# MONTGOMERY COUNTY CORONER'S OFFICE / MIAMI VALLEY REGIONAL CRIME LABORATORY QUALITY MANUAL

Based on the requirements of ISO/IEC 17025:2017 and ANAB AR 3125 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements

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**Introduction**

The Montgomery County Coroner's Office / Miami Valley Regional Crime Laboratory (MCCO/MVRCL) is committed to quality performance and conformance to recognized forensic science and laboratory best practices. As new and improved methods of scientific analysis are developed it is essential for the organization's quality standards to progress in parallel. The MCCO/MVRCL is dedicated to implementing policy and procedural changes to ensure quality in all facets of its operations.

This document has been developed with the objective of defining the quality assurance system and establishing uniform standards for operation at the MCCO/MVRCL. This document contains requirements for the organization to demonstrate they operate competently and can generate valid results. This document requires the MCCO/MVRCL to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results, and preventing negative effects. The MCCO/MVRCL management is responsible for deciding which risks and opportunities need to be addressed.

The continued development and improvement of the MCCO/MVRCL quality system serves to increase confidence in our work product while strengthening the professional integrity of the organization and its employees. Using recognized quality practices and procedures, MCCO/MVRCL will continue to meet the challenges of the future.

## 1 About this Document

### 1.1 Purpose.

This manual establishes the minimum quality assurance requirements for forensic science work performed at MCCO/MVRCL.

### 1.2 Scope.

The MCCO/MVRCL Quality Manual (QM) is based on the ISO/IEC 17025:2017 standard complemented by the ANAB AR3125 - Forensic Science Testing and Calibration Laboratories Accreditation Requirements which are wholly relevant to the work of the MCCO/MVRCL. This manual is subordinate, in all non-forensic science areas, to any applicable governmental policy, procedure, practice, requirement, or law that is issued at the county level or above.

### 1.3 Document Conventions

#### *1.3.1 Use of the Term "Shall", "Should", "May", and "Can"*

In this document, the following verbal forms are used:

— "shall" or "must" indicates a requirement or the execution of a requirement and the verification of its implementation;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

#### *1.3.2 Responsibilities and Authority*

The MCCO/MVRCL QM is issued under the authority of the Coroner and the Director of Operations. The MCCO/MVRCL QC shares in the responsibility for incorporating quality practices and procedures into their daily operation and for adhering to established quality measures. All MCCO/MVRCL employees are crucial to the overall success of the quality management program.

Each requirement below includes a marker at the end of the sentence indicating who has the responsibility for satisfying the requirement. If QC appears after a requirement, the TL for each section is responsible for the requirement as it affects their section.

The following names, phrases and abbreviations shall be used to designate responsibility:

- [TM] – Top Management; a team comprised of the Coroner, the Director of Operations, the Scientific Director of MVRCL, and the Quality Manager of MCCO
- [TL] – Technical Leader; responsible for the technical operations of a specific forensic unit in the organization. When QC appears next to a requirement below, it is the TL's responsibility to ensure their specific section is meeting the specific requirement.
- [QC] –Quality Committee; responsible for the organization's quality assurance program; formulating quality control policies; ensuring work product acceptability; and improving organizational efficiency. This committee is comprised of the TL of each section, the Scientific Director of MVRCL, Quality Manager of MCCO, and is chaired by the Director of Operations.
- [Examiner] – An individual who conducts and/or directs the analysis of casework samples, interprets data, reaches conclusions, and issues reports concerning conclusions. This term may be defined as forensic scientist, analyst, examiner, chemist, pathologist, investigator, or toxicologist. Refer to each section's procedure manuals for more information.
- [Evidence Officer (EO)] – Individual responsible for the receipt and storage of submitted forensic evidence.
- [Evidence Collector (EC)] – Individual responsible for collecting evidence either from a decedent or from a death scene.
- [Technician] – Individual who performs tasks under the direction of an Examiner. This term may be defined as toxicology technician, morgue technician, or laboratory technician.
- [All Personnel] – All employees

### *1.3.3 Document Control Markings*

When the document is viewed either electronically or in printed form, the footer shall state:

*"Uncontrolled if printed"*.

Any conflict between the electronic version and any other form shall be resolved in favor of the electronic version.

### *1.3.4 External Disclosure of MCCO/MVRCL Quality Documents*

Any dissemination and/or distribution, in whole or in part, of any portion of the MCCO/MVRCL Quality System documentation, including but not limited to the Quality Manual, Standard Operating Procedures (SOP), Training Manuals (TM), or guidance documents, to entities outside MCCO/MVRCL for litigation purposes is done upon request. Requests for documents for purposes other than litigation (e.g., public record request) are handled by the DO and tracked in Qualtrax.

## 2 References

ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories

AR 3125, ISO/IEC 17025:2017 – Forensic Science Testing and Calibration Laboratories Accreditation Requirements.

ANAB – GD3150 Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel

ISO/IEC 17000:2004 – Conformity assessment -- Vocabulary and general principles

ISO 9000:2015 – Quality management systems -- Fundamentals and vocabulary

National Institute of Standards and Technology (NIST) SP 800-171 Rev. 1, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations

Federal Criminal Justice Information Services (CJIS) Security Policy,

**3 Terms and Definitions**

**Accreditation cycle** – The period of time (generally four years) between the date that accreditation is granted and the date accreditation expires.

**Administrative records** – Records, whether electronic or hardcopy, that do not constitute data or information resulting from examination, such as case related conversations, examination item (evidence) receipts, chain of custody records, description of evidence packaging and seals, incident reports, service requests, correspondence received/sent, reports issued related to an examination, and other pertinent information.

**Audit** – A systematic, independent, documented process for obtaining records, statements of fact, or other relevant information, and assessing them objectively to determine the extent to which specified requirements are fulfilled.

**Case records** – Administrative, examination records, and any other applicable technical records, whether electronic or hardcopy, generated or received by the organization pertaining to a particular case, which may be stored in one or more locations.

**Category of testing** – A specific type of analysis within an accredited discipline of forensic science.

**Certified reference material (CRM) –** 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 (ISO Guide 30:2015, modified). The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence.

**Competency test** - The evaluation of a person's knowledge, skills, and/or ability to perform work.

**Control** - Any measure or action that modifies or regulates risk. Controls include any policy, procedure, practice, process, technology, technique, method, or device that modifies or regulates risk. Risk treatments become controls, or modify existing controls, once they are implemented. (ISO 31000:2018)

**Contract** – For the purpose of this manual, a contract is a formal and legally binding agreement between MCCO/MVRCL and a customer.

**Corrective actions** – Documented actions taken by the organization to address nonconformities in the quality management system.

**Customer** – For the purpose of meeting accreditation requirements, a person or organization which could or does receive a product or service that is intended for or required by this person or organization. A customer can be internal or external.

**Complaint** - expression of dissatisfaction by any person or organization regarding MCCO/MVRCL relating to the activities or results of MCCO/MVRCL, where a response is expected.

**Decedent –** Any individual whose death was reported to MCCO.

**Decedent Seal –** All decedents received by MCCO must be in a closed body bag upon receipt. Decedents must have an identification tag affixed to the body. If the body bag is closed with a bag lock, the identification tag may be secured to the outside of the bag and affixed to the body during the time of the examination.

**Director of Operations (DO)** - The highest-ranking administrator within MCCO/MVRCL.

**Discipline** – A major area of activity in forensic science.

**Evidence** – Material, regardless of form, which is received or collected by MCCO/MVRCL for the purpose of determining information relevant to a criminal investigation or death investigation. Evidence may include a decedent, items collected during a death investigation, or items submitted to MVRCL for analysis.

**Evidence Control Facility** - A controlled access space for processing and storing evidence, such as an evidence room or vault.

**Examination** – The procedure utilized by the examiner to obtain information from evidence in order to reach relevant conclusions.

**Examination documentation/records** – The documentation, whether hardcopy or electronic, of procedures followed, examinations conducted, standards and controls used, diagrams, printouts,

photographs, observations and results of examinations. Examination records constitute a part of "technical records."

**Examiner** – An individual who conducts and/or directs the analysis of casework samples, interprets data, reaches conclusions, and issues reports concerning conclusions. This term may be defined as forensic scientist, analyst, examiner, chemist, pathologist, investigator, or toxicologist.

**Impartiality** – presence of objectivity. Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the organization.

**Individual characteristic database** - A computerized, searchable collection of features, generated from samples of known origin from which individual characteristic information originates (e.g., friction ridge data or firearm bullet/cartridge case images).

**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

**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.

**Management –** a team comprised of the QC and TM.

**Method** - The course of action or technique followed in conducting a specific examination or comparison leading to a result.

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

**Observation-Based Performance Monitoring –** When intra laboratory/inter laboratory comparisons or proficiency tests are not available or appropriate, an examiner/technician may be monitored by another qualified examiner with appropriate documentation of their successful completion of the monitored test.

**Organization** – body that performs testing and or sampling, associated with subsequent testing.

**Policy** - A guiding principle, operating practice, or plan of action governing decisions made on behalf of an organization.

**Preliminary results** – Results of an examination released to the customer prior to a final report being issued.

**Preventive actions** – Documented actions taken to eliminate potential nonconformities in order to prevent their occurrence or evaluating patterns/trends through corrective actions and taking steps to prevent their reoccurrence.

**Problem -** A situation that is unsatisfactory and causes difficulties. Problems are dealt with in the same way as complaints. All problems are investigated, and corrective action steps are taken as needed to eliminate the problem and to prevent recurrence. A problem could be the cause of one or more incidents or nonconformities.

**Procedure** – Detailed documents of how to perform a specific task, also known as Standard Operating Procedures (SOPs).

**Proficiency testing** – evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons* with results that are submitted to the organization providing the test, as well as an accreditation body.

**Proper evidence seal** - A seal that prevents loss, cross-transfer, or contamination while ensuring that attempted entry into the container is detectable. When the seal is done by a MCCO/MVRCL staff member, the initials or other identification of the person creating the seal should be placed on the seal or across the seal onto the container when possible. When the organization receives evidence from an external agency without a proper seal it is documented within the case record. Decedent seals are defined separately.

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

**Quality committee** – A committee responsible for the organization's quality assurance program; formulating quality control policies; ensuring product acceptability; and improving organizational efficiency. This committee is comprised of the TL of each section, the Scientific Director of MVRCL, Quality Manager of MCCO, and is chaired by the Director of Operations.

**Quality Manager** – Designated MCCO employee with overall responsibility for quality assurance in death investigations, morgue operations, and pathology.

**Quality system** - The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management; includes all activities which contribute to quality, directly or indirectly.

**Reagent** – A substance used because of its known chemical or biological activity.

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

**Reference material (RM) -** 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 (ISO Guide 30:2015).

**Reference material producer (RMP)** - Body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance of a reference material certificate or other statements for the reference material it produces (ISO 17034:2016).

**Reference standard** - A measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location (JCGM 200:2012).

**Request** – the process utilized by a customer when seeking analysis from the organization. This includes both requests for analysis on evidence through MVRCL and requests for death investigation and/or autopsy through MCCO.

**Risk** - the "effect of uncertainty on objectives" and an effect is a positive or negative deviation from what is expected. The traditional definition of risk combines three elements: 1) a potential event; 2) its probability; and 3) its potential severity. A high-risk event would have a high likelihood of occurring and/or a severe impact if it occurred.

**Sampling –** Selection of a sample for testing, according to a procedure; it may be either statistical or non-statistical.

**Scene Investigation –** Any homicide, suicide, accidental, or suspicious death that may require an investigator to respond to the scene of a death to perform a medicolegal death investigation.

**Scientific Director (SD)** - The highest-ranking manager within the MVRCL.

**Secure area** - A locked space (for example, cabinet, vault, or room) with access restricted to personnel authorized by top management.

**Technical Leader** - An individual designated by management to oversee unit-specific quality documentation and procedures.

**Technical records** – Technical records are accumulations of data and information which result from carrying out examinations and which indicate whether specified quality or process parameters are achieved. They may include forms, worksheets, workbooks, check sheets, work notes, control graphs, external and internal examination reports, customers' notes, and feedback.

**Technical Support Personnel / Technician** - Individuals who perform casework related duties within the organization at the direction of an examiner but do not issue reports related to conclusions reached. (Morgue Technicians)

**Tender** – The organization's response to a customer regarding their request. For most requests, a final report is the organization's response. A final report is not issued for death investigations where it is determined that no further examination is necessary.

**Verification** – Provision of objective evidence that a given item fulfills specified requirements. Example: confirmation of a test result/opinion by performance of the comparison between the unknown and the known by a different person.

## 4 General requirements

### 4.1 Impartiality

**4.1.1** *Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality. [QC]*

MCCO/MVRCL policies and procedures follow peer reviewed and published forensic science best practices, are fully documented, and are controlled through the organization's document management system (i.e., Qualtrax). Examination of evidence is performed in an unbiased and independent manner.

For the MVRCL, all final reports are technically and administratively reviewed by another qualified examiner to ensure laboratory policies and procedures were followed and to verify the integrity of the examination work performed.

For the MCCO, at least 10% of pathology final reports are technically reviewed by another qualified pathologist to ensure policies and procedures were followed and that any conclusions were supported by the available information.

A contract with the organization's customers is established when evidence or a decedent is received. This contract includes that this organization will not disclose private information provided by a customer to any other party, unless directed to by the customer. In addition, if a conflict of interest between a customer, a request, and/or an employee is identified, TM will be notified, and safeguards will be taken to mitigate the conflict of interest.

**4.1.2** *The laboratory management shall be committed to impartiality. [TM]*

MCCO/MVRCL top management is committed to impartiality. Organization personnel receive annual compliance and training in proper conduct and ethics, which includes an annual review of ANAB – GD3150 Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel.

**4.1.3** *The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial, or other pressures to compromise impartiality. [TM]*

MCCO/MVRCL operates as an impartial independent agency within the Montgomery County Government, which ensures the organization, and its personnel are free from any undue commercial, financial, or other pressures that might influence the organization's judgment and impartiality. If an undue pressure is identified, it will be communicated to TM for investigation.

***4.1.3.1*** *The management system shall:*

*a) have a code of ethics as part of the management's commitment to good professional practice; [TM]*
*b) ensure annual review of the code of ethics by all personnel and retain a record of the review; [TM] and*
*c) ensure appropriate actions are taken when necessary. [TM]*

*NOTE An equivalent document is one that covers the same topics and demonstrates that the relevant aspects are covered.*

All personnel support and adhere to the ANAB – GD3150 Guiding Principles of Professional Responsibility for Forensic Service Providers and Forensic Personnel. Documentation of this is downloaded from the ANAB Forensic Accreditation Documents website and a copy is retained in the organization's Qualtrax system. Personnel review the guiding principles of professional responsibility document annually; documentation of this review is retained electronically. Appropriate actions are taken if staff fails to comply with the accreditation requirement or adhere to the guiding principles of professional responsibility.

**4.1.4** *The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. [QC]*

*NOTE A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.*

MCCO/MVRCL reviews risks to its impartiality on an on-going basis and the results are briefed to TM through the risk management workflow in Qualtrax which is used for documentation purposes.

MCCO/MVRCL's activities are governed by: contracts; criminal investigation, litigation, and evidence handling laws; forensic laboratory best practices; and ISO/ANAB/ABFT/NAME accreditation requirements.

Persons outside MCCO/MVRCL have no direct influence on the forensic science work performed by the organization nor can they adversely influence the organization's compliance with any accreditation requirements.

**4.1.5** *If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk. [QC]*

If a risk to impartiality is identified, MCCO/MVRCL applies risk management tactics to mitigate the adverse effects and control the damages and financial consequences of the threatening events. This process is documented and retained in Qualtrax.

### 4.2 Confidentiality

**4.2.1** *The laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. [QC] The laboratory shall inform the customer in advance, of the information it intends to place in the public domain. [QC] Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. [QC]*

The organization complies with governmental, MCCO/MVRCL, and contract requirements for customer and information confidentiality. The organization maintains properly secured networks for use with criminal justice evidence, case records, and stand-alone-workstations to protect sensitive information. Personnel only share information on cases with individuals who have a need to know. Precautions are taken to prevent the release of information to unauthorized persons. These precautions may include verifying the identity of a requestor, verifying that the requestor can provide case specific information, or that the requestor has approval to receive the information. Access to electronic case files is limited to MCCO/MVRCL personnel provided with a username and password. Access to evidence is limited using locked doors requiring badge access.

All staff sign a confidentiality agreement upon start of employment.

