination is in process and the examiner is seeking a discussion regarding the examination before reaching any final conclusion(s) about the result(s) of the examination.

Each laboratory examiner is ultimately responsible for determining the final conclusion(s) of the forensic examinations they have been assigned to perform and for documenting their final conclusion(s). The acceptance of responsibility for the examination is signified by the placement of the examiner(s) name on the laboratory report.

Consultation will be conducted in accordance with the Laboratory Administrative Procedure for Consultation.

**5.9.5**

Technical reviews of technical records and reports will be conducted according to the Laboratory Administrative Procedure for Technical and Administrative Reviews.

**5.9.6**

Administrative reviews on all documentation in the case file will be conducted prior to release and according to the Laboratory Administrative Procedure for Technical and Administrative Reviews.

**5.9.7**

The CCBI Crime Laboratory Division will follow the Laboratory Administrative Procedure for Courtroom Testimony Review. If the evaluation is less than satisfactory, then it will be investigated to determine if corrective action is needed.

## 5.10 Reporting the Results

**5.10.1 General**

CCBI Crime Laboratory Division employees will accurately, clearly, unambiguously, and objectively report the results of each examination according to Laboratory Unit Technical Procedures and CCBI Report Writing Manual. CCBI employees are responsible for all of the information provided in the report, except that provided by the submitting agency and any data provided by the agency will be identified and if it can affect the results, a disclaimer will be included in the report.

**5.10.1.1**

All cases in which evidence has been submitted for forensic examination but a request has been made to stop the forensic examination will be returned with a laboratory report indicating the Stop Work request. The policy for reporting Stop Work cases shall be provided in the Laboratory Administrative Procedure for Laboratory Reports.

**5.10.2 Content of Reports of Examination**

CCBI Crime Laboratory Division case records will be reported according to the Laboratory Unit Technical Procedures and the CCBI Report Writing Manual. When agreed with the customer, the results may be reported in a simplified way. Reports will contain the following information unless otherwise agreed to with the customer:

* Title.
* Identification of the City-County Bureau of Identification as performing the casework.
* The location of the performance of the laboratory activity.
* The unique identification of the report, the unique identification on each page and a clear indication of the end of the report.
* The name and address of the submitting agency.
* The type of analysis used.
* An unambiguous description of the items analyzed.
* The date of receipt of the items analyzed as well as the date of analysis and date of issuance of the report.
* The test results, including the unit of measurement, if applicable.
* A reference to the sampling plan or method, if applicable.
* The name and signature of the individual authorized to report the results.
* A statement the results relate only the items analyzed, when relevant.
* Any deviations from, additions to, or exclusions from the test method.

**5.10.3 Additional Report of Examination Guidelines**

**5.10.3.1**

When it is necessary for the interpretation of the examination results, CCBI Crime Laboratory Division reports may include additional information including:

* Information on test conditions, such as environmental conditions.
* A statement on the conformance or non-conformance with requirements and/or specifications.
* A statement on the uncertainty of measurement, when applicable.
* Opinions and interpretations.
* Additional information which may be required by the submitters.
* A disclaimer indicating any results which are affected by a deviation when there is doubt about

the suitability of an item for testing.

**5.10.3.2**

CCBI Crime Laboratory Division reports may include additional information regarding sampling when it is necessary for the interpretation of the examination results according to Laboratory Unit Technical Procedures and the CCBI Report Writing Manual. When CCBI employees are not responsible for the sampling, the laboratory report will state that the results apply to the sample as it was received if necessary, for interpretation of the examination results.

**5.10.3.3**

CCBI Crime Laboratory Division reports are issued according to the Laboratory Administrative Procedure for Laboratory Reports.

**5.10.3.4**

Analysts who issue findings, including writing reports and providing testimony based on the technical records generated by another person will document the review of the technical records.

**5.10.3.5**

The significance of an association will be included in CCBI Crime Laboratory Division reports.

**5.10.3.6**

All eliminations resulting from comparative examinations shall be communicated clearly in the laboratory report.

**5.10.3.7**

When a definitive conclusion cannot be reached, the reason shall be stated clearly in the laboratory report.

**5.10.4 Calibration Certificates**

The CCBI Crime Laboratory does perform calibrations activities and does not issue calibration certificates.

**5.10.5 Opinions and Interpretations**

Opinions and interpretations are identified in CCBI Crime Laboratory Division reports under “Results and Conclusions” and will only be released by authorized personnel. The basis for any opinions and/or interpretations shall be clearly documented in the case record. When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue will be retained in the case’s communication log.

**5.10.6**

Reserved for Future Use.

**5.10.7 Electronic Transmission of Results**

The transmission of all CCBI Crime Laboratory Division reports and examination results by telephone, facsimile, or other electronic means must follow the CCBI Standard Operating Procedure for Records Management System Administration.

**5.10.8 Format of Report of Examination**

CCBI Crime Laboratory Division reports are formatted according to the CCBI Report Writing Manual.

**5.10.9 Amendments to Reports of Examination**

Once CCBI Crime Laboratory Division reports have been issued, any amendments or additional reports must be made in the form of another report and will meet all the requirements of the CCBI Standard Operating Procedure for Records Management System Administration and the Laboratory Administrative Procedure for Laboratory Reports.

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| **Revision History** |
| **Effective Date** | **Version Number** | **Reason** |
| January 1, 2020 | 1 | New 2020 FSQM |
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