**4.2.2** *When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided. [TM]*

MVRCL - By submitting evidence to the laboratory, the customer agrees to the release of any final report to legal entities associated with their case. In addition, the laboratory will release additional information to attorneys associated with a given case, upon request. Unreasonable requests (e.g., temperature logs for all refrigerators and freezers in the laboratory) will not be fulfilled and the analyst providing the requested information will communicate this to the requestor. Public record requests (i.e., requests from entities not legally associated with a case) will be handled by the DO.

MCCO – Information regarding Montgomery County cases may be released following approval by the attending pathologist. Requested information regarding non-Montgomery County cases is referred to the specific contracting county for release.

**4.2.3** *Information about the customer obtained from sources other than the customer (e.g., complainant, regulators) shall be confidential between the customer and the laboratory. The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source. [TM]*

Customer information confidentiality is maintained by following organizational and government policies and procedures concerning customer information confidentiality, and by managing access to the data to those that have a need to know. The information obtained from the source remains confidential to the organization and is not shared with another customer, unless agreed by the source.

**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. [TM]*

Organization staff and subcontractors will maintain confidentiality of all information provided to MCCO/MVRCL and any information created by, during, or after working on a case, except as required by law.

## 5 Structural requirements

**5.1** *The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities. [TM]*

*NOTE 1 For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status.*

*NOTE 2 Publicly funded government laboratories are recognized as meeting 5.1*

The MCCO/MVRCL is funded publicly as a county agency whose services are provided when evidence or a decedent is brought to this facility. The MCCO/MVRCL is a forensic science facility dedicated to assisting law enforcement agencies with criminal investigations and the public with death investigations. The MCCO/MVRCL offers services to agencies throughout Ohio and Indiana. Agencies are either billed yearly or on a case-by-case basis.

The MCCO is a county agency which follows the regulations outlined in the Ohio Revised Code 313.

**5.2** *The laboratory shall identify management that has overall responsibility for the laboratory. [TM]*

The TM have overall authority and responsibility for MCCO/MVRCL forensics services and support to ensure quality policies, practices, and procedures are implemented within the organization. They have responsibility for the overall administration of the laboratory, for project management of all forensics services and support, and for those items specifically called out in this document. They have the authority to make and enforce decisions pertaining to all lab operations.

***5.2.1*** *There shall be a director, whose duties shall be defined. [DO]*

The DO has the authority and overall responsibility for the policies and procedures, administrative and technical operations, and for providing the resources needed to ensure the quality of laboratory operations.

**5.3** *The laboratory shall define and document the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis. [TM]*

The organization performs the following forensic activities: Seized Drugs, Latent Prints, Firearms, Toxicology, and Medicolegal Death Investigation which are defined and documented in the organization's Standard Operating Procedure (SOP) manuals (forensics procedures, evidence handling, safety, supplemental documents). MCCO/MVRCL policies, procedures, systems, programs, and instructions are available electronically on Qualtrax.

**5.4** *Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. [TM] This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility. [TM]*

The MCCO/MVRCL provides forensic services and support to contracted customers who request services and support. Forensic examination activities are conducted in such a way as to meet contractual obligations as well as relevant accrediting body requirements and the policies of the MCCO/MVRCL. The MCCO/MVRCL quality management system applies to all forensics services and support conducted by the laboratory regardless of location. The MCCO/MVRCL has no temporary or mobile facilities.

***5.4.1*** *Laboratories shall conform to requirements in PR 1018 ANAB Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation Status. [TM]*

The organization will only use the ANAB issued specific accreditation symbols and only claim accreditation status in accordance with PR1018 guidelines. Any work that is performed outside of the currently approved scope of testing will not include any ANAB wording or logo. The organization was approved to use these symbols on 6/19/2018 by ANAB.

***5.4.2*** *Any event or nonconformity that could substantially affect the integrity of laboratory activities and is related to an accreditation requirement or the requirements of regulatory authorities shall be disclosed to ANAB within 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. [TM]*

The organization notifies ANAB within 30 days of any event or nonconformity that substantially affects the activities conducted. This notification may be tracked in Qualtrax within the nonconformity workflow.

***5.4.3*** *National DNA Index System (NDIS) participating laboratories shall conform to requirements in the NDIS Operational Procedures Manual and in applicable FBI Quality Assurance Standards [NA]*
N/A

**5.5** *The laboratory shall:*

*a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; [TM]*

The MCCO/MVRCL is an organization within Montgomery County. The organization and management structure of the MCCO/MVRCL and its relationship between management, technical operations and support services are illustrated in the Organizational Charts located in Qualtrax.

*b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; [TM]*

The organization defines its top and key management as:

| Top and Key Level Management | |
|---|---|
| **Position** | **Level** |
| Coroner | Top Management |
| Director of Operations | Top Management |
| Scientific Director | Top Management |
| Quality Manager | Top Management |
| Quality Committee (comprised of TLs) | Key Management |

*c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results. [TM]*

*NOTE c) Documenting procedures to the extent necessary to assure the consistent application of activities and the validity of the results includes analysis and data interpretation to arrive at a result, opinion or interpretation*

The organization quality management system requirements (i.e., policies, systems, programs, procedures and instructions) are documented in this Quality Manual (QM) and in the MCCO/MVRCL standard operating procedure (SOP) manuals. MCCO/MVRCL policies, procedures, systems, programs, and instructions (i.e., supplemental documents) are available electronically in Qualtrax.

**5.6** *The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:*

*a) implementation, maintenance and improvement of the management system; [QC]*
*b) identification of deviations from the management system or from the procedures for performing laboratory activities; [QC]*
*c) initiation of actions to prevent or minimize such deviations; [QC]*
*d) reporting to laboratory management on the performance of the management system and any need for improvement; [QC]*
*e) ensuring the effectiveness of laboratory activities. [QC]*

Irrespective of other responsibilities:

- TM provide management oversight and have the authority and resources to make and enforce decisions pertaining to administrative and technical operations.
- The TL provides management and has the authority and resources to make and enforce decisions pertaining to their specific section's technical operations.
- The QC provides management oversight of the organization's accreditation and quality program and has the authority and resources to make and enforce decisions pertaining to the implementation, maintenance and improvement of the organization's quality management system.
- Administrative personnel to include EOs and ECs have the authority and resources needed to conduct administrative and evidence handling and preservations tasks.
- Examiners have the authority and resources to conduct forensics examinations and submit reports to customers under the guidance of the Quality Management System.

When departures from the quality management system are necessary there is a deviation authorization system (QM 7.2.1.7) available, and a corrective action system (QM 8.7) is available for departures noted after the fact. Deviations are approved, and this approval is documented. To minimize deviations, all deviations are thoroughly reviewed by the appropriate party (DO, QM, SD, TL, or QC) and compared against previously submitted requests to ensure the same deviation is not continuously being sought and to verify no other approved solution exists.

The QC maintains the quality management system and reports on the performance of the quality management system. Improvements to the management system can be identified by MCCO/MVRCL staff and are reported to either the TLs or the QC.

TM's commitment to the development, implementation and continuous improvement of the quality management system is demonstrated through the completion of:

- annual management reviews,

- staff and management review meetings,
- conducting internal audits which provide data on the effectiveness of MCCO/MVRCL's policies and procedures,
- the implementation of a corrective and preventive action program,
- and by identifying and mitigating risks that improve identified deficiencies and risks to laboratory operations.

Documentation of these reviews, audits, corrective/preventive actions, risk mitigations, and process improvements are retained in the laboratory's administrative files.

Opportunities for improvement are prioritized and approved by TM prior to implementation. Improvement targets may be set to cover quality, value, capability, cost, productivity, resource utilization and risk reduction; the organization's management policies, plans, processes, and procedures are revised as necessary; relevant MCCO/MVRCL employees are notified of change via email and improvements are reported in management review and/or staff meetings. Improvements are recorded and tracked on the Action and Improvements Items log. Necessary actions are taken if implemented improvements do not achieve set targets.

**5.7** *Laboratory management shall ensure that:*

*a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; [QC]*
*b) the integrity of the management system is maintained when changes to the management system are planned and implemented. [QC]*

Communication from TM occurs through, but is not limited to staff meetings, memorandums, training sessions, personnel reviews, e-mails, and verbal conversations with personnel. This communication continuously stresses the importance of meeting the customer's expectations. Other modes of communicating the management system include participation of the QC in management reviews, internal and external audits.

Staff meetings are held with MCCO/MVRCL personnel to discuss the importance of meeting customer requests and the importance of following the organization's quality system.

Only the QC have the authority to make changes to the quality management system. All changes are planned and implemented by the QC. Any changes or updates to the Quality Management System (QMS) are approved by TM and updated in Qualtrax.

## 6 Resource requirements

### 6.1 General

*The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities. [TM]*

The organization maintains an in-house staffing level that is balanced to handle the existing workload at any given point in time. Staffing levels and workload are continuously monitored to ensure this balance and the DO has the authority to hire additional staff, as needed. The facility was specifically built to be a multi-discipline forensics organization. There are separate rooms for evidence storage that are properly secured to prevent loss of evidence. There are separate administrative and examination workspaces. The forensic workspaces and evidence storage rooms are access controlled via badge readers or keys.

### 6.2 Personnel

**6.2.1** *All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system. [QC]*

Each section ensures the competence of all who operate specific equipment, perform forensics examinations, evaluate results, and sign test reports by either assessing their knowledge with a written test, examining their professional credentials (e.g., board certified forensic pathologist), and/or their skill and ability with a hands-on practical exercise. If it is determined the employee's knowledge is deficient in specific areas, training is provided in those areas and the employee is retested. Once the employee successfully passes the knowledge assessment/training program, their skill and ability are tested with a hands-on exercise (i.e., a competency test).

Forensic pathologists shall maintain their board certification through ABPath CertLink annually.

The organization uses personnel who are employed by MCCO/MVRCL. When contracted personnel are used, the MCCO/MVRCL ensures that such personnel are competent as determined by testing as defined in paragraph 6.2.3.1 and that they work in accordance with MCCO/MVRCL and/or customer policies and procedures, as applicable.

**6.2.2** *The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. [TM]*

Competence requirements are located in each section's training manuals. Competence is maintained through continuing education.

***6.2.2.1*** *Personnel who authorize results, opinions, and/or interpretations in the following disciplines shall meet the minimum educational requirements below. [TM]*

| *Discipline* | *Minimum Education Requirements* |
|---|---|
| *Biology, Wildlife Forensics, Fire Debris and Explosives, Geological Materials, Gunshot Residue, Materials (Trace), Seized Drugs, Toxicology* | *A baccalaureate or an advanced degree in a chemical, physical, or biological science or forensic science.* |
| *Bloodstain Pattern Analysis, Firearms/Toolmarks, Footwear and Tire, Document Examination, Friction Ridge, Digital Evidence, Video/Imaging Technology and Analysis, Crime Scene Investigation, Fire and Explosion Investigation* | *Meet the educational requirement(s) specified for competence (see ISO/IEC 17025:2017 6.2.2).* |
| *Anthropology, Disaster Victim Identification, Odontology, Medicolegal Death Investigation* | *An advanced degree in anthropology, dentistry, or medicine.* |

*NOTE 1 Minimum educational requirements apply to personnel working in any discipline for which training begins after the date of initial accreditation in that discipline under these requirements.*

*NOTE 2 This table is not exhaustive and additional disciplines may be added as appropriate.*

Examiners meet the minimum educational requirements outlined in the chart above as dictated in each job position description. Documentation is retained by management either in personnel records or on Qualtrax.

***6.2.2.2*** *The training program, to the extent necessary based on job function, shall include:*

*a) the knowledge, skills, and abilities needed to perform work; [QC]*
*b) general knowledge of forensic science; [QC]*
*c) the application of ethical practices in forensic science; [QC]*
*d) criminal law, civil law, and testimony; [QC]*
*e) provisions for retraining; [QC]*
*f) provisions for maintenance of skills and expertise; and [QC]*
*g) criteria for acceptable performance. [QC]*

*NOTE 1 Past work experience and training may be substituted for portions of the training program to the extent that it has been demonstrated to be relevant and sufficient.*

*NOTE 2 ISO/IEC 17025:2017, section 7.3 may be applicable to training programs.*

Each section has a documented training program for each specific section posted in Qualtrax that is used to provide examiners with the knowledge, skills, and abilities needed to perform forensic examinations. Each program provides information on forensic sciences, laboratory/morgue operations, initial basic-level training in evidence handling and preservation, ethics, bias/human factors, legal overview, provisions for retraining, and case documentation. The program also includes testing (i.e., competency and/or proficiency) to determine acceptable and continued performance qualification. Training records are retained either electronically or on paper.

**6.2.3** *The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations. [TM]*

See section 6.2.3.1

***6.2.3.1*** *All personnel who influence the results of testing or calibration activities shall be competency tested. The competency test shall include practical examination(s) that cover the spectrum of anticipated activities related to the test or calibration. The competency test intended results shall be achieved prior to performing the activity on a test or a calibration item. [TM]*

*NOTE Competency testing can be conducted for an individual task or a group of tasks covered by a module of a training program.*

Each section ensures the competence of their forensic examiners who work at the MCCO/MVRCL and who operate specific forensic equipment, perform forensic examinations, evaluate results, opinions, interpretations, testimony, and sign test reports by assessing their knowledge with a written test and/or through a hands-on practical exercise (i.e., competency test). All examiners are required to meet the competency requirements prior to performing unsupervised examination activities on evidence. If it is determined the examiner's knowledge is deficient in specific areas, training is provided in those areas and the examiner is retested. Competency tests are created to closely resemble actual casework so that an analyst is adequately prepared following authorization.

Successful completion of a fellowship in forensic pathology may serve as the competency test for a pathologist.

***6.2.3.2*** *Personnel who perform technical review of results or testimony, shall meet the competency requirements as specified in 6.2.3.1 for the testing or calibration tasks being reviewed. [TM]*

Only staff members who are authorized to author reports within a specific section may technically review reports from that section and review the testimony of that section. Individuals contracted to perform technical reviews must have prior experience in the specific section and must pass a competency test before being authorized to perform technical reviews.

**6.2.4** *The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities. [TM]*

Upon hiring, each staff member is informed of their duties, responsibilities, and authorities. These are also listed in the employee's job description. Current job descriptions are maintained in Qualtrax. A typical job description may include the following:

- Responsibilities with respect to performing examinations.
- Responsibilities with respect to planning and reviewing results of examinations.
- Responsibilities for reporting opinions and interpretations.
- Responsibilities with respect to modifying examination procedures and the development and validation of new examination procedures.
- Expertise and experience required.
- Qualifications and training required.
- Managerial duties and authorities.

**6.2.5** *The laboratory shall have procedure(s) and retain records for:*

*a) determining the competence requirements; [QC]*
*b) selection of personnel; [DO/QC]*
*c) training of personnel; [QC]*
*d) supervision of personnel; [TM/TLs]*
*e) authorization of personnel; [QC]*
*f) monitoring competence of personnel. [QC]*

MCCO/MVRCL provides forensic support and services to law enforcement and county coroners throughout Ohio and Indiana. Forensic science standards define the competency requirements (e.g., education, experience, skills and abilities, training, certifications, etc.) for the forensic support and services provided. QC ensures all assigned forensic staff meets identified competency requirements. The selection of personnel is typically done through an application process that determines if someone meets the minimum requirements and includes a formal interview.

The training of personnel is completed in accordance with section 6.2.

The supervision of personnel and defined authorizations are defined in section 5.5.

Initial competency requirements are addressed in 6.2.3.1. Proficiency testing is used to monitor the organization's performance as well as identify areas where improvement may be needed. The organization's proficiency testing program verifies the technical procedures are valid and the quality of each examiner's work is being maintained. The MCCO/MVRCL tests in the categories of seized drugs, latent prints, firearms, and toxicology, and when possible, purchases commercially available proficiency

tests from accredited vendors. Tests are process-based, and representative of items routinely examined. Examiners need only demonstrate proficiency in those processes which are representative of their routine activities. Furthermore, examiners need not demonstrate competency in all the discipline's processes in order to be considered qualified to perform individual examination processes.

All training records, including documentation of successfully completed competency tests, are retained. The training records include the name of the training or competency test and the date on which the training was completed, or the competency confirmed.

Each examiner should either complete the necessary amount of continuing education to maintain their certification or complete an average of 16 hours in continuing education per year (48 hours for every three years). These hours may come from any of the following: reading relevant journal articles, attending conferences (in-person or virtual), vendor training, attending workshops (in-person or virtual), in-house development meetings, etc. For tracking purposes, journal articles count for one-hour of education; all-day conferences count for eight hours per day; all other training is on a one-for-one hourly rate (e.g., two-hour workshop earns two hours of continuing education). After completing a training, employees document the training in Qualtrax, to include how many total hours of continuing education were earned. It is the employee's responsibility to update their CV with any relevant training and to retain all training certificates, when issued.

**6.2.6** *The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:*

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

*NOTE Authorization of personnel includes all aspects of testing or calibration activities including, as applicable, the use of equipment.*

After successfully completing their training, examiners assigned to the MCCO/MVRCL are authorized to perform forensics examinations, to authorize results, to issue examination reports, to give opinions and interpretations, to develop, modify, verify, and validate methods, and to operate types of equipment needed to perform the forensics work. Additional training and authorization are provided to experienced examiners so they can perform technical and administrative reviews of laboratory work and train staff in their respective areas.

Some sections within the organization may separately authorize someone to authorize results and authorize reports; others may combine the authorization for both authorizing results and reports at the same time. Refer to each section's manuals for how these two specific authorizations are handled.

An authorization form for each examiner is maintained on Qualtrax and is updated when the TL or TM determines that an examiner has met the criteria to be authorized for a given activity. Documentation supporting this decision is retained electronically. The documentation should include:

- A detailed description of the work to be authorized (including equipment, techniques, report generation, etc.)
- Details of any relevant training for the authorization and the results of any competency test(s) administered

### 6.3 Facilities and environmental conditions

**6.3.1** *The facilities and environmental conditions shall be suitable for the laboratory activities and shall not adversely affect the validity of results. [TM]*

*NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.*

The organization's facilities (i.e., energy sources, lighting, and environmental conditions) are appropriate to attain correct equipment performance and to avoid adverse effect on examination results. Either permanent or temporary uninterrupted power supplies are used, when applicable; overhead or desk lighting and ventilation hoods are provided, and heat/air conditioning is applied to keep room temperatures within an acceptable range for operating computer systems and equipment.

**6.3.2** *The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented. [QC]*

Facility requirements include electrical power; lighting; floor to ceiling walls; radiation shielding; separate work areas for administration, forensic examination, and evidence storage; access control; and continuous alarm monitoring. Outside of HVAC, no special environmental requirements are needed for the performance of forensic activities at the MCCO/MVRCL. Environmental conditions that can affect the results of examinations are documented in the appropriate Standard Operating Procedure (SOP).

**6.3.3** *The laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results. [QC]*

If environmental conditions (e.g., humidity, electrical supply, or temperature) could affect the correctness of a forensics examination, the examination is stopped and those conditions are controlled or mitigated, to the extent possible, and monitored.

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

*a) access to and use of areas affecting laboratory activities; [TM]*
*b) prevention of contamination, interference or adverse influences on laboratory activities; [QC]*
*c) effective separation between areas with incompatible laboratory activities. [QC]*

Access to MCCO/MVRCL is controlled. Access to examination areas is granted to employees, authorized contractors, and authorized visitors only. Employees will only be given access to relevant examination and evidence storage areas.

Each examiner is assigned a forensic work area and mitigation strategies (e.g., single case assignment, evidence control, physical barriers or separation between work areas, etc.) are applied to prevent the comingling of physical evidence between cases.

***6.3.4.1*** *There shall be a procedure that addresses security and access to areas where activities occur. [QC or TM]*

*NOTE Topics to consider may include, but not limited to: access to building, access by personnel, access by visitors, security during operational hours and non-operational hours, and devices that grant access.*

The MCCO/MVRCL is a secured facility that requires a badge to enter. Front office personnel may open the doors during normal business hours for visitors. These entrances are also monitored by security cameras. Visitors must stay in the lobby unless being supervised by an appropriate employee or authorized to visit an area within the building to conduct business (e.g., electrician to repair equipment, police officer entering cartridge case into NIBIN or viewing an autopsy, etc.).

Employees are given a security badge and access appropriate to their job function. Physical keys are assigned to authorized employees as necessary, and the location of any key is documented in the key log.

Replacement security badges are issued to an employee after the original badge has been deactivated.

The NIBIN office is always secured; only approved employees and outside agency law enforcement officers are given key card access. Access to the NIBIN computers is only issued to individuals by the ATF.

**6.3.5** *When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this document are met. [TM]*

If work is performed at a site or facility outside of MCCO/MVRCL's permanent control, any requirements or environmental conditions needed for the specific work will be met prior to performing the work. For death scene investigations, the scene must be deemed safe by the attending examiner(s) prior to performing any work.

### 6.4 Equipment

**6.4.1** *The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. [QC]*

*NOTE 1 A multitude of names exist for reference materials and certified reference materials, including reference standards, calibration standards, standard reference materials and quality control materials. ISO 17034 contains additional information on reference material producers (RMPs). RMPs that meet the requirements of ISO 17034 are considered to be competent. Reference materials from RMPs meeting the requirements of ISO 17034 are provided with a product information sheet/certificate that specifies, amongst other characteristics, homogeneity and stability for specified properties and, for certified reference materials, specified properties with certified values, their associated measurement uncertainty and metrological traceability.*

*NOTE 2 ISO Guide 33 provides guidance on the selection and use of reference materials. ISO Guide 80 provides guidance to produce in-house quality control materials.*

The organization is amply furnished with equipment for conducting forensic examinations and if additional equipment is needed, it is procured when funds are available.

**6.4.2** *When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements for equipment of this document are met. [QC]*

If equipment outside the organization's permanent control is used, it is tested and/or validated prior to use following the specific section's SOPs. The TL is responsible for retaining documentation of this verification.

**6.4.3** *The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration. [QC]*

Equipment used by the organization is procured using MCCO/MVRCL's procurement process. Once received, hardware undergoes performance checks and software goes through validation testing to ensure they operate and function as intended (See 6.4.4 for schedule).

Each item of equipment and its software, where applicable, used for examination purposes is uniquely identified by manufacturer, model, and serial number, and version, where applicable. Hardware identified for use is placed in service and assigned to a section and placed in their assigned work area. The proper functioning of hardware is determined through a documented, predetermined validation process. See each section for their validation process.

Equipment is operated by authorized personnel. Up-to-date instructions on the use and maintenance of the equipment are readily available in Qualtrax, electronically, or physically near the equipment. Most

equipment maintenance is outsourced, and maintenance reports are provided by the vendor and kept in Qualtrax, electronically, or near the equipment.

Records are maintained for each item of equipment electronically, which includes the identity of the item, its software, manufacturer's name, type identification, and serial number or other unique identification (e.g., service tag), as well as information on calibration and maintenance. The official MCCO/MVRCL equipment/maintenance log is kept up to date and is stored electronically.

***6.4.3.1*** *In addition to the procedural requirements in ISO/IEC 17025:2017, clause 6.4.3, reagents prepared shall be labeled with the identity of the reagent and the date of preparation or lot number. Records shall be retained identifying who made the reagent and the components used in preparation. [QC]*

Prepared reagents are labeled with a minimum of the name of the standard or reagent and the preparation date or lot number. Additional information may appear on a reagent based on the needs of the section. The reagent log within a specific section shall reflect who made a particular reagent and all the components that were used to make the reagent.

***6.4.3.2*** *Reference collections of data or materials which are maintained for identification, comparison, or interpretation purposes (e.g., mass spectra, motor vehicle paints or headlamp lenses, drug samples, wood fragments, bullets, cartridges, DNA profiles, laboratory developed population databases) shall have each entry in the collection documented, uniquely identified and handled properly to protect the characteristic(s) of interest. [QC]*

Reference data or material maintained for identification, comparison, or interpretation is uniquely identified and maintained in a manner to preserve the characteristics of interest.

**6.4.4** *The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service. [QC]*

Equipment (i.e., hardware and software) that has a significant effect on the results of forensics examinations undergoes performance verification:

- Before first use.
- After undergoing repair, maintenance, or calibration.
- As scheduled by the QC.

**6.4.5** *The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result. [QC]*

All equipment used by MCCO/MVRCL for measurements can achieve the measurement accuracy and/or measurement uncertainty required to provide valid results for the examinations performed.

Measurements taken during a death investigation or autopsy are considered descriptive measurements and are not considered critical measurements that require uncertainty.

**6.4.6** *Measuring equipment shall be calibrated when: [QC]*

- *the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or*
- *calibration of the equipment is required to establish the metrological traceability of the reported results.*

*NOTE Types of equipment having an effect on the validity of the reported results can include:*

- *those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;*
- *those used to make corrections to the measured value, e.g. temperature measurements;*
- *those used to obtain a measurement result calculated from multiple quantities.*

All measurement equipment that has significant influence on interpretation and conclusions made during a forensic examination will be traceable. That is, all measurements will be related to a reference standard of measurement through a documented chain of calibrations. These calibrations are used to determine the associated uncertainties of measurement when the measurement will appear on a final report.

**6.4.7** *The laboratory shall establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration. [QC]*
Equipment calibration must be performed on measuring equipment having a significant effect on the interpretations and conclusions made during a forensics examination. Measuring devices will be calibrated before being put into service and at intervals described below. Refer to each section's SOPs for more detailed information about the measuring devices that are subject to calibration in the MCCO/MVRCL.

*NOTE: Temperatures in evidence storage refrigerators and freezers are monitored for quality improvement purposes, but those thermometers do not require traceability or determination of uncertainty of measurement. These temperatures allow for proper maintenance of evidence samples but are not critical measurements in interpretation or conclusions.*

***6.4.7.1*** *The program for the calibration of equipment shall include a list of the equipment requiring calibration, specifications for the calibration laboratory, specified requirements for the calibration, and the interval of calibration. [QC]*

A list of the equipment requiring calibration is maintained electronically. The external calibration laboratory must be an ISO accredited calibration laboratory. The service requested must be part of the

provider's ISO accreditation scope; when applicable, "as found" and "as left" data are requested. Refer to each section's SOPs for the interval of calibration for section equipment requiring calibration.

**6.4.8** *All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity. [QC]*

Following successful calibration, the calibration laboratory will affix a calibration sticker detailing when the calibration will expire.

**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, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10). [QC]*

When laboratory equipment cannot be properly adjusted, fails to meet performance validation and verification or calibration, or produces suspect results, that item is immediately removed from service, labeled appropriately, or segregated to prevent inadvertent use. Only when it is shown by performance verification or calibration to perform correctly is the equipment returned to service. The laboratory determines the effects of the defect or departure from specified requirements on examination results and implements a non-conforming work procedure when necessary.

**6.4.10** *When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure. [QC]*

*NOTE When evaluating the need for intermediate checks, topics to consider include, but are not limited to: the calibration interval, the use of the equipment, the stability of the equipment, the method specifications, and risk associated with a failed check.*

See section specific SOPs for when intermediate checks are performed and how they are evaluated.

**6.4.11** *When calibration and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements. [QC]*

When a specific section is updating information (e.g., uncertainty budget), the most recent calibration certificate for a particular piece of equipment will be utilized.

**6.4.12** *The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results. [QC]*

Equipment that may be adjusted unintentionally shall have intermediate checks performed to confirm the continuing validity of the results.

**6.4.13** *Records shall be retained for equipment which can influence laboratory activities. [QC] The records shall include the following, where applicable:*

*a) the identity of equipment, including software and firmware version;*
*b) the manufacturer's name, type identification, and serial number or other unique identification;*
*c) evidence of verification that equipment conforms with specified requirements;*
*d) the current location;*
*e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;*
*f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;*
*g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;*
*h) details of any damage, malfunction, modification to, or repair of, the equipment.*

Records are maintained for each item of equipment that can influence examination results. A master list of equipment is maintained electronically. Some of the above records are maintained within a specific piece of equipment's logbook or binder or within the master list. Purchased reagents and reference standards are verified as meeting specified requirements by comparing the purchased item to the purchasing order request. For example, if LC grade water was requested in the purchase order, confirm that the received reagent is labelled as LC grade water.

### 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. [QC]*

*NOTE 1 In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".*

*NOTE 2 See Annex A for additional information on metrological traceability.*

*Note 3 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.*

The MCCO/MVRCL documents in a case record the specific equipment used during a critical measurement. This allows an unbroken chain of calibrations to be established for a given measurement.

When measurement traceability is required, all equipment used to change a certified reference material is tracked on a log. The equipment may include balances, pipettes, volumetric flasks, etc.

***6.5.1.1*** *If available, suppliers of external calibration services for measuring equipment and/or reference standards, and certified reference materials used to establish or maintain metrological traceability shall be either: [QC]*

*a) a National Metrology Institute that is a signatory to the BIPM - CIPM Mutual Recognition Arrangement with the calibration of measuring equipment and/or reference standard to be performed or the certified reference material listed to be purchased in Appendix C of the BIPM key comparison database (KCDB); or*
*b) a service supplier accredited to ISO/IEC 17025 by an accrediting body that is a signatory to the ILAC Mutual Recognition Arrangement, with the calibration of measuring equipment and/or reference standard to be performed listed in a scope of accreditation; or*
*c) an accredited reference material producer that is accredited to ISO 17034 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC Mutual Recognition Arrangement, with a scope of accreditation covering the certified reference material.*

To ensure calibration measurements are traceable, MCCO/MVRCL only uses approved and vetted vendors that meet one of the following requirements:

- A NMI that is a signatory to the BIPM-CIPM Mutual Recognition Agreement
- A service supplier accredited to ISO/IEC 17025 with calibration or reference standard listed in its scope
- An accredited reference material producer accredited to ISO 17034 with a scope over the certified reference material

The supplier's accreditation scope is retained electronically and updated when appropriate.

***6.5.1.2*** *In situations where a supplier that meets 6.5.1.1 is not available, the competence, capability, and metrological traceability for the supplier and the external product or service being purchased shall be confirmed. Objective evidence of the confirmation shall be available for review. [QC]*

When a supplier that meets 6.5.1.1 is unavailable, the MCCO/MVRCL will determine if another supplier may be used. The evidence proving the supplier's competence is documented, reviewed by the appropriate TL, and stored electronically.

***6.5.1.3*** *For the purpose of establishing traceability of a measurement, an accredited laboratory may calibrate its own equipment that supports an accredited parameter on the scope if the related requirements in ISO/IEC 17025 and this document are met: [QC]*

*a) the calibration and any check of the calibration status shall be carried out by appropriately trained, competency tested, and authorized personnel;*
*b) the calibration method shall be validated or verified prior to use;*
*c) certified reference materials or measuring instruments used in the calibration method shall be traceable with appropriate measurement uncertainties;*
*d) the calibration shall be carried out in an appropriate environment;*
*e) technical records of the calibration shall be established and retained;*
*f) the laboratory shall have and apply a procedure for calculating the measurement uncertainty for each equipment calibration it conducts; and*
*g) a technical review of the technical records including any data transfers and calculations shall be completed by an individual other than the person(s) who performed the work.*

N/A

**6.5.2** *The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through: [QC]*

*a) calibration provided by a competent laboratory; or*

*NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.*

*b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or*

*NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.*

*c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.*

*NOTE 3 Details of practical realization of the definitions of some important units are given in the SI brochure.*

The laboratory has traceability to SI in its measurements through a combination of the above requirements.

**6.5.3** *When metrological traceability to the SI units is not technically possible, the laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.: [QC]*

*a) certified values of certified reference materials provided by a competent producer;*
*b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.*

The laboratory does not have any measurements that aren't traceable to SI.

### 6.6 Externally provided products and services

**6.6.1** *The laboratory shall ensure that only suitable externally provided products and services that affect laboratory activities are used [QC], when such products and services:*

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

*NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services.*

When supplies and services are procured from sources external to MCCO/MVRCL, the QC will ensure the vendor selected is capable of providing the sought-after services and/or supplies. This determination is made by conducting research on the vendor and the services/supplies it provides or by past knowledge and experience using the vendor.

Laboratory supplies and consumables that could affect the quality of a test/examination are inspected for damage and compliance with procurement requirements upon receipt. This inspection is documented by initialing the receipt, packing slip, or invoice, which is retained with the procurement documentation. Supplies and consumable material found to be insufficient or of questionable quality upon receipt are returned or discarded and not used. Appropriate storage requirements are determined by each section of the laboratory. Supplies, chemicals and gases are stored in accordance with OSHA requirements, MCCO/MVRCL standards, and manufacturer's recommendations.

The QC determines the competency of a subcontractor through an evaluation of the company's capabilities (i.e., knowledge, skills, and ability to perform the task), review of the company's accreditations, or by past knowledge and experience using the vendor.

**6.6.2** *The laboratory shall have a procedure and retain records for:*

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

The MCCO/MVRCL maintains an electronic list of approved vendors and subcontractors defining what product/service they provide, how their service was evaluated, and for which laboratory section the product/service is provided. This list will be re-evaluated annually, and appropriate updates made as needed. Vendor accreditation certificates will be updated as old ones expire. If a vendor is unable to produce an updated accreditation certification (when applicable), the QC will determine if the vendor will be removed from the approved vendor list.

Proficiency tests are purchased from vendors that are accredited and listed on ANAB's website as acceptable. If a proficiency test is only available from a vendor not listed on the website, the QC will evaluate the vendor for acceptability.

If an unacceptable product or service is provided by an approved vendor, the staff member who observes the unacceptability will inform the QC. The QC will then evaluate all currently provided products/services by that vendor and decide if another vendor must be utilized. Depending on the reason or infraction reported, a formal complaint may be filed with the vendor or subcontractor and depending upon the nature of the transgression and the corrective action applied by the external provider, the QC will determine if the vendor continues to be used on future assignments.

Purchasing documents are retained by administrative services, which store packing lists by vendor and manages Purchase Orders (POs) as well as vendor reimbursement. POs contain detailed data describing the services and supplies ordered.

See section 6.6.1 for additional details.

**6.6.3** *The laboratory shall communicate its requirements to external providers for:*

*a) the products and services to be provided; [QC]*
*b) the acceptance criteria; [QC]*
*c) competence, including any required qualification of personnel; [QC]*
*d) activities that the laboratory, or its customer, intends to perform at the external provider's premises. [QC]*

MCCO/MVRCL communicates its requirements to external providers in one of the following ways:

1) For services (e.g., pipette calibration), MCCO/MVRCL chooses an accredited external provider and communicates its requirements, acceptance criteria, and competence of personnel by requesting that provider's service that meets those specificities. For example, for pipette calibration a service is chosen that is done by an ISO accredited facility for the pipettes our laboratory uses, uses acceptance criteria as designated by ISO, and uses personnel competent to perform the calibration.

2) For products, MCCO/MVRCL places orders with vendors, either electronically or by phone, with the relevant requirements detailed while placing the order.

## 7 Process requirements

### 7.1 Review of requests, tenders and contracts

**7.1.1** *The laboratory shall have a procedure for the review of requests, tenders and contracts. [QC] The procedure shall ensure that:*

*a) the requirements are adequately defined, documented and understood;*
*b) the laboratory has the capability and resources to meet the requirements;*
*c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;*
*d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.*

*NOTE 1 It is recognized that externally provided laboratory activities can occur when:*
*— the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;*
*— the laboratory does not have the resources or competence to perform the activities.*

*NOTE 2 For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way.*

The QC/Examiner is responsible for reviewing submitted service requests, tenders, and contracts to ensure the:

- request is adequately defined, properly documented and clearly understood
  - Additional information is requested, prior to acceptance, if the request is inadequate, improperly documented or unclear.
  - If any legal or time aspects cannot be met, this should be communicated to the customer prior to acceptance
- has the capability and resources to perform the requested work
  - Capabilities and resources include subcontractors, necessary forensic equipment, competent and certified personnel, and facilities
  - If the organization or its subcontracted partners do not have the capability or resources to meet the customer's requirements, the request for service is declined and the customer is informed. No forensics work is subcontracted without explicit knowledge and approval from the customer, unless previously authorized within the contract or service request. If not previously authorized, the customer's knowledge and approval is documented in the appropriate case folder.

- appropriate test method is selected and that it can meet the customer's requirements
  - Test methods are selected by MCCO/MVRCL personnel and approved, when necessary, by the customer
  - If a customer dictates the test method, the laboratory will test and validate the method prior to its use and if it does not perform as intended or it will not meet the customer's requirements as believed, the customer will be informed, and an alternative method will be suggested.

An outside county calling initiates a contract to perform an autopsy. They may dictate exactly what they do or do not want performed. When a decedent is reported within Montgomery County, this is considered an internal customer and the determination to perform a service is done based on Ohio law.

**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. [QC]*

The organization informs the customer when a method proposed by the customer is inappropriate or out of date or an agreed-to method needs to be changed because it does not function as intended. In the absence of customer directed methods, the MCCO/MVRCL selects the appropriate method that will meet the customer's needs and the customer is informed of the method selected. This information may be provided on the MCCO/MVRCL website, handbook, or on the final report given to the customer.

Requests to perform GSR during an autopsy are not performed by MCCO staff but may be performed by an attending agent.

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

*NOTE For further guidance on statements of conformity, see ISO/IEC Guide 98-4.*

MCCO/MVRCL does not provide statements of conformity to a specification or standard.

**7.1.4** *Any differences between the request or tender and the contract shall be resolved before laboratory activities commence. [QC/Examiner] Each contract shall be acceptable both to the laboratory and the customer. [QC/Examiner] Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results. [QC/Examiner]*

MCCO/MVRCL only performs work under case requests in which all differences have been resolved and the contract has been accepted by both MCCO/MVRCL and the customer. The organization provides forensic support to customers as a direct support element (i.e., the contract includes only forensic support and services). Customer requested deviations to a contract are handled as contract modifications. If a

customer-directed contract modification presents a risk to the integrity of the organization or to the validity of its work product, the organization does not accept the modification until the risks have been mitigated.

For MVRCL contracts, forensic work is requested on a submission form that accompanies evidence submitted by a customer. The submission form details what evidence needs to be tested and by which forensic section of the laboratory. Submissions may also be received via the LIMS portal. These contractual documents are considered "requests" for the purpose of this manual. Each laboratory service request is accepted by both the laboratory and the customer before any work is performed. Customer requested deviations to these documents are handled by documenting the deviation either on the submission form or within the specific case file. Should the requested deviation present a risk to the integrity of the laboratory or to the validity of its work product, the laboratory does not accept the deviation until the risks have been mitigated. The customer will be informed of any work to be performed that is not covered by the laboratory's current scope of accreditation. This is done by providing the current scope on the laboratory's website and through a laboratory handbook.

For MCCO contracts, a letter is sent to potential contracting counties annually. The letter states fee for service and outlines procedural policies. By sending a decedent to the MCCO, the customer is agreeing to the terms of the letter. Customer requested deviations will be addressed on a case-by-case basis and notated in the case file. The customer will be informed of any work that is to be performed that deviates from the contract supplied by and requested from the MCCO.

**7.1.5** *The customer shall be informed of any deviation from the contract. [QC/Examiner]*

As defined in section 7.1.4, the customer is informed of any deviations to the contract. For MCCO/MVRCL directed deviations because of unforeseen operational or security issues, the customer is informed of the deviation by the QC or their designee and that communication is documented in the case record.

**7.1.6** *If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel. [QC/Examiner]*

As defined in section 7.1.4, contract amendments/modifications are handled in a prescribed formal process and all affected personnel are made aware of the impending change(s) and are part of the review and approval process.

**7.1.7** *The laboratory shall cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed. [QC/Examiner]*

*NOTE Such cooperation can include:*

*a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;*

*b) preparation, packaging, and dispatch of items needed by the customer for verification purposes.*

The MCCO/MVRCL communicates with customers to clarify service requests, answer questions concerning its performance, and provide status updates. Email is the best method to complete this task as it provides a means to document the communication. Customers are notified of any significant delays or deviations in the examination. Additionally, as needed, customers may be provided policy and procedure information should they require verification of examination protocols and methodologies. Customers, including prosecution or defense experts, are not given access to witness laboratory activities. Other death investigators (e.g., law enforcement, contract county investigator) may attend autopsies as observers.

**7.1.8** *Records of reviews, including any significant changes, shall be retained. [QC/Examiner] Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities. [QC/Examiner]*

All service request documentation and associated communication with the customer is recorded electronically in the case record.

***7.1.9** The extent of database (e.g., CODIS, AFIS, NIBIN) searches shall be communicated to customers and updated as needed. [QC]*

*NOTE This may be communicated on a case-by-case basis, in the report, or in a general customer communication.*

Customers are informed, when appropriate, of the MVRCL use of the AFIS and NIBIN database systems on their final reports.

**7.2 Selection, verification and validation of methods**

**7.2.1 Selection and verification of methods**

**7.2.1.1** *The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. [QC]*

The MCCO/MVRCL uses current industry/laboratory accepted and approved technical procedures (e.g., standards published by ASTM-International, OSAC, ABFT, SWGs, NIST, or developed in-house) that meet the needs of the customer while taking into account the nature of the evidence, the facts of the case, and the customer's request. Activities (e.g. examinations, data analysis, interpretation) are conducted using forensic equipment and software supplied or authorized for use by the QC that has either been approved following adequate testing and validation or otherwise authorized in writing. In the absence of customer directed methods, the organization selects the appropriate method that will meet the customer's needs and the customer is informed of the method selected.

***7.2.1.1.1*** *The laboratory shall use appropriate methods and procedures for all associated data analysis and interpretation.*

See above.

***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). [Examiner/QC]*

*NOTE 1 Characteristics include, but are not limited to, alleles in a DNA profile, friction ridge detail in a latent print, striation detail on a bullet and features of handwriting.*

*NOTE 2 This requirement is not focused on the process of assessing an unknown in order to identify the test item that will be the subject of further comparison. In these circumstances, it may be appropriate to perform a preliminary characterization of the known sample prior to the assessment of the unknown.*

All test methods that involve the comparison of known and unknown items include an evaluation to identify characteristics suitable for comparison. See each section's SOPs for details.

***7.2.1.1.3*** *A breath alcohol measuring instrument calibration method shall assess accuracy (bias and precision) of the instrument across a range of ethanol values that meets the needs of the customer.*

*The source of material(s) used to calibrate a breath alcohol measuring instrument shall be different from that used to adjust a breath alcohol measuring instrument and that used to verify calibration status.*

*NOTE Preference should be given to material(s) from different manufacturers, followed by different lot numbers of material from the same manufacturer.*

N/A

**7.2.1.2** *All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3). [QC]*

Standard operating procedures have been developed and validated for all examination related processes to include handling, preservation, transport, storage and preparation of evidence, and instructions on the use and operation of equipment. See each sections Standard Operating Procedures for further details. Instructions, standards, manuals, documents, and reference data relevant to the work of the organization are kept up to date through annual reviews and are readily available to personnel in Qualtrax, electronically, or within each section.

**7.2.1.3** *The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. [QC] When necessary, the application of the method shall be supplemented with additional details to ensure consistent application. [QC]*

*NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.*

Documents in Qualtrax are the latest version and shall be utilized for reference. Printed versions from Qualtrax are considered uncontrolled and are superseded by anything in Qualtrax.

**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. [QC] Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. [QC] Laboratory-developed or modified methods can also be used. [QC]*

Any method, either published or developed in-house, must be verified and/or validated prior to use on casework.

**7.2.1.5** *The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. [QC] Records of the verification shall be retained. [QC] If the method is revised by the issuing body, verification shall be repeated to the extent necessary. [QC]*

The MCCO/MVRCL properly validates methods before they are used for casework. See each section for method validation documentation. Once a method is validated, an SOP is written and stored on Qualtrax for use by the relevant staff.

**7.2.1.6** *When method development is required, this shall be a planned activity and shall be assigned to competent personnel equipped with adequate resources. [QC] As method development proceeds, periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled. [QC] Any modifications to the development plan shall be approved and authorized. [QC]*

The creation of developed methods is a planned activity. The ever-changing forensics environment requires, at times, the rapid development of innovative methods, in order to address new technologies. The development of new methods is performed by qualified personnel that are equipped with adequate resources to complete the task. The TL for the relevant section monitors the progress and makes updates as necessary. Modifications to the development plan are approved and authorized by the TL, as appropriate.

**7.2.1.7** *Deviations from methods for all laboratory activities shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer. [QC]*

*NOTE Customer acceptance of deviations can be agreed in advance in the contract.*

Deviations from organization policies and procedures are requested, technically justified, documented, and approved prior to performing the deviation, unless exigent circumstances exist. If a deviation is performed because of exigent circumstances the examiner reports the deviation to the TL at the first available opportunity.

Deviations shall be tracked to allow for review of trends. Requests for repeated deviations shall be investigated and corrective actions performed as necessary.

### 7.2.2 Validation of methods

**7.2.2.1** *The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. [TL] The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. [TL]*

*NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.*

*NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:*

*a) calibration or evaluation of bias and precision using reference standards or reference materials;*
*b) systematic assessment of the factors influencing the result;*
*c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;*
*d) comparison of results achieved with other validated methods;*
*e) interlaboratory comparisons;*
*f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.*

Appropriate validation studies are conducted on new technical processes, non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, modifications of standard methods, and tools used for the examination of evidence. When changes are made to a validated method the influence of such changes is identified and where they are found to affect the original validation, a new method validation is performed. Validation studies conducted by outside accredited laboratories (e.g., DEA, NIST, etc.) or published by the National Institute of Justice (NIJ) are considered authorized validations for use by the MCCO/MVRCL. All validations are evaluated prior to use with MCCO/MVRCL equipment.

The validation testing is as extensive as is necessary to meet the needs of the given application. The performance characteristics of validated methods, as assessed for the intended use, are relevant to the customers' needs and consistent with specified requirements. Testing is accomplished by following a testing plan designed to check that the procedure is suitable for the purpose intended, establishes the data

required to report a result, opinion, or interpretation, identifies limitations of the method, and it produces repeatable results, using known reference standards/materials, equipment, and configurations representative of those used in the laboratory. If the testing does not produce the expected results, the test documentation is compared to the procedure tested to ensure the procedure was followed, results are compared with other validated methods through inter or intra laboratory comparisons and, as needed, modifications are made and/or retests completed. A designated reviewer conducts a technical review of the test results. The laboratory records the results obtained, associated data interpretations, if applicable, the procedure used for the validation, limitations, comments, and a statement as to whether the procedure or tool is fit for the intended use. Test records include, but are not limited to: test requests, validation procedure used, specification of the requirements, known standards and material used, determination of the performance characteristics of the method and results obtained, review documentation, and a summary of the validation. The results of the validation are submitted to the TL for approval. If the validation is accepted and the procedure is appropriate for the purpose, the new method is approved for use.

***7.2.2.1.1*** *Method validation [TL] shall:*

*a) be conducted according to a validation plan*
*b) include the associated data analysis and interpretation;*
*c) establish the data and acceptance criteria required to report a result, opinion, interpretation, or statement of conformity; and*
*d) identify limitations of the method.*

See section 7.2.2.1

**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. [TL]*

See section 7.2.2.1

***7.2.2.2.1*** *The associated data interpretation is considered part of a validated method. [TL] When changes are made, then ISO/IEC 17025:2017, 7.2.2.2 applies. [TL]*

See section 7.2.2.1

**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. [TL]*

*NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.*

See section 7.2.2.1

**7.2.2.4** *The laboratory shall retain the following records of validation:*

*a) the validation procedure used; [TL]*
*b) specification of the requirements; [TL]*
*c) determination of the performance characteristics of the method; [TL]*
*d) results obtained; [TL]*
*e) a statement on the validity of the method, detailing its fitness for the intended use. [TL]*

See section 7.2.2.1

**7.3 Sampling**

**7.3.1** *The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.*

Refer to each section's SOPs for sampling methods and plans.

**7.3.2** *The sampling method shall describe:*

*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.*

*NOTE When received into the laboratory, further handling can be required as specified in 7.4.*

*NOTE 2 The intent of ISO/IEC 17025 is that the activity of sampling occurs prior to the item being submitted to the laboratory. A laboratory can choose to perform further sampling after receipt of the item, in which case the requirements for sampling are applicable.*

Refer to each section's SOPs for sampling methods and plans.

***7.3.2.1*** *The sampling method shall:*

*a) require an evaluation of the selected population for homogeneity;*
*b) require the population to have a reasonable expectation of homogeneity to use a sampling plan;*
*c) require that the sampling plan makes use of probability and provides an opinion or interpretation with a minimum confidence level of 95.45% (often referred to as approximately 95%);*
*d) require each item selected to meet the sampling plan level of confidence to be tested completely; and*

*e) provide instruction regarding the course of action to take if one or more selected items demonstrate a lack of homogeneity.*

Refer to each section's SOPs for sampling methods and plans.

**7.3.3** *The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:*

*a) reference to the sampling method used;*
*b) date and time of sampling;*
*c) data to identify and describe the sample (e.g. number, amount, name);*
*d) identification of the personnel performing sampling;*
*e) identification of the equipment used;*
*f) environmental or transport conditions;*
*g) diagrams or other equivalent means to identify the sampling location, when appropriate;*
*h) deviations, additions to or exclusions from the sampling method and sampling plan.*

All records of sampling performed, and relevant information are retained within the specific case's records.

**7.4 Handling of test or calibration items**

**7.4.1** *The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. [TL] Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for testing or calibration. [Examiner/Evidence Custodian] Handling instructions provided with the item shall be followed. [Examiner/Evidence Custodian]*

See the MCCO/MVRCL Front Office Manual or each section's SOPs in Qualtrax for additional details.

***7.4.1.1*** *For all test items received except known origin individual characteristic database samples, the procedure shall:*

*a) address requirements for storage, packaging, and sealing of items to:*
  *1) protect the integrity of all items; and*
  *2) require items to be re-sealed as soon as practicable;*
*b) address measures to be taken to secure unattended items;*
*c) require chain-of-custody for:*
  *1) all items received; and*

2) *items that are collected or created and preserved for future testing (e.g., ESDA lifts, test-fired ammunition, latent print lifts, photos, trace evidence, DNA extracts);*

*d) require chain-of-custody to securely and accurately identify:*
1) *the individual(s) or location(s) receiving or transferring the item(s);*
2) *the item(s) being transferred; and*
3) *the chronological order of all transfers, minimally including the date;*

*e) require communication to the customer regarding the disposition of all items received;*

*f) address communication to the customer regarding items collected or created and preserved for future testing.*

*NOTE 1 d) An item being tracked could contain multiple components and be tracked as one item.*
*NOTE 2 d) Documentation of internal transfers does not need to include use of personal storage locations.*

See the MCCO/MVRCL Front Office Manual or each section's SOPs in Qualtrax for additional details.

**7.4.2** *The laboratory shall have a system for the unambiguous identification of test or calibration items. [TM] The identification shall be retained while the item is under the responsibility of the laboratory. [Evidence Custodian] The system shall ensure that items will not be confused physically or when referred to in records or other documents. [TM] The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items. [TM]*

MVRCL - All evidence received by the laboratory is uniquely identified using Justice Trax LIMS-plus (LIMS) that creates a laboratory case number for every item entered. Evidence can be additionally sub-itemized in LIMS. Using the laboratory case number, LIMS maintains an item description, custodian details, and storage location for each item/sub-item. The system maintains a full chain of custody from initial entry through internal transfers to evidence disposition. After evidence is received by the Front Office, all subsequent transfers of evidence internally to an analyst must include the analyst's private PIN. Created sub-items are in possession of the parent when created and do not need a PIN.

MCCO – Each decedent is given a unique case number in LIMS. Receipt of the decedent into the morgue area and release of the decedent out of the building are tracked electronically in LIMS.

***7.4.2.1*** *The system used to identify items shall cover all items received. [TM]*

See section 7.4.2

**7.4.3** *Upon receipt of the test or calibration item, deviations from specified conditions shall be recorded. [Evidence Custodian/Examiner] When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation. [Evidence Custodian/Examiner] When the customer requires the item to be tested or calibrated acknowledging a*

*deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation. [TL/Examiner]*

Any communication between the laboratory and the customer about deviations from normal testing or suitability of items for testing is documented in the case record. See the MCCO/MVRCL Front Office Manual and each section's manuals in Qualtrax for specific details.

Changes to a decedent's demographic information (e.g., name, date of birth, SSN, etc.) are documented in LIMS; changes to a decedent's non-identifying information (e.g., race, gender, address, etc.) are performed in LIMS without additional documentation.

**7.4.4** *When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. [TL]*

Refrigerators and freezers within MCCO/MVRCL are monitored by TempGenius for inappropriate temperature fluctuations and alerts are sent out to the appropriate staff members to document and/or troubleshoot. Multiple cameras monitor the area around the evidence storage facility.

MVRCL - The laboratory's evidence storage facility includes a card-controlled (with accompanying PIN number) access limited to relevant staff members. Each section has additional storage locations appropriate for the work performed. Examiners may have personal lockers for short term storage. Special handling instructions, when provided, are followed unless they conflict with or are lesser than the laboratory's current handling protocols; discrepancies are addressed with the customer prior to evidence acceptance. The laboratory stores biological evidence for toxicology refrigerated or frozen when not being tested. Drug chemistry stores some food products and certain plant materials in the refrigerator or freezer.

MCCO – Decedents are stored in a secure access cooler while not being examined. Evidence collected from decedents is stored in a card-controlled evidence storage room with access limited to relevant staff members. Drugs and high value items collected from a decedent are stored in a card-controlled (with accompanying PIN number) room limited to relevant staff members.

### 7.5 Technical records

**7.5.1** *The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. [TL/Examiner] The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. [TL/Examiner] Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task. [TL/Examiner]*

MVRCL - The laboratory's technical records for a specific case shall be stored in LIMS within that case record. The technical records contain all documentation necessary to support the actions of the examiner and support the examination conclusions. This includes, when applicable but is not limited to, original observations, derived data, a copy of each test report issued, evidence submission forms, chain of custody records not already retained in the laboratory's evidence management system, correspondence notations, examination notes, work sheets, laboratory notes, deliverables, and other documents relating to processing casework. The records for each examination contain sufficient information to enable the test to be repeated under similar conditions. The records include the identity of personnel responsible for the examination and review of results. Examination records in the laboratory's case management system, by default, reflect the starting and ending date(s) of each case request. Items in the technical record are recorded contemporaneously with the actions and are identifiable to the procedure(s) performed.

MCCO – LIMS contains which pathology technician(s), photographer, and pathologist were responsible for the examination of a decedent. The responsible investigator is notated at the bottom of the investigator report. The final autopsy report is signed by the responsible pathologist(s). The original observations of the responsible personnel are recorded in the respective final reports and are stored in LIMS. Photographs taken either at the scene or during an examination are stored on a network drive.

***7.5.1.1*** *Define the technical record(s) to be retained if all related technical records are not retained.* *[QC]*

The following records are retained as administrative documentation:

- Laboratory service requests or emails requesting service.
- Evidence/property Chains of Custody or material transfer forms
- Evidence destruction authorization memos or emails from customers authorizing the destruction or disposition of submitted evidence.
- All correspondence (i.e., letters, faxes, emails, and phone calls).
- Records of technical and administrative reviews, as applicable
- Subcontractor service documentation (e.g., service requests and emails, description of items and transfers of custody, documentation from service vendor showing technical information and/or results of services performed)

The following items are retained as technical records:

- All analytical documentation generated by the analyst in the examination of evidence (e.g., laboratory notes, diagrams, photographs, spectrographs, micrographs, etc.).
- Photographs taken by personnel to support the examination (e.g., spectra, printouts, charts, data, or records).

***7.5.1.2*** *Where abbreviations or symbols specific to the laboratory are used, the meaning of the abbreviations or symbols shall be defined. [QC]*

Acronyms and abbreviations that are not widely accepted by the forensic/medical community are defined when used. Currently accepted abbreviations are listed within each section.

***7.5.1.3*** *Technical records to support a report (including results, opinions, and interpretations) shall be such that, another reviewer possessing the relevant knowledge, skills, and abilities could evaluate what was done and interpret the data. [Examiner]*

Examination records are comprehensive and have sufficient detail to enable another qualified examiner to understand the results and following the same procedures produce the same or similar results.

***7.5.1.4*** *Records shall be created or maintained in a permanent manner. [TM]*

Examination records are maintained in the organization's case management system and are considered permanent.

***7.5.1.5*** *If an observation, data, or calculation is rejected, the reason, the identity of the individual(s) taking the action and the date shall be recorded in the technical record. [Examiner]*

Rejected observations, data, or calculations determined as a result of a tool or method failing to produce expected results is documented, to include the rejection reason and the date of rejection, by the examiner in the examination case notes.

***7.5.1.6*** *For laboratories that perform calibration**,** if an adjustment or repair is performed due to a calibration that does not meet specifications, pre and post adjustment/repair data shall be retained.*

*NOTE See related clause ISO/IEC 17025:2017, 7.8.4.1.d)*

N/A

**7.5.2** *The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations. [QC]*

Any changes to technical records must be documented with a forensic correction that involves a single line cross out, the date of the change, and the person responsible for the change. Changes to technical records after a report is marked as "draft complete" must be tracked. This may be done by attaching both sets of data with an explanation of what was changed or it may be tracked through the use of an electronic log. If amended or supplemental reports are issued, a copy of all reports is maintained in LIMS.

### 7.6 Evaluation of measurement uncertainty

**7.6.1** *Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.*

See section SOPs for measurement uncertainty evaluations.

***7.6.1.1*** *The method of analysis for evaluation of measurement uncertainty shall:*

*a) require the specific measuring device or instrument used for a reported result to have been included in or evaluated against the estimation of measurement uncertainty for that method;*
*b) include the process of rounding the expanded uncertainty;*
*c) require the coverage probability of the expanded uncertainty to be a minimum of 95.45% (often referred to as approximately 95%); and*
*d) specify the schedule to review and/or recalculate the measurement uncertainty.*

See section SOPs for measurement uncertainty evaluations.

**7.6.2** *A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.*

N/A

***7.6.3*** *A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.*

*NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.*

*NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.*

*NOTE 3 For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series.*

See section SOPs for measurement uncertainty estimations.

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

*NOTE An item descriptor that includes a number is not considered a result. This difference should be clear to the reader of the report.*

See section SOPs for measurement uncertainty evaluations and reporting.

***7.6.4*** *The following records shall be retained for each evaluation and estimation of measurement uncertainty:*

*a) statement defining the measurand;*
*b) statement of how traceability is established for the measurement;*
*c) the equipment (e.g., measuring device[s] or instrument[s]) used;*
*d) all uncertainty components considered;*
*e) all uncertainty components of significance and how they were evaluated;*
*f) data used to estimate repeatability, intermediate precision, and/or reproducibility;*
*g) all calculations performed; and*
*h) the combined standard uncertainty, the coverage factor, the coverage probability, and the resulting expanded uncertainty.*

See section measurement uncertainty budgets for the above records.

**7.7 Ensuring the validity of results**

**7.7.1** *The laboratory shall have a procedure for monitoring the validity of results. [QC] The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. [QC] This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:*

*a) use of reference materials or quality control materials;*
*b) use of alternative instrumentation that has been calibrated to provide traceable results;*
*c) functional check(s) of measuring and testing equipment;*
*d) use of check or working standards with control charts, where applicable;*
*e) intermediate checks on measuring equipment;*
*f) replicate tests or calibrations using the same or different methods;*
*g) retesting or recalibration of retained items;*
*g).1. When a verification of a result is carried out:*

- *a) It shall be conducted by personnel who are currently authorized or an external service provider qualified to perform the testing;*
- *b) a record of the verification shall be made and the record shall identify who performed the verification, when it was performed, and the result of the verification; and*
- *c) the resolution of any discrepancy shall be recorded.*

*NOTE a) See requirement of 6.2.6 in ISO/IEC 17025:2017*
*h) correlation of results for different characteristics of an item;*
*i) review of reported results;*
*j) intralaboratory comparisons;*

*k) testing of blind sample(s).*
*l) There shall be a procedure for the technical review of technical records, including reports, and testimony. The procedure shall:*

1. *require the individual performing the technical review to have been competency tested to perform the testing or calibration work that is being reviewed;.*
2. *preclude an individual from technically reviewing their own work;*
3. *define the process to be used to ensure a representative sample of technical records and reports in each discipline are subjected to technical review;*
4. *define the process to be used to ensure testimony in each discipline is reviewed;*
5. *define the process to be used to conduct and record the review;*
6. *ensure that the results, opinions and interpretations are accurate, properly qualified and supported by the technical record;*
7. *ensure conformance with methods and applicable management system documents; and*
8. *describe a course of action to be taken if a discrepancy is found.*

*NOTE 1 An individual conducting the technical review need not be an employee of the forensic service provider, currently proficiency tested or currently performing the work.*
*NOTE 2 An individual who performs a verification can also perform a technical review.*
*NOTE 3 The sampling rate may vary for different disciplines.*

The MCCO/MVRCL monitors the validity of examination results using a multitude of overlapping mechanisms. This monitoring is planned, and the resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to analyze the results. The following are some of the mechanisms used:

**Controls, performance verification, intermediate checks, and method validation:** When applicable, MCCO/MVRCL applies the use of controls to verify procedures are working correctly and the results are valid. Performance verification checks are performed at scheduled intervals to ensure forensic equipment is functioning as expected. See each section's SOPs for specifics on performance checks. Method validation is performed prior to use and is intended to ensure applied methods perform properly for the intended use. Appropriate forensics standards, either developed internally or acquired from external sources (e.g., NIST-traceable), are used during control, performance verification, and method validation processes. The result of this testing is recorded, and the documentation is retained electronically.

**Re-examination using different methods/equipment:** In some cases, multiple methods are applied to examinations to confirm method validity and equipment functionality. In addition, different instruments of the same type (GC/MS) may be used to demonstrate the validity of the results.

**Training and proficiency testing:** Laboratory personnel, whose actions have a direct impact on the evidence or the results of an examination, receive initial training upon hiring followed by testing to verify competency. Additionally, continuing education is encouraged on an annual basis to ensure laboratory

personnel's knowledge, skills, and abilities remain current. Proficiency and inter- or intra-laboratory testing is also performed annually to evaluate the laboratory and its personnel's performance and technical capabilities.

**Technical/administrative reviews:** Technical and/or administrative reviews may be performed on forensic examination activities prior to release of the results. The reviews are documented in the organization's case management system.

Technical reviews include a comprehensive review of the case record, examination activity, and final report, to include (when applicable) the client request, evidence handling documentation, examination records, test reports, and examination results. For MVRCL, 100 percent of all completed cases are technically reviewed. For MCCO, at least 10% of pathology reports are reviewed. These reviews are completed by an experienced examiner who has the knowledge and forensic experience and has successfully completed a competency test in technical review. Technical reviews are not conducted by the author or co-author.

The technical review is conducted in LIMS. If the technical reviewer identifies discrepancies, insufficiencies, or inaccuracies during the review, they are noted and briefed to the examiner who makes the corrections and resubmits the case for a confirmation review. If a resolution cannot be reached or a critical issue is discovered, they are brought to the attention of the QC.

An administrative review of the case record, examination activity, and final report may be performed to ensure completeness and accuracy. The administrative review (e.g., spelling, grammar, unique identifiers, and other key information) may be completed at the time of technical review or by someone else who has been authorized to perform administrative reviews by utilizing the AR button in the MVRCL LIMS

A technical/administrative review ensures that:

- Appropriate examinations have been performed.
- The procedures performed are documented in the examination documentation and the report.
- If applicable, opinions and confirmations are properly documented.
- If deviations were made, they are properly documented.
- The legibility, detail, and completeness of the examination documentation are such that, in the absence of the examiner, another competent examiner could evaluate what was done and interpret the data.
- The report is consistent with the examination documentation.
- The results are supported in the examination documentation.
- The results are within the limitations of the discipline.
- The results meet the customer's request and are consistent with the examination method(s) used.
- Spelling and grammatical accuracy is verified.
- A review of the test report or equivalent is conducted to ensure that all key information is included.

**Testimony Monitoring:** Personnel who provide testimony have it monitored annually using one of the following methods:

- Direct observation.
- Audio/video recording review.
- Court transcript review.
- Virtual livestream

Testimony is monitored by another examiner competent in the field for which the testimony is given. The results of the evaluation are provided to and reviewed with the person monitored. If unsatisfactory conditions are reported, appropriate steps are taken to verify the information and if the unsatisfactory rating is valid, improvement actions are initiated. Both court appearances and testimony monitoring are tracked in Qualtrax.

If an analyst who is currently performing casework that could result in testimony has not testified in over 3 years, they will participate in a mock testimony conducted by other members of their section. Their mock testimony will be monitored as described above.

It should be noted that analysts that may be called to testify in a court proceeding are not permitted to view testimony as direct observation or virtual livestream due to separation of witnesses.

**7.7.2** *The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. [QC] This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:*

*a) participation in proficiency testing; [QC]*
*NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.*
*b) participation in interlaboratory comparisons other than proficiency testing. [QC]*

MVRCL - Each examiner performing casework completes either a proficiency test or an interlaboratory comparison each calendar year. Independent examination of a proficiency test that was submitted by a different analyst to the proficiency test company is regarded as an interlaboratory comparison. At no point may someone perform the same task on the same proficiency sample or test (e.g., perform technical review on the same proficiency sample for two different examiners). The laboratory's own approved methods are used when conducting this testing. This includes performing all tasks from evidence receipt to writing a final report, as applicable (e.g., evidence handing and preservation, case documentation, and quality assurance reviews). Results are only released to the proficiency test provider after having gone through all normal in-house review processes (e.g., batch review of data, verification, technical/administrative review). Results may be released to the proficiency test provider without undergoing a full review process if outside individuals (e.g., contracted technical reviewer) are involved.

This would typically happen when the contracted technical reviewer has participated in the same proficiency test for another laboratory.

MCCO – Each calendar year, every investigator, morgue employee, and Pathologist will be directly observed by another employee authorized to perform the observation. The Observation Form will be completed and stored in that employee's personnel folder on Qualtrax. Each Observation Form is reviewed and approved by the QC prior to its use.

The results of this testing are used to monitor the organization's and/or examiner's performance, identify areas where improvement may be needed, verify that technical procedures are valid, and verify that the quality of each examiner's work is being maintained. Tests are process-based, representative of items routinely examined, and the results are not known or readily available to the participant being monitored. Examiners participate in those processes which are representative of their routine activities. Furthermore, each year examiners do not need to participate in all the processes listed in order to be considered qualified to perform individual examination processes. The proficiency test may include, but is not limited to, one or more of the processes listed in **Table** :

| | |
|---|---|
| **Chemistry** | |
| Qualitative Determination | Weight Measurement |
| Quantitative Determination | |
| **Latent Prints** | |
| Collection | Enhancement |
| Physical Comparison | Individual Characteristic Database |
| **Firearms** | |
| Collection | Physical Comparison |
| Determination of Functionality | Length Measurement |
| Serial Number Restoration | Individual Characteristic Database |
| Product (Make/Model) Determination | |
| **Medicolegal Death Investigation** | |
| Cause/Manner Determination | Identification |
| Inquest/Investigation | Postmortem Exam |
| Scene Investigation | |
| **Toxicology** | |
| Qualitative Determination | Quantitative Determination |
| Carbon Monoxide Analysis | Vitreous Chemistry Analysis |
| Drug-Facilitated Crimes | |

**Table 1 Proficiency Testing Topic Areas**

***7.7.2.1*** *The laboratory's monitoring of performance by comparison with results of other laboratories shall, where available and appropriate for the laboratory activities:*

*a) demonstrate successful performance in at least one proficiency test or an approved alternate means of interlaboratory comparison for each discipline for which the laboratory is seeking accreditation; and [QC]*

*b) demonstrate successful performance in at least one proficiency test or an approved alternate means of interlaboratory comparison for each accredited discipline per calendar year at each location. [QC]*

*NOTE 1 To be considered an interlaboratory comparison, there must be participants from two or more laboratories operating under separate management systems.*
*NOTE 2 For proficiency tests taken at the end of one calendar year, evaluation of successful performance can occur in the subsequent calendar year.*

Each calendar year, the organization completes at least one proficiency test per discipline, obtained from an ANAB approved vendor, if possible. MCCO/MVRCL examiners complete proficiency testing annually in the category of testing in which they work. The MCCO/MVRCL has a documented proficiency testing schedule. Seized drugs performs an observational test for weighing; death investigators perform an observational test for scene investigation. If no proficiency test is available from an ANAB approved vendor, observational testing may be used with prior approval from the QC.

**7.7.3** *Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. [QC] If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported. [QC]*

The TL for each section is responsible for determining whether a proficiency test has acceptable results and documenting their determination in Qualtrax.

If during a proficiency test, the reported results are considered acceptable, but inconsistencies have been identified (e.g., inconclusive results, administrative errors, flagged results), these will be addressed by the TL during their assessment of the proficiency test in Qualtrax.

***7.7.4*** *The laboratory shall monitor the performance of all personnel who perform laboratory activities. [QC] The monitoring shall demonstrate successful performance in at least one proficiency test, other intralaboratory comparison, or interlaboratory comparison per calendar year in each accredited discipline in which the individual is authorized to conduct work. [QC] In the event that the preceding options are not available or appropriate, observation-based performance monitoring is acceptable. [QC]*

*NOTE 1 The monitoring should be varied over time to cover all aspects of assigned job functions, but does not have to include all aspects of the work performed each time.*

*NOTE 2 Solely performing verifications (7.7.1.f).1) or solely reviewing and authorizing results (7.8.1.1) are considered to influence results and are subject to these requirements.*
*NOTE 3 For performance monitoring conducted at the end of one calendar year, evaluation of successful completion can occur in the subsequent calendar year.*

If personnel do not successfully complete their performance evaluation, they shall be removed from casework and a non-conformance evaluation will be performed. After the successful completion of any corrective action (e.g., retraining, successful proficiency test) they may be returned to casework. If during a proficiency test in which a verification or technical review changes the original examiner's conclusion, the test will be worked per usual procedure and the agreed upon result will be submitted to the proficiency provider. If the verifier/technical reviewer's change was correct, the original examiner is deemed to have failed the proficiency test and a non-conformance evaluation is performed.

***7.7.5*** *The process for monitoring the performance of the laboratory and personnel shall: [QC]*

*a) ensure that results are not known or readily available to the participant being monitored;*
*b) ensure use of approved methods by the individual(s) whose performance is being monitored;*
*c) establish criteria for successful performance prior to the monitoring activity being conducted;*
*d) require a mechanism to ensure the quality of the monitoring activity prior to personnel performance being monitored; and*
*e) for calibration laboratories, require the monitoring activity to be performed using an item that was calibrated by the person whose performance is being monitored.*
*f) Require notification to ANAB within 30 days when the expected result is not attained during any monitoring activity.*

*NOTE 1 f) For a consensus-based proficiency test, the consensus results is the expected result.*

*NOTE 2 f) When an identification or exclusion is the expected result, an outcome of inconclusive is considered an unexpected result.*

See section 7.7.2 for details concerning items: a, b, and d.

The laboratory maintains records of proficiency testing that include test planning, preparation, execution, and proficiency test results. At a minimum, the following information is documented:

- Test set identifier, including category of testing, and how samples were obtained or created.
- Indication of results for each tested examiner.
- If remediation was required, the details of the corrective actions taken.

7.7.5 e is not applicable to MCCO/MVRCL operations.

Results of proficiency testing are automatically sent to ANAB by the PT provider or by MCCO/MVRCL within 30 days if the proficiency test results for intralaboratory examinations are not as expected. This includes when an identification or exclusion is the expected result and an inconclusive is reported.

***7.7.6*** *There shall have a performance monitoring plan that will:*

*a) demonstrate conformance with the requirements stated in clause 7.7.2.1.b) and 7.7.4; [QC] and*
*b) ensure inclusion of a portion of the components/parameters and equipment/technologies within each accredited discipline. [QC]*

See sections 7.7.2.1 and 7.7.4

***7.7.7*** *To satisfy the proficiency test or interlaboratory comparison requirements in clauses 7.7.2.1.a) and b), the laboratory shall:*

*a) use a proficiency test provider that is accredited to ISO/IEC 17043 by an accreditation body that is a signatory to the ILAC MRA and has the applicable proficiency test(s) on its scope of accreditation, [QC] and*
*b) submit results to the proficiency test provider on or before the date determined by the test provider; and*
*c) authorize the proficiency test provider to release the test results to ANAB; or*
*d) gain approval from ANAB for alternative means of interlaboratory comparison. To obtain approval for an interlaboratory comparison other than proficiency testing, the laboratory must demonstrate that the proposed alternative means of monitoring performance is substantially similar to proficiency testing. [QC]*

The organization completes at least one proficiency test in each category of testing, obtained from an ANAB approved vendor each calendar year, following all test provider instructions, when available. If a proficiency test is not available or not appropriate for the work conducted, management will gain approval from ANAB for an alternate means of assessing performance.

***7.7.8*** *The following records shall be retained for all performance monitoring of the laboratory and its personnel [QC]:*

*a) discipline(s) monitored;*
*b) design of the monitoring activity;*
*c) expected results;*
*d) location, when more than one location is associated with a single accreditation certificate;*
*e) records submitted to a proficiency test provider, if applicable;*
*f) evaluation of results and action taken for unexpected results; and*
*g) feedback on individual performance provided to the participant.*

Results are tracked in Qualtrax.

See section 7.7.4 and 7.7.5 for proficiency tests, comparison and observational-based monitoring

**7.8 Reporting of results**

**7.8.1 General**

**7.8.1.1** *The results shall be reviewed and authorized prior to release. [TL/Examiner]*

See section 7.7.1 for details on Technical and Administrative reviews

MVRCL - The approved signed "final" report is issued only after it has been technically and administratively reviewed. Release is documented and retained in the case management system. Absent the adoption of a contrary policy by the laboratory, there shall be only one signed original examination report. Release of "preliminary" results with or without a report is avoided except when per the customer's request. Refer to each section's SOPs for more information on how and when preliminary results are released.

If additional copies of an already issued report are requested, the request is granted to anyone within the customer's organization. If the customer is a defense attorney, reports will only be released to the requesting attorney, as to abide by the Rules of Evidence. For any other requests, the customer must be contacted and give documented authorization for the release.

For some testing that was performed at this laboratory, a static report was not created. While the reported findings will not change unless the request is moved to "findings entered", the current report template will be used for formatting the report. When a request is made for a copy of a final report that is not static, the employee providing the report must communicate this fact to the report requester.

MCCO – The investigator report is authorized and reviewed by the assigned investigator and attached in LIMS. The final autopsy report is authorized and reviewed by the assigned pathologist and attached in LIMS. Preliminary results can be released by the assigned pathologist to the customer.

***7.8.1.1.1** The authorizer of results shall review the technical record and document the review. [Examiner]*

See section 7.7.1 for details on Technical and Administrative reviews.

The assigned pathologist is the authorizer of their results and their documentation of review of the technical record is documented when they mark the request as draft complete.

**7.8.1.2** *The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the*

*information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. [QC] All issued reports shall be retained as technical records.*

*NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.*
*NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.*

The results of each applicable forensic examination carried out by the organization are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the examination methods. The applicability of an examination is determined by the type of support being provided and the customer's reporting requirements. Results are normally reported using the service specific report in LIMS, which includes all the information requested by the customer and necessary for the interpretation of the results and all information required by the method used; see below for exceptions to this requirement. Provided test reports clearly communicate the results, including when the results are inconclusive. When no definitive conclusions can be reached, the test report shall clearly communicate the reason(s).

In the case of a written agreement with the customer, the results can be reported in a simplified way (e.g., email). Any required information that is not reported to the customer is readily available in the laboratory's case management system.

No report is required if the request is cancelled prior to examination; however, if work has been performed and the request is cancelled, a final report shall be issued. It should be noted on the report that testing was not completed due to the customer cancelling the request.

Refer to each section's SOPs for any approved alternate report or reporting formats.

Refer to the appropriate section's SOPs for how database entry and searches are reported.

**7.8.1.2.1** *The results shall be provided in a written report. [QC]*

See section 7.8.1.2

**7.8.1.2.2** *There shall be a procedure for reporting of results that:*

*a) identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for all (partial and complete) work performed; [QC]*
*b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement; [QC]*
*c) requires communicating the reason(s) in the report when the reported results are inconclusive; [QC]*
*d) requires reporting of the initial database entry (e.g., CODIS, AFIS, NIBIN); [QC] and*

*e) requires reporting of an association resulting from a database search (e.g., CODIS, AFIS, NIBIN). [QC]*

*NOTE 1 a) The reporting of results does not include work performed for the purpose of constructing an individual characteristic database or maintaining the quality and/or effectiveness of information in such a database.*
*NOTE 2 b) Associations for multiple results may be qualified by a single statistic or qualitative statement if the statistics are identical or, where applicable, meet or exceed a defined minimum threshold.*

See section 7.8.1.2

***7.8.1.2.3*** *The documented process for reporting of results of calibration shall:*

*a) identify what information will be reported in the calibration certificate; and*
*b) require the issuance of an endorsed calibration certificate if requested by the customer.*

N/A

**7.8.1.3** *When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available. [QC]*

See section 7.8.1.2

***7.8.1.3.1*** *When results are reported in a simplified way, the agreement with the customer shall specify the content of a simplified report. [QC]*

See section 7.8.1.2

**7.8.2 Common requirements for reports (test, calibration or sampling)**

**7.8.2.1** *Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse [QC]:*

*a) a title (e.g. "Test Report", "Calibration Certificate" or "Report of Sampling");*
*b) the name and address of the laboratory;*
*c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;*
*d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;*
*e) the name and contact information of the customer;*
*f) identification of the method used;*
*g) a description, unambiguous identification, and, when necessary, the condition of the item;*
*h) the date of receipt of the test or calibration item(s), and the 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) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;*
*l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;*
*m) the results with, where appropriate, the units of measurement;*
*n) additions to, deviations, or exclusions from the method;*
*o) identification of the person(s) authorizing the report;*
*p) clear identification when results are from external providers.*

*NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.*
*NOTE 2 A legal requirement that dictates the information to be included in a report is a valid reason to not include one or more listed report elements.*
*NOTE 3 I) Date(s) may be reflected as a range of dates or the date of each activity.*
*NOTE 4 o) Authorization of the report does not have to be performed by the same person(s) who authorized the results. (see ISO/IEC 17025:2017 7.8.1.1)*

Examiners attempt to add in as many of the applicable requirements listed into the reports, but when not possible (i.e., usually in client reports) those requirements are documented in the case record.

MCCO/MVRCL considers the dates of the performance of the laboratory activity(s) to be a range encompassed from when the request is created in LIMS and when the laboratory report is draft completed. These dates will appear on the final report designating the date range.

Pathologist and investigator scene reports are simplified and do not meet the above criteria.

**7.8.2.2** *The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. [QC] Data provided by a customer shall be clearly identified. [QC] In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. [QC] Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received. [QC]*

MVRCL is responsible for all data on the final report, except when that data is provided by the customer. Administrative items such as date of offense or address of offense are not considered data on the final report. If customer provided data appears on the final report, it is clearly identified, and a disclaimer is included if the data can affect the validity of results.

MCCO – Clinical histories or information provided about a decedent that appears on a report is considered to be customer provided.

**7.8.3 Specific requirements for test reports**

**7.8.3.1** *In addition to the requirements listed in 7.8.2, test reports shall, where necessary for the interpretation of the test results, include the following [QC]:*

*a) information on specific test conditions, such as environmental conditions;*
*b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);*
*c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:*
*— it is relevant to the validity or application of the test results;*
*— a customer's instruction so requires, or*
*— the measurement uncertainty affects conformity to a specification limit;*
*c)1 The measurement uncertainty shall:*
*a) be included in the report or an annex to the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement;*
*b) include the measured quantity value, y, along with the associated expanded uncertainty, U, and the coverage probability;*
*c) be in the format of y ± U;*
*d) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and*
*e) be reported to the same number of decimal places or digits as the measurement result.*
*NOTE 1 a) A legal requirement is created, imposed, and enforced by a third-party external to the laboratory agency.*
*NOTE 2 c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.*
*d) where appropriate, opinions and interpretations (see 7.8.7);*
*e) additional information that may be required by specific methods, authorities, customers or groups of customers.*

In addition to the items reported in section 7.8.2, environmental conditions, opinions and interpretations, and additional customer requested information may be included in the report where applicable. A properly formatted measurement uncertainty to include the measured quantity value, associated expanded uncertainty, and coverage probability is included in the report when it impacts the evaluation of a specification limit stated by a regulatory body, a statute, case law, or other legal requirement. The following measurements have uncertainty reported on final reports: drug chemistry weight measurements; hemp determination quantitation's; toxicology *per se* drug quantitation's for OVI cases; and firearm barrel length measurements.

***7.8.3.1.1*** *If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a result or prohibits including measurement uncertainty in the report, the laboratory shall [QC]:*

*a) have objective evidence of the regulation, statute, case law or other legal requirement; and*
*b) if prohibited from reporting measurement uncertainty, have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the result.*

N/A

**7.8.3.2** *Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results. [QC]*

MCCO/MVRCL sampling activity test reports meet the requirements of 7.8.5.

**7.8.4 Specific requirements for calibration certificates**

**7.8.4.1** *In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:*

*a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);*

*NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.*

*a).1The measurement uncertainty shall:*

*a) include the measured quantity value, y, along with the associated expanded uncertainty, U, the coverage factor, and the coverage probability;*
*b) be in the format of y ± U;*
*c) be limited to at most two significant digits, unless there is a documented rationale for reporting additional significant digits; and*
*d) be reported to the same level of significance as the measurement result.*

*NOTE c) For asymmetrical uncertainties, it may be inappropriate to quote a single result for the uncertainty and presentations other than y ± U may be needed.*

*b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;*
*c) a statement identifying how the measurements are metrologically traceable (see Annex A);*
*d) the results before and after any adjustment or repair, if available;*
*e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);*
*f) where appropriate, opinions and interpretations (see 7.8.7).*

N/A

***7.8.4.1.1*** *If a regulatory body, statute, case law or other legal requirement specifies the format for the reporting of a calibration result or prohibits including measurement uncertainty in the calibration certificate, the laboratory shall:*

*a) have objective evidence of the regulation, statute, case law or other legal requirement; and*
*b) have a process for applying the measurement uncertainty at the established level of confidence prior to reporting the calibration result.*

N/A

**7.8.4.2** *Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.*

N/A

**7.8.4.3** *A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.*

N/A

***7.8.4.4*** *If applicable, a label (in addition to the calibration certificate) attached to a calibrated breath alcohol measuring instrument shall not give the impression that the breath alcohol instrument itself is approved and shall include:*

*a) the name of the accredited calibration laboratory or its accreditation certificate number;*
*b) the unambiguous identification of the item calibrated;*
*c) the date of the current calibration; and*
*d) cross reference to the calibration certificate issued in respect to the calibration.*

N/A

**7.8.5 Reporting sampling – specific requirements**

*Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results: [QC]*

*a) the date of sampling;*
*b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);*
*c) the location of sampling, including any diagrams, sketches or photographs;*
*d) a reference to the sampling plan and sampling method;*
*d)If a sampling plan is used, the report shall contain information about the sampling plan, including confidence levels and corresponding inference(s) 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.*

In addition to the items reported in section 7.8.2, the items listed in 7.8.5a through 7.8.5f may be included in the report where necessary for the interpretation of the results.

### 7.8.6 Reporting statements of conformity

**7.8.6.1** *When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule. [QC]*

*NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.*

N/A

**7.8.6.2** *The laboratory shall report on the statement of conformity, such that the statement clearly identifies: [QC]*

*a) to which results the statement of conformity applies;*
*b) which specifications, standards or parts thereof are met or not met;*
*c) the decision rule applied (unless it is inherent in the requested specification or standard).*

*NOTE For further information, see ISO/IEC Guide 98-4.*

N/A

### 7.8.7 Reporting opinions and interpretations

**7.8.7.1** *When opinions and interpretations are expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement. [QC] The laboratory shall document the basis upon which the opinions and interpretations have been made. [QC]*

*NOTE It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6.*

If opinions or interpretations are communicated, they are only communicated by authorized laboratory personnel and the basis is documented. If they are communicated, by direct dialogue with the customer, the dialogue is documented. Opinions and interpretations are clearly marked in a test report.

**7.8.7.2** *The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such. [QC/Examiner]*

See section 7.8.7.1.

**7.8.7.3** *When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained. [QC/Examiner]*

See section 7.8.7.1.

**7.8.8 Amendments to reports**

**7.8.8.1** *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. [QC]*

When it is necessary to issue an amended report, the following steps are performed:

1. The original report will be saved in LIMS imaging.
2. The reason for the amendment will be documented in LIMS.
3. The report milestone status will be changed from admin. review to findings entered.
4. Under the individuals tab, add a new individual. Type "AMENDED REPORT" in the last name field. Under type, select "TypeReport". Relate requests affected by this report.
    a. For requests other than Chemistry or Toxicology:
        i. Under the requests tab, select findings entered for the request being corrected. Go to "results and conclusions" and at the top of the page type, "This replaces the (insert section) report dated (insert date). The (insert correction/issue) has been corrected." Under type, select "TypeReport".

    b. For Chemistry Reports:
        i. Edit the request and in the Reviewer box add, "This replaces the report dated (insert date). The (insert correction/issue) has been corrected.

    c. For Toxicology Reports:

        i. Edit the request and in the Assignor Notes box define the date of the previous report as well as the reason the report is being reissued.
    d. For Pathologist Reports:
        i. An amended report is created in LIMS.

5. An analyst in the section then reviews the amended report for correctness and marks the request as "draft complete". The request then goes through standard technical and administrative review before being released.

**7.8.8.2** *Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this document.*

See section 7.8.8.1.

**7.8.8.3** *When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.*

See section 7.8.8.1.

**7.9 Complaints**

**7.9.1** *The laboratory shall have a documented process to receive, evaluate and make decisions on complaints. [QC]*

All received complaints, regardless of communication method, are reported to TM or QC. The QC is responsible for all decisions for the handling of complaints and for notifying, via formal notice, when practicable, the complainant or identifier of the end of the review process and its resolution. TM confirms receipt of a complaint and provides periodic progress reports if the resolution takes too long.

Each complaint identified by the laboratory is confirmed as to whether it relates to laboratory's activities and, if so, it is recorded, analyzed, and resolved as quickly as possible by the QC. Complaints with high-impact or high-urgency are prioritized and worked continuously until resolution. Non-specific or anonymous "complaints", whether documented or not, will not be considered for action. General complaints about a section's turn-around time are also not considered for action.

The QC investigates the complaint and gathers any information or evidence required to fully evaluate and consider the complaint. All activities regarding the investigation are documented. The QC takes appropriate action to address the complaint and assesses the effectiveness of the action. TM or QC advises the complainant of the outcome of the actions regarding the complaint. Records of all complaints and the corrective actions taken are retained in the laboratory's administrative files. When necessary, complaints are elevated and addressed using the corrective action process.

If a member of the QC is directly involved with the complaint (e.g., the complaint is against them), they will not participate in the resolution of the complaint.

**7.9.2** *A description of the handling process for complaints shall be available to any interested party on request. [QC] Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. [QC] The laboratory shall be responsible for all decisions at all levels of the handling process for complaints. [QC]*

See section 7.9.1

**7.9.3** *The process for handling complaints shall include at least the following elements and methods [QC]:*

*a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;*
*b) tracking and recording complaints, including actions undertaken to resolve them;*
*c) ensuring that any appropriate action is taken.*

See section 7.9.1

**7.9.4** *The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint. [QC]*

See section 7.9.1

**7.9.5** *Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome. [QC]*

See section 7.9.1

**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. [QC]*

*NOTE This can be performed by external personnel.*

See section 7.9.1

**7.9.7** *Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant. [QC]*

See section 7.9.1

**7.10 Nonconforming work**

**7.10.1** *The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). [QC] The procedure shall ensure that:*

*a) the responsibilities and authorities for the management of nonconforming work are defined;*
*b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;*

*c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;*
*d) a decision is taken on the acceptability of the nonconforming work;*
*e) where necessary, the customer is notified and work is recalled;*
f) *the responsibility for authorizing the resumption of work is defined.*

The QC is responsible for the management of nonconforming work and has the authority to remediate identified nonconformities and mitigate related risks. TM has authority for nonconformity and risk acceptance and for authorizing the resumption of work.

Nonconformities that are detected from internal audits, management reviews, major incidents, internal observations, or review of documents and records are forwarded to the QC for review. Nonconformities may have two outcomes: correction or a corrective action. Corrections are performed when a problem can be easily remedied and does not appear likely to happen again. These corrections are documented on a correction log and reviewed periodically to detect any trends.

If a correction is not appropriate for the nonconformity, the nonconformance workflow is started in Qualtrax. The following is then documented: what happened, what is the suspected root cause, what the corrective action will be, when the corrective action will be monitored, the extent of the nonconformity, and any follow up. Once the responsible member of the QC believes the problem has been addressed and properly monitored, they will present their findings to the QC for a vote to close the nonconformance. A majority of "close" votes must be received to close the nonconformance. During the voting, the DO does not vote; their vote may be used in an event to break a tie amongst the other members of the QC.

When corrective actions are required, work is halted immediately and sequestered or repeated and reports are withheld until a determination is made. If work is halted due to the severity of the nonconformance or unacceptable level of risk, laboratory personnel are notified when work may be resumed. Where necessary, the customer is notified of the nonconformity and, if necessary, work is recalled and reworked. At this time, any applicable accrediting bodies (ANAB and/or ABFT) are also notified. Corrective actions follow the procedures outlined in section 8.7. Records of nonconforming work and the actions taken are retained in the laboratory's administrative files.

The accrediting bodies will be kept informed of the nonconformity and the corrective actions taken to remedy it.

**7.10.2** *The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).*

See section 7.10.1

**7.10.3** *Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory shall implement corrective action.*

See section 7.10.1

**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. [TM]*

Laboratory personnel have access to the data and information they need to perform their respective jobs. Examiners and Evidence Custodians have access to forensic evidence, service request information, and laboratory policies and procedures.

**7.11.2** *The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. [QC] Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation. [QC]*

*NOTE 1 In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.*
*NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.*

MCCO/MVRCL's laboratory information management system (LIMS) is a COTS product. The system was functionally assessed prior to purchase to ensure it provided the necessary capabilities to collect, process, record, report, store, and retrieve case and evidence related data. Changes to software configurations are authorized, documented, and tested prior to implementation.

**7.11.2.1** *There shall be a plan for validation of computer software developed by the user and records of the validation shall be retained. [QC]*

MCCO/MVRCL does not develop computer software.

**7.11.3** *The laboratory information management system(s) shall [TM]:*

*a) be protected from unauthorized access;*
*b) be safeguarded against tampering and loss;*

*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;*
*e) include recording system failures and the appropriate immediate and corrective actions.*

The laboratory uses an electronic case management system, which manages each technical (i.e., case) record individually. Each case record contains a unique case identifier that is linked to every item in that case record. Each employee is assigned a unique login and every entry/modification made by that employee is linked to that employee and subsequently tracked in an audit log. The LIMS application resides on a Cisco UCS Blade Hardware with complete HA redundancy capabilities. The virtual server is managed utilizing Vmware 6.5. All databases and transaction logs run daily backup routines within SQL Studio Management Suite. Once completed Montgomery County's backup server creates image and file backups of the virtual server. The data backup is copied to offsite Disaster Recovery Facility. Any system failures of LIMS will be addressed through the nonconformance process.

**7.11.4** *When a laboratory information management system is managed and maintained 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. [TM]*

MCCO/MVRCL's laboratory information management system is managed and retained within Montgomery County's IT department.

**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. [TM]*

Up-to-date instructions on the use and maintenance of laboratory equipment are readily available from the original equipment manufacturer (OEM) within the help function.

**7.11.6** *Calculations and data transfers shall be checked in an appropriate and systematic manner. [Examiner]*

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

Calculations and data transfers made during the examination are checked in a systematic manner and documented in the case record. "Data" includes any information that will appear on the final report. Weights of seized drugs are directly transferred from the balance to the examiner's computer and are not subject to human error.

**7.11.6.1** *The technical record shall indicate that the check of calculations and data transfers was conducted and who conducted the check. When possible, this check shall be conducted by individuals other than the personnel who performed the calculation(s) or the data transfers. [QC/Examiner]*

*NOTE This check may be part of a technical review.*

Calculations and data transfers are checked during the technical/administrative review process, which is documented and retained in the case record. Checks are not performed by the person who performed the calculation or data transfer.

## 8 Management system requirements

### 8.1 Options

### 8.1.1 General

*The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B. [QC]*

*NOTE See Annex B for more information.*

The laboratory's Quality Management System (QMS) supports the effective implementation of, and compliance with, ISO/IEC 17025 and applicable accrediting body supplemental requirements and is intended to yield quality products and services.

To accomplish defined goals, the laboratory will:

- Establish responsibilities for coordinating QMS process development and improvement activities.
- Develop and maintain a usable set of QMS process assets that improve performance across forensic projects and provide a basis for cumulative long-term benefits.
- Develop the management and technical skills and knowledge of laboratory employees to ensure forensic projects are successfully and competently completed.
- Consistently perform a well-defined quality management process that integrates all activities to produce correct consistent products.
- Establish a means for Forensic Examiners to actively participate with each other to better satisfy customer needs effectively and efficiently.
- Remove processing deficiencies from work products in a timely manner, using techniques such as Technical and Administrative Reviews to improve product accuracy.

TM approves and authorizes the QMS and the QC coordinates and retains documentation supporting the QMS. All staff members are responsible for the implementation of the QMS.

In particular, the QC:

- Identifies all processes needed for the QMS and their application.
- Determines the sequence and interaction of these processes.
- Determines the criteria and methods needed to ensure that both the operation and control of forensic processes are effective.
- Ensures the availability of resources and information necessary to support the operation and monitoring of forensic processes.
- Implements actions necessary to achieve planned results and continual improvement of forensic processes.
- Monitors backlogged or pending cases to ensure timely reporting of results and conclusions. A case or request is considered backlogged when it has been open for longer than 30 days. MVRCL strives to have all requests completed within 30 days; MCCO strives for 90% of reports completed within 60 days and shall have 90% of reports completed within 90 days.

### 8.1.2 Option A

*As a minimum, the management system of the laboratory shall address the following [QC]:*

— *management system documentation (see 8.2);*
— *control of management system documents (see 8.3);*
— *control of records (see 8.4);*
— *actions to address risks and opportunities (see 8.5);*
— *improvement (see 8.6);*
— *corrective actions (see 8.7);*
— *internal audits (see 8.8);*
— *management reviews (see 8.9).*

MCCO/MVRCL complies with Option A and has addressed the aforementioned items within the sections identified.

### 8.2 Management system documentation (Option A)

**8.2.1** *Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization. [QC]*

MCCO/MVRCL QMS requirements (i.e., policies, systems, programs, procedures and instructions) are documented in this Quality Assurance Manual (QM), in the MCCO/MVRCL standard operating procedure (SOP) manuals – forensic procedures, evidence handling, health and safety, and in MCCO/MVRCL supplemental documents. MCCO/MVRCL policies, procedures and instructions are

available Qualtrax, electronically, or in the section. MCCO/MVRCL systems, programs, and instructions (i.e., supplemental documents) are also available in Qualtrax, in MCCO/MVRCL shared network drives, and on various MCCO/MVRCL websites or networks.

Personnel are trained on the quality management system and related policies, practices, and technical procedures when they are initially hired and then annually thereafter. Documentation of this training (e.g., staff call attendance logs and training attendance and testing documentation) is retained in the laboratory's administrative folders (paper, electronic, or in Qualtrax). Current quality system policies, procedures, and instructions shall be followed by all personnel.

***8.2.1.1*** *The following words (to include forms of the same word) used in ISO/IEC 17025:2017 or in ANAB AR3125 require addressing the requirement in writing: agreed, authorize, define, instructions, method, plan (noun only), procedure, program, record, schedule, specify [QC]*

When the following words: agreed, appoint, authorize, define, instructions, method, plan, procedure, program, record, schedule, and specify are used they are addressed in writing.

**8.2.2** *The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory. [QC]*

MCCO/MVRCL's quality policies and objectives address the competence, impartiality and consistent operation of the laboratory and support the application of a controlled QMS to ensure that standards and working practices are consistent with forensic best practices, fully understood by laboratory staff, provide quality products/services that meet customer requirements and expectations, and ensure continuous improvement of the QMS.

**8.2.3** *Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. [TM/QC]*

Laboratory management's commitment to the development, implementation and continuous improvement of the laboratory's QMS is demonstrated through the completion of annual management reviews, staff and management review meetings, the conduct of internal audits which provide data on the effectiveness of MCCO/MVRCL's policies and procedures, and the implementation of a corrective and preventive action review program that identifies actions taken to improve identified deficiencies. Documentation of these reviews, audits, and corrective/preventive actions are retained electronically.

Opportunities for improvement are prioritized and approved by the TM/QC prior to implementation. Improvement targets are set in one or more of quality, value, capability, cost, productivity, resource utilization and risk reduction; the laboratory's policies, plans, processes and procedures are revised when necessary; all MCCO/MVRCL employees are notified of change via email and improvements are reported

in management review and/or staff meetings. Improvements are recorded and tracked on an Action Item log. Necessary actions are taken if implemented improvements do not achieve set targets.

**8.2.4** *All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system. [QC]*

This document, in conjunction with the separately published SOPs and laboratory supplemental manuals, constitutes the primary components of the laboratory's quality management system.

**8.2.5** *All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities. [QC]*

See section 8.2.1

**8.3 Control of management system documents (Option A)**

**8.3.1** *The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. [QC]*

*NOTE In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.*

Laboratory management controls all internally created documents, including this Quality Manual, the separately published MCCO/MVRCL SOPs, and supplemental manuals such as the Safety manual. Documents are reviewed for adequacy and approved for use prior to issue. A master list of documents is maintained and is readily available to all MCCO/MVRCL personnel. The master list includes each document's title, revision number, and issue date. Authorized editions of controlled documents (i.e., official copy) and most recent versions of documents are posted in Qualtrax, which is access controlled via assigned permissions by TM.

All documents are readily identifiable and legible. All controlled documents are reviewed at least annually, updated as necessary, and documented with a dated notation in the document history section of the current revision. Altered or new text is identified using the document track changes feature and the altered document is saved for historical reference. Records of the review are retained in the Qualtrax testing reports.

Laboratory generated controlled documents are uniquely identified within the header of the document under revision number.

Changes to documents are tracked and obsolete documents are promptly removed from points of use, marked or moved to an obsolete folder to prevent unintended use, and retained for historical information purposes. For documents in Qualtrax, retained copies of obsolete documents are properly marked, kept

separate from active documents and are stored in Qualtrax. Obsolete documents prior to Qualtrax are retained in archived locations. Obsolete controlled documents are identified/marked as no longer in use.

All new and/or revised versions of controlled documents are communicated to MCCO/MVRCL staff via email.

Equipment and software manuals retained for general reference purposes only are not subject to document control requirements -- this includes digital and paper manuals to which personnel may refer for conducting examinations, maintenance (repair), or performance verification. In order to ensure laboratory personnel are using current versions of externally generated equipment manuals, when possible, personnel shall access these manuals from the vendor's Internet website or from same media provided with the hardware or software.

For new technical documents (e.g., SOPs), the drafter is technically qualified to perform the task.

**8.3.2** *The laboratory shall ensure that [QC]:*

*a) documents are approved for adequacy prior to issue by authorized personnel;*
*b) documents are periodically reviewed, and updated as necessary;*
*c) changes and the current revision status of documents are identified;*
*d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;*
*e) documents are uniquely identified;*
*f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.*

See section 8.3.1

**8.4 Control of records (Option A)**

**8.4.1** *The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document. [QC]*

The laboratory has implemented the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. All records are legible and readily identifiable and available to authorized individuals consistent with the laboratory's confidentiality policies. The records are stored electronically in such a way as to be retrievable and to prevent damage and loss. Access to the case record storage areas is access controlled using assigned login and password credentials. The following records are retained:

- Quality Records: Document control, subcontractor and service/supply evaluation, complaints, improvement, risk management and corrective actions, audits and management reviews, training,

competency/proficiency testing, guiding principles, position descriptions, statement of qualifications and work authorizations, facilities management, equipment, and verification and validation.

- Administrative Records: General office management, budget and finance, contracts and business development, human resources, procurement, asset management, security, health and safety, and reference publications.
- Technical / Case Records: Technical records, including examination records (i.e., notes), related to specific cases such as case records and reports

Stored records are not destroyed.

**8.4.2** *The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. [QC] The laboratory shall retain records for a period consistent with its contractual obligations. [QC] Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available. [QC]*

*NOTE Additional requirements regarding technical records are given in 7.5.*
*NOTE 2 Contractual obligations for records retention include legal requirements and customer expectations.*

See Section 8.4.1

**8.5 Actions to address risks and opportunities (Option A)**

**8.5.1** *The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to [QC]:*

*a) give assurance that the management system achieves its intended results;*
*b) enhance opportunities to achieve the purpose and objectives of the laboratory;*
*c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities;*
*d) achieve improvement.*

The laboratory considers the risks and opportunities associated with its activities in order to verify the effectiveness of its quality management system, increase opportunities to achieve its business and operational goals, mitigate or minimize undesirable influences and potential failures in its operations; and continually improve its effectiveness, operational efficiency, and ensure its continued compliance with accreditation and laboratory requirements. This also includes risks and opportunities related to health and safety. Effective risk management allows the laboratory to assure its purpose and achieve its objectives.

**8.5.2** *The laboratory shall plan [QC]:*
*a) actions to address these risks and opportunities;*
*b) how to:*
*— integrate and implement these actions into its management system;*

— *evaluate the effectiveness of these actions.*

*NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.*

The laboratory manages risk in the following ways:

- Through the nonconformance process described below.
- By identifying and discussing possible risks during routine QC meetings and the annual management review.

When risks are identified that are likely to reoccur or would be very detrimental to the product produced by this laboratory, a corrective or preventive action will be performed and documented in the appropriate log.

**8.5.3** *Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results [QC].*

*NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.*
*NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.*

See section 8.5.2

**8.6 Improvement (Option A)**

**8.6.1** *The laboratory shall identify and select opportunities for improvement and implement any necessary actions. [QC]*

*NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.*

The laboratory continually identifies opportunities for improvement to fine-tune the effectiveness of its quality management system and efficiency and competency of its operations. The laboratory uses the following methods to identify potential areas for improvement:

- Quality and technical policies and procedures are regularly reviewed to ensure continued compliance with accreditation and industry best practices.
- Results of audits, management reviews, corrective actions and risk management processes are analyzed.

- Customer and staff feedback and complaints are assessed.

All MCCO/MVRCL employees are encouraged to identify improvements; opportunities of improvements can be submitted in-person, via email or during staff meetings. Opportunities for improvement are prioritized and managed by:

a) Setting targets for improvements of quality.
b) Top and key management ensure that approved improvements are implemented by tracking them in Action and improvement log.
c) Quality management documents may be updated if improvement is implemented.
d) Necessary actions will be taken if implemented improvements do not achieve targets. In some cases, corrective action and root cause analysis will be performed.
e) Implemented improvements will be reported as part of the management review.

**8.6.2** *The laboratory shall seek feedback, both positive and negative, from its customers. [QC] The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service. [QC]*

*NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.*

- Annually, the MCCO/MVRCL conducts an online survey of customer satisfaction. The results of that survey are shared with top and key management. Any specific complaints are addressed. NOTE: Nonspecific or anonymous complaints will not be addressed unless the QC determines otherwise.

- Customers may also contact the TM, QC, or any examiner with a complaint. These complaints shall be forwarded to the QC to investigate.

In all cases, the feedback is analyzed and, if needed, customer service improvements are implemented.

**8.7 Corrective actions (Option A)**

**8.7.1** *When a nonconformity occurs, the laboratory shall [QC]:*

*a) react to the nonconformity and, as applicable:*
*— take action to control and correct it;*
*— address the consequences;*
*b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:*
*— reviewing and analysing the nonconformity;*
*— determining the causes of the nonconformity;*
*— determining if similar nonconformities exist, or could potentially occur;*

*c) implement any action needed;*
*d) review the effectiveness of any corrective action taken;*
*e) update risks and opportunities determined during planning, if necessary;*
*f) make changes to the management system, if necessary.*
*g) The process for corrective action shall establish a reasonable timeframe for completion for each corrective action.*

The QC is responsible for the management of corrective actions and has the authority to remediate identified nonconformities and mitigate related risks documenting all phases of the process electronically. The QC has authority for nonconformity, risk, and corrective action acceptance and for authorizing the resumption of work after consulting with TM. The corrective action process includes the initial issue review process and has specific corrective action steps, including problem identification, risk impact assessment, remedial action/containment, investigation /root cause analysis, correction, monitoring when needed and closure.

Nonconformities that are detected from internal audits, management reviews, major incidents, internal observations, or review of documents and records are forwarded to the QC for review. Complaints from customers, employees, or interested parties related to the quality management system are forwarded to the TM for review. If the complaint is determined to be a nonconformity, then the corrective action process is implemented.

The corrective action process may take two different paths. The first path is a simple correction to the nonconformance. This remediation is typically performed when the nonconformity is rare and does not have a major impact on the work being performed in this laboratory. The correction is tracked in the correction log by section. The correction log is reviewed by the QC to determine if any trends exist and if additional remediation is necessary.

The second path is when a simple correction may not stop the nonconformance from reoccurring or the impact on the work product is too great. This path results in a nonconformance investigation, to include root cause determination, corrective action planning, risk assessment, monitoring period, and evaluation of the chosen corrective action. The person responsible for completing the nonconformance documentation is typically the TL for the section affected.

When corrective actions are required to remediate a severe or unacceptable level of risk, work is halted immediately and sequestered or repeated and reports are withheld until a determination is made. When work is halted laboratory personnel are notified when work may be resumed. Where necessary, the customer is notified of the nonconformity and, if necessary, work is recalled and reworked. Records of nonconforming work and the actions taken are retained in the laboratory's administrative files.

The QC conducts a methodical investigation (i.e., root cause analysis) to identify the factors that resulted in the nature, magnitude, location, and timing of the nonconformity and to determine what behaviors, actions, inactions, or conditions need to be changed in order to prevent recurrence of similar nonconformities. All conclusions and root causes identified are supported by documented evidence.

NOTE 1: Root cause analysis is the most difficult part in the corrective action process and often the root cause is not obvious, therefore, a careful analysis of all potential causes (e.g., customer requirements; evidence handling processes; examination specifications, methods and procedures; staff skills and training; consumables, and equipment) is required.

Where corrective action is needed, the following steps are followed to verify the nonconformity, document the process, and identify what corrective actions, appropriate to the magnitude and risk of the nonconformity, need to be implemented to eliminate the problem and prevent recurrence:

1) Nonconformity/Complaint/Problem Review
   a) The QC conducts an evaluation of the reported/identified nonconformity, complaint or problem.
   b) Immediate actions are taken to correct the issue and to address the consequences. A root cause analysis is conducted in order determine the cause(s). All nonconformities, complaints, problems and known errors are recorded and tracked to close. The effectiveness and impact of risk resulting from corrective action is evaluated and if needed changes to the management system are made.
   c) All clause/paragraph numbers and associated requirements, policies/procedures, or standards (i.e., source) that are not in compliance are documented.
   d) A description of the event and when it occurred is documented as the "Details of the Event".
   e) The root cause is determined after evaluating some or all the following:
      i) Personnel (competency, proficiency, training, certifications, etc.)
      ii) Documentation (case records, policies and procedures, training records, etc.)
      iii) Equipment (hardware, software, validations, etc.)
      iv) Environment/Work Conditions
      v) Communications
      vi) External and customer requirements
      vii) Other, as appropriate to the nonconformity
   f) A corrective action (plan) is created to eliminate the issue and prevent recurrence.

g) A monitoring period is established to set a time frame of when the effectiveness of the corrective action will be assessed.

h) At the completion of a successful monitoring period, updates are documented.

i) The QC then votes on whether the nonconformance has been successfully handled and may be closed. A majority vote is needed to close a nonconformance with the DO's vote used as a tiebreaker.

j) All documentation of the above is stored electronically.

**8.7.2** *Corrective actions shall be appropriate to the effects of the nonconformities encountered. [QC]*

See section 8.7.1

**8.7.3** *The laboratory shall retain records as evidence of [QC]:*

*a) the nature of the nonconformities, cause(s) and any subsequent actions taken;*
*b) the results of any corrective action.*

See section 8.7.1

**8.8 Internal audits (Option A)**

**8.8.1** *The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system [QC]:*

*a) conforms to:*
*— the laboratory's own requirements for its management system, including the laboratory activities;*
*— the requirements of this document;*
*a).1 Internal audits shall provide information on whether the management system conforms to the requirements of this document.*
*b) is effectively implemented and maintained.*

The laboratory conducts internal audits in one of two ways 1) the audit requirements are broken down and a portion is completed throughout the year; or 2) the entire audit is completed annually. The primary objective of the internal audit is to verify the laboratory's operations are effectively implemented and maintained and continue to comply with the requirements of the QMS and accrediting body standards. The duration of each internal audit may vary, and there is no set number of days in which an internal audit must be completed. The number of internal audits for any given calendar year may vary depending on the needs of the laboratory. The number of audits in any one year, the scope of each audit, and the resources needed for each audit are recommended by the QC and approved by TM.

The QC is responsible for planning, organizing, conducting, and documenting the audit in accordance with general auditing principles and in full compliance with all applicable laboratory policies and procedures. All MCCO/MVRCL employees are responsible for fully cooperating with any assigned auditors to facilitate the completion of each audit and any follow-up activities (including the implementation of risk treatments, process improvements, and corrective actions). The QC is responsible for reviewing the documented conclusions of each internal audit; ensuring the audit conclusions are shared with laboratory staff, as needed; and for providing general oversight to ensure the completion of all risk treatments, corrective actions, and process improvements.

For each internal audit, the QC identifies qualified individuals to conduct or assist with the audit. A record of how the QC determined each auditor's qualifications is retained with the internal audit records for the year in which the auditor is used.

NOTE 2: "Qualified" means the individual has completed a training course in internal audits. They may also have external auditing experience, but this is not a necessity.

After completing the audit, the QC reviews each nonconformity and prepares a written audit report in which the nonconformity and related risk treatment, corrective action, or process improvement is identified and documented. If no action is taken for an identified nonconformity, that decision to include the reason is documented.

After the written report is prepared a quality review meeting with the relevant section is held. During the quality review meeting, the internal audit, subsequent results, corrective action, and process improvements are reviewed. All approved corrective actions or process improvement plans are completed prior to the next internal audit unless an extension is granted by the QC.

When an internal audit identifies a finding that casts doubt on the effectiveness of the laboratory's operations or correctness of examination results or places the laboratory at risk, timely corrective action (section 8.7) or process improvement (section 8.6) is taken in accordance with the guidance provided in the identified sections. Corrective actions and process improvements related to internal audits are documented and monitored to verify the effectiveness of the actions taken.

Audit records are retained by the QC and stored electronically. At a minimum, the following records are retained for each audit:

- Objective evidence of auditor qualifications
- Completed checklists, to include results from direct observation of a sample of different services for which the laboratory is accredited
- Audit report
- Response to audit findings

The QC continuously monitors the internal audit program to assess its overall effectiveness and reports on its activities and condition during the management review which may include:

- Adherence to audit schedules
- Capabilities of audit team selected, if applicable
- Feedback from the auditors, if applicable
- Feedback from those being audited
- Any trends detected through auditing
- Any evolving needs which may necessitate changes to the audit program
- Completeness of audit records
- Consideration of any new auditing practices

***8.8.1.1*** *Internal audits shall be conducted at least annually, as well as prior to the initial accreditation assessment. [QC]*

See section 8.8.1

**8.8.2** *The laboratory shall [QC]:*

*a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;*
*b) define the audit criteria and scope for each audit;*
*b).1 Internal audits shall include direct observation of a portion of accredited laboratory activities within each discipline.*
*c) ensure that the results of the audits are reported to relevant management;*
*d) implement appropriate correction and corrective actions without undue delay;*
*e) retain records as evidence of the implementation of the audit program and the audit results.*

*NOTE ISO 19011 provides guidance for internal audits.*

See section 8.8.1

**8.9 Management reviews (Option A)**

**8.9.1** *The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document. [QC]*

Laboratory management conducts an annual review of its management system to verify its continued suitability to perform forensics support, examination adequacy, and operational and quality program

effectiveness. The meeting is attended by top management, the TLs of each section, the grant administrator, and the safety officer. The details (who, when, where) and substantive results discussed during the meeting are documented and retained by the QC.

***8.9.1.1*** *Management reviews shall be conducted at least annually, as well as prior to the initial accreditation assessment. [QC]*

See section 8.9.1

**8.9.2** *The inputs to management review shall be recorded and shall include information related to the following [QC]:*

*a) changes in internal and external issues that are relevant to the laboratory;*
*b) fulfilment of objectives;*
*c) suitability of policies and procedures;*
*d) status of actions from previous management reviews;*
*e) outcome of recent internal audits;*
*f) corrective actions;*
*g) assessments by external bodies;*
*h) changes in the volume and type of the work or in the range of laboratory activities;*
*i) customer and personnel feedback;*
*j) complaints;*
*k) effectiveness of any implemented improvements;*
*l) adequacy of resources;*
*m) results of risk identification;*
*n) outcomes of the assurance of the validity of results; and*
*o) other relevant factors, such as monitoring activities and training.*

See section 8.9.1

**8.9.3** *The outputs from the management review shall record all decisions and actions related to at least [QC]:*

*a) the effectiveness of the management system and its processes;*
*b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;*
*c) provision of required resources;*
*d) any need for change.*

All decisions and actions to include corrective actions, process and quality improvements, and resource provisioning and updates are planned, documented, and carried out to effectively address any needed changes to the laboratory's QMS and technical operations. Follow-up audits or meetings are scheduled to

confirm the completeness and adequacy of any risk treatments, corrective or improvement actions, and resource readiness